



1           IN THE SUPREME COURT OF THE UNITED STATES  
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3   FOOD AND DRUG ADMINISTRATION,           )  
4   ET AL.,                                            )  
5                                            Petitioners,            )  
6                                            v.                                            ) No. 23-235  
7   ALLIANCE FOR HIPPOCRATIC MEDICINE, )  
8   ET AL.,                                            )  
9                                            Respondents.            )  
10  - - - - -  
11  DANCO LABORATORIES, L.L.C.,            )  
12                                            Petitioner,            )  
13                                            v.                                            ) No. 23-236  
14  ALLIANCE FOR HIPPOCRATIC MEDICINE, )  
15  ET AL.,                                            )  
16                                            Respondents.            )  
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18  
19                                            Washington, D.C.  
20                                            Tuesday, March 26, 2024

21  
22           The above-entitled matter came on for  
23   oral argument before the Supreme Court of the  
24   United States at 10:04 a.m.

25

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8 of the Respondents.  
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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

1 specific doctor who faces imminent harm.

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

12           And there's no basis to conclude that  
13 any of that would be traceable to the  
14 incremental changes that FDA made in 2016 and  
15 2021 as opposed to the availability of  
16 mifepristone in general. Respondents' theories  
17 are too attenuated as a matter of law. The  
18 Court should say so and put an end to this case.

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

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

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

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

18 I welcome the Court's questions.

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

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

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

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

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

24           And the Court has said in many cases  
25 that in a situation like that, when you are not



1 the direct object of the agency's regulation, it  
2 can be substantially more difficult to establish  
3 standing.

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

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

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

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

1 of these doctors.

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

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

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

22 But we have an objection here to the  
23 underlying theory as a legal matter because it  
24 rests on so many different things that would  
25 have to happen one on top of another and that

1 turn on independent decisions made by third  
2 parties who are strangers to this litigation,  
3 who are not part of the suit.

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

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

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

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

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

25 GENERAL PRELOGAR: No. We think the

1 states lack standing. They're asserting  
2 indirect injuries that would, if it provided a  
3 basis for standing, mean that states could  
4 always sue the federal government. And the  
5 Court cautioned against that result in United  
6 States versus Texas, Footnote 3 of that  
7 decision.

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

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

22 GENERAL PRELOGAR: We would agree that  
23 that would represent past harm, so we're not  
24 disputing that that kind of conscience  
25 violation, providing care in violation of one's

1 conscience, would be cognizable. But, yes, we  
2 think that that situation has never come to  
3 pass. Respondents haven't identified any  
4 incident in more than 20 years that mifepristone  
5 has been available on the market that resembles  
6 that kind of hypothetical situation.

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

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

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

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

23 JUSTICE ALITO: Okay. Is there  
24 anybody who can sue and get a judicial ruling on  
25 whether what FDA did was lawful? And maybe what

1 they did was perfectly lawful, but shouldn't  
2 somebody be able to challenge that in court?  
3 Who in your view? Who would have standing to  
4 bring that suit?

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

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

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

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

25 GENERAL PRELOGAR: Certainly, we think

1       that this --

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

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

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

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

25                   JUSTICE ALITO:  I mean, so your

1 argument here is -- and as I said, I have great  
2 respect for Article III. We all do. We have to  
3 comply with it.

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

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

20 JUSTICE JACKSON: General --

21 JUSTICE SOTOMAYOR: I'm assuming that  
22 if there were an -- if this had been unsafe in a  
23 grossly visible way, you know, 40 percent more  
24 increased hospitalizations, that some doctor who  
25 was prescribing it would have challenged the



1 lack of an in-person --

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

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

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

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

20 GENERAL PRELOGAR: -- evidence to  
21 suggest it.

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

24 GENERAL PRELOGAR: But I do want to be  
25 clear that FDA's regulations here don't require

1 doctors to -- to not grant an in-person visit if  
2 they think that that is the best way to provide  
3 a standard of care here. So they are not  
4 directly required to dispense mifepristone  
5 through any particular arrangement.

6 JUSTICE SOTOMAYOR: All right.

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

14 So I just want to be clear, the  
15 federal government's position is that though a  
16 doctor would have conscience objections -- I'm  
17 thinking about the EMTALA litigation, and the  
18 Fifth Circuit criticized the government's  
19 inconsistent positions -- but it is your  
20 position that such doctors would have recourse  
21 to the conscience protections of federal law?

