



What the Media Missed  
in Its Coverage of the  
U.S. Fifth Circuit Court of Appeals  
Decision Regarding:  
**mifepristone**

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# What the Media Missed in Its Coverage of the U.S. Fifth Circuit Court of Appeals Decision Regarding Mifepristone

By Randall K. O'Bannon, Ph.D., NRL Director of Education & Research

Most reporters accurately reported the recent decision by the U.S. Fifth Circuit Court of Appeals to reinstate safeguards that the FDA imposed on mifepristone prior to 2016. They generally failed to report the legal reasoning and medical evidence backing this decision, though, making this appear to be simply one more volley in a long running political controversy. Those taking care to read the decision will see that the court had ample reason to rein in the agency, given that the FDA was the one who had clearly put abortion politics over medical science and the interests of women.

On Wednesday, August 16<sup>th</sup>, 2023, three judges from the U.S. Fifth Circuit Court of Appeals (New Orleans) released their opinion in *Alliance for Hippocratic Medicine v. the U.S. Food and Drug Administration* (AHM v. FDA). This is the case where a group of pro-life doctors challenged the federal agency's approval and later loosening of restrictions on mifepristone, the abortion pill.

The court ruled that AHM's challenge to the FDA's 2000 approval of mifepristone, whatever its merits, came too late, after the statute of limitations had run out, allowing the drug to stay on the market until or unless the Supreme Court said otherwise. The FDA's approval of the generic mifepristone from GenBioPro would also continue to stand, the court said, since AHM had shown no unique issues with the generic to distinguish it from the original.

But the court agreed that challenges AHM made to decisions made by the FDA to loosen regulations on mifepristone made in 2016 and then later in 2021 (later formalized in 2023) were, in fact, well founded, so that the agency was bound to return to the more restrictive distribution and certification process in place before 2016.

Mifepristone was considered and approved under Subpart H, a section of the Administrative Procedures Act governing how the agency evaluates drugs. This provision of the code allows the FDA to accelerate approvals of drugs needed to treat life-threatening diseases or illnesses for which there was not yet complete clinical data. It was set up by the FDA in the 1990s to be able to fast track drugs that were being developed for the AIDS crisis.

- *Original protocol and distribution limits (2000)*

Under the approved FDA protocol, mifepristone, sold in the U.S. under the name Mifeprex, was originally limited to women no more than 49 days, or seven weeks past their last menstrual period (LMP).

It was only to be prescribed under the supervision of a physician who could certify that he or she could accurately estimate gestational age and diagnose ectopic pregnancies. Studies and trials of the drug had shown that the rate of complications increased, and the effectiveness dropped off, further along in the pregnancy.

Experience had shown that the pills were ineffective in the circumstances of ectopic pregnancy.

The original protocol outlined a multi-step process involving at least three required visits. In the first visit, a woman visited the doctor's office, was screened for any contraindications or red flags that might make the pill particularly dangerous for her. She also underwent some sort of exam or questioning to ascertain her gestational age, to make sure there were no signs of ectopic pregnancy. Finally, she was counseled about the process and the risks before being given the mifepristone pills, which she took there in the physician's office.

Those pills essentially blocked progesterone, the pregnancy hormone in the body that ensures the mother's body welcomes, nourishes, and protects the developing young embryo. With that signal blocked, the child's life support system starts to degrade, and the child begins to starve or die. A second drug, a prostaglandin (usually misoprostol) is given to the woman a couple of days later to stimulate powerful contractions to expel the dying or dead corpse of the tiny child. Typically, heavy bleeding and painful cramping ensue within a few hours while the woman's body tries to abort the child.

A third visit a week or so later gives the doctor a chance to confirm completion of the abortion or to recommend additional medication or follow-up surgery.

Doctors were to report any significant complications or serious "adverse events" such as hemorrhage, infection, transfusion, hospitalization, or death directly to the FDA along with details about the woman's age, the drugs she took, how they were administered, the effects and side effects she suffered, the treatment she received, and her final outcome.

The final element of the original FDA protocol was a pledge by the prescribing physician that he or she could either perform the surgery needed to complete the abortion or stop the bleeding or could refer the woman to someone who could.

These elements were built into the official protocol and had to be acknowledged by prescribing doctors as part of the certification system imposed under the distribution system authorized under Subpart H.

- *Brought under REMS system (2011)*

When the FDA revised its drug safety monitoring system in 2007, replacing it with something called Risk Evaluation and Mitigation Strategies (REMS), many of the drugs approved under Subpart H were brought under the new REMS system.

REMS are officially

... a drug safety program that the U.S. Food and Drug Administration (FDA) can require for certain medications with serious safety concerns to help ensure the benefits of the medication outweigh its risks. REMS are designed to reinforce medication use behaviors and actions that support the safe use of that medication (FDA, "Risk Evaluation and Mitigation Strategies | REMS," 5/16/23).

The previous protocol and distribution rules applied to mifepristone were officially brought under the new REMS system in 2011.

- *FDA revises, loosens mifepristone REMS (2016, 2021)*

Abortion advocates found these conditions cumbersome and annoying. Wishing to minimize their work and their responsibilities, they petitioned the FDA to drop them.

In 2016, the FDA complied, dropping the required visits from three to one, allowing women to take the misoprostol at home and do any follow up by phone. They expanded the pool of prescribers to include any health care provider who was willing to sign the certification and extended the gestational deadline from seven to ten weeks LMP.

They also reduced reporting requirements at this time, requiring after that point that prescribers only report deaths back to the sponsor.

Though this greatly expanded the market, abortion advocates were still not satisfied and lobbied the FDA to drop regulations entirely and allow these pills to be bought online or at local pharmacies and shipped directly to women's homes without any required visits or monitoring.

