SUPREME COURT
OF THE UNITED STATES

IN THE SUPREME COURT OF THE UNITED STATES

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FOOD AND DRUG ADMINISTRATION,)
ET AL.,)
Petitioners,)
v.) No. 23-235
ALLIANCE FOR HIPPOCRATIC MEDICINE,)
ET AL.,)
Respondents.)

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DANCO LABORATORIES, L.L.C.,)
Petitioner,)
v.) No. 23-236
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Pages: 1 through 104

Place: Washington, D.C.

Date: March 26, 2024

HERITAGE REPORTING CORPORATION
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FOOD AND DRUG ADMINISTRATION, ET AL., Petitioners, v. ALLIANCE FOR HIPPOCRATIC MEDICINE, ET AL., Respondents.) No. 23-235

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DANCO LABORATORIES, L.L.C., Petitioner, v. ALLIANCE FOR HIPPOCRATIC MEDICINE, ET AL., Respondents.) No. 23-236

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Washington, D.C.

Tuesday, March 26, 2024

The above-entitled matter came on for oral argument before the Supreme Court of the United States at 10:04 a.m.

APPEARANCES:

GEN. ELIZABETH B. PRELOGAR, Solicitor General, Department of Justice, Washington, D.C.; on behalf of the Federal Petitioners.

JESSICA L. ELLSWORTH, ESQUIRE, Washington, D.C.; on behalf of Petitioner Danco Laboratories, L.L.C.

ERIN M. HAWLEY, ESQUIRE, Washington, D.C.; on behalf of the Respondents.

C O N T E N T S

P R O C E E D I N G S

(10:04 a.m.)

CHIEF JUSTICE ROBERTS: We will hear argument this morning in Case 23-235, the Food and Drug Administration versus Alliance for Hippocratic Medicine, and the consolidated case.

General Prelogar.

ORAL ARGUMENT OF GEN. ELIZABETH B. PRELOGAR
ON BEHALF OF THE FEDERAL PETITIONERS

GENERAL PRELOGAR: Mr. Chief Justice, and may it please the Court:

FDA approved mifepristone based on the agency's scientific judgment that the drug is safe and effective. It's maintained that judgment across five presidential administrations, and millions of Americans have used mifepristone to safely end their pregnancies. Respondents may not agree with that choice, but that doesn't give them Article III standing or a legal basis to upend the regulatory scheme.

At the outset, Respondents lack standing. They now concede they can't rely on a statistical theory of injury like the lower courts did. Instead, they have to identify a

specific doctor who faces imminent harm.

But their theories rest on a long chain of remote contingencies. Only an exceptionally small number of women suffer the kind of serious complications that could trigger any need for emergency treatment. It's speculative that any of those women would seek care from the two specific doctors who asserted conscience injuries. And even if that happened, federal conscience protections would guard against the injury the doctors face.

And there's no basis to conclude that any of that would be traceable to the incremental changes that FDA made in 2016 and 2021 as opposed to the availability of mifepristone in general. Respondents' theories are too attenuated as a matter of law. The Court should say so and put an end to this case.

If the Court reaches the merits, FDA's actions were lawful. The agency relied on dozens of studies involving tens of thousands of women. Respondents don't identify any evidence that the agency overlooked. They just disagree with the agency's analysis of the data before it, but that doesn't provide a license to

authorize judicial second-guessing of the agency's expert judgments.

Finally, on remedy, the relief entered below would severely disrupt the federal system for developing and approving drugs, harming the agency and the pharmaceutical industry. It would also inflict grave harm on women across the nation. Rolling back FDA's changes would unnecessarily restrict access to mifepristone with no safety justification.

Some women could be forced to undergo more invasive surgical abortions. Others might not be able to access the drug at all. And all of this would happen at the request of plaintiffs who have no certain injury of their own. The Court should reject that profoundly inequitable result.

I welcome the Court's questions.

JUSTICE THOMAS: General, if we agree with you on standing, could you give us an example of who would have standing to challenge -- to challenge these FDA actions?

GENERAL PRELOGAR: As a general matter, we've seen lawsuits in the past that are brought by, for example, prescribing physicians

or patients who want greater access to a drug. Sometimes we've seen theories of competitor standing, where a competing drug manufacturer might sue and claim that FDA's approval of a drug creates a competitive harm or in -- or injury in that sense.

You know, Justice Thomas, I think that if the question is whether there would be individuals who generally oppose abortion who would have standing and want to challenge FDA's actions, the answer to that is no, but the reason is because those people aren't regulated in any relevant way under FDA's decisions here.

You know, take these Respondent doctors. They don't prescribe mifepristone. They don't take mifepristone, obviously. FDA is not requiring them to do or refrain from doing anything. They aren't required to treat women who take mifepristone. FDA is not directing the women who take the drug to go seek out care from these specific doctors. And so they stand at a far distance from the upstream regulatory action they're challenging.

And the Court has said in -- in many cases that in a situation like that, when you

are not the direct object of the agency's regulation, it can be substantially more difficult to establish standing.

JUSTICE THOMAS: But isn't that sort of a criticism of some of our associational standing cases and organizational standing cases?

GENERAL PRELOGAR: I don't think it is for a couple of different reasons.

With respect to associational standing, this Court has said time and again that the association needs to identify a specific member who is suffering a concrete harm, a cognizable injury that's non-speculative. And I don't take Respondents now to take issue with that fact. They're agreeing that it would be necessary to come forward and identify a specific doctor.

The problem with their associational standing theories is that they rest on this chain of remote possibilities, so many different steps in the process that would have to occur, each one layering one's speculative remote odds of a chance of injury on top of another to get to the ultimate harm they're claiming on behalf

of these doctors.

CHIEF JUSTICE ROBERTS: Well, you emphasized the remote nature of the injury, the small number of adverse effects, the likelihood that they'll -- the -- the patients will go to the emergency room and so on.

Is there a number at which your argument would -- would change? A significant number of consequences? A higher likelihood of an emergency room visit? Doctors who spend more time in the emergency room? At -- at -- at some point, does this analysis lead to the other result?

GENERAL PRELOGAR: It's hard for me to imagine that it could, and -- and there are a couple of different reasons for that. I take the point that you might pick out different links in the chain and suggest that there are ways to wildly depart from the facts here and suggest maybe, as a statistical matter, one or two of those events could be probabilistically more likely to occur.

But we have an objection here to the underlying theory as a legal matter because it rests on so many different things that would

have to happen one on top of another and that turn on independent decisions made by third parties who are strangers to this litigation, who are not part of the suit.

So we think that brings the case within those like Clapper or Summers, where this Court has recognized that when the theory of injury really turns on so many different intervening events separated by independent decisions, it can mean that there is just an insurmountable hurdle to establishing standing.

JUSTICE ALITO: Could you provide a more specific answer to the first question that Justice Thomas asked you? Is there anybody who could challenge in court the lawfulness of what the FDA did here?

GENERAL PRELOGAR: In this particular case, I think the answer is no.

JUSTICE ALITO: Well, that wasn't my question. Is there anybody who can do that?

Let's -- let's start with the states that intervened below. Will you say in that litigation, fine, you can challenge it, and let's get to the -- to the merits of this issue, the lawfulness of what the FDA did?

GENERAL PRELOGAR: No. We think the states lack standing. They're asserting indirect injuries that would, if it provided a basis for standing, mean that states could always sue the federal government. And the Court cautioned against that result in United States versus Texas, Footnote 3 of that decision.

JUSTICE ALITO: Okay. How about a -- a doctor who opposes abortion? So she's on duty in an emergency room when a woman comes in with complications from having taken mifepristone, and the doctor is the only one there on duty who can attend to this woman's problem and, as a result, in order to save her life, the doctor has to abort a viable fetus.

Now would that doctor then have standing to seek injunctive relief, or would you say that's too speculative? This was like being struck by lightning and there's no -- it's not sufficiently likely that this is going to happen to this doctor again?

GENERAL PRELOGAR: We would agree that that would represent past harm, so we're not disputing that that kind of conscience

violation, providing care in violation of one's conscience, would be cognizable. But, yes, we think that that situation has never come to pass. Respondents haven't identified any incident in more than 20 years that mifepristone has been available on the market that resembles that kind of hypothetical situation.

And so, yes, our view would be it's unduly speculative. And you have to think about all of the events that would have to transpire to get to that moment in time.

JUSTICE ALITO: Sure. No, I -- I understand the argument.

Now how about a woman who suffers adverse consequences from having taken mifepristone? Would she be able to sue for damages, or you would say that's barred by sovereign immunity?

GENERAL PRELOGAR: I expect that we would have sovereign immunity arguments in that kind of case. I -- I recognize that respect -- with respect to traceability, that's a harder argument for us.

JUSTICE ALITO: Okay. Is there anybody who can sue and get a judicial ruling on

whether what FDA did was lawful? And maybe what they did was perfectly lawful, but shouldn't somebody be able to challenge that in court? Who in your view? Who would have standing to bring that suit?

GENERAL PRELOGAR: I think that with respect to these regulatory changes, it's hard to identify anyone who would have standing to sue, but the Court has said time and again that the fact that no one would have standing doesn't provide a basis to depart from Article III principles.

It said that in Raines, in Richardson, in Valley Forge, and in Clapper, and so I think it's clear that even if there is no alternative person here who could sue, that doesn't mean that the Court should dispense with the indispensable requirements of Article III.

JUSTICE ALITO: Okay. I understand that. And Article III is important.

So your argument is that it doesn't matter if FDA flagrantly violated the law, it didn't do what it should have done, endangered the health of women, it's just too bad, nobody can sue in court?

GENERAL PRELOGAR: Certainly, we think that these --

JUSTICE ALITO: There's no -- there's no remedy? The American people have no remedy for that?

GENERAL PRELOGAR: Well, I -- I -- I think that it would be wrong to suggest that if FDA had made a mistake and a drug were actually producing safety consequences that there would be nothing to be done. I -- I don't think that these Respondents could invoke Article III jurisdiction to have the Court step in.

But FDA takes very seriously its responsibility to ensure the safety of drugs. It conducts ongoing surveillance and can make adjustments to the regulatory regime if safety situations emerge. The drug sponsors themselves remain responsible at all times. We have a tort system in this country, and that can help ensure that if there are safety problems that come to pass, the sponsors will take action in reaction to that.

So, if the premise here is that unsafe drugs could somehow remain on the market, I think that that's incorrect.

JUSTICE ALITO: I mean, so your argument here is -- and as I said, I have great respect for Article III. We all do. We have to comply with it.