22 GENERAL PRELOGAR: Yes, absolutely.  
23 And let me be clear about this because I think  
24 the Fifth Circuit did fundamentally  
25 misunderstand our arguments and Respondents have

1 repeated that misunderstanding here.

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

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

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

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

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

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

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

23           Can you distinguish that from Havens  
24 Realty?

25           GENERAL PRELOGAR: Yes. So I think

1 Havens itself was trying to distinguish between  
2 two types of potential organizational injuries,  
3 and what Havens said is that in that case, the  
4 organization had come forward with direct and  
5 concrete demonstrable injury to itself.

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

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

21           And I recognize -- and you -- your  
22 question touches on it, Justice Barrett -- that  
23 some lower courts in particular have seemed to  
24 red -- read Havens to -- to endorse far broader  
25 theories of standing, including in the

1 immigration context.

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

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

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

20 JUSTICE BARRETT: I'm done.

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

25 I -- I -- I've heard and listened to

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

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

15 JUSTICE GORSUCH: Well --

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

19 JUSTICE GORSUCH: -- let -- let me  
20 just push back on that a little bit because  
21 standing is standing. It's Article III, right  
22 --

23 GENERAL PRELOGAR: Yes.

24 JUSTICE GORSUCH: -- that we're  
25 interpreting here, and so I think it's got to --

1 we've got to find some way to stitch it all  
2 together, and I'm looking for guidance from you.

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

8 JUSTICE GORSUCH: Should we?

9 GENERAL PRELOGAR: Well --

10 JUSTICE GORSUCH: I guess as a  
11 preliminary.

12 GENERAL PRELOGAR: No. I mean, I --

13 JUSTICE GORSUCH: No?

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

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

25 And, here, our argument is that the



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

9 JUSTICE GORSUCH: Thank you.

10 CHIEF JUSTICE ROBERTS: Thank you,  
11 counsel.

12 Justice Thomas, anything further?

13 Justice Alito?

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

24 GENERAL PRELOGAR: I think the only  
25 way that that would be true would be if the

1 three changes are interconnected and mutually  
2 reinforcing, guarding against the same kind of  
3 safety risk. So I agree that if there were a  
4 reason to think that the -- the reason why  
5 mifepristone is safe up to 10 weeks' gestation  
6 is because it's being prescribed by doctors  
7 instead of nurse practitioners, for example,  
8 then those changes would be interconnected  
9 because one change would effectively be the  
10 safety net for another.

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

21 So, in the absence of that kind of  
22 correlative effect of the changes, I don't think  
23 you can fault the agency for not giving even  
24 more explicit attention to this issue. And it  
25 did. It cited multiple studies that combined

1 multiple changes precisely because the standard  
2 of care had evolved over the 15 years  
3 mifepristone had been approved, and many of the  
4 changes were already being deployed together  
5 safely.

6 JUSTICE ALITO: Shouldn't the FDA have  
7 at least considered the application of 18 U.S.C.  
8 1461?

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

19 Now that doesn't affect other sources  
20 of law. FDA was not affirmatively approving  
21 mailing in violation of Comstock, even if you  
22 interpreted it that way. We don't think it  
23 means what Respondents suggest it means. But,  
24 at the very least, I don't think that it was  
25 FDA's responsibility to consider that, nor could

1 it have permissibly considered that under the  
2 statute.

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

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

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

25 But the other thing I would say,

1 Justice Alito, is that the agency did have a  
2 memorandum on Comstock. It's at JA 535. That  
3 was the advice that FDA received from OLC  
4 conveying the interpretation of Comstock.

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

7 GENERAL PRELOGAR: In the 2021  
8 decision, no. But the REMS was then modified in  
9 2023, and this was part of the administrative  
10 record for that.

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

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

24 Does that really count as a reasoned  
25 explanation to the suggestion that the data

1 shows there are going to be more emergency room  
2 visits? This is -- the -- the increase in  
3 emergency room visits is just of no consequence?  
4 It doesn't even merit some -- some comment?

