No. 23-10362

IN THE UNITED STATES COURT OF APPEALS
FOR THE FIFTH CIRCUIT

ALLIANCE FOR HIPPOCRATIC MEDICINE, ET AL.,
***Plaintiffs-Appellees*,**

v.

U.S. FOOD AND DRUG ADMINISTRATION, ET AL.,
***Defendants-Appellants*.**

v.

DANCO LABORATORIES, L.L.C.,
***Intervenor-Appellant*.**

On Appeal from the United States District Court
for the Northern District of Texas, Amarillo Division
No. 2:22-CV-00223-Z, The Honorable Matthew J. Kacsmaryk, Judge Presiding

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AMICUS CURIAE BRIEF OF THE ASSOCIATION OF AMERICAN PHYSICIANS AND SURGEONS EDUCATIONAL FOUNDATION IN SUPPORT OF PLAINTIFFS-APPELLEES, IN SUPPORT OF AFFIRMANCE

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CERTIFICATE OF INTERESTED PERSONS

The case number here is No. 23-10362, *Alliance for Hippocratic Medicine, et al. v. U.S. Food and Drug Administration, et al.*

Amicus Curiae Association of American Physicians and Surgeons Educational Foundation is a non-profit corporation that has no parent corporation, and no publicly held corporation owns 10% or more of its stock.

Pursuant to the fourth sentence of Circuit Rule 28.2.1, the undersigned counsel of record certifies that the parties' and amici's list of persons and entities having an interest in the outcome of this case is complete, to the best of the undersigned counsel's knowledge, with the following additions:

Amicus Curiae Association of American Physicians and Surgeons Educational Foundation,

Andrew L. Schlafly, counsel for *Amicus Curiae*

These representations are made in order that the judges of this court may evaluate possible disqualification or recusal.

/s/ Andrew L. Schlafly
Andrew L. Schlafly
Counsel for Association of American Physicians and Surgeons Educational Foundation

Dated: May 10, 2023

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IDENTITY, INTEREST AND AUTHORITY TO FILE[1]

Amicus curiae Association of American Physicians and Surgeons Educational Foundation ("AAPS") was founded 1996. It is a non-profit organization headquartered in Tucson, Arizona, and incorporated under the laws of that state. AAPS co-sponsors medical education conferences where medical information is presented to and discussed among physicians, including medical students, and AAPS is at the forefront of developments in the medical field. Amicus AAPS is informed by the many experts who speak at its conferences and share the latest information on medical-related issues. AAPS itself is a litigant in federal court within this Fifth Circuit. *See Ass'n of Am. Phys. & Surgs. Ed. Fdn. v. ABIM, et al.*, 3:22-cv-00240 (S.D. Tex.).

AAPS has an interest in medical disputes at issue in this case, and the governing legal doctrines that are at stake here. Multiple medical groups have filed amicus briefs in support of Appellants, to which AAPS responds here.

[1] All parties have stated through their counsel of record that they do not oppose the filing of this brief by Amicus AAPS. Pursuant to FED. R. APP. P. 29(a)(4)(E), undersigned counsel certifies that: counsel for the Amicus AAPS authored this brief in whole; no counsel for a party authored this brief in any respect; and no person or entity – other than Amicus AAPS, its members, and its counsel – contributed monetarily to this brief's preparation or submission.

Moreover, AAPS has an interest in averting any misperception that the medical profession is aligned with the FDA and its decision-making here.[2]

SUMMARY OF ARGUMENT

This case presents a major question of enormous significance, for which judicial deference to a mere administrative subagency – the biased FDA – is inappropriate. A handful of unelected bureaucrats at this partisan federal subagency should not be dictating abortion policy for our entire nation. Pregnancy is not properly classified among "serious or life-threatening illnesses" that were the limiting scope of FDA authority in this context; the FDA cannot properly redefine this phrase to expand its power for ideological objectives. Federalism is undermined, even imperiled, by allowing a few federal agency employees to transform American culture without any involvement by elected congresspersons and state legislators. State governance over this fundamental issue is infringed by the FDA's abuse of its power, and the injunction below against the agency misconduct was entirely warranted. The district court decision should be affirmed here.

The FDA approved mifepristone back in 2000, but its use has increased as promoted over TikTok and social media, and by multiple recent regulatory changes

[2] References here to the "FDA" are, of course, to the U.S. Food and Drug Administration, and also to all the other government defendants in this case.

by the Biden Administration. The unilateral promotion of mifepristone by the Biden Administration includes:

- discarding the longstanding requirement that the pill be obtained in person, which was an important safeguard against pressured abortion and unrecognized complications;
- allowing any retail pharmacy to become certified to distribute the pill, which increases the likelihood of a lack of informed consent; and
- violating a longstanding prohibition in a federal statute in order to allow widespread distribution by mail.