But your argument here is that even if the FDA acted unlawfully, nobody can challenge that in court? I mean, that's basically the argument you made last week, right, in the Murthy case. We shouldn't get to the question whether the White House and others violated the right to freedom of speech. We should just say, well, these plaintiffs can't bring suit, right?

GENERAL PRELOGAR: We -- we are looking at the specific Respondents in this case and their theories of standing. We don't think they come within a hundred miles of the kind of circumstances this Court has previously identified of non-speculative harm that can create the kind of cognizable injury for forward-looking relief.

JUSTICE JACKSON: General --

JUSTICE SOTOMAYOR: I'm assuming that if there were an on -- if this had been unsafe in a grossly visible way, you know, 40 percent more increased hospitalizations, that some

doctor who was prescribing it would have challenged the lack of an in-person --

GENERAL PRELOGAR: Well, no doctor is required, Justice Sotomayor, to dispense other -- in person, so they would have --

JUSTICE SOTOMAYOR: No, but a doctor who wants to, just like a doctor who wants to do abortion, we have said, if there's regulations that stop them from doing it, I guess that doctor could come in and say: This is unsafe, I can't -- by not having people visit me beforehand, we're not warning them, et cetera, et cetera.

GENERAL PRELOGAR: Certainly, I think, if those kinds of -- of distinct safety concerns emerge, there would be steps taken at the agency level. There's nothing like that here. There's no contrary --

JUSTICE SOTOMAYOR: No, I'm -- I'm pondering --

GENERAL PRELOGAR: -- evidence to suggest it.

JUSTICE SOTOMAYOR: -- I'm pondering a hypothetical.

GENERAL PRELOGAR: But I do want to be

clear that FDA's regulations here don't require doctors to -- to -- to not grant an in-person visit if they think that that is the best way to provide a standard of care here. So they are not directly required to dispense mifepristone through any particular arrangement.

JUSTICE SOTOMAYOR: All right.

JUSTICE BARRETT: Counsel, can I ask you a question about the conscience injury. So that's one of the roadblocks you identify in the speculative chain because you say a doctor could invoke federal conscience protections to refuse to complete an abortion that was when the -- the embryo or fetus was still alive.

So I just want to be clear, the federal government's position is that their doctor would have conscience objections -- I'm thinking about the EMTALA litigation, and the Fifth Circuit criticized the government's inconsistent positions -- but it is your position that such doctors would have recourse to the conscience protections of federal law?

GENERAL PRELOGAR: Yes, absolutely. And let me be clear about this because I think the Fifth Circuit did fundamentally

misunderstand our arguments and Respondents have repeated that misunderstanding here.

The federal government has never taken the position that EMTALA would override an individual doctor's conscience objections. We said exactly the opposite. If you go and look at our Fifth Circuit reply brief in the Texas litigation, we disclaimed that understanding of EMTALA and made clear that we understand the conscience protections to continue to apply and shield a doctor who doesn't want to provide care in violation of those protections.

JUSTICE BARRETT: Would that be true in a healthcare desert as well?

GENERAL PRELOGAR: Yes. So we don't think that EMTALA would override conscience protections for the individual doctor. It, of course, imposes obligations on hospitals, and hospitals have all kinds of plans in place to address these types of contingencies. You know, they have staffing plans. I understand, as a matter of best practices, they often ask for doctors to articulate their conscience objections in advance so they can take account of that in staffing. They have cross-staffing

agreements with other hospitals.

And in the government's experience enforcing EMTALA -- this is almost four decades of experience -- we are not aware of any situation where there has been that kind of direct conflict between EMTALA and conscience protections.

JUSTICE BARRETT: Okay. Just one last question. This is about the association's standing, so its own standing in its own right I'm talking about, not its standing that based -- is based on injury to one of its members.

So the injuries that the association is arguing sound in the Havens Realty associational standing, and they're the kinds of allegations we see by immigration advocacy groups, diversion of resources, increased expenses that result from the complications of having to address and explain the new changes.

And I'm not talking about the expenses of filing the petition. That's not what I'm talking about. Let's just talk about the diversion of resources.

Can you distinguish that from Havens Realty?

GENERAL PRELOGAR: Yes. So I think Havens itself was trying to distinguish between two types of potential organizational injuries, and what Havens said is that in that case, the organization had come forward with direct and concrete demonstrable injury to itself.

And there the organization had a contract to provide low-income housing or -- or search to secure it for clients and the racial steering practices directly interfered with that, made it more difficult for the organization to carry out its contractual obligations.

But Havens itself said that it was not blessing a theory of standing that would allow an organization to assert a setback to its abstract social interests. So I think that reflects the Court trying to distinguish between more concrete, direct demonstrable harms on the one hand and that kind of abstract setback on the other hand.

And I recognize -- and you -- your question touches on it, Justice Barrett -- that some lower courts in particular have seemed to read -- read Havens to -- to endorse far broader

theories of standing, including in the immigration context.

The government has been routinely resisting standing because we think that that would essentially mean that any advocacy organization could say it opposes what the federal government is doing and so, therefore, has to devote resources to that opposition.

If that were enough, then every organization would have standing and it would be a vast expansion of ordinary Article III principles. So we would welcome an eventual clarification from this Court on organizational standing, but, here, I think that the organization's assertion of injury falls in the bucket of the abstract setback and doesn't come close to the kind of demonstrable harm that was at issue in Havens.

JUSTICE GORSUCH: General, that's -- I'm sorry.

JUSTICE BARRETT: I'm done.

JUSTICE GORSUCH: Okay. That -- that -- that's a helpful clarification. I -- I'd like a -- a similar clarification -- thank you -- with respect to individuals.

I -- I -- I've heard and listened to your argument and read the briefs and I think I understand it, but how does it fit in your mind with offended observer standing under the Establishment Clause or some injuries about I access a park and I like to look at it in -- in a certain way and those kinds of injuries that the Court has sometimes recognized and other times cast doubt on?

GENERAL PRELOGAR: So it's true. I think that there are different strands of this Court's precedent, you know, and -- and I would put the Establishment Clause precedent and First Amendment precedent generally in its own bucket because --

JUSTICE GORSUCH: Well --

GENERAL PRELOGAR: -- the Court has sometimes recognized different theories in the First Amendment context.

JUSTICE GORSUCH: -- let -- let me just push back on that a little bit because standing is standing. It's Article III, right --

GENERAL PRELOGAR: Yes.

JUSTICE GORSUCH: -- that we're

interpreting here, and so I think it's got to -- we've got to find some way to stitch it all together, and -- and I'm looking for guidance from you.

GENERAL PRELOGAR: So I -- I -- I think the way to approach this is to -- if you're going to recognize some kind of offense or distress type of injury, that -- to recognize that there has --

JUSTICE GORSUCH: Should we?

GENERAL PRELOGAR: Well --

JUSTICE GORSUCH: I guess as a preliminary.

GENERAL PRELOGAR: No. I mean, I --

JUSTICE GORSUCH: No?

GENERAL PRELOGAR: -- I represent the government, so I think that that kind of theory of injury would likely go far, far too much in the direction of allowing Article III courts to -- to weigh in based on generalized grievances.

But I guess what I would say is to distinguish the cases where this Court has sometimes found that type of injury cognizable, generally, it's in a situation where there is a kind of direct governmental action producing

that type of injury.

And, here, our argument is that the FDA's actions in approving mifepristone specifically in 2016 and 2021 and -- if you're looking at that, which was an incremental change, is so far upstream of the downstream assertion of harm or distress that the Respondents are asserting that there is just as a matter of law an attenuated link here that cannot suffice for Article III jurisdiction.

JUSTICE GORSUCH: Thank you.

CHIEF JUSTICE ROBERTS: Thank you, counsel.

Justice Thomas, anything further?

Justice Alito?

JUSTICE ALITO: You say that the -- the Fifth Circuit didn't give any reason to think that the three changes made in 2016 would be more dangerous in combination than they were individually. But isn't that -- isn't that obvious, that three things that may be innocuous or not excessively dangerous, if engaged in by themselves, may become very dangerous when they're all done together? And why shouldn't the FDA have addressed that?

GENERAL PRELOGAR: I think the only way that that would be true would be if the three changes are interconnected and mutually reinforcing, guarding against the same kind of safety risk. So I agree that if there were a reason to think that the -- the reason why mifepristone is safe up to 10 weeks' gestation is because it's being prescribed by doctors instead of nurse practitioners, for example, then those changes would be interconnected because one change would effectively be the safety net for another.

But there was nothing like that in this record. The studies that FDA examined instead demonstrated that these changes -- and -- and it was an exhaustive examination -- were safe not because there were other different safeguards in place to guard against risks but, rather, because, if you go up to 10 weeks of gestation, there is no observable increase in serious adverse events, no matter who's prescribing.

So, in the absence of that kind of correlative effect of the changes, I don't think you can fault the agency for not giving even

more explicit attention to this issue. And it did. It cited multiple studies that combined multiple changes precisely because the standard of care had evolved over the 15 years mifepristone had been approved, and many of the changes were already being deployed together safely.

JUSTICE ALITO: Shouldn't the FDA have at least considered the application of 18 U.S.C. 1461?

GENERAL PRELOGAR: So I -- I think that the Comstock provisions don't fall within FDA's lane. FDA, under the FDCA, can only maintain restrictions under the REMS program if it's necessary to ensure safe use. In 2021, what FDA determined is you don't need in-person dispensing for safe use, so the FDCA did not independently require that REMS restriction, and, in fact, it couldn't be imposed once FDA had made that determination.

Now that doesn't affect other sources of law. FDA was not affirmatively approving mailing in violation of Comstock, even if you interpreted it that way. And we don't think it means what Respondents suggest it means. But,

at the very least, I don't think that it was FDA's responsibility to consider that, nor could it have permissibly considered that under the statute.

JUSTICE ALITO: Well, it didn't say any of that. It didn't say anything about it. And this is a prominent provision. It's not some obscure subsection of a complicated obscure law. They -- they knew about it. Everybody in this field knew about it.

Shouldn't they have at least addressed it? You have answers to the arguments that are made on the other side. Shouldn't the FDA have at least said we've considered those and provide some kind of an explanation?

GENERAL PRELOGAR: Let me give two responses. One is that I don't think it would have even been permissible for FDA to consider maintaining this restriction because of Comstock. If you look at the relevant statutory section here -- it's 355-1(g)(4). This is reproduced at page 6a of the appendix to our brief. It's very clear that the only thing FDA can take into account for restrictions are safety and efficacy concerns in deciding whether

to maintain a REMS program.

But the other thing I would say, Justice Alito, is that the agency did have a memorandum on Comstock. It's at JA 535. That was the advice that FDA received from OLC conveying the interpretation of Comstock.