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

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

22 And, you know, at the end of the day,  
23 FDA carefully parsed those studies. It made  
24 specific determinations about the results to be  
25 gleaned with respect to safety and efficacy. It

1 fully explained its decision-making, and I think  
2 it falls well within the zone of reasonableness  
3 under arbitrary and capricious review.

4 JUSTICE ALITO: All right. Thank you.

5 CHIEF JUSTICE ROBERTS: Justice  
6 Sotomayor?

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

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

16 I also want to emphasize, Justice  
17 Sotomayor, that the studies were far from the  
18 only evidence FDA consulted. At the time it  
19 acted in 2021, it had real-world experience  
20 during the COVID-19 pandemic, a period of time  
21 when the in-person dispensing requirement was  
22 not enforced, and FDA started by looking at, as  
23 a comparative analysis, the two periods of time  
24 when you had in-person dispensing and when you  
25 didn't and saw that there was no relevant

1 increase in serious adverse events or a  
2 difference between those two time frames. So  
3 that further supported the safety conclusion.

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

7 GENERAL PRELOGAR: Yes, virtually all.

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

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

14 JUSTICE SOTOMAYOR: But putting that  
15 aside, here, whatever the statistical increase  
16 was, FDA determined under the REMS standard that  
17 it wasn't sufficient to create a risk that  
18 counterbalanced the need for access, correct?

19 GENERAL PRELOGAR: Correct, because  
20 FDA is instructed to take into account burdens  
21 on the healthcare delivery system as well, and  
22 it looked at a variety of sources of data to  
23 conclude that, on balance, the burdens were --  
24 suggested that it was not necessary to keep this  
25 restriction in place to ensure safe use.



1 JUSTICE SOTOMAYOR: Thank you.

2 CHIEF JUSTICE ROBERTS: Justice Kagan?

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

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

21 JUSTICE KAGAN: Those two are who?

22 GENERAL PRELOGAR: Those are Dr. Skop  
23 and Dr. Francis. The relevant language for Dr.  
24 --

25 JUSTICE KAGAN: The other five don't

1 refer to conscience objections?

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

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

21 GENERAL PRELOGAR: I think that the  
22 fairest reading of the declarations is they are  
23 not objecting to that. Now I acknowledge that  
24 Respondents, in their red brief, have suggested  
25 there's a broader conscience injury in play here

1 and that there might be other doctors who have a  
2 broader concern about providing any care.

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

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

18 GENERAL PRELOGAR: Yes.

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

22 GENERAL PRELOGAR: Yes. And I think,  
23 on these declarations, they have not asserted a  
24 broader injury. But, even if they could  
25 conceivably come forward with other doctors or

1 try to adjust their declarations in some way,  
2 still that would not suffice.

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

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

21 GENERAL PRELOGAR: That is still to  
22 our knowledge the only time a court has done  
23 that. We have seen a disturbing trend of courts  
24 sometimes also overriding FDA's judgment to try  
25 to grant greater access to drugs when that

1 overrides FDA's expert judgment about what's  
2 necessary to ensure safe use.

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

8 JUSTICE KAGAN: Thank you.

9 CHIEF JUSTICE ROBERTS: Justice  
10 Gorsuch?

11 Justice Kavanaugh?

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

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

23 The Church Amendments have the most  
24 comprehensive protection here, and we think that  
25 those amendments guard against the kind of

1 injury that Respondents are asserting. There  
2 are also state law protections that often apply  
3 in this context.

4 JUSTICE KAVANAUGH: Thank you.

5 CHIEF JUSTICE ROBERTS: Justice  
6 Barrett?

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

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

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

24 As I understand it, the serious  
25 adverse consequences that have to be reported or

1 that FDA considers risks are death and  
2 transfusion but not, say -- I mean, it -- it  
3 seems to me, and I think the data bears this  
4 out, that the elimination of the in-person  
5 dispensing requirement or, you know, the  
6 in-person visit at the outset would lead to  
7 mistakes in gestational aging, which could  
8 increase the need for a D&C or the amount of  
9 bleeding, et cetera.