What the FDA did in 2000 was unlawful in approving this medication, while the foregoing recent changes increase the impact such that most abortions nationwide today are by this pill. States, communities, and families are left helpless to steer clear of it. Few are warned about its psychological harm, and amicus briefs for Appellants here implausibly deny it. The practical effect is that the FDA and the Biden Administration override the will of the People in roughly half of the states, fracturing national unity. The decision below correctly halted this.

The district court decision is being decried as the first-ever instance of a court reversing an approval of a drug by the FDA, but this first step is long overdue. Increased judicial scrutiny of the FDA is necessary as the Biden Administration unconstitutionally misuses federal agencies to transform our culture. Based on political pressure rather than good medicine, the FDA could next approve new transgender medications for minors, potentially inflicting life-

long injuries to them in a manner analogous to the mifepristone drug at issue here. The FDA has a history of approving medications for which it took far too long to reverse itself, and judicial review is an appropriate check on FDA malfeasance. The court below correctly rejected deference to this subagency. Moreover, there is no statute of limitations obstacle when harm from an unlawful approval by the FDA continues.

There is harm to federalism in addition to victims of this drug. An amicus brief filed by pro-*Roe v. Wade* states led by New York implicitly seeks to impose its vision of easy abortion-on-demand throughout the entire country. But if there is to be nationwide unlimited access to abortion, then that is for congresspersons and state legislators to decide, not merely a D.C.-centric federal subagency. Legislative hearings should be held, and those who advocate that mifepristone is safe should answer questions by elected officials and respond to many women who regret taking the drug. Data concerning the harm caused by the drug should be publicly disclosed, with redactions to protect individualized information, and then publicly analyzed and vetted. The New York-led states' vision of the FDA alone setting national policy on this issue violates federalism and representative government, and is contrary to the reasoning of the Supreme Court decision last year in *Dobbs v. Jackson Women's Health Org.*, 142 S. Ct. 2228 (2022).

The amicus brief filed by medical groups led by the American College of Obstetricians and Gynecologists (ACOG) – a group that advocates for abortion[3] – is even less persuasive. Without citing *Dobbs* or any applicable precedent, that brief relies on many citations to ACOG's own publications rather than to independent authority. Their brief asserts that an at-home medication abortion, which typically results in the pregnant mother-to-be being traumatized by seeing her unborn child after discharge from her womb, is somehow not psychologically harmful at all. (ACOG Amicus Br. 17 & n.38). ACOG's citations for its implausible denial are to older articles which, by their titles, apparently have nothing to do with medication abortions. The most recent of their citations on this point is to a study discussed in an article available, as updated, on the internet, yet this article makes no mention of abortion by medication, let alone address the visual impact on a mother of having to see her own deceased unborn child.[4]

In this post-*Roe v. Wade* era, each state should be able to set its own standards concerning abortion. Yet the Biden Administration and its amici, including an amicus brief on behalf of 203 House members and 50 Senators, fail to

[3] "Abortion Advocacy" is the first item on the pulldown menu on the front page of the ACOG website, under "Advocacy". See https://www.acog.org/ (viewed May 5, 2023).

[4] M. Antonia Biggs et al., "Women's Mental Health and Well-being 5 Years After Receiving or Being Denied an Abortion," 74 *JAMA Psychiatry* 169-78 (Feb. 2017) https://jamanetwork.com/journals/jamapsychiatry/fullarticle/2592320 (viewed May 5, 2023).

respect that distribution of power throughout our federalism, and instead essentially insist that the FDA dictate a nationwide abortion policy. An injunction against the FDA would not cause the sky to fall as falsely predicted by that and other briefs submitted for Appellants, but would compel the Biden Administration and the same group of 253 congresspersons to negotiate with their colleagues who disagree, in order to attain a political resolution of this dispute. Perhaps at least a temporary political resolution could thereby be attained once this fiat by the FDA is ended. The Constitution and *Dobbs* require that the role of representative government in our federalism be respected, and affirming the decision below would facilitate the republican process of governance central to our Republic.

ARGUMENT

It is not representative government when a few unelected, unaccountable bureaucrats at the FDA impose a fundamental cultural change on society without specific congressional authorization or consent by the state legislatures. By approving chemical abortion, improperly frustrating judicial review of its decision for two decades, and then unilaterally widening the pill distribution for easy, repeated, and uninformed access by nearly everyone, including teenagers, the FDA has interfered with how our Constitution allocates authority among the states. The well-reasoned decision below correctly blew the whistle against this agency overreach, and the opinion should be affirmed as explained further below.

I. Only Congress and the States Can Decide this Major Question, and the FDA Imperils Federalism by Trying to Dictate Abortion Policy Nationwide.

In *Dobbs*, the U.S. Supreme Court essentially held that nine learned Justices of that court in D.C., although thoroughly vetted and confirmed by the U.S. Senate, should not be imposing an abortion policy on our entire nation. Instead, this is an issue that belongs with the states and the People. Yet before this Court now is a demand by the Biden Administration for a small number of employees at the FDA, unknown to the public, to wield similar vast power concerning abortion. The answer to such an anti-democratic demand is, of course, "no".