JUSTICE ALITO: It -- they got the advice from OLC, but it didn't refer to that, did it?

GENERAL PRELOGAR: In the 2021 decision, no. But the REMS was then modified in 2023, and this was part of the administrative record for that.

JUSTICE ALITO: Okay. One -- one last question. The plaintiffs say that the studies that the FDA relied on for the 2021 amendments say that mail-order mifepristone suggests more frequent trips to the emergency room.

Now this is what I see as the FDA's response to that. "Although the literature suggests there may be more frequent emergency room care visits related to the use of mifepristone when dispensed by mail from the clinic, there are no apparent increases in other serious adverse events related to mifepristone

use."

Does that really count as a reasoned explanation to the suggestion that the data shows there are going to be more emergency room visits? This is -- the -- the increase in emergency room visits is just of no consequence? It doesn't even merit some -- some comment?

GENERAL PRELOGAR: That is a reasoned explanation. What FDA was observing in that passage is that although it acknowledged the fact that some of the studies reported additional emergency room visits, that didn't equate to additional serious adverse events.

And, in fact, one of the studies, half of the women who went to the emergency room didn't get any treatment at all. Many women might go because they're experiencing heavy bleeding, which mimics a miscarriage, and they might just need to know whether or not they're having a complication. But, in that kind of circumstance, the woman is not having a -- a -- a serious adverse event from mifepristone, and so it doesn't call into question the safety determinations regarding the drug.

And, you know, at the end of the day,

FDA carefully parsed those studies. It made specific determinations about the results to be gleaned with respect to safety and efficacy. It fully explained its decision-making, and I think it falls well within the zone of reasonableness under arbitrary and capricious review.

JUSTICE ALITO: All right. Thank you.

CHIEF JUSTICE ROBERTS: Justice Sotomayor?

JUSTICE SOTOMAYOR: On that last question, because that did trouble me, but the reality is, even if there is some increase in emergency room visits, the question of when that rises to a sufficient safety risk is up to the FDA, correct?

GENERAL PRELOGAR: That's right. And, you know, FDA acknowledged it, so it's not like it overlooked this aspect of the studies.

I also want to emphasize, Justice Sotomayor, that the studies were far from the only evidence FDA consulted. At the time it acted in 2021, it had real-world experience during the COVID-19 pandemic, a period of time when the in-person dispensing requirement was not enforced, and FDA started by looking at, as

a comparative analysis, the two periods of time when you had in-person dispensing and when you didn't and saw that there was no relevant increase in serious adverse events or a difference between those two time frames. So that further supported the safety conclusion.

JUSTICE SOTOMAYOR: The problem with all drugs is there are complications in virtually all of them.

GENERAL PRELOGAR: Yes, virtually all.

JUSTICE SOTOMAYOR: And at what level the cost/benefit analysis tells you to stop prescribing something is a very difficult question, isn't it?

GENERAL PRELOGAR: And that's a question that Congress has entrusted to FDA.

JUSTICE SOTOMAYOR: And -- but putting that aside, here, whatever the statistical increase was, FDA determined under the REMS standard that it wasn't sufficient to create a risk that counterbalanced the need for access, correct?

GENERAL PRELOGAR: Correct, because FDA is instructed to take into account burdens on the healthcare delivery system as well, and

it looked at a variety of sources of data to conclude that, on balance, the burdens were -- suggested that it was not necessary to keep this restriction in place to ensure safe use.

JUSTICE SOTOMAYOR: Thank you.

CHIEF JUSTICE ROBERTS: Justice Kagan?

JUSTICE KAGAN: General, if I could take you back to the discussion that you were having with Justice Barrett about the conscience objection and just ask you -- I'm sure that you've read the declarations carefully, and I'm sure Ms. Hawley will have things to say about this too. But, as you read those declarations, what is the conscience objection? What -- what are the doctors objecting to exactly?

GENERAL PRELOGAR: I think the declarations are specific on this point. There are only seven doctors who regularly practice and submitted evidence, and the declarations are relatively short. This is at JA 150 to 200. I encourage reading them because there are only two doctors out of the seven who even provide any information about their specific conscience objections.

JUSTICE KAGAN: Those two are who?

GENERAL PRELOGAR: Those are Dr. Skop and Dr. Francis. The relevant language for Dr. --

JUSTICE KAGAN: The other five don't refer to conscience objections?

GENERAL PRELOGAR: They don't refer to their own conscience objections or provide any specific detail about exactly what care would violate their conscience. Dr. Francis is at JA 155. Dr. Skop is at JA 167. Both describe the injury in the same terms. They object to ending the life of a human being in the womb and fear that they might have to complete an abortion for a woman who has an ongoing pregnancy.

JUSTICE KAGAN: So, as you understand those declarations, they do not object to providing whatever care is necessary to a person who may have complications from taking mifepristone? In other words, for example, suppose somebody has bled significantly, needs a transfusion, or, you know, any of a number of other things that might happen. As you understand the declarations, there's not an objection to that?

GENERAL PRELOGAR: I think that the

fairest reading of the declarations is they are not objecting to that. Now I acknowledge that Respondents, in their red brief, have suggested there's a broader conscience injury in play here and that there might be other doctors who have a broader concern about providing any care.

Even if that broader conscience injury had been in this declaration, we think still, as a matter of law, they could not demonstrate that they have a non-speculative injury, in part because of all of the upstream things that would have to happen in terms of a woman having the serious event, going to these specific doctors, but also the fact the federal conscience protections are specifically designed to deal with this issue, and they would cover the range of conscience objections that exist in this context.

JUSTICE KAGAN: Right, there are obviously conscience objections of all kinds. I was just asking --

GENERAL PRELOGAR: Yes.

JUSTICE KAGAN: -- about the particular declarations of these particular members of the organizations.

GENERAL PRELOGAR: Yes. And I think, on these declarations, they have not asserted a broader injury. But, even if they could conceivably come forward with other doctors or try to adjust their declarations in some way, still that would not suffice.

JUSTICE KAGAN: Okay. Can I just ask a quick question about the merits? You -- you open your brief with a -- a somewhat arresting statement, but it starts with, "To the government's knowledge," and this was written a few months ago, and since then, I'm sure that you've had lots of time to think about this case and to get all background information on it.

So I'll just read you this sentence and ask you whether it's still true to the government's knowledge. "To the government's knowledge, this case marks the first time" -- and I'm going to say is it -- is it the first time, is it the only time -- "any court has restricted access to an FDA-approved drug by second-guessing FDA's expert judgment about the conditions required to assure that drug's safe use." Is it still the only time?

GENERAL PRELOGAR: That is still to

our knowledge the only time a court has done that. We have seen a disturbing trend of courts sometimes also overriding FDA's judgment to try to grant greater access to drugs when that overrides FDA's expert judgment about what's necessary to ensure safe use.

And no matter which direction you come at it from, we, on behalf of FDA, think that courts have no business making those judgments in the absence of the kind of arbitrary and capricious error that would satisfy the APA.

JUSTICE KAGAN: Thank you.

CHIEF JUSTICE ROBERTS: Justice Gorsuch?

Justice Kavanaugh?

JUSTICE KAVANAUGH: Just to confirm on the standing issue, under federal law, no doctors can be forced against their consciences to perform or assist in an abortion, correct?

GENERAL PRELOGAR: Yes. We think that federal conscience protections provide broad coverage here. Just to be super precise, there are some triggering requirements of receiving federal funding and so forth. We've cited the relevant provisions at page 5 of our reply

brief.

The Church Amendments have the most comprehensive protection here, and we think that those amendments guard against the kind of injury that Respondents are asserting. There are also state law protections that often apply in this context.

JUSTICE KAVANAUGH: Thank you.

CHIEF JUSTICE ROBERTS: Justice Barrett?

JUSTICE BARRETT: Would that be true even if the declarations were interpreted as Respondents do to say that they regard any participation, even transfusions or D&Cs after the abortion is otherwise complete because tissue needs to be removed?

GENERAL PRELOGAR: Yes, I think that would be true. So the most relevant Church Amendment provision is 42 U.S.C. 300a-7(d), and its language says that a doctor shall not be required to perform or -- or assist in any part of the healthcare program that would violate the doctor's religious or moral beliefs. So it's tied to the nature of the doctor's beliefs rather than particular procedures.

JUSTICE BARRETT: And one other question, and this goes to the merits.

As I understand it, the serious adverse consequences that have to be reported or that FDA considers risks are death and transfusion but not, say -- I mean, it -- it seems to me, and I think the data bears this out, that the elimination of the in-person dispensing requirement or, you know, the in-person visit at the outset would lead to mistakes in gestational aging, which could increase D& -- the need for a D&C or the amount of bleeding, et cetera.

But that does not count, correct, as an adverse event?

GENERAL PRELOGAR: So I -- I want to be careful because there's a list of serious adverse events and I'm not sure that I have all of them down to be able to recite them to you, although they're in the record, but I -- I do think the premise of the question is wrong. This idea that the change to in-person dispensing would necessarily increase the risk of those events, that was not reflected in the data that FDA consulted, and I would point you

to JA 383 to 384 in particular --

JUSTICE BARRETT: Okay.

GENERAL PRELOGAR: -- where FDA -- FDA explained that even in person you're not necessarily getting an ultrasound. That's never been required. And so the relevant question might be is your -- your provider going to ask you a series of screening questions, like when was your last menstrual period, in person or via telemedicine, and there's no evident reason why that difference would actually lead to different safety outcomes.

JUSTICE BARRETT: So there was not even a -- I thought that there was a small percentage increase in the tracking. I'm wrong about that? Which I may well be.

GENERAL PRELOGAR: So --

JUSTICE BARRETT: You know the JA way better than I do, General.

GENERAL PRELOGAR: Yeah. So I -- I -- I think that with respect to the ER visits, there was some evidence that there were increased ER visits, although, as I explained to Justice Alito, that wasn't actually correlated with an increase in serious adverse events.

You know, I -- I don't want to represent all of the different --

JUSTICE BARRETT: Yeah.

GENERAL PRELOGAR: -- findings of the different studies because they varied a little bit, but FDA's ultimate conclusion was that mifepristone could safely be dispensed without in-person visits. It had voluminous evidence, I think, to support that conclusion in 2021. And there's been no contrary evidence that's been introduced.

JUSTICE BARRETT: So there was no requirement of either an ultrasound or detecting a fetal heartbeat or anything like that even before the doctor could just go based on the woman's recounting when her last menstrual period was?

GENERAL PRELOGAR: That's right. And that dates all the way back to the initial approval of this drug in 2000. It has never been a required condition of use to have an ultrasound. FDA has always left that up to medical judgment.