This is largely what the FDA did in 2021, at first temporarily in response to COVID, but later that year, after what was supposed to be an official reexamination of data, as a permanent change (formalized in January of 2023).

- *Fifth Circuit addresses most recent changes*

These are the modifications to protocol, those regulatory changes made in 2016 and 2021, that the Fifth Circuit claimed were unlawful in its decision. They agreed with the doctors of AHM that the FDA authorized those changes without the scientific data needed to show use of the pills under these new circumstances would be safe and effective.

This means, should the Supreme Court agree with the Fifth Circuit, that mifepristone would still be available in the U.S., but only under the conditions that held prior to 2016. Only a physician

could prescribe the pills. A woman would have to visit the doctor's office directly, in person, to be screened, examined, counseled, and to pick up the pills, and would need to return for follow up visits. She was not to be given mifepristone if she was more than seven weeks pregnant. She could not pick up the pills at her local pharmacy or have them mailed to her home.

That is what the Fifth Circuit decided and that is what most reporters have accurately reported. But there are a number of critical things about the decision that the mainstream media has missed or at least glossed over, making people wonder whether they intentionally meant to mislead the public or just failed to read anything but the summary.

Read carefully, the opinion makes clear that:

- 1. The FDA doesn't think anyone, much less pro-life doctors, has the right to challenge their decisions.**
- 2. The FDA thinks it can bend the rules to do whatever it wants.**
- 3. Medical science took a back seat to abortion politics at the FDA with mifepristone.**
- 4. Safe, simple chemical abortions are a crumbling myth.**
- 5. Abortion takes the life of an innocent unborn child and that still matters to a lot of people.**

As it too often the case with abortion, the media's commitment to abortion causes them to miss a lot of the important details.



The FDA doesn't think anyone, much less pro-life doctors, has the right to challenge their decisions.

One of the major issues with which the court deals is "standing" – whether the doctors bringing the suit had the legal right to challenge the FDA. To file a legal complaint, individuals or a group must prove that they are harmed or in some way affected by the action under scrutiny.

The reason that the court devoted a major portion of its decision to standing was that the FDA asserted that as pro-life doctors who did not prescribe mifepristone, those doctors were in no way affected by decisions the FDA made about the drug, and thus lacked standing to bring the case.

This legal tactic appears to have backfired, however, giving the court the chance to show not only how this negatively affected those pro-life doctors but also harmed many of their patients.

- *Harms to doctors, harms to patients*

The AHM doctors were able to make clear by their testimony that they were harmed in several ways. Because of the drug's inherent ineffectiveness and its tendency to cause complications, these doctors, particularly when on call or working the emergency department, had to, under enormous mental and physical stress, deal with dangerous complications or to were forced, against their consciences, to participate in or complete abortions.

On a practical level, this also diverted their time, skills, and resources away from other patients and because of the inherent risks associated with these abortions and the complications they treated, increased their medical and financial liability.

These effects were not simply theoretical, nor were they just based on extrapolations of study data or FDA reports. These doctors shared their actual experiences, and the judges of the Fifth Circuit quoted them extensively (even if the media did not).

[T]he patient presented back at our emergency room with heavy vaginal bleeding and unstable vital signs as a result of taking chemical abortion drugs... Due to the amount of bleeding that she was experiencing and evidence of hemodynamic instability, however, my partner had no choice but to perform an emergency D&C. The patient needed to be hospitalized overnight for close observation after the D&C.

Not only did my partner need to provide several hours of critical care for this patient, but my partner also needed to call in a back-up physician to care for another critically ill patient. And because the

preborn baby still had a heartbeat when the patient presented, my partner felt as though she was forced to participate in something that she did not want to be a part of -- completing the abortion (pp. 16-17).

Another doctor noted that

In my practice, I have cared for at least a dozen women who have required surgery to remove retained pregnancy tissue after a chemical abortion. Sometimes this includes the embryo or fetus, and sometimes it is placental tissue that has not been completely expelled. I have cared for approximately five women who, after a chemical abortion, have required admission for a blood transfusion or intravenous antibiotics or both.

For example, in one month while covering the emergency room, my group practice admitted three women to the hospital. Of the three women admitted in one month due to chemical abortion complications, one required admission to the intensive care unit for sepsis and intravenous antibiotics, one required a blood transfusion for hemorrhage, and one required surgical completion for the retained products of conception (i.e., the doctors had to surgically finish the abortion with a suction aspiration procedure) (p. 18).

The seriousness of these injuries and the level of care required was made clear by this other doctor's experience with another mifepristone patient.

After taking the chemical abortion drugs, [the patient] began having very heavy bleeding followed by significant abdominal pain and a fever. When I saw her in the emergency room, she had evidence of retained pregnancy tissue along with endometritis, an infection of the uterine lining. She also had acute kidney injury, with elevated creatinine. She required a dilation and curettage (D&C) surgery to finish evacuating her uterus of the remaining pregnancy tissue and hospitalization for intravenous (IV) antibiotics, IV hydration, and a blood transfusion (p. 17).

This is clearly not the sort of safe and simple chemical abortion mifepristone advocates like to advertise.

In a not-so-subtle aside at the end of its discussion of standing, the court notes that the pro-life doctors here -- who have provided firsthand care to dozens of mifepristone patients experiencing acute physical and emotional distress in an emergency setting -- have a relationship with their patients that is more than adequate to support third party standing."

"In many respects," the court says, "such a relationship may be closer than those previously recognized by the Supreme Court."

The court cites *June Medical Services*, *Whole Women's Health*, and *Gonzales v. Carhart* as examples where abortionists were given standing to challenge state laws supposedly on behalf of their patients (p. 35).