Making an at-home abortion drug easily and widely available, even accessible by teenagers through the U.S. Postal Service as recently ordered by President Biden, is a major question to be decided by Congress and state legislatures, rather than a federal subagency obscure to the electorate. By implicitly and falsely redefining "pregnancy" as an "illness", the FDA has bootstrapped its own power far beyond its outermost parameters. Allowing this to continue would tear at the seams of our federalism, putting at least half of the states in the dilemma of choosing between compliance with a federal agency or compliance with the will of its People. No state should be subjected to that quandary, and the American People should not be victimized by the FDA's lawless approach.

A. At-Home Chemical Abortion Is a Major Question of Policy for Legislative Resolution.

If there is ever a "major question" beyond the scope of administrative authority, it is at-home chemical abortion performed through self-administered medication. Are life-changing transgender pills-by-mail next in the FDA's pipeline? Congress has not delegated the authority over this fundamental matter to a mere division of an agency, the FDA, which is not even prominent enough to have a seat in the Cabinet, nor could Congress delegate such vast power consistent with the Constitution. Some tough decisions can be debated and decided only in the halls of legislatures. This is plainly one of those issues.

This Fifth Circuit was the leader in adopting the major questions doctrine, tracing its roots to at least 2014 when Justice Scalia used this principle without its current label, citing as precedent a decision in 2000 by Justice O'Connor that struck down an attempt by the FDA to regulate tobacco. "Congress must 'speak clearly if it wishes to assign to an agency decisions of vast economic and political significance.'" *BST Holdings, L.L.C. v. OSHA*, 17 F.4th 604, 617 (5th Cir. 2021) (quoting *Util. Air Regul. Grp. v. EPA*, 573 U.S. 302, 324 (2014) (Scalia, J.), which cited *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120 (2000) (O'Connor, J.)). This fundamental, necessary judicial check on overreach by a federal agency applies here, where the FDA and the Biden Administration are

promoting easy access-by-mail and through strangers for teenagers to take a chemical abortion drug contrary to the policy of at least 20 states.

By a 6-3 vote last June, the Supreme Court expressly embraced the "major questions doctrine" that had already been recognized by this Fifth Circuit, and used it to rein in the Environmental Protection Agency (EPA). "The agency instead must point to clear congressional authorization for the power it claims," Chief Justice Roberts wrote for the court in that seminal decision. *West Virginia v. EPA*, 142 S. Ct. 2587, 2609 (2022) (inner quotation omitted). He persuasively rejected objections raised by the dissent on this issue:

> The dissent criticizes us for "announc[ing] the arrival" of this major questions doctrine, and argues that each of the decisions just cited simply followed our "ordinary method" of "normal statutory interpretation" (opinion of Kagan, J.). But in what the dissent calls the "key case" in this area, *Brown & Williamson*, the Court could not have been clearer: "In extraordinary cases . . . there may be reason to hesitate" before accepting a reading of a statute that would, under more "ordinary" circumstances, be upheld. 529 U. S., at 159. Or, as we put it more recently, we "typically greet" assertions of "extravagant statutory power over the national economy" with "skepticism." *Utility Air*, 573 U. S., at 324. The dissent attempts to fit the analysis in these cases within routine statutory interpretation, but the bottom line—a requirement of "clear congressional authorization"—confirms that the approach under the major questions doctrine is distinct.

West Virginia, 142 S. Ct. at 2609 (cleaned up).

The Supreme Court then explained in that high-profile energy regulation case – which received nearly as much attention as the *Dobbs* decision rendered the prior month – that while the Court was newly adopting the label "major questions

doctrine," its underlying principles are not new or seriously doubted as to their vitality. Chief Justice Roberts continued, on behalf of the Court:

> As for the major questions doctrine "label", it took hold because it refers to an identifiable body of law that has developed over a series of significant cases all addressing a particular and recurring problem: agencies asserting highly consequential power beyond what Congress could reasonably be understood to have granted. Scholars and jurists have recognized the common threads between those decisions. So have we. See *Utility Air*, 573 U. S., at 324 (citing *Brown & Williamson* and *MCI*); *King* v. *Burwell*, 576 U. S. 473, 486 (2015) (citing *Utility Air*, *Brown & Williamson*, and *Gonzales*).

West Virginia, 142 S. Ct. at 2609 (cleaned up).

The rationale expressed by the Supreme Court for the major questions doctrine is "both separation of powers principles and a practical understanding of legislative intent." *Id.* But this doctrine is also plainly necessary to protect a republican form of government, which the Constitution expressly guarantees to the states and to the People. U.S. CONST. Art. IV, § 4 ("The United States shall guarantee to every state in this union a republican form of government"). The FDA's conduct at issue in this case runs afoul of this constitutional guarantee, and frustrates the ability of states and the People to establish their own preferred policies concerning abortion. Ironically, the very next clause in the Constitution is to protect every state "against invasion" (*id.*), yet here the Biden Administration's promotion of the FDA's embrace of mifepristone has the effect of invading every state with an easily accessed chemical abortion pill, contrary to policies in many

states as discussed further below. The Constitution protects local autonomy on which a federal subagency is improperly infringing.