Now it is, of course, necessary for providers to be able to diagnose ectopic

pregnancy and to date gestational age. That remains true under the REMS now. Prescribers still have to have that capability, and they have to deploy whatever mechanisms they believe would accurately allow them to identify contraindications for use of mifepristone.

But it's wrong to suggest that if the Court reverses 2021 changes, then every woman's going to get an ultrasound. That's never been the -- the state of play in how this drug has been administered.

JUSTICE BARRETT: How, even under the pre-2021 REMS, was it possible to detect an ectopic pregnancy without an ultrasound unless the woman was presenting with pain?

GENERAL PRELOGAR: So there's a set of screening questions that are often deployed. You can ask things like, do you have unilateral pelvic pain? Did you become pregnant while you had an IUD in or after a tubal ligation? Are you experiencing unusual bleeding? You could ask whether the woman has had a prior ectopic pregnancy.

And if the woman has those kinds of risk factors, then imaging may be necessary, but

that remains true under the 2021 REMS as well. The prescriber has to be confident that it has excluded those kinds of conditions before prescribing this drug.

And the standard of care around the world, most medication abortion occurs without an ultrasound.

JUSTICE BARRETT: Thanks.

CHIEF JUSTICE ROBERTS: Justice Jackson?

JUSTICE JACKSON: Good morning, General.

So I'm worried that there is a significant mismatch in this case between the claimed injury and the remedy that's being sought and that that might or should matter for standing purposes. I don't know that our doctrines sort of capture this, but I -- I guess I see it that the injuries that the Respondents allege, as you've articulated them, are a conscience injury, that they are being forced to participate in a medical procedure that they object to.

And so the obvious common-sense remedy would be to provide them with an exemption, that

they don't have to participate in this procedure. And you say, and you've said here several times, that federal law already gives them that.

So I guess then what they're asking for in this lawsuit is -- is more than that. They're saying, because we object to having to be forced to participate in this procedure, we're seeking an order preventing anyone from having access to these drugs at all.

And I -- I guess I'm just trying to understand how they could possibly be entitled to that given the injury that they have alleged.

GENERAL PRELOGAR: I agree, Justice Jackson, and -- and I do think it's relevant to standing. There's a profound mismatch here between the claimed injury and the remedy they were seeking.

And, you know, you can almost think of this as a -- a type of zone of interest kind of analysis. You know, if the doctors have a conscience injury, there's a specific statute designed to deal with it, to specifically tailor-made guard against the risk of that injury occurring.

And, instead, they're reaching out and seeking to invoke rights under a different statute, the FDCA, that doesn't regulate them at all, that doesn't make them do or not do anything, and the -- the relief that they're seeking would dramatically alter the approved conditions of use for mifepristone and affect women all around the nation simply because of this conscience injury that's already directly addressed by other --

JUSTICE JACKSON: Right. And if it wasn't --

GENERAL PRELOGAR: -- protections under federal law.

JUSTICE JACKSON: -- if it wasn't addressed, then we would see this lawsuit and the remedy would be to exempt them, right?

GENERAL PRELOGAR: Yes, yes. I mean, I think that --

JUSTICE JACKSON: Yeah.

GENERAL PRELOGAR: -- one of the hard things about trying to tailor relief here is that they're asserting such a diffuse theory of injury that it's almost as though the only option was to grant a nationwide remedy of the

kind the lower courts issued, and that runs counter to ordinary Article III principles of party-specific relief.

But I just think it shows that there's something wrong with the theory of injury in the first place because it's so attenuated and because they claim they would need so much relief all over the country.

JUSTICE JACKSON: Let me ask you another question. In addition to the challenges that we have here, the Respondents below challenged the FDA's initial decision to approve mifepristone in -- in the year 2000.

Of course, that occurred a very long time ago. The Fifth Circuit found that that challenge wasn't timely because of the statute of limitations. As -- as you're aware, in the context of another case we heard this term, the Court is currently considering the statute of limitations issue.

So setting aside standing, have you thought about how a ruling from this Court on the statute of limitations in either direction might impact what happens in these kinds of cases with these kinds of challenges?

GENERAL PRELOGAR: Yes. I -- I -- I think that it just reflects the stakes of the Corner Post case and provides a vivid example of the way that it might be possible, if this Court were to approve the request for a broader theory of the statute of limitations in that case, the way it could open the door to plaintiffs coming in and saying, well, I only became a doctor later, or I only started working in an emergency room later and would try to unsettle longstanding agency actions that maybe occurred decades previously.

I do want to say that I understand the Corner Post petitioner to have suggested maybe there would be equitable defenses that the government could raise in those kinds of cases. We would certainly want to raise that type of defense with respect to the approval of mifepristone, which I think has generated tremendous reliance interests and proven to be safe and effective over decades of use.

JUSTICE JACKSON: Thank you.

CHIEF JUSTICE ROBERTS: Thank you, counsel.

Ms. Ellsworth.

ORAL ARGUMENT OF JESSICA L. ELLSWORTH

ON BEHALF OF PETITIONER

DANCO LABORATORIES, L.L.C.

MS. ELLSWORTH: Mr. Chief Justice, and may it please the Court:

In 2016 and 2021, FDA made certain changes to the labeling and use restrictions for Danco's drug, Mifeprex. The decision below stops Danco from selling Mifeprex in line with that scientific judgment based on a highly attenuated claim that an unknown doctor could be called someday to an unknown emergency room after a series of decisions by third parties. No facts causally link that possible future encounter to a specific change FDA made in 2016 or 2021.

Respondents' view of the Food, Drug, and Cosmetic Act is so inflexible it would upend not just Mifeprex but virtually every drug approval and REMS modification FDA has made for decades.

Reversal is required for two reasons:

First, Article III standing is not an academic exercise in what's conceivable. Respondents lack standing under every prong of

the analysis.

Second, on the merits, FDA exhaustively considered the evidence and reasonably explained its conclusions, which is what is required to do.

I welcome the Court's questions.

JUSTICE THOMAS: The government, the Solicitor General points out, would not be susceptible to a Comstock Act problem. But your -- in your case, you would be.

So how do you respond to an argument that mailing your product and advertising it would violate the Comstock Act?

MS. ELLSWORTH: Justice Thomas, we agree very much with the government that FDA's charge under the Food, Drug, and Cosmetic Act is limited to looking at safety and efficacy considerations. That's true for new drug approvals. It's also true for REMS modifications. FDA routinely approves drugs whose manufacture and distribution is restricted by other laws, like the Controlled Substances Act, environmental laws, customs laws, and so on.

I think this Court should think hard

about the mischief it would invite if it allowed agencies to start taking action based on statutory responsibilities that Congress has assigned to other agencies.

On the merits, this issue was not presented below -- excuse me -- was not ruled on below, and in any event, I would also point out that in 2021, FDA's decision allows use of brick-and-mortar pharmacies, in addition to mail-order pharmacies.

JUSTICE THOMAS: Well, my problem is that you're private. The government -- I understand the government's argument. But you're private, and the statute doesn't have the sort of safe harbor that you're suggesting, and it's fairly broad, and it specifically covers drugs such as yours.

MS. ELLSWORTH: Your Honor, we disagree that that's the correct interpretation of the statute, but we think that in order to address the correct interpretation, there would need to be a situation in which that issue was actually teed up.

This statute has not been enforced for nearly a hundred years, and I -- I don't believe

that this case presents an opportunity for this Court to opine on the reach of the statute.

CHIEF JUSTICE ROBERTS: Counsel, I'd like to ask you the same questions I was posing to the Solicitor General. You know, our precedents, Clapper and Susan B. Anthony List, talk about requiring a substantial risk that harm will recur, and you argue that's not present here.

How are we supposed to find the spot at which the risk becomes substantial?

MS. ELLSWORTH: Your Honor, I -- I think this Court has always thought about these standing inquiries as really a question of degree, and you're trying to evaluate whether something is actual and imminent or whether it's conjectural and hypothetical. And these terms, "substantial risk," "certainly impending," which has been used dating all the way back to 1923, get at where a claim falls in this spectrum.

CHIEF JUSTICE ROBERTS: Right. I mean, we toss around a lot of adjectives, but I'm just trying -- as a practical matter, how do you figure out -- I mean, what percentage of adverse consequences would be enough? What

percentage of emergency room visits would be enough?

MS. ELLSWORTH: I think the way Clapper got at that question -- and -- and you can see this in Footnote 5 of the opinion -- is to really think about whether there is an attenuated chain of contingencies that have to happen.

And in situations where there is this kind of attenuated chain of circumstances involving third-party decisions that have to play out in a particular way -- and, here, that chain is quite long -- that that squarely puts a plaintiffs' theory on the side of the conjectural or hypothetical and not the certainly impending injury.

JUSTICE ALITO: How is your company aggrieved by the challenge that is brought in this case? I -- I gather this is -- your version of mifepristone is the only product you are currently marketing, is that right?

MS. ELLSWORTH: That's correct, Justice Alito.

JUSTICE ALITO: And the Fifth Circuit decision does not prohibit you from continuing

to produce and -- and sell that product, right?

MS. ELLSWORTH: That is correct.

JUSTICE ALITO: All right. And so I gather your injury is that you think you're going to sell more if the restrictions that previously were in place were lifted?

MS. ELLSWORTH: Yes.

JUSTICE ALITO: So you're going to make more money?

MS. ELLSWORTH: The -- the injury is that we are prevented from selling our product in line with FDA's scientific judgment about the safe and efficacious use of the drug.

JUSTICE ALITO: And you're going to be harmed because you're going to sell more?

MS. ELLSWORTH: I think that certainly a company's ability to market its product is a part of how it considers the regulatory scheme that governs its conduct.

JUSTICE ALITO: During the questioning of the Solicitor General, the statement was made that no court has ever previously second-guessed the FDA's judgment about access to a -- to a drug, right? It's never second-guessed that?

MS. ELLSWORTH: That -- that's

correct.

JUSTICE ALITO: Do you think the FDA is infallible?

MS. ELLSWORTH: No, Your Honor, we don't think that at all. And we don't think that question is really teed up in -- in any way in this case.

JUSTICE ALITO: Has the FDA ever approved a drug and then pulled it after experience showed that it had a lot of really serious adverse consequences?

MS. ELLSWORTH: It -- it has certainly done that. And, Your Honor, I think that underscores why the adverse event reporting, the post-market surveillance that FDA does, the ability that these plaintiffs have, even if they don't have standing, certainly, if there are -- if they are seeing patients who are presenting with adverse events, if they are doing studies that show there is some unknown safety component that FDA should acknowledge, they can take significant steps to bring that to the agency's attention, to bring that to Danco's attention.