- *Court uses the FDA's own data against them*

The doctors and the court cited these and many more examples. Against the argument that these were merely random, not necessarily likely to happen with any of these doctors in the future, the court noted that the FDA's own data and official statements showed that complications like these were common.

The court points out that FDA's patient agreement tells patients that "the treatment will not work" in "about 2 to 7 out of 100 women" and its 2011 REMS asserts that "about 5-8 out of 100 women taking Mifeprex will need a surgical procedure to end the pregnancy or to stop too much bleeding."

The court also notes that FDA's most recent REMS medication guide notes that in U.S. studies, between 2.9% and 4.6% of women visited the emergency room after taking mifepristone (p. 15).

- *Likely to happen again*

Ignoring their own data as well as dismissing the case histories shared by the AHM doctors, the FDA and mifepristone distributor Danco Laboratories assert that claims of injury AHM used to try and establish standing are "speculative," giving the doctors no real grounds for claiming the likelihood of these occurring again.

The court disagreed, saying

...testimony was offered from multiple doctors who have personally given emergency care to women suffering complications from mifepristone [testimony cited]. Given those prior instances, and given mifepristone's continued availability, the Medical Organizations reason that these members are reasonably likely to be injured again. The record amply supports that claim (p. 23).

Even if it might be argued that it was unlikely that this would happen again to the exact same doctors (despite this already occurring in many cases), the courts notes that the sizes of membership of the groups involved in the AHM case<sup>1</sup> and the nature of their involvement with patients make it virtually certain that other members of their associations will indeed suffer future harms due to FDA reduced safeguards.

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<sup>1</sup> The American Association of Pro-Life Obstetricians & Gynecologists, the American College of Pediatricians, the Christian Medical & Dental Associations.

- *Questioning FDA's authority?*

The vehemence and persistence of the FDA's protest against the standing of pro-life doctors makes clear not only their willingness to try to silence their critics by employing a legal technicality, but their contempt for anyone who would dare to challenge the agency's decisions or its authority.

In validating these doctors' claims of harm and quoting from their testimony, the court made clear that it was not going to let the agency play that game.

Though the court's decision dialing back the regulations for mifepristone back to what they were prior to 2016 was unanimous, one judge, James C. Ho, would have gone further, rescinding the approval altogether.

Judge Ho notes in his concurrence/dissent that the FDA had disparaged the earlier federal district court ruling as "an unprecedented judicial assault on a careful regulatory process" and the FDA's blasting of the opinion of "non-expert" Judge Matthew Kacsmaryk as an "unprecedented order countermanding the scientific judgment of the Food and Drug Administration."

We will consider the court's legal authority and its responsibility to ensure the integrity of agency decisions in coming segments, but the FDA's attitude with regard to this oversight is unmistakable. As Ho puts it, the message is clearly that "The scientists at the FDA can do no wrong. So courts [as well as presumably doctors representing their own interests and the interests of their patients] have no business reviewing their actions."

Ho continued:

Scientists have contributed an enormous amount to improving our lives. But scientists are human beings just like the rest of us. They're not perfect.... None of us are. We all make mistakes.

And the FDA has made plenty. Several of the FDA's past mistakes are detailed in the amicus briefs from the United States Medical Association and the Association of American Physicians and Surgeons Educational Foundation (p. 89).

Ho goes on to list several times the FDA has erred, singling out Makena, DES, and the agency's contributing to the national opioid crisis by giving Purdue Pharma the green light on extended-release oxycodone in 1995 when there was a troubling surge in consumption (pp. 89-91).

The scientists at the FDA deserve our respect and our gratitude, but not our blind deference. That would defy Congress's clear directive that courts conduct independent legal review of FDA action under the APA (p. 92).

The court says that in approving these modifications to the mifepristone protocol, in removing the safeguards the FDA had put in place before 2016, the agency not only failed women but also failed to live up to its own rules and standards.

The FDA thinks it can bend the rules to do whatever it wants.

One thing the court opinion and the accompanying concurrence/dissent of Judge James C. Ho both make clear is that the FDA does not seem bound by its own rules and procedures when it already knows where it wants to end up.

Anxious to get the drug on the market by any means possible, the FDA approved mifepristone under “Subpart H,” the section of federal code allowing for an accelerated approval of drugs intended to treat “serious” or “life-threatening illnesses,” particularly those “that provide meaningful therapeutic benefit to patients over existing treatments.”

This allows the approval process to proceed with less study data up front, but also grants the agency the authority to impose certain restrictions on the distribution of the drug, such as limiting who may prescribe the drug and who may use the drug, and how it will be delivered.

That the FDA recognized that mifepristone was a drug whose prescription and use required special monitoring and supervision is evidence that the agency saw special risks involved with use of the drug. Yet that the agency felt it necessary to twist its own regulations to bring up the drug for consideration betrays the compromise of the whole enterprise.

- *Pregnancy is not a life-threatening illness*

It was obvious to all that pregnancy was not a “serious or life-threatening illness,” but the FDA proceeded anyway, arguing that pregnancy was a “condition” and that the term “condition” could easily be substituted for “illness,” using that unwarranted equivocation to justify reinterpreting and misapplying the Subpart H statute to facilitate mifepristone’s approval.

The Fifth Circuit as a whole in their main opinion notes but does not directly comment on the use of Subpart H, as it decided that complaints about the original approval in 2000 were filed too late for them to adjudicate the matter. But Judge Ho, in his concurrence/dissent blasted the FDA’s use of the Subpart H rule.