Just last week the Supreme Court granted *certiorari* on a petition against another federal agency which imposed a financial burden on fishermen, without clear authority by Congress, and it is widely expected that the Supreme Court will trim back agency power in that case too. "In *Loper Bright Enterprises v. Raimondo*, the court will reconsider a 40-year-old precedent, known as the *Chevron* doctrine, that says courts should defer to agencies' reasonable interpretations of ambiguous statutes," recently shouted the top headline on the widely respected SCOTUSblog.[5] While that is not judicial precedent yet, this independent prognostication is more credible than the self-serving, implausible predictions of a catastrophe chanted by the Appellants and their amici in this case as they urge reversal of the decision below.

The sky-will-fall type of prophecy made by the pro-mifepristone advocates here, if they were to lose, falsely asserts that everyday drug approvals and even investment in pharmaceutical research and development will be disrupted if the district court decision is affirmed. (Big Pharma Br. 23, discussed in Point II, *infra*) Yet their doomsday forecast omits mention of a real train that is barreling down the tracks: powerful new transgender medication for minors. Not a word about this

[5] https://www.scotusblog.com/ (viewed May 6, 2023).

new billion-dollar industry in the pharmaceutical amicus brief; nary a reference to it in the medical groups' presentation either. Transgender medication is an issue raging in state legislatures now,[6] while the media has run many stories relating to transgender medication for minors. "Puberty blockers and sex hormones do not have U.S. Food and Drug Administration (FDA) approval for children's gender care."[7] The notion that the FDA has virtually unlimited power to wade further into the political arena by approving transgender drugs for minors without submitting to judicial review is untenable. Yet that is the implication of the FDA's arguments here.

As summed up by Justice Gorsuch in his concurrence, joined by Justice Alito, in the landmark *West Virginia v. EPA* decision last June:

> To resolve today's case the Court invokes the major questions doctrine. Under that doctrine's terms, administrative agencies must be able to point to clear congressional authorization ***when they claim the power to make decisions of vast economic and political significance***.

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[6] Here within the Fifth Circuit, the biennial session of the Texas legislature in Austin has recently ground to a halt in a week-long attempt to hold a vote on banning puberty blockers, a ban that would have doubtful efficacy if the FDA and Biden Administration can make them available through the mail as they are doing with mifepristone. Alex Nguyen, "Democrats again delay Texas House debate on banning puberty blockers and hormone therapy for trans kids" (May 5, 2023) https://www.texastribune.org/2023/05/05/texas-trans-kids-health-care-ban/ (viewed May 6, 2023).

[7] Chad Terhune, Robin Respaut, and Michelle Conlin, "As more transgender children seek medical care, families confront many unknowns," *Reuters Special Report* (Oct. 6, 2022). https://www.reuters.com/investigates/special-report/usa-transyouth-care/ (viewed May 6, 2023).

West Virginia v. EPA, 142 S. Ct. at 2616 (inner quotations omitted, emphasis added). Likewise, the major questions doctrine should apply here to enjoin the FDA's approval of mifepristone amid the Biden Administration's recent push for pervasive access to it.

The pharmaceutical industry argues otherwise. Never mentioning the "major questions doctrine" despite its emphasis in the landmark energy decision by the Supreme Court last term, the pharmaceutical industry's amicus brief opens with its assertion that "Congress vested FDA with [this] authority" and that "[t]he district court's order strikes a severe blow to Congress's regulatory framework …." (Big Pharma Br. 5). Really? That Congress somewhere authorized the FDA to facilitate millions of abortions by teenage girls at home, whereby some then post their upsetting result on TikTok while others face a lifetime of likely psychological harm from the experience?[8] No, certainly not. Congress did not delegate such authority to the FDA, and this case presents yet another example of a runaway administrative state that federal courts are increasingly and properly reining in. TikTok may be protected by freedom of speech under the First Amendment, but administrative fiat by the FDA to set abortion policy for our entire nation is not.

[8] Many videos promoting the abortion pill can be viewed at https://www.tiktok.com/@abortionpillsforsell (viewed May 8, 2023).

B. The Severe Disruption to Federalism Being Caused by the FDA's Conduct Is Unsustainable.

At least 20 states strongly disagree with what the FDA has done in approving and facilitating chemical abortion, and persuasively object to how the Biden Administration is making it easily available by mail contrary to longstanding federal law.