JUSTICE ALITO: But don't you think the FDA should have continued to require

reporting of non-fatal consequences?

MS. ELLSWORTH: Your Honor, the FDA decided not to continue that reporting requirement in 2016 based on more than 15 years of a well-established safety profile when that reporting was required. There is no drug on the market today under any REMS that requires the kind of reporting that the plaintiffs are saying should be reimposed here.

JUSTICE ALITO: So why would that be a bad thing? Wouldn't your company -- you don't want to sell a product that -- that causes very serious harm to the people who take your product, relying on your tests and the FDA's tests. Wouldn't you want that -- that data?

MS. ELLSWORTH: Your Honor, that -- that data is certainly something that we are looking for all the time. It is part of the reporting obligations for a manufacturer to be aware of any data that's becoming available through any means. We have a 1-800 number on our website. There is a 1-800 number on the labeling.

I think Your Honor's question, though, gets at concern I heard in some of the earlier

questioning about who would have standing if these plaintiffs don't have standing. And one of the things I want to note is that drug manufacturers are very frequently subject to tort litigation, product liability suits, failure to warn suits, deceptive advertising suits, when someone is claiming harm from a pharmaceutical manufacturer's product.

What is so, I think, revolutionary really about the -- the arguments here, both on standing and the merits, are the way that they attempt by individuals who do not use this product, do not prescribe this product, and have a conscience right not to treat anyone who has taken this product, those individuals want to prevent anyone else from using it in line with FDA's considered scientific judgment.

JUSTICE ALITO: Does --

JUSTICE KAGAN: Could you go --

JUSTICE ALITO: -- does your company -- just one more point along the same -- sort of along the same lines. Does your company think that what the FDA has done preempts state laws that prohibit the dispensation of mifepristone within their borders?

MS. ELLSWORTH: We have not taken a position on that issue, and it has not been teed up in this case.

JUSTICE ALITO: Well, what is your -- what is your company's position on it? You haven't even thought about it? One of your competitors made that argument, right?

MS. ELLSWORTH: That's right. There are some lawsuits that have been brought by the generic company that do make that argument. And I think that is for later courts to -- to sort out.

Our position in this case has been that this is about FDA's scientific judgments reached in 2016 and 2021.

JUSTICE ALITO: So you don't want to answer that question?

MS. ELLSWORTH: I don't think we have a position that's -- that's -- on that that I'm prepared to state today.

JUSTICE KAGAN: Could you go back to Justice Alito's questions about adverse event reporting? And you said you were subject, your product, to higher standards, and now we're being brought down to the sort of regular -- at

-- could you talk about that a little bit? What are the normal standards for adverse event reporting as you understand them? Why are they there? What instead were you subject to in the past?

MS. ELLSWORTH: May I answer the question?

CHIEF JUSTICE ROBERTS: Go ahead.

MS. ELLSWORTH: Justice Kagan, what changed was not Danco's adverse event reporting responsibility. Danco's adverse event reporting responsibility has been the same throughout this period.

What changed was that from 2000 until 2016, prescribers were obligated to report adverse events to Danco and then Danco then had its separate reporting obligation to FDA.

So what -- in -- in 2016, the REMS for mifepristone were aligned to be more consistent with the reporting requirement that applies to all 20,000-plus FDA-approved drugs. There are only today seven REMS that continue to have even the limited higher adverse event reporting for deaths that apply to -- to mifepristone. So it is only one of seven that have that.

JUSTICE KAGAN: Thank you.

CHIEF JUSTICE ROBERTS: Justice Thomas?

Justice Alito, anything further?

Justice Sotomayor?

Justice Kavanaugh?

Justice Barrett?

Justice Jackson, anything further?

JUSTICE JACKSON: Yeah, I just have one quick question.

So you were asked if the agency is infallible, and I'm -- I guess I'm wondering about the flip side, which is do you think that courts have specialized scientific knowledge with respect to pharmaceuticals, and as a company that has pharmaceuticals, are -- do you have concerns about judges parsing medical and scientific studies?

MS. ELLSWORTH: Yes, Your Honor, I think we have significant concerns about that. And there are two amicus briefs from the pharmaceutical industry that expand on why exactly that's so concerning for pharmaceutical companies who do depend on FDA's gold standard review process to -- to approve their drugs and

then to be able to sell their products in line with that considered judgment.

JUSTICE JACKSON: Can you say a little bit about what they say?

MS. ELLSWORTH: I -- I'm -- I'm happy to.

I think the -- the reality is -- and this Court is a -- this decision below is a good example of it. You have a district court that among other things relied on one study that was an analysis of anonymous blog posts.

You have a -- another set of studies that he relied on that were not in the administrative record and would never be because they post-date the FDA decisions here. They have since been retracted for lack of scientific rigor and for misleading presentations of data.

Those sorts of errors can infect judicial analyses precisely because judges are not -- they are not experts in statistics. They are not experts in -- in the methodology used for scientific studies, for clinical trials.

That is why FDA has many hundreds of pages of analysis in the record of what the scientific data showed, and courts are just not

in a position to parse through and second-guess that.

JUSTICE JACKSON: Thank you.

CHIEF JUSTICE ROBERTS: Thank you, counsel.

MS. ELLSWORTH: Thank you.

CHIEF JUSTICE ROBERTS: Ms. Hawley?

ORAL ARGUMENT OF ERIN M. HAWLEY

ON BEHALF OF THE RESPONDENTS

MS. HAWLEY: Mr. Chief Justice, and may it please the Court:

FDA approved abortion by mail based on data it admitted was "not adequate." That violates the APA. The lower court's decision merely restored longstanding and crucial protections under which millions of women used abortion drugs.

We've heard a lot this morning about standing. Article III is satisfied here because, one, the FDA relies on OB hospitalists to care for women harmed by abortion drugs. Two, the FDA concedes that between 2.9 and 4.6 percent of women will end up in the emergency room. And, three, the FDA acknowledges that women are even more likely to

need surgical intervention and other medical care without an in-person visit.

According to Guttmacher, nearly 650,000 women take mifepristone every single year. It's no surprise that Respondents have experienced an increase in emergency room visits and, indeed, treated women suffering from abortion drug harms tens of thousands of times -- excuse me, dozens of times, women have suffered tens of thousands of times.

That Respondent doctors will be forced to manage abortion drug harm is not a bug in FDA's system but part of its very design. Ruling against Respondents on standing here would allow federal agencies to conscript non-regulated parties into violating their consciences and suffering other harm without judicial recourse. Article III neither demands nor permits this.

FDA's outsourcing of abortion drug harm to Respondent doctors forces them to choose between helping a woman with a life-threatening condition and violating their conscience. This Hobson's Choice is intolerable.

On the merits, FDA failed to comply

with basic APA requirements. In 2021, it eliminated the initial in-person visit based on data it says elsewhere is unreliable. And in 2016, it failed to consider or explain the cumulative effects of its wholesale removal of safeguards. These actions fall far short of what the APA requires. This Court should affirm.

I welcome the Court's questions.

JUSTICE THOMAS: Counsel, you assert the -- an injury on -- on the part of the Alliance of diverted time and resources.

Isn't that just the cost of litigating, of -- of pursuing this litigation?

MS. HAWLEY: I -- I don't think so, Your Honor, for a couple of reasons.

First, what Respondent doctors have done here is chosen their particular practice, as well as structured that medical practice to bring life into the world.

When they are called from their labor and delivery floor down to the operating room to treat a woman suffering from abortion drug harm, that is diametrically opposed to why they entered the medical profession.

It comes along with emotional harm. Dr. Skop talks about these being heartbreaking situations and some of the most stressful work she's had to deal with, Your Honor.

JUSTICE THOMAS: Well, I -- I -- I understand that, but I'm talking about the injury of having to divert resources to litigate this.

MS. HAWLEY: Oh, for -- with respect to the organizational standing?

JUSTICE THOMAS: The Alliance.

MS. HAWLEY: Absolutely, Your Honor. So we think Havens Realty is on all fours with this case. The best evidence of that, I believe, is the FDA's reply brief. The government resorts to the underlying briefs in the case to say that there was a contract and an economic harm, but this Court's case specifically said that the fact that the harm -- the nature of the harm was "non-economic" did not prevent the Court from finding an injury.

In Havens, the Court looked to two things, whether there -- whether there was an impairment of the organization's mission and, second, whether there was an expenditure of

resources. Both things are satisfied here.

If you look at how our organizations have been harmed, they've been forced to divert resources from speaking and advocating for their pro-life mission generally to explaining the dangers of the harm from abortion drugs.

One of the primary reasons that that's required is because, in 2016, FDA took away the requirement that abortion providers report adverse events --

JUSTICE THOMAS: Well --

MS. HAWLEY: -- aside from deaths.

JUSTICE THOMAS: -- but that would be anyone who is aggressive or vigilant about bringing lawsuits. Just simply by using resources to advocate their position in court you say now causes an injury. That seems easily -- easy to manufacture.

MS. HAWLEY: So I don't think that's true in this case, Justice Thomas. I acknowledge that the lower courts have cabined Havens to say where you have sort of prelude to litigation types of activities, in those sorts of cases, those resource justifications don't count.

In this case, if you look at Respondents' declarations, they note that they have performed studies. They've analyzed studies. Several of those are in the record and -- and they're not short.

They came -- comb through Medicaid data, they comb through FAERS data, so they get at the true nature of adverse events. And all those sorts of things are neither a prelude to litigation, nor would they have occurred but for FDA's unlawful conduct in this case.

JUSTICE SOTOMAYOR: Counsel, in the line you quoted about economic harm, that had to do with the fact that they didn't intend through their testers to rent an apartment, and so there was no economic loss to them or gain to them from renting the apartment.

But what was, I think, the SG is pointing to is that they provided services on their own. It wasn't just the member services that they were relying upon. They were providing services to people to help them rent apartments.

And so that's a very important distinction from here. Separate from the

individual defendants' claims of -- of standing based on wasted resources, their resources, the organizations are not losing anything.

MS. HAWLEY: So --

JUSTICE SOTOMAYOR: Their job is to do exactly what you're talking about and they're doing it. They're investigating certain problems, but that's not an injury that's redressable by this -- by vacating this rule.

MS. HAWLEY: So a couple of things, Your Honor. This Court's opinion in Havens did not rely on the economic nature at all. Again, I'd point Your Honor to the line in Havens where the Court says the non-economic nature of respondents' interest in housing. They were speaking broadly. Again, you have to dig to the underlying briefs to find the economic interest that this Court did not rely on.

With respect to our own injury, it's absolutely redressable. For example, if the regulations are put back in place, the protections whereby individual abortion providers need to provide information about adverse events, that would provide our Respondent organizations with more accurate

information about the harms from abortion drugs.