Judge Ho argued it was clear that pregnancy was not a “serious or life-threatening illness” and by any standard use of the law or the language that Subpart H did not apply here, yet “[T]he FDA implausibly ‘determined’ that it does...There’s only one reasonable construction” of the word ‘illness’ – and it doesn’t include pregnancy,” wrote Ho. This means, Ho says, that “There is accordingly no basis for deferring to the agency. The FDA simply got it wrong” (p. 77).

It is something, Ho points out, with which even the abortion pill’s sponsors agreed. The Population Council, which owned the patent and brought mifepristone to the United States in the 1990s, complained to the FDA in a letter that “Neither pregnancy nor unwanted pregnancy is an illness, and Subpart H is therefore inapplicable to that reason alone....The plain meaning of

these terms does not comprehend normal, everyday occurrences such as pregnancy and unwanted pregnancy” (again, at p. 77).

- *Ambivalence at the agency*

Perhaps aware of its shaky legal grounding, the FDA tried to fudge whether the mifepristone approval was or was not done under the Subpart H authority.

Repeatedly, Ho details, the agency claims or makes statements to the effect that “FDA Properly Approved Mifepristone Under Subpart H” (argued in the agency’s brief to the court). But then, even in the brief just cited, the FDA turns around and claims that the approval was “based on FDA’s statutory authority under 21 U.S.C. §355, not Subpart H.”

Ho agrees that Section 355 does indeed give the FDA the power to approve drugs, but notes that “the regulatory path it chose was Subpart H.... The FDA did not have to adopt Subpart H in the first place. But once it did, it was bound to follow it” (p.81).

The point is not whether the FDA had the legal right to issue drug approvals, but that it was obviously choosing the method of consideration that facilitated the easiest, quickest approval, with the least exacting criteria, reserved for the emergency approvals of drugs needed for life threatening illnesses, even though it was clearly not warranted to employ that route.

The agency bent the rules to consider mifepristone and get it through the process.

Though the FDA used that same regulation (and the REMS regulations which replaced them, keeping basically the same terms) to impose limits on the distribution and use of the drug, when it came time to consider modifications to those regulations, the FDA once again shirked its duties and failed to consider how those modifications might affect the health or safety of the women of this proven dangerous drug.

Medical science took a back seat to abortion politics at the FDA with mifepristone.

The media liked to portray the changes made to the mifepristone protocol as the FDA loosening standards that time, testing, and experience had shown to be unnecessary. The FDA and the abortion industry carefully cultivated that myth.

As the court found out, the truth was far different. Trials performed before the FDA's 2000 approval showed significant failure and complication rates, more than justifying the FDA's restrictions, and experience and testing done afterwards continued to show that safety and effectiveness were still problems.

But the abortion industry was impatient, and frustrated at the way this protocol and these certification conditions were keeping them from expanding their prescriber pool and growing their markets for abortion pills.

Danco filed a supplemental new drug application (NDA) in May of 2015 seeking the dropping of the number of required visits, attempting to expand the prescriber pool, and extending the gestational range.

In less than a year's time, the FDA had agreed to all these changes and more, based on studies submitted by the sponsor.

- *An agency in denial*

Concerns about patient injuries like those mentioned by AHM doctors were dismissed as rare. In its Clinical Review for Danco's supplemental NDA, the FDA claimed that "MAB ["medical abortion"] has been increasingly used as its efficacy and safety have become well-established by both research and experience, and serious complications have proven to be extremely rare" (FDA's Clinical Review of Mifeprex, March 29, 2016, p. 12).

The FDA admitted there had been a number of deaths among mifepristone patients but likewise dismissed these as "very low" (Clinical Review, p. 82) and expressed the belief that serious adverse events are tapering off with oral (or buccal) versus vaginal administration of misoprostol and would remain "acceptably low" (Clinical Review, p. 47).<sup>2</sup>

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<sup>2</sup> One common feature of many of the infection deaths was the vaginal self-administration of the second drug in the process, misoprostol, a clear departure from the FDA protocol (mandating oral administration of the prostaglandin in the second step) that had been promoted by many in the abortion industry. By drawing attention to this unauthorized deviation from the agency protocol, the FDA hoped to avert such tragedies in the future. The record shows, however, that infection deaths continued to be a problem after the FDA issued its warnings and revised its protocol.



- *Failing to collect data on the cumulative impact of protocol changes*

As both AHM doctors and the Fifth Circuit court observed, though, the FDA failed to consider the impact of these changes as a whole.

It was one thing to test whether the pills worked at later gestations or whether gestations could be properly estimated, or ectopic pregnancies identified without ultrasound examinations, and another entirely as to whether women could skip all these steps and administer misoprostol (or mifepristone) to themselves at home and manage the complications.

This was a critical issue for the Fifth Circuit.

FDA admits that none of the studies it relied on examined the effect of implementing all of those changes together.... FDA neither considered the effects as a whole, nor explained why it declined to do so. The cumulative effect of the 2016 Amendments is unquestionably an important aspect of the problem; indeed that was the whole point of FDA's action. Because FDA failed to seek data on the cumulative effect, and failed to explain why it did not, its decision to approve the amendments was likely arbitrary and capricious (pp. 44-45).

The FDA and Danco asserted that they were not legally bound to conduct a study that precisely matched the normal circumstances under which the drugs would be used. They say the law gives them the discretion to determine whether a study is "adequate and well controlled."

The court was not satisfied with this response.

The problem is not that FDA failed to conduct a clinical trial that included each of the proposed changes as a control. It is that FDA failed to address the cumulative effect at all. At a minimum, the agency needed to acknowledge the question, determine if the evidence before it adequately satisfied the concern, and explain its reasoning. See *All. for Hippocratic Med.*, 2023 WL 2913725, at \*17

The court continued

"[FDA] relied on zero studies that evaluated the safety-and-effectiveness consequences of the 2016 Major REMS Changes *as a whole*. This deficiency shows that FDA failed to consider 'an important aspect of the problem' when it made the 2016 Major REMS Changes." (p. 45).