For example, 20 state Attorneys General signed and sent a remarkable letter to CVS pharmacy on Feb. 1, 2023, to tell CVS that President Biden is violating the law and that CVS should not provide mifepristone in their states. Their letter, a similar copy of which was also sent to Walgreens pharmacy, explains that:

> In December, the Biden administration's Office of Legal Counsel encouraged the U.S. Postal Service to disregard this plain text [of federal law]. … [T]he Biden administration's opinion [to broadly distribute mifepristone] fails to stand up even to the slightest amount of scrutiny.[9]

This joint letter by 20 states explains further that:

> Abortion pills are far riskier than surgical abortions, according to established scientific consensus: "Medication abortions were 5.96 times as likely to result in a complication as first-trimester aspiration abortions." Abortion pills carry the added risk that when these heightened complications invariably occur, women suffer those harms at home, away from medical help. And finally, mail-order abortion pills also invite the horror of an increase in coerced abortions. When abortion drugs are mailed or consumed outside a regulated medical facility, the risk of coercion is much higher—indeed, guaranteed—because there is no oversight. Outside the regulated medical context, a person

[9] https://acrobat.adobe.com/link/review?uri=urn:aaid:scds:US:50ee3999-cf8d-4a26-9d4a-ec56c854e352 (viewed May 6, 2023).

> can obtain an abortion pill quite easily and then coerce a woman into taking it.[10]

This Court need not determine whether this compelling view of these 20 states, which include the large or noteworthy states of Ohio, Texas, Florida, West Virginia, and Georgia, is more accurate about the harm from chemical abortion than the sweeping denials by Appellants and their amici in their briefs to this Court. The legal issue here is whether the FDA can essentially flood these states with this abortion drug contrary to the policies in these states, and contrary to applicable statutory law as confirmed by their Attorneys General.

The FDA itself has recently leveraged off its prior approval of mifepristone in order to promote it further. This year the FDA permanently discarded the requirement that the pill be obtained in-person, thereby increasing the likelihood of pressure on teenagers to take this pill at a party or otherwise.[11] This year the FDA also expanded distribution of this pill to open it up to any retail pharmacy to seek

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[10] *Id.* (quoting Upadhyay, et al., "Incidence of Emergency Department Visits and Complications After Abortion," Obstet. Gynecol. 2015 Jan.; 125:175, 181, https://www.ansirh.org/sites/default/files/publications/files/upadhyay-jan15incidence_of_emergency_department_visits.pdf, parenthetical omitted).

[11] FDA, "Questions and Answers on Mifepristone for Medical Termination of Pregnancy Through Ten Weeks Gestation" (Jan. 4, 2023). https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/questions-and-answers-mifepristone-medical-termination-pregnancy-through-ten-weeks-gestation (FDA "removes the in-person dispensing requirement") (viewed May 8, 2023).

certification to dispense it.[12] The FDA thereby acts in violation of the abortion policies in many states, and this Court should decide in favor of federalism rather than this abuse of federal administrative power.

C. Pregnancy Is Not an Illness, and the FDA Is Not Entitled to Any Deference as It Pretends Otherwise.

The decision below addresses and correctly debunks the position taken by the FDA that pregnancy is somehow a serious or life-threatening illness. As the district court judge pointed out, not even the politically liberal *Wikipedia* considers pregnancy to be an illness. *See All. for Hippocratic Med. v. United States FDA*, No. 2:22-CV-223-Z, 2023 U.S. Dist. LEXIS 61474, at *62 (N.D. Tex. Apr. 7, 2023). In fact, though conspicuously omitted from the medical groups' amicus brief here, it is well-established (but rarely disclosed) that carrying a pregnancy to term is beneficial to a woman's long-term health. "Women who gave birth to a child when they were younger than 24 years of age exhibit a decrease in their lifetime risk of developing breast cancer, and additional pregnancies increase the protection." Jose Russo, et al., "The protective role of pregnancy in breast cancer," 7 BREAST CANCER RES 131-42 (2005).[13]

[12] *Id.* ("The January 2023 modification to the Mifepristone REMS Program removed the requirement that did not allow mifepristone to be dispensed from retail pharmacies.")

[13] https://pubmed.ncbi.nlm.nih.gov/15987443/ (viewed May 7, 2023).

The FDA's approval of mifepristone in 2000 entailed shoehorning it under a regulation limited to drugs for treating life-threatening illnesses such as HIV. *See* 57 Fed. Reg. 58,942, 58,958 (Dec. 11, 1992) (codified at 21 C.F.R. § 314.520). Its Subpart H, invoked by the FDA, is entitled "Accelerated Approval of New Drugs for Serious or Life-Threatening Illnesses," and is expressly limited to drugs that were "studied for their safety and effectiveness in treating serious or life-threatening illnesses." 21 C.F.R. § 314.500. Invoking Subpart H as the basis for the FDA's original approval required it to falsely view mifepristone as somehow targeting "serious or life-threatening illnesses."