JUSTICE JACKSON: Counsel --

CHIEF JUSTICE ROBERTS: Can --

JUSTICE JACKSON: -- can I ask you --

CHIEF JUSTICE ROBERTS: Go ahead.

JUSTICE JACKSON: -- about the remedy and sort of the way that I was talking with the SG. I mean, it makes perfect sense for the individual doctors to seek an exemption, but as I understand it, they already have that, and so what they're asking for here is that in order to prevent them from possibly ever having to do these kinds of procedures, everyone else should be prevented from getting access to this medication.

So why isn't that plainly overbroad scope of the remedy the end of this case?

MS. HAWLEY: So, with respect to the premise of that question, Justice Jackson, I don't think our doctors necessarily are -- are able to object for two reasons.

One of this -- this is the emergency nature of these procedures. As the FDA acknowledges, many women do go to the emergency room, and if we just think about what that might

look like, take Dr. Francis. She's on the labor and delivery floor, supervising --

JUSTICE JACKSON: No, I don't -- I'm sorry. I don't want to hypothesize. Tell me in her declaration where she talks about not being able to object or pose a conscientious objection.

MS. HAWLEY: She talks about, Your Honor, being a -- an -- a --

JUSTICE JACKSON: I mean, can you point me to any place in the declarations where a declarant states that they attempted to object but were unable to?

MS. HAWLEY: No, Your Honor, for two reasons. One is, these are emergency situations. Respondent doctors don't necessarily know until they scrub into that operating room whether this may or may not be abortion drug harm. It could be a miscarriage, it could be an ectopic pregnancy, or it could be an elective abortion, Your Honor.

In addition, the government simply cannot get its story straight on EMTALA. If you look at the district court brief in that case, we just heard that the Church Amendment applies,

and while we would love for this Court to adopt that position, they told the district court the very opposite.

JUSTICE JACKSON: All right. Let me ask you this. If we were to find that there are conscientious objections that, say, hospitals take them into account and these doctors do have a way to not do these kinds of procedures, should we end this case on that basis?

MS. HAWLEY: No, Your Honor. We would welcome that holding, but it's not broad enough to remedy our doctors' harm.

JUSTICE JACKSON: Why?

MS. HAWLEY: Because these are emergency situations, they -- they can't waste precious moments scrubbing in, scrubbing out --

JUSTICE JACKSON: No, no, no. I'm saying -- I'm saying, assuming we have a world in which they can actually lodge the objections that you say that they have, my question is, isn't that enough to remedy their issue? Do we have to also entertain your argument that no one else in the world can have this drug or no one else in America should have this drug in order to protect your clients?

MS. HAWLEY: So, again, Your Honor, it's not possible given the emergency nature of these situations --

JUSTICE GORSUCH: Counsel, let me -- let -- let me interrupt there. I'm sorry.

I -- I -- I think Justice Jackson's saying let's spot you all that, okay, with respect to your -- your clients. Normally, in Article III traditional equitable remedies, we issue and we say over and over again, provide a remedy sufficient to address the plaintiff's asserted injuries and go no further.

We have before us a handful of individuals who have asserted a conscience objection. Normally, we would allow equitable relief to address them. Recently, I think what Justice Jackson's alluding to, we've had one might call it a rash of universal injunctions or vacaturs. And this case seems like a prime example of turning what could be a small lawsuit into a nationwide legislative assembly on -- on -- on an FDA rule or any other federal government action. Thoughts?

MS. HAWLEY: Yes, Your Honor. Again, I have to say that I think it's impracticable to

-- to raise a -- a conscience objection. But -- but, even spotting that, I think the -- the district court remedy here was perfectly appropriate under Section 705.

Section 705 grants the reviewing courts the authority to issue all necessary and appropriate relief. And as the government acknowledged in oral argument in Corner Post, when the parties before the court are non-regulated parties, the only avenue in which they can possibly get relief -- and, of course, that's sort of the sine qua non of equitable relief, is that the parties before the court get it, and that's for, as in this case, a stay to issue or -- or another case is a vacatur, and that's because, without that sort of relief, the very parties before the court won't get it.

JUSTICE ALITO: I think --

CHIEF JUSTICE ROBERTS: Why can't you --

JUSTICE ALITO: -- something as --

CHIEF JUSTICE ROBERTS: Why can't the court specify that this relief runs to precisely the parties before the court, as opposed to looking to the agency in general and saying,

Agency, you can't do this anywhere?

MS. HAWLEY: So -- so I think, Your Honor, that might be impracticable. If we're thinking again about the emergency room situation, would Dr. Francis, again, have to know when she's in the emergency room whether this is a miscarriage, an ectopic pregnancy, or an elective abortion? This is what she does day in and day out.

And so it seems like to say that -- that these would run to particular plaintiffs would be missing that the FDA regulations would still be in place and permit things like mail-order abortions. They would have removed the reporting requirements.

And if we look at the merits of what FDA did in 2021, FDA relied on two things. They relied first on the FAERS data.

JUSTICE GORSUCH: Counsel -- counsel, before you pivot back to the merits, and I can understand your impulse there, but -- but I went back and looked, and there are exactly zero universal injunctions that were issued during Franklin Delano Roosevelt's 12 years in office, pretty consequential ones.

And over the last four years or so, the number is something like 60 and -- maybe more than that, and they're -- they're a relatively new thing. And you're asking us to extend and -- and pursue this relatively new remedial course which this Court has never adopted itself. Lower courts have kind of run with this. And I -- I just want to give you one more shot at that.

MS. HAWLEY: Sure, Your Honor. So, again, the APA, of course, encapsulates equitable remedies. And as Pomeroy and others have said from the beginning of the 19th Century, equity requires that the parties before the court get relief.

In this instance, again, as the government pointed out in Corner Post, where you have non-regulated parties, those -- those parties could be farmers, they could be ranchers, they could be the seed farms in Geertson, but their only availability for relief is if the court does something to the FDA order or regulation at issue. Otherwise, those parties are simply out of luck, and that's inconsistent with equity.

JUSTICE KAGAN: May I ask, Ms. Hawley, about your basic theory of standing? And just -- this is a clarification question as much as it's anything.

When you did your 1, 2, 3 in your opening statement, it sounded very probabilistic to me. I mean, I don't remember exactly what the 1, 2, 3 are, but, you know, let's say it's something along the lines of we represent a lot of doctors, and there are a lot of women out there taking mifepristone, and some fraction of them are going to have adverse events, and some fraction of those are going to come to the emergency room, and -- and so there's some probability or likelihood that one of our doctors who has a conscience objection is going to come face-to-face with one of these women who has an adverse event.

Is that your theory?

MS. HAWLEY: No, Your Honor. What we think really shows that Respondents have standing here is FDA's own acknowledgments. I would point you to JA 384. And in regulating mifepristone, FDA has continually said that emergency room doctors and OB-GYN hospitalists

are critical to the safe use of drug.

JUSTICE KAGAN: Well, I think then it is your theory. I mean, you're just saying even FDA admits that there are going to be some adverse events, people are going to show up in emergency rooms, people are going to come face-to-face with one of our doctors who objects to some aspect of the treatment. That's the theory, yes?

MS. HAWLEY: Well, we certainly think all of that is true, but we don't think it's a problem with probabilistic standing, as was the case under Summers, for three reasons.

First, Summers involved unidentified members. Here, we have seven named plaintiffs. In addition, no one in Summers at least that was still part of the case had --

JUSTICE KAGAN: Yeah. So does your theory really depend on your having at least one person? Because I take Summers to be saying these probability theories, they sound very nice; they have nothing to do with our Article III requirements. You need a person. You need a person to be able to come in and meet the courts' regular standing requirements.

So you agree with that, yes?

MS. HAWLEY: I think that's correct, Your Honor, yes.

JUSTICE KAGAN: Okay. So who's your person? I know you have seven of them.

MS. HAWLEY: Mm-hmm.

JUSTICE KAGAN: But, if you had to pick one and say go read that declaration and that declaration is going to tell you why -- why, you know, we're entitled to be up here, who's the person?

MS. HAWLEY: So I have to pick two, Your Honor, but Dr. Francis and Dr. Skop.

JUSTICE KAGAN: Okay. And what about those two doctors gives you the kind of imminent injury, let alone the traceability, that we've typically required?

MS. HAWLEY: So, to speak to Dr. Francis, at the beginning, there's been some confusion, I think, about the precise nature of the conscience harm. But, if you look at JA 155, paragraph 15, she talks about her and other AAPLOG members who object not only to taking the life of an unborn child during an elective abortion but also to "completing that process."

That echoes the CMDA declaration at 142 and 143. It's also consistent with --

JUSTICE KAGAN: Has she ever been -- because I -- I -- I -- I read that declaration pretty carefully. Has -- what actual emergency treatment has she participated in that she objects to and that -- and that she has stated an objection to?

MS. HAWLEY: So the prior page, Your Honor, JA 154, talks about a D&C which she was required to perform due to a life-threatening emergency.

JUSTICE KAGAN: She herself performed that?

MS. HAWLEY: That is correct, Your Honor.

JUSTICE KAGAN: And did she have an opportunity to object? Did she object?

MS. HAWLEY: No, Your Honor. Again, these are life-threatening situations in which the choice for a doctor is either to scrub out and try to find someone else or to treat the woman who's hemorrhaging on the --

JUSTICE KAGAN: Well, usually --

MS. HAWLEY: -- emergency room table.

JUSTICE KAGAN: -- conscience objections, the way people with conscience objections do this is they make those objections known. And, you know, that may be harder. It may be easier in a particular context, but most hospitals have mechanisms in place, routines in place to ensure that doctors who are allowed to do this, you know, in advance, right, and are allowed to do it at the moment, they say so.

And I -- I -- when I looked at Dr. Francis's and Dr. Skop's, there's just nothing that you have there that suggests -- and, you know, this is like there are, you know, other requirements that you need, but at the very least, to be able to say, well, this happened to them in the past, I don't think you have it for either one of those doctors.

MS. HAWLEY: So I -- I think we do, Your Honor. Given the emergency nature, it's simply impracticable to have a objection lodged prior to understanding what's going on in that operating room.

And, again, I'd point Your Honor to the district court Fifth Circuit brief in EMTALA where the government says that neither the

church nor any of the other sponsors of those federal conscience protections intended them to apply in emergency situations.

So it's a lot to ask our Respondent doctors to go up to the top floor and litigate this with the general counsel when the federal government's telling them they don't have a conscience protection.