- *Representing whose interests?*

The FDA's actions raise serious questions about whose interests the agency was serving. Was it the health and safety of the women taking this dangerous drug, or the interests of the abortion industry and its political supporters?

It seems more than coincidental that each of these major changes – mifepristone 2000 approval, the reduced regulations of the 2016 REMS, the 2021 decision to suspend the requirement for in-person distribution of the pills, all came when the FDA was in the hands of an abortion-friendly presidential administration, often seeking exactly those changes.

- *Dropping reporting of non-fatal “adverse events”*

The Fifth Circuit also criticized the FDA's decision to reduce required reporting of complications or “adverse events.”

One of the changes that the agency made to the REMS in 2016 was to drop the requirement that prescribers had to report all significant adverse events to the FDA. They were still required to report any deaths, but certified prescribers no longer had to report infections, hemorrhages, ectopic pregnancies, hospitalizations, or the like back to the FDA.

Though problematic in its own right, what troubled AHM and the Fifth Circuit was that the FDA dropped this reporting requirement at precisely the time when that sort of data would have proven crucial to evaluation of the safety of the drug's use under the new REMS and protocols.

...FDA failed to consider ...whether it needed to continue to collect data of non-fatal adverse events in light of the “major” changes to the mifepristone REMS. When considering the data collection question, FDA reasoned that non-fatal adverse events did not have to be recorded because the risks associated with mifepristone were well known. FDA Summary Review of 2016 Amendments at 26 (“[A]fter 15 years of reporting serious adverse events, the safety profile for Mifeprex is essentially unchanged.”).

But FDA failed to account for the fact that it was about to significantly loosen mifepristone's conditions for use. At no point during the decision did the agency acknowledge that the 2016 Amendments might alter the risk profile (pp. 45-46).

FDA claims that Danco was still supposed to be reporting these adverse events rang hollow with the judges, who said that without prescribers first reporting these to Danco – which was no longer required – Danco would have no new data to report to the FDA. And, as the judges pointed out, Danco didn't, sending the FDA reports virtually identical to the ones the agency already had in its files.

- *Using lack of data to support dropping safeguards*

What is worse, the judges pointed out, was that the FDA used that deficient data to support the changes the agency made to mifepristone policy in 2021, choosing not to enforce the in-person dispensing requirement.

In that decision, “FDA gave dispositive weight to adverse event data in FAERS [the FDA’s Adverse Events Reporting System].” Judges quoted from the earlier Fifth Circuit judicial panel which first reviewed the case: “It’s unreasonable for an agency to eliminate a reporting requirement for a thing and then use the resulting absence of data to support its decision” (p. 50).

The FDA did this, the court pointed out, knowing that there were already deficiencies in the FAERS data from before, aware that there were multiple reasons and considerable evidence that many serious adverse events were never reported (p. 50).

The FDA data upon which the agency relied was clearly deficient, or at least incomplete, and the agency knew this.

- *A weak response makes FDA deficiencies clear*

Considering the limited evidence regarding the safety of mifepristone under the new proposed conditions, the best that the FDA could muster was to claim that published literature on “remote prescription” of the abortion pills was “not inconsistent” with the agency’s conclusion that use of the drug would “remain safe and effective if the in-person dispensing requirement is removed” (p. 48).

The FDA admitted that the studies it used were “not adequate on their own to establish the safety of the model of dispensing mifepristone by mail” (p. 52).

What the record showed was not the FDA going through a careful examination of the medical data and record, but an agency sloppily going through the motions to get a predetermined result.

In the face of concededly limited data, and lacking more probative information from prescribers, FDA fell back on studies that were merely “not inconsistent” with its *intended* conclusion (p. 53, but emphasis added).

- *The FDA failed to honor its legal obligations*

In doing so, the judges concluded that there was clear evidence that the FDA violated its statutory obligations.

The court points out that the Administrative Procedures Act governing the conduct of the FDA and other government regulatory agencies

... requires federal courts to “hold unlawful and set aside agency action, findings, and conclusions found to be arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with the law.” 5 U.S.C. § 706(2)(A) (p.43).

In overturning the FDA’s actions, the Fifth Circuit was only doing its duty.

- *FDA failed to justify its actions*

The Fifth Circuit wanted to make clear that this was not a matter of the courts overreaching into the agency’s area of expertise.

Courts must set aside agency action where there are “shortcomings in the agency’s explanations” or where “[n]o record evidence affirmatively makes” the agency’s case. *Sw. Elec. Power Co.*, 920 F.3d at 1018–19; see also *State Farm*, 463 U.S. at 56 (“While [an] agency is entitled to change its view. . . it is obligated to explain its reasons for doing so.”). That is the case here (p. 53).

What was guiding the FDA policy was clearly not scientific objectivity and neutral application of the law, but political commitment to a cause.

The record showed the FDA was not prompted to relax mifepristone safety standards by any new evidence demonstrating the statistical superiority of the new protocol. It was, however, clearly responsive to administration prodding and abortion industry pressure to take steps to expand the list of prescribers and broaden the customer base.

## Safe, simple chemical abortions are a crumbling myth.

Throughout the hearing, Danco and the FDA continued to insist that chemical abortions with mifepristone were safe and no longer in need of the tight regulations the FDA had for years imposed on use and distribution of the drug.

Sarah Harrington, the FDA's lawyer, told the court that studies found the method was extremely safe, and "the rate of serious complications is well under 1 percent" (*NY Times*, 5/17/23).