This incoherent position taken by the FDA in order to approve mifepristone, in the last year of the Clinton Administration, justifies the rejection by the district court of *Auer* deference, whereby a federal agency is allowed some leeway in interpreting its own regulations. *See Auer v. Robbins*, 519 U. S. 452 (1997); *Bowles v. Seminole Rock & Sand Co.*, 325 U.S. 410 (1945). The FDA's misconduct falls within multiple exceptions to *Auer* deference: "when the agency's interpretation is plainly erroneous or inconsistent with the regulation" or "when there is reason to suspect that the agency's interpretation does not reflect the agency's fair and considered judgment." *Christopher v. SmithKline Beecham Corp.*, 567 U.S. 142, 143-44 (2012) (internal quotation marks omitted). Here "an agency's interpretation of a ... regulation that conflicts with a prior interpretation is

entitled to ***considerably less deference*** than a consistently held agency view." *Thomas Jefferson Univ. v. Shalala*, 512 U. S. 504, 515 (1994) (internal quotation omitted, emphasis added). *See generally Perez v. Mortg. Bankers Ass'n*, 575 U.S. 92, 104 n.4 (2015).

II. If This is the First Ever Judicial Invalidation of an FDA Drug Approval, This is Overdue and Similar Invalidations of Harmful New Transgender Drugs May Be Needed Next.

Appellants, the pharmaceutical industry, and supporters of mifepristone in the media are deploring how this is apparently the first time a court has overturned an FDA drug approval. "The district court's invalidation of an FDA drug approval ***for the first time*** based on the court supplanting the role of FDA threatens to disrupt the cycle of drug development and upend the investment-backed expectations of industry." (Big Pharma Br. 23, emphasis added; see also Appell'ts Br. 2) The amicus brief filed by the medical groups in support of Appellants relies on an article in *The New York Times*, which declared about the decision below:

> Legal scholars said the Texas ruling appeared to be the first time a court had tried to invalidate the approval of a drug over the objection of the F.D.A. For decades, Congress has given the agency authority to determine whether drugs are safe and effective.

Pam Belluck and Christina Jewett, Christina, "Drug Company Leaders Condemn Ruling Invalidating F.D.A.'s Approval of Abortion Pill." *The New York Times* (April 10, 2023) (cited by ACOG et al Amicus Br. 26 n.65). These ACOG-led medical groups predict that a ruling against the FDA could open the floodgates to

challenging HIV drugs. (*Id.* at 27) But that apocalypse is hardly plausible, as the American People of course welcome life-saving medications.

A. Improper Approvals by the FDA Should Be Reviewable in Court.

Put in perspective, the complete lack of judicial review of the FDA in the past is not anything to try to perpetuate. Today the FDA is widely perceived to be a highly politicized agency that has a history both of wrongly approving certain medication, and also wrongly interfering with access to safe medication by patients having terminal illnesses. An historical lack of meaningful judicial review of the distorted decision-making at the FDA is not something to defend, or cite as a reason to criticize the lower court ruling.

Consider, for example, the medication diethylstilbestrol, abbreviated as DES. The FDA formally approved this medication in 1954 specifically for use by pregnant women, despite ample evidence that it caused harm in animal studies. The drug then caused decades of harm in unborn children as confirmed by numerous published studies, but the FDA did not revoke its approval until a half-century later, in 2000. The harm caused by DES included infertility in the unborn children of women who were misled into taking this medication, and also unusual cancers in their children, with some of the harm even extending to the third generation of mothers misled by the FDA into taking this medication.[14]

[14] https://desaction.org/des-timeline/ (viewed May 5, 2023).

Yet the amicus brief filed by the pharmaceutical industry here complains that the district court enjoined a "a 23-year-old drug approval." (Big Pharma Br. 28-29) But that is merely half the time it took the FDA itself to withdraw its approval of DES despite overwhelming reported evidence of decades-worth of harm. Moreover, as the decision below thoroughly explained, the delay here was due to the FDA itself, not the courts. In a more recent case of the FDA being too slow to withdraw an approval, it took 12 years and the withdrawal of the drug from the market by its manufacturer before the FDA corrected its own improper approval.[15]

Federal agencies, like anyone else, inevitably make mistakes. But the FDA is uniquely arrogant in its attitude of somehow being above judicial review, as though it has a special expertise not commonly available. The FDA does not have any such special expertise, and it would benefit from more transparency. Judicial review to correct FDA errors sooner should be welcomed, not opposed.

Meanwhile, the statute of limitations should not be an obstacle in this context implicating the major questions doctrine. In addition to the reasons given below, there is a further basis for rejecting application of a statute of limitations: the actions by the Biden Administration to vastly expand access to mifepristone,

[15] https://medicalxpress.com/news/2023-04-fda-drug-meant-preterm-births.html (viewed May 6, 2023).

even in the 20 states that oppose it. As explained by a joint letter by their Attorneys General quoted above in Part I.B, contrary to federal law the Biden Administration seeks to open up access to mifepristone through the mails. An old mistake that causes new harm – such as applying long-ago segregation in the federal government in a newly pernicious way – is surely not protected from legal challenge to the original wrong based on a statute of limitations technicality.