JUSTICE JACKSON: Counsel --

JUSTICE ALITO: Is it true that our standing decisions have not relied on probabilistic determinations like the Department of Commerce case? The Court said there was standing because, if a question about citizenship was included on the -- on the -- the questionnaire, a certain percentage, an unknown percentage of residents would then not fill out the census at all and, therefore, it was probable that there was some risk that New York State would risk losing a representative in the House of Representatives or would risk losing money under some federal program, and you put together this chain of probabilities and that was sufficient to establish standing.

MS. HAWLEY: Absolutely. We agree

with that, Justice Alito.

In particular, you can look at the Geertson Seed Farms case, which also involved non-regulated parties, and this Court looked at the distance that bees might fly in order to pollinate seed farms.

So it's certainly true that data is appropriate to consider in determining whether there's a substantial risk under SBA List. Here, the FDA admits -- this is at 533 -- that between 2.9 and 4.6 percent of women will go to the emergency room. It acknowledges -- this is at 542 -- that up to 7 percent of women will need surgical intervention.

And when the FDA talks about there being no increase in adverse events from the increased gestational age, the only way they can say that is by ignoring surgical interventions, and that's because, at JA 207, the FDA --

JUSTICE SOTOMAYOR: Counsel, what do we do with the fact that these two people that you reply -- rely on, Francis and Skop, that Indiana and Texas have abolished abortions and abolished them by pills or otherwise?

Now we can get into whether other

people are illegally breaking the law and supplying it contrary to law, but what does that do to your probability, which is -- it's already infinitesimally small because there are thousands of hospitals in the country, 50 states, I don't know how many territories, thousands and thousands of -- of -- of places where pregnant women go who may be suffering from miscarriages or otherwise, to know or to even imagine how one doctor is going to ever actually see a patient that it's going to be -- that he or she is going to be forced to intervene on their behalf, but then add to it that this is illegal in these states.

MS. HAWLEY: So I think the -- the best answer, Justice Sotomayor, is that past is prologue. In our declarations, we have three doctors who have treated harms from abortion drugs at least a dozen times.

We have two examples when women went out of state. And if you go out of state, there's a higher likelihood you're not going to have a follow-up visit. What FDA's regime has done is turn ER rooms into those follow-up visits.

We've had that happen with both Dr. Jester, where a woman went to New Mexico and returned to Texas, as well as Dr. Johnson, where a woman went to Illinois and returned to Indiana. Indeed, according to Guttmacher, one in five abortions take place out of state in certain states, like New Mexico, like Illinois, the border states in which our doctors reside.

JUSTICE BARRETT: Ms. Hawley, can I take you back to the affidavits and some of Justice Kagan's questions?

You were talking about Dr. Francis. And as I read her allegations or her -- her -- as her affidavit reads, she said that her partner was forced to perform a D&C when there was a living fetus, and she said she performed a D&C on a woman who was suffering serious complications, but the fact that she performed a D&C does not necessarily mean that there was a living embryo or a fetus because you can have a D&C after, you know, a miscarriage.

So, if that's right, I mean, I think the -- difficulty here is that at least to me, these affidavits do read more like the conscientious -- the objection is strictly to

actually participating in the abortion to end the life of the embryo or fetus, and I don't read either Skop or Francis to say that they ever participated in that.

So do you want to address that?

MS. HAWLEY: Sure. So -- so, first, Justice Barrett, I think Dr. Francis's, combined with CMDA, can be read for the broader conscience harm. Again, that's how the district court up -- understood that. I'd point you to pages 7 and 8. That's how both the state panel and the Fifth Circuit understood Respondents' conscience harms to extend beyond simply requiring the ending of an unborn life.

And with respect to -- to even the more narrow conscience harm, to whether a doctor may need to end a life, we think there's still a substantial risk of that occurring. If you look at the numbers of the increase from 7 to 10 weeks in gestational age, that means that 3.1 percent of pregnancies will be ongoing, requiring a D&C. We know at JA -- or, excuse me, ROA 870, that 55 percent of those D&Cs occur in the emergency room.

This is a substantial number of women

suffering abortion drug harm. Again, Guttmacher says 650,000 women took the drug in 2023.

JUSTICE BARRETT: But not all of those D&Cs will involve a pregnancy that would otherwise be viable or an embryo or a fetus that would otherwise be living, because you can have complications or excessive bleeding even after the abortion is complete in that respect, but there's pregnancy tissue remaining?

MS. HAWLEY: So with the 3.1, Your Honor, is ongoing pregnancies.

JUSTICE BARRETT: Is ongoing pregnancies?

MS. HAWLEY: Yes. And -- and DA says at JA 542 that up to 7 percent will need surgeries to stop either bleeding or ongoing pregnancies or failures.

JUSTICE BARRETT: How many members of your organization -- you have a broad number of, you know, doctors that are in your organization, I gather dentists, some doctors who have retired. How many members of your organization are OB-GYNs who practice in hospitals who might be called into these ERs?

MS. HAWLEY: There -- there are

hundreds of them, Your Honor. But -- but I think -- may I finish?

CHIEF JUSTICE ROBERTS: Sure.

MS. HAWLEY: I think, in particular, that the named plaintiffs are OB-GYN hospitalists who spend most of their time on the labor and delivery floors but also are called to the OR to treat these sorts of emergencies.

JUSTICE JACKSON: Ms. Hawley, can you clarify the broader conscience harm from the narrow one? Because I had understood the conscience harm as Justice Barrett does, but you suggest that there's a broader one. So what -- what is that?

MS. HAWLEY: Yes, Your Honor. I'd point you to pages 7 and 8 of the district court opinion, and the district court understands the conscience harm to be either taking the life of an unborn child, which would sometimes be required, Dr. Francis testifies to a partner who was required to do that because of emergency situations --

JUSTICE JACKSON: That's what I understood the narrow one to be, right? "I'm participating in a procedure that is ending the

life."

MS. HAWLEY: Yes, I think that's correct.

JUSTICE JACKSON: That's narrow?

MS. HAWLEY: Yes.

JUSTICE JACKSON: Okay. So what's the broader one?

MS. HAWLEY: So -- so the broader one, Your Honor, is being complicit in the process that unnecessarily leaves -- takes an unborn life, such as performing a D&C and abortion. And it's really not that hard to -- to see.

JUSTICE JACKSON: No, wait, I'm sorry. Complicit like I'm -- I work in the emergency room and this is going on? I'm handing them a water bottle? I'm -- like, what do you mean complicit in the process?

MS. HAWLEY: So -- so this Court, of course, takes religious beliefs and conscience beliefs --

JUSTICE JACKSON: Yes.

MS. HAWLEY: -- as -- as it finds them.

JUSTICE JACKSON: Yes.

MS. HAWLEY: But what harms our

doctors, Your Honor, is -- is being involved in completing in the terms of our declaration an elective abortion, and -- and it's really not that hard to see why that might be a conscience harm if you think about what's involved in a D&C.

JUSTICE KAGAN: But you just said, again, it's being involved in completing an elective abortion, so I -- I took that to be the conscience objection.

I think what Justice Jackson is asking or what I asked before or what Justice Barrett is, is there any broader conscience objection that appears -- I don't -- I'm not sure I care all that much about the district court, but that appears in the declarations?

MS. HAWLEY: Yes, Your Honor. And -- and in this sense, completing an elective abortion means removing an embryo, a fetus, whether or not they're alive, as well as placental tissue. Again, Dr. Francis talks about being required to perform a D&C -- this is at 154 --

JUSTICE KAGAN: So --

MS. HAWLEY: -- and remove placental

tissue.

JUSTICE KAGAN: -- whether or not there's any live tissue?

MS. HAWLEY: Yes, Your Honor. And, again, this makes sense --

JUSTICE KAGAN: And -- and -- and where are we looking for that?

MS. HAWLEY: So I would point Your Honor to JA 155, paragraph 15, where, again, she talks about completing an abortion. The CMDA declaration at pages 142 and 143 also describe this sort of complicity harm from being involved in -- in an elective abortion, Your Honor.

And, again, these doctors performing a D&C must scrape out a woman's uterus of -- of a child, the embryo, the fetus, or placental tissue. And this Court has recognized harms like that in cases like Little Sisters of the Poor as well as Hobby Lobby.

JUSTICE JACKSON: May I --

JUSTICE KAGAN: No, go ahead.

JUSTICE JACKSON: It's -- sorry. It's my understanding that sometimes the completion, it doesn't involve surgical intervention. Do you have a sense of how often? I mean, we -- we

may get all the way down the chain to the doctor's there, the person is having an emergency procedure. My understanding is, with some of these chemical abortion scenarios, the completion occurs by prescribing additional medication.

Do you have a sense of how many times the completion is that route and could be done by another physician as opposed to your clients and doing a -- a medical procedure?

MS. HAWLEY: So -- so that second dose, Your Honor, of misoprostol has been part of the regimen since 2016, really I think all the way back to 2001, but -- but it's been approved by FDA since 2016. So the best numbers we have from FDA are still consistent with that, and that means that 3.1 percent of pregnancies at 10 weeks will be ongoing.

I -- I'd encourage you to look at -- at JA 405 through 407, and this explains that these risks go up without an in-person visit.

JUSTICE JACKSON: Yeah, no, I guess I'm just trying to get at -- we're still -- I'm still working on how many circumstances or how often it would be that your clients actually

have to complete the procedure in the way that you are describing.

MS. HAWLEY: So Dr. Skop talks about doing this at least a dozen of times, either a D&C or a suction-aspiration abortion to remove, again, embryos, fetuses, or placental tissue.

In -- in addition, Your Honor, if you think about the numbers, again, it says 3.1 percent at 10 weeks, and this has only gone up. In 2020, FDA told this Court that the in-person visit was both "necessary and minimally burdensome" and necessary to preserve women's health precisely so these sorts of situations occur less frequently.

CHIEF JUSTICE ROBERTS: Thank you, counsel.

Justice Thomas?

JUSTICE THOMAS: Ms. Hawley, the -- I am sure you heard the answers of the Solicitor General and the counsel -- counsel for Danco with respect to the Comstock Act.

I'd like you to comment on their answers.

MS. HAWLEY: Sure, Justice Thomas. We don't think that there's any case of this Court

that empowers FDA to ignore other federal law.

With respect to the Comstock Act as relevant here, the Comstock Act says that drugs should not be mailed through the -- either through the mail or through common carriers. So we think that the plain text of that, Your Honor, is pretty clear.

JUSTICE THOMAS: When did you first raise the -- the Comstock Act?

MS. HAWLEY: So I believe the Comstock Act was first raised at -- at the district court, Your Honor. But we think that exhaustion does not apply for two reasons.