We have already seen where the court used the agency's own documents against them, pointing out that the FDA's patient agreement for mifepristone tells women that "the treatment will not work" in "about 2 to 7 out of 100 women and the 2011 REMS document admits that "about 5-8 out of 100 women taking Mifeprex will need a surgical procedure to stop too much bleeding."

In the light of such admissions, the only way that the FDA can continue to maintain that the rate of serious complications "well under 1 percent" is to redefine what counts as "serious," so that failures, surgery to complete the abortion or to stop the bleeding do not count.

- *How to define "serious complications" out of existence*

One of the studies the FDA relied upon to make this claim (FDA, Clinical Review, March 29, 2016, at p. 56) was a study led by Ushma Upadhyay, an abortion researcher from the University of California-San Francisco.

A 2015 study of emergency room visits by University of California, San Francisco researcher Ushma Upadhyay is one of those often cited as proof that the rate of serious complications is "less than 1%." Indeed, in "Incidence of emergency department visits and complications after abortion," from the January 2015 issue of *Obstetrics & Gynecology*, Upadhyay officially found that "The major complication rate was 0.23%," less than a quarter of one percent.

But this depends on several questionable moves to finesse the data.

First, Upadhyay specifically limits what can be counted as a "serious" or "major" complication. "Major complications were defined as serious unexpected adverse events requiring hospital admission, surgery, or blood transfusion," the article asserts. "Minor complications were all other expected adverse events."

While this sounds reasonable, consider the things included in Upadhyay's "minor complications": hemorrhage, infection, incomplete or "failed" abortion requiring "uterine aspiration" (i.e., surgical abortion). Even things like "uterine perforations" were classified as "minor."

Second, with this knowledge, consider that when Upadhyay added in and counted both major and “minor” complications, the complication rate for chemical abortions was 5.19% – considerably higher than the “less than one percent” advertised (R.K. O’Bannon, National Right to Life News, June 2023).

If serious incidents were really rare, the number of encounters reported by the AHM doctors represents an extreme and unlikely statistical aberration. How they just happened to be in the right place at the right time to come into contact with so many women dealing with these chemically-induced emergencies defies all odds.

- *Numbers contradict FDA claims*

The court heard not just of random individual doctors relating rare individual events, but stories of multiple encounters by AHM doctors. In a case mentioned earlier, the court quoted board certified obstetrician-gynecologist Ingrid Skop.

In my practice, I have cared for at least a dozen women who have required surgery to remove retained pregnancy tissue after a chemical abortion. Sometimes this includes the embryo or fetus, and sometimes it is placental tissue that has not been completely expelled. I have cared for approximately five women who, after a chemical abortion, have required admission for a blood transfusion or intravenous antibiotics or both.

For example, in one month while covering the emergency room, my group practice admitted three women to the hospital. Of the three women admitted in one month due to chemical abortion complications, one required admission to the intensive care unit for sepsis and intravenous antibiotics, one required a blood transfusion for hemorrhage, and one required surgical completion for the retained products of conception (i.e., the doctors had to surgically finish the abortion with a suction aspiration procedure) (p. 17).

The seriousness of these complications is indisputable. But so are the statistical implications.

That one doctor or even one medical group (other than the ones prescribing abortion pills) might encounter one or, maybe on rare occasions, two women facing such crises, might be believable, but a *dozen* needing surgery, *five* needing transfusions or IV antibiotics, *three* being hospitalized? That's a clear indication that something's wrong with the original statistical data and the claims being made about the safety and efficacy of mifepristone.

- *Without data, safety claims in doubt*

The court notes that even the FDA admits that the data it receives is insufficient to yield a conclusive adverse event rate for mifepristone. Because FAERS, the FDA's adverse event reporting system, is

voluntary, the court says, “many adverse events will go unreported,” and the agency grants that this data “cannot be used to calculate the incidence of an adverse event or medication error in the U.S. population” (p. 50).

Even abortion advocates report higher numbers of complications. The court cites the testimony of one doctor who in a published study compared FDA data with that published by abortion provider Planned Parenthood for the same year.<sup>3</sup> “For 2010, the provider reported 1,530 adverse events,” the court related, “whereas FAERS reported only 664 events for all providers nationwide” (p. 50).

This can only be the case if some events are not being reported to the FDA or the FDA is reclassifying events some found major as insignificant.

- *Changes may increase adverse incidents*

The judges were concerned not only that these reports gave a false notion of the drug’s safety, but also that the loosening of the regulations and the alteration of the protocol by the FDA in 2016 and 2019 might mean *more* adverse events.

Because the likelihood of failure and the incidence of complications increases with gestational age, the FDA’s extension of the deadline for mifepristone from 49 to 70 days after a woman’s last menstrual period automatically increases the likelihood of adverse events. Add to this the FDA’s broadening the pool of prescribers to include non-physicians with less skill and experience in ascertaining gestational age or diagnosing ectopic pregnancy and the risk will rise more.

Changes made in 2021 (and formalized in 2023) dropping any requirement that the woman see her prescriber (or his agent) in person make the precise clinical determination of gestational age and the identification of ectopic pregnancy considerably more difficult and less likely, putting more women’s lives at risk.

Judges share accounts provided by the AHM doctors that complications increased with these changes and say that the doctors have made their case. “Given the already substantial risk of harm,” the court says, “the evidence of increased risk is sufficient to confer standing to challenge the 2016 Amendments” (p. 32).

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<sup>3</sup> Christina A. Cirucci, Kathi A. Aultman , and Donna J. Harrison, “Mifepristone Adverse Events Identified by Planned Parenthood in 2009 and 2010 Compared to Those in the FDA Adverse Event Reporting System and Those Obtained Through the Freedom of Information Act,” *Health Services Research and Managerial Epidemiology* Volume 8: 1-5 (December 2021).