Put another way, there is no statute of limitations on protecting the federalism central to our Constitution, and in correcting mistakes that jeopardize it. "After 'eight years' of experience under that regime showed *Usery*'s standard was unworkable and, in practice, undermined the federalism principles the decision sought to protect," the Supreme Court corrected its own mistake. *Dobbs*, 142 S. Ct. at 2354 (Breyer, Sotomayor, and Kagan, JJ., dissenting) (citing *Garcia v. San Antonio Metropolitan Transit Authority*, 469 U.S. 528, 531 (1985), and *National League of Cities v. Usery*, 426 U.S. 833 (1976)). *Dobbs* itself, of course, was the Supreme Court reversing its own decision of nearly 50 years prior.

B. The Predictions of a Catastrophe if the Decision Below is Affirmed Are Absurd.

The American Medical Association (AMA) has repeatedly filed amicus briefs in this case on the side of chemical abortion, while making public statements predicting regulatory chaos if the well-reasoned district court decision below is affirmed. For example, the AMA declares on its website:

> In an op-ed published in *The New York Times,* AMA President Jack Resneck, MD, explained how the stakes extend beyond medication abortion:
>
> > "In seeking to restrict access to abortion across the United States, the plaintiffs in this case have, intentionally or not, seriously jeopardized our nation's 85-year-old drug regulatory system," Dr. Resneck wrote. "We must be cleareyed; upholding any parts of the district court's dangerous ruling would in all likelihood almost immediately prompt challenges to other longstanding safe and effective FDA-approved drugs that doctors and patients rely on every day."[16]

These Chicken Little predictions by partisan advocates of greater access to abortion are unpersuasive and belied by their advocacy against access to medication possibly reversing the effects of the abortion pill.

In Colorado, the AMA and its co-amici the American College of Obstetricians and Gynecologists (ACOG) have vocally opposed access by the public to an FDA-approved medication that potentially reverses the abortion pill at issue in this case. In 2019 the AMA even filed a lawsuit a lawsuit in North Dakota "challenging two laws that required physicians to tell patients about abortion pill reversal and that abortion terminates 'the life of a whole, separate, unique, living human being,'"[17] and the AMA reportedly continues to pursue that lawsuit while arguing here against meaningful accountability for the FDA. The only consistency

[16] https://www.ama-assn.org/delivering-care/public-health/next-steps-mifepristone-court-fight-what-doctors-should-know (viewed May 5, 2023).
[17] https://19thnews.org/2023/05/colorado-bans-abortion-pill-reversals/ (viewed May 4, 2023).

in the AMA's positions is that the AMA apparently sides with the abortion business every time, even when patient freedom is on the other side.

If there are any dire consequences from an outcome to this appeal, it would be if the district court decision were reversed. Then the FDA would continue to have a blank check to approve unsafe medications for a variety of other political goals, starting with medications purporting to change one's gender. Many teenagers go through a growth period of temporarily wondering if they would be happier as the opposite gender, yet the FDA could approve powerful medications to lock in a transgender change while causing long-term harm. If the FDA evades judicial review for mifepristone, then life-changing transgender medications could be next from this federal subagency.

III. Post-*Roe v. Wade*, the Executive Branch Should Negotiate with Congress and the Objecting States for a Political Resolution to this Contentious Dispute, a Negotiation that an Affirmance Would Facilitate.

In this post-*Roe v. Wade* era, each state should be setting its own standards concerning abortion. Yet the Biden Administration and its amici fail to respect that distribution of power throughout our federalism, and instead insist that the FDA dictate national abortion policy now. An injunction against the FDA would not cause the sky to fall, but would compel the Biden Administration to negotiate with Congress and the objecting states for a mutually agreeable political resolution.

That is how representative government in our federalism should work, and affirming the decision below would facilitate that.

The pharmaceutical industry argues that "since 2000, PhRMA member companies have invested more than $1.1 trillion in the development of new treatments and cures, including $102.3 billion in 2021 alone." (Big Pharma Br. 25) But mifepristone is not a treatment or cure for any illness. Despite that fundamental distinction, the pharmaceutical industry insists "there would be even fewer new drugs, because there would be less incentive for companies to spend on research and development" if the FDA loses here, and "[t]hat would be to the detriment of both patients and industry." (*Id.* at 26, cleaned up)

But the pro-mifepristone side hardly needs any extra help from the courts. In 2020 alone the pharmaceutical industry spent a breathtaking $317 million on lobbying activities, utilizing 1,634 lobbyists of whom more than two-thirds were former government employees themselves.[18] On the issue of mifepristone, the group on the side of the Biden Administration also benefits from hundreds of millions of dollars-worth of free publicity in the media to advocate their point of view.

[18] https://www.opensecrets.org/federal-lobbying/industries/summary?cycle=2020&id=H04 (viewed May 6, 2023).