First, it would be plainly futile, as FDA's adoption of the OLC memorandum goes. In addition, this is a whole 'nother kettle of fish. But, if you look at Section 704, adoption or -- excuse me -- exhaustion is only required in two instances, either when required by a statute or when an -- by an agency rule when that agency rule is stayed pending litigation.

This is consistent with this Court's case in Darby. The -- the lower courts have taken conflicting opinions. But we think the better reading of Section 704 is that there is

no exhaustion required unless either a statute or agency rule stays the proceeding during judicial review.

CHIEF JUSTICE ROBERTS: Justice Alito?

Justice Sotomayor?

Justice Kagan?

JUSTICE KAGAN: May I ask about your view of traceability? And, you know, on -- on -- on one understanding -- and I want you to tell me if you agree with this -- that even beyond proving whatever injury you're trying to prove, that you have to show that that injury is traceable to the 2016 and 2021 FDA actions --

MS. HAWLEY: Yeah.

JUSTICE KAGAN: -- that you're challenging. And, of course, that means showing that these incidents that you're talking about in the emergency room are caused by whatever incremental increase in risk there is as a result of those 2016 and 2021 actions.

And I guess my first question is, do you agree with that statement of what you need to show? And, if you do, how do you satisfy that? Why do you satisfy that?

MS. HAWLEY: So we believe, Justice

Kagan, under the case law that -- that we need to show that -- that each of the 2016 action and the 2021 action increased the risk of harm. And we think the way --

JUSTICE KAGAN: But that -- I guess what I'm saying is that you have to link whatever injury your members have to that increased risk. Do you agree with that?

MS. HAWLEY: We do, and we think we can do that for a couple of reasons. First of all, traceability, of course, is de facto. We're not in the Palsgraf sort of world of -- of tort causation.

And when you look at the 2021 action, we think traceability is satisfied by FDA's own words. It says at JA 405 that without the in-person visit -- this is the Anger study -- in-person -- without that in-person visits, ER and other medical care is likely to increase, as well as surgical interventions. And these are the very same surgical interventions that harm Respondent clients.

JUSTICE KAGAN: So there's -- there might be some dispute between the two of you as to exactly how big the increased risk is, but

let's even take your view that there is, you know, some measurable increased risk.

How do you connect that risk to particular actions that your members have -- to particular injuries that your members have undergone or imminently will undergo?

MS. HAWLEY: I --

JUSTICE KAGAN: I mean, it could be --

MS. HAWLEY: I think --

JUSTICE KAGAN: -- you know, the -- the -- the -- the original risk.

MS. HAWLEY: So I think the declarations are actually quite clear on this. If you look at Dr. Francis's declaration, she says that when the in-person visit was enjoined in 2020 by a federal district court that she saw an increase in emergency room visits from abortion drug harm. Dr. Johnson, Dr. Skop say the same thing.

And, again, this is entirely consistent with FDA's own numbers. Again, in 2020, FDA told this Court that the in-person visit was necessary to preserve women's health because an in-person exam -- visit is the best opportunity to examine for things like ectopic

pregnancy and accurately assess gestational age.

JUSTICE KAGAN: Thank you.

CHIEF JUSTICE ROBERTS: Justice Gorsuch?

Justice Kavanaugh?

Justice Barrett?

JUSTICE BARRETT: So General Prelogar said that that initial in-person visit did -- had no requirement of an ultrasound or, you know, any effort to detect fetal heartbeat, so it wouldn't necessarily give an accurate read on gestational age or detect an ectopic pregnancy. So why would that necessarily -- the elimination -- why would the elimination of the visit necessarily increase the risks?

MS. HAWLEY: So I think, Your Honor, FDA's own data shows that those risks did go up. If you look at the Kerestes study, it shows a nearly threefold increase in emergency room visits when you have the in-person visit and when you removed it. There was 5.8 percent with an in-person visit, and it was also -- and about 2.1 without.

JUSTICE BARRETT: Is that because doctors were just kind of voluntarily saying,

hey, it would be a good idea to give you an ultrasound or try to detect a fetal heartbeat or what?

MS. HAWLEY: So -- so, when FDA removed the in-person visit, Your Honor, it took away the opportunity to do that. I think ACOG -- I think medical organizations agree that that is best practice, so if a woman comes into a doctor's office, she's likely to get an ultrasound to accurately assess both ectopic pregnancies, diagnose or assess gestational age.

But -- but what's allowed under FDA's rules currently is to be able to order these online with a couple of screening questions, and I don't think that's nearly as good as an in-person exam.

JUSTICE BARRETT: Let me just pivot to the organizational standing question. So let's say that I'm just going to carve out and put aside the costs of filing a petition or litigation as harms to your organization itself.

MS. HAWLEY: Mm-hmm.

JUSTICE BARRETT: Explain to me what additional costs you might have incurred or how your resources were diverted in a way that would

satisfy Havens.

MS. HAWLEY: Absolutely, Your Honor. So putting to one side the citizen petition, the AAPLOG declaration is clear that Respondent organizations conducted studies and analyzed studies. This included going through the Medicaid data. It included going through the FAERS data to the extent it was available.

JUSTICE BARRETT: That it?

MS. HAWLEY: Well -- well, those studies, Your Honor, I -- I would point to you, one of them is at ROA 5 -- excuse me -- ROA 870 and before and after, and those are pretty comprehensive studies, Your Honor.

JUSTICE BARRETT: And are they to the end of the litigation and the citizen petition, or what are they to the end of?

MS. HAWLEY: To accurately assess the harm from abortion drugs, Your Honor. So I think it's absolutely separate from the litigation.

And one thing to note with the citizen petition is that is the only way in which anyone can raise a -- a concern to the FDA. These proceedings go on between Danco and the FDA

behind closed doors. This is not a notice-and-comment process. The first time anyone can raise these objections is a citizen petition.

CHIEF JUSTICE ROBERTS: Justice Jackson?

JUSTICE JACKSON: So what deference, if any, do courts owe the opinion of the expert agency concerning the safety and efficacy of drugs?

MS. HAWLEY: So, under this Court's administrative procedure precedents, Your Honor, APA review, of course, is not toothless. Instead, in this case, we're not asking that the Court second-guess the agency determinations at all but, rather, look at what FDA said.

Again, in 2021, when FDA took away the in-person visit, it did so based on FAERS data it says elsewhere cannot be used to calculate the instance of an adverse event, as well as studies that says that JA 407 are "not adequate."

JUSTICE JACKSON: I guess I don't understand how that scope of review is not second-guessing the agency. I mean, they're

looking at studies and you're saying that the Court can look at studies, maybe different studies, maybe the same studies, and critique their conclusions about them.

So what -- what deference do we owe them at all with respect to their assessment that these studies establish what it is that they say they do about safety and efficacy?

MS. HAWLEY: I don't think that's an accurate portrayal of the -- the APA claim at issue here, Your Honor, and the reason being, again, is we're just asking this Court to look at what FDA said. The FDCA says you have to have adequate tests and test results, as well as sufficient information.

JUSTICE JACKSON: I understand. But didn't the lower courts go beyond that? I mean, representations were made here today that the lower courts actually relied on studies that have since been found discredited and removed. So they were obviously looking at not just what the FDA was looking at in order to make their assessment.

So are you asking us to just look at the FDA and not anything else?

MS. HAWLEY: So -- so, yes. That claim is not even before this Court. But, with respect to the two claims that are before the Court, the 2016 and the 2021, we think the FDA's own statements here are -- are arbitrary.

In 2016, what the FDA said was we're going to look at individual studies and then, even though we say they're interrelated at JA 298, we're going to take all of the protections away at once.

That was arbitrary in State Farm. It would be arbitrary here as well.

JUSTICE JACKSON: Thank you.

CHIEF JUSTICE ROBERTS: Thank you, counsel.

Rebuttal, General Prelogar.

REBUTTAL ARGUMENT OF GEN. ELIZABETH B. PRELOGAR
ON BEHALF OF THE FEDERAL PETITIONERS

GENERAL PRELOGAR: Thank you.

On associational standing, Mr. Chief Justice, you asked where do you cross the line to get to a certainly impending injury.

One thing the Court has looked at is whether that harm has materialized in the past and how often. Now it doesn't always guarantee

there will be a future injury, but it can be a source of information.

And, here, what is so telling is that Respondents don't have a specific example of any doctor ever having to violate this care in violation of their conscience. Instead, Respondents have pointed to generalized assertions in the declarations that never come out and specifically say by one of their identified members: Here's the care I provided, here's how it violated my conscience, and here is why conscience protections were unavailable to me.

The fact that they don't have a doctor who's willing to submit that kind of sworn declaration in court, I think, demonstrates that the past harm hasn't happened, and the reason for that is because it is so speculative and turns on so many links in the chain that would have to occur and at the end would be backstopped by having the federal conscience protections in play.

On organizational standing, my friend has pointed to the fact that they invested time in preparing their citizen petition. She says

they voluntarily conducted studies and then generally refers to diversion of resources.

If that is enough, then every organization in this country has standing to challenge any federal policy they dislike. Havens Realty cannot possibly mean that. The Court should say so and clarify it is at the outer bounds and Respondents don't qualify under that standard.

On remedy, Justice Gorsuch, Justice Jackson, you pointed out the striking anomaly here of the nationwide nature of this remedy. Justice Jackson, you suggested maybe a more tailored remedy to the parties protecting their conscience protections should have been entered.

The problem here is they sued the FDA. FDA has nothing to do with enforcement of the conscience protections. That's all happening far downstream at the hospital level. And the only way to provide a remedy based on this theory of injury, therefore, was to grant this kind of nationwide relief that is so far removed from FDA's regulatory authority that it's ultimately requiring all women everywhere to change the conditions of use of this drug.

And I think it's worth stepping back finally and thinking about the profound mismatch between that theory of injury and the remedy that Respondents obtained. They have said that they fear that there might be some emergency room doctor somewhere, someday, who might be presented with some woman who is suffering an incredibly rare complication and that the doctor might have to provide treatment notwithstanding the conscience protections. We don't think that harm has materialized.

But what the Court did to guard against that very remote risk is enter sweeping nationwide relief that restricts access to mifepristone for every single woman in this country, and that causes profound harm.

It harms the agency, which had the federal courts come in and displace the agency's scientific judgments. It harms the pharmaceutical industry, which is sounding alarm bells in this case and saying that this would destabilize the system for approving and regulating drugs. And it harms women who need access to medication abortion under the conditions that FDA determined were safe and

effective.

The Court should reverse and remand with instructions to dismiss to conclusively end this litigation.

CHIEF JUSTICE ROBERTS: Thank you, counsel.

The case is submitted.

(Whereupon, at 11:37 a.m., the case was submitted.)

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