Pages later, it adds that the doctors “have made a clear showing that the 2021 Non-enforcement Decision causes an increased risk of injury” (p. 34)

Judge Ho, in his concurrence/dissent, said “the FDA initially authorized mifepristone under certain safeguards to minimize harm. Remove these safeguards, and you’ve significantly altered the stakes of judicial review” (p. 74).

Even before the FDA relaxed the safeguards, the impact of chemical abortion on women’s health was already so great that it raised concerns with the doctors at AHM and judges at the district and circuit courts. Subsequent modifications the FDA made to mifepristone’s REMS only raised the stakes higher.

- *Even the FDA projects high numbers of complications*

However rare or common these complications may be, the sheer number of uses of the abortion pills prompted by the FDA’s approval and the industry’s promotion of the drug mean that the raw number of those affected is substantial.

Recent reports that more than half of the abortions performed in the U.S. each year are chemical merit special concern (Guttmacher data for 2020). With more than 900,000 abortions now being performed annually in America, mifepristone potentially impacts close to half a million women a year.

Even if one takes the most conservative estimates of adverse events, assertions by FDA and Danco that 5 million have used mifepristone mean that “thousands of women, and as many as hundreds of thousands, have experienced serious adverse events as a result of taking the drug, and required surgery or emergency care to treat those effects” (p. 16).



Abortion takes the life of an innocent unborn child and that still matters to a lot of people.

Though this case was brought and argued after *Dobbs*, some may have been surprised to see little direct mention of that case or much about the Supreme Court's action overturning *Roe v. Wade* in the Fifth Circuit's opinion.

The main reason for this is that the case did not deal with any state or federal abortion law *per se*, but with the regulatory actions of a federal agency that impacted the availability of an abortion drug in the marketplace.

The reason for this may be that the court did not believe the legal status of abortion was directly at issue and perhaps felt that to go there would invite a diversion. Or maybe it was that the court thought it was primarily the safety of chemical abortion patients and the integrity of the drug approval process that were at stake.

But there is no denying that the issue of abortion hovers over much of the discussion and exactly what mifepristone does to unborn children and their mothers.

While the media notes the way the court's decision may impact mifepristone's availability and thus the nation's larger abortion debate, it largely fails to consider its impact on unborn children. To some extent, the court remedies this.

- *The FDA ignores the baby*

There is the basic question of why the FDA even considered a drug for killing unborn children in the first place. If it was considering a drug for curing some disease, or treating some deleterious condition, the balancing of risks and benefits, the testing and trials, the careful attenuation of considerations of the proper dosage and delivery all made sense, and were defensible.

But when the drug was used to put a woman with a normal, healthy pregnancy through great pain and misery, to expose her to significant and totally unnecessary risks, the agency's policies and their application made little sense.

Only by treating the unborn child as a non-entity, or worse, as a tumor or some diseased body part could the drug approval process move forward.

- *The "abortion distortion" affects the agency's approval process*

This is why the FDA was virtually forced to go the route of considering mifepristone under the Subpart H statute, to treat pregnancy as a "life threatening illness," when by any reasonable legal or scientific standard, it clearly did not apply and was ill suited to the purpose.

To make this happen, the FDA had to treat abortion, the death of a healthy human child, as a legitimate outcome or the desired medical objective, putting their ordinary concerns for the health and safety of their patients – in this case, it should have been mothers and their unborn babies – aside or at least redefining the rules so as to be nearly unworkable and unrecognizable.

Abortion, however, is by nature a violent and destructive process, whether by surgical or chemical means. This is not only for the child, but also for the mother. And this is why, even when supposedly addressing the health needs of the woman, favoring her interests over the needs of her child, the FDA ended up helping neither, subverting their health and safety for the sake of the larger abortion political cause.

- *The Fifth Circuit saw this deviation from standard procedure and called “foul”*

What you have in the court’s opinion is not an activist judiciary, but doctors and judges who see and consider the interests of all the patients involved, and this puts the FDA and Danco, the abortion pill producer, in a deservedly negative light.

The agency’s legal scheme was an ill-fitted contortion and obvious misapplication of the Administrative Procedures Act, the law granting the FDA authority over drug approvals. The studies upon which the FDA relied, determining what happened when healthy women received drugs that turned their bodies against them and the children they carried were not simply unusual, but bordering on unethical. The whole process created the bizarre and troubling spectacle of a government agency treating, with undue seriousness and unwarranted respect, results that perhaps would have been considered, under normal circumstances, the cruel experiments of some mad scientist.

Having committed itself to this agenda and this compromised course, the FDA faced a dilemma when Danco and its allies began pressing for broader access and lighter regulations, even while reports of maternal deaths and injuries came flooding in.

Did it suddenly recall and resume its mandated concern for women’s health and safety, or did it finally show regard for the health and safety of the child she carried? Or did it double down on its errors and evasions, continuing to lend its considerable authority and expertise to support a cause which treats the lives of pregnant women and their unborn children as expendable?

The FDA chose the latter course and the Fifth Circuit and AHM called them on it.

- *Pro-life doctors showed concern for both mother and child*

AHM doctors demonstrated to the Fifth Circuit that they showed appropriate concern for the health and safety of both the patients involved, for the mother and the child, something the FDA decidedly and intentionally did not do, despite their statutory mandate.

The AHM doctors who had to treat the complications of women who suffered after taking the FDA-approved pill had a clearer sense of mifepristone's problems than the agency which relied on less than objective reports from an abortion industry angling for reduced regulations.