Similarly, the states led by New York that advocate for national access to mifepristone are well-represented in Congress. Both the Senate Majority Leader and the House Minority Leader are from New York State. They can easily introduce legislation in Congress to make the same points that the New York brief makes here. For nearly the last half-decade the Speaker of the House in Congress has been from California. It can make its arguments about abortion policy there in Congress, and hold extensive legislative hearings, rather than demand that this Court prop up a decision made by unelected employees at a federal subagency. Likewise, the medical groups that weighed in on their side have full access to the legislative process; the American Medical Association (AMA) alone spent $21,060,000 on lobbying activities in 2022.[19]

Also on the side of mifepristone are 253 members of Congress: 203 in the U.S. House of Representatives and 50 in the U.S. Senate, who joined their amicus brief in this appeal. With Vice President Kamala Harris, the pro-mifepristone side has a majority in the U.S. Senate. They could hold hearings on the harm, or their alleged lack of harm, from this drug. They could take public testimony on both sides, including women who were pleased with the medication and those who felt harmed or betrayed by it. These 253 congresspersons, and certainly the 50

[19] https://www.opensecrets.org/federal-lobbying/clients/summary?cycle=2022&id=D000000068 (viewed May 6, 2023).

senators, have the power to require transparency by the FDA that it has not yet provided about this medication. They have the power to persuade the Biden Administration to stop pushing access by mail to mifepristone in the 20 states that oppose it.

Instead, their amicus brief functions as an attempted end-run around *Dobbs*, which returned authority over abortion policy to the states. The pro-mifepristone congresspersons complain about the policies concerning abortion in states that these senators do not represent. These partisan legislators implicitly argue for imposing their expansive view of abortion-on-demand, which in practice is often by teenagers without parental oversight, on states that reject that approach. *Dobbs* stands completely against that approach of a one-size-fits-all abortion policy emanating from a small group of federal employees. Rather than argue here, these congresspersons should make their case in the halls of Congress.

The U.S. Supreme Court did not address the ready availability of a legislative approach to mifepristone on the first expedited trip of this case there, when the Court granted Appellants' emergency application for a stay of the prior injunction by this Court. Next time, the Supreme Court could easily preserve the status quo for a short period to give Congress and the White House time to negotiate a resolution. But the placing of the full weight of the federal judiciary on

the side of the FDA would remove any incentive for the Biden Administration to resolve this through the legislative process.

The New York-led states argue that *Dobbs* "emphatically endorsed the States' authority to safeguard access to abortion for their residents, explaining that it was 'return[ing] the issue of abortion to the people's elected representatives.'" (NY States Amicus Br. 4-5, quoting *Dobbs*, 142 S. Ct. at 2243). That statement does not support what the Biden Administration is doing by imposing abortion-on-demand for all, including teenagers, with mifepristone-by-mail in the 20 states that oppose it. *Dobbs* did not, and the Supreme Court would not, create a right nationwide to a chemical abortion. If *Dobbs* were to stand for that, then it meant very little.

In the wake of *Dobbs*, as fully understood, the FDA and the Biden Administration have gone beyond federal limitations in attempting to impose the political views of one side of the abortion dispute on our entire nation, and on every state and community that objects. That approach does not and should not work in our Republic. Rather than uniting the country, that approach causes fracture and disunity. Courts should seek to encourage political solutions to contentious disputes, rather than taking the issue out of the hands of elected representatives. Affirming the decision below would facilitate a proper resolution by representative government, as the Constitution requires.

CONCLUSION

For the foregoing reasons and those stated in the briefs by Appellees and other amici on the side of Appellees, the decision below should be fully affirmed.

Respectfully submitted,

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Dated: May 10, 2023

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CERTIFICATE OF SERVICE

I hereby certify that, on May 10, 2023, I electronically filed the foregoing brief with the Clerk of the Court for the U.S. Court of Appeals for the Fifth Circuit by using the Appellate CM/ECF system. Participants in the case who are registered CM/ECF users will be served by the CM/ECF system.

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CERTIFICATE OF COMPLIANCE

1. This brief has been prepared using Times New Roman 14-point, proportionately spaced, serif typeface, in Microsoft Word.

2. This brief complies with FED. R. APP. P. 29(a)(5) and 32(a)(7)(B) because it contains a total of 6,460 words, excluding material not counted under Rule 32(f).

Dated: May 10, 2023

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United States Court of Appeals

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May 12, 2023

Mr. Andrew Layton Schlafly
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No. 23-10362 Alliance Hippocratic Medicine v. FDA
USDC No. 2:22-CV-223

Dear Mr. Schlafly,

You must submit the 7 paper copies of your brief required by 5th Cir. R. 31.1 **via overnight delivery** pursuant to 5th Cir. ECF Filing Standard E.1.

Sincerely,

LYLE W. CAYCE, Clerk

Melissa Mattingly

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