That these AHM doctors also happened to be doctors who grieved the loss of life of those mothers' children and were troubled by being forced to participate in their abortion was part of the same package – their being medical professionals who had an authentic commitment to the health and safety of all human life, no matter what its age or stage of development.

The FDA lacked this fundamental commitment to human life, and thus failed in its statutory duties.

- *Judges give the unborn their due*

As we have seen, the court's main opinion makes this clear by extensively quoting from the AHM doctors and juxtaposing their concerns and actions with the FDA's compromised process.

Judge James C. Ho makes the case more directly in his concurrence/dissent. Beyond taking on the FDA's improper use of Subpart H directly, Ho's is the opinion which explicitly makes it a point to refer to the unborn child.

Ho feels it is necessary to have this sense to fully appreciate the injury the FDA's lax regulation imposes on doctors who have this appropriately deep and sincere commitment to human life.

Unborn babies are a source of profound joy for those who view them. Expectant parents eagerly share ultrasound photos with loved ones. Friends and family cheer at the sight of an unborn child. Doctors delight in working with their unborn patients—and experience an aesthetic injury when they are aborted.

Plaintiffs' declarations illustrate that they experience aesthetic injury from the destruction of unborn life (p. 68).

He fleshes it out more directly with a quote from a Dr. Jester that was part of the court's record.

When my patients have chemical abortions, I lose the opportunity . . . to care for the woman and child through pregnancy and bring about a successful delivery of new life (p. 69).

Though Ho makes these observations in the context of the discussion over whether the AHM doctors have standing, this aptly illustrates what should have been the true moral, medical, and legal context of the decisions made by the FDA. Yet instead of acknowledging those obligations

and seeking to fulfill them, the FDA challenges the legitimacy and interests of those who do acknowledge and accept those obligations, showing how badly the FDA's accommodation of and entanglement with the abortion industry has corrupted the agency's mission.

- *FDA's authorization to mail mifepristone raises old federal issues*

While this is not a situation that *Dobbs* addresses directly, the outcome of *AHM v. FDA* does have bearing on the national abortion discussion.

Many states, appalled by the loss of human life within their borders, have put in place protections for unborn babies, effectively prohibiting the use of abortifacients like mifepristone for all but the most serious situations and emergencies.<sup>4</sup>

The mailing of mifepristone, something the FDA authorized in REMS modifications announced in 2021 and formalized in 2023 – one of the challenged decisions in this case – is in direct violation of the Comstock Act, a federal law which has been in place since 1873, making it illegal to mail any “obscene, lewd, or lascivious” materials, like pornography, or any article or thing “intended for the prevention of conception or procuring of abortion.”

Though some applications of the law, such as its prohibitions on the mailing of pornography or contraceptives, have been modified, reinterpreted or overruled in the 150 years since its passage, the section on the mailing of abortifacients has never been repealed, despite some efforts to do so.

For the court to allow the FDA to make its most recent REMS revision and allow these pills to be shipped to women's homes would be for the court to countenance defiance of federal law, the same law that they are sworn to defend and uphold.

The FDA, once again, imagines itself as above the law, or worse, sees itself as the unquestioned source of the law, as the agency duly empowered and deputized to make absolute determinations about the safety and availability of various foods, drugs, and medical devices.

This is an overreach, the Fifth Circuit says. The FDA is bound to stay in its lane, make appropriate and objective scientific judgments, and discharge its statutory responsibilities to protect the health and safety of all Americans.

It is to work for the people, for the county as a whole, not for the pharmaceutical companies, not for the abortion industry, not for the political parties.

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<sup>4</sup> It should be noted that mifepristone does not work in cases of ectopic pregnancy, one of the more common emergencies, so the drug's value, even in these circumstances, is questionable.

- *Dobbs allows states to limit mifepristone access*

The FDA forgets, or at least chooses to ignore, that one of the consequences of *Dobbs* is that the agency no longer has the authority or excuse to presume, facilitate or enforce a national right to abortion or to abortion pills. The Supreme Court allowed people who saw the humanity of the unborn child to protect them through the power of their elected representatives.

In some States, voters may believe that the abortion right should be even more extensive than the right that *Roe* and *Casey* recognized. Voters in other States may wish to impose tight restrictions based on their belief that abortion destroys an “unborn human being.” Miss. Code Ann. §41–41–191(4)(b). Our Nation’s historical understanding of ordered liberty does not prevent the people’s elected representatives from deciding how abortion should be regulated (*Dobbs*, p. 31).

We therefore hold that the Constitution does not confer a right to abortion. *Roe* and *Casey* must be overruled, and the authority to regulate abortion must be returned to the people and their elected representatives (*Dobbs*, p. 69).

There are people who care for unborn children and their mothers, and both the Supreme Court and the Fifth Circuit have said that lives of both these patients and their interests may no longer be summarily ignored, particularly by an agency supposedly dedicated to their welfare.

## Summary

**T**he media likes to portray this case as if it were solely a case about abortion or abortion pills, but in truth, it is a case about whether a powerful federal agency will do its job and look after the health and safety of all those who live within its borders.

The government's past treatment (particularly under some administrations) of abortion as "health care" – treating the killing of unborn children and the endangerment of their mothers' lives as if it was some wholesome, therapeutic treatment – has led to the corruption of many government institutions and agencies, as well as society as a whole.

The Fifth Circuit and the doctors of AHM finally said, "Enough!"

In essence, they declared, "You can't keep bending the rules, throwing around your weight as a federal agency, ignoring the science and pretending that these dangerous drugs are a safe and effective, treating this as just another form of treatment, as a morally, legally unproblematic way of taking the life of an innocent unborn child when the evidence clearly says otherwise."