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

12 GENERAL PRELOGAR: So I want to be  
13 careful because there's a list of serious  
14 adverse events and I'm not sure that I have all  
15 of them down to be able to recite them to you,  
16 although they're in the record, but I do think  
17 the premise of the question is wrong. This idea  
18 that the change to in-person dispensing would  
19 necessarily increase the risk of those events,  
20 that was not reflected in the data that FDA  
21 consulted, and I would point you to JA 383 to  
22 384 in particular --

23 JUSTICE BARRETT: Okay.

24 GENERAL PRELOGAR: -- where FDA -- FDA  
25 explained that even in person you're not

1 necessarily getting an ultrasound. That's never  
2 been required. And so the relevant question  
3 might be is your -- your provider going to ask  
4 you a series of screening questions, like when  
5 was your last menstrual period, in person or via  
6 telemedicine, and there's no evident reason why  
7 that difference would actually lead to different  
8 safety outcomes.

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

13 GENERAL PRELOGAR: So --

14 JUSTICE BARRETT: You know the JA way  
15 better than I do, though.

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

22 You know, I don't want to represent  
23 all of the different findings of the different  
24 studies because they varied a little bit, but  
25 FDA's ultimate conclusion was that mifepristone



1 could safely be dispensed without in-person  
2 visits. It had voluminous evidence, I think, to  
3 support that conclusion in 2021. And there's  
4 been no contrary evidence that's been  
5 introduced.

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

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

18 Now it is, of course, necessary for  
19 providers to be able to diagnose ectopic  
20 pregnancy and to date gestational age. That  
21 remains true under the REMS now. Prescribers  
22 still have to have that capability, and they  
23 have to deploy whatever mechanisms they believe  
24 would accurately allow them to identify  
25 contraindications for use of mifepristone.

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

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

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

18                  And if the woman has those kinds of  
19 risk factors, then imaging may be necessary, but  
20 that remains true under the 2021 REMS as well.  
21 The prescriber has to be confident that it has  
22 excluded those kinds of conditions before  
23 prescribing this drug.

24                  And the standard of care around the  
25 world, most medication abortion occurs without

1 an ultrasound.

2 JUSTICE BARRETT: Thanks.

3 CHIEF JUSTICE ROBERTS: Justice  
4 Jackson?

5 JUSTICE JACKSON: Good morning,  
6 General.

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

18 And so the obvious common-sense remedy  
19 would be to provide them with an exemption, that  
20 they don't have to participate in this  
21 procedure. And you say, and you've said here  
22 several times, that federal law already gives  
23 them that.

24 So I guess then what they're asking  
25 for in this lawsuit is -- is more than that.

1 They're saying, because we object to having to  
2 be forced to participate in this procedure,  
3 we're seeking an order preventing anyone from  
4 having access to these drugs at all.

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

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

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

20 And, instead, they're reaching out and  
21 seeking to invoke rights under a different  
22 statute, the FDCA, that doesn't regulate them at  
23 all, that doesn't make them do or not do  
24 anything, and the -- the relief that they're  
25 seeking would dramatically alter the approved

1 conditions of use for mifepristone and affect  
2 women all around the nation simply because of  
3 this conscience injury that's already directly  
4 addressed by other --

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

7 GENERAL PRELOGAR: -- protections  
8 under federal law.

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

12 GENERAL PRELOGAR: Yes. I mean, I  
13 think that --

14 JUSTICE JACKSON: Yeah.

15 GENERAL PRELOGAR: -- one of the hard  
16 things about trying to tailor relief here is  
17 that they're asserting such a diffuse theory of  
18 injury that it's almost as though the only  
19 option was to grant a nationwide remedy of the  
20 kind the lower courts issued, and that runs  
21 counter to ordinary Article III principles of  
22 party-specific relief.

23 But I just think it shows that there's  
24 something wrong with the theory of injury in the  
25 first place because it's so attenuated and

1 because they claim they would need so much  
2 relief all over the country.

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

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

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

20 GENERAL PRELOGAR: Yes. I think that  
21 it just reflects the stakes of the Corner Post  
22 case and provides a vivid example of the way  
23 that it might be possible, if this Court were to  
24 approve the request for a broader theory of the  
25 statute of limitations in that case, the way it

1 could open the door to plaintiffs coming in and  
2 saying, well, I only became a doctor later, or I  
3 only started working in an emergency room later  
4 and would try to unsettle longstanding agency  
5 actions that maybe occurred decades previously.

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

15 JUSTICE JACKSON: Thank you.

16 CHIEF JUSTICE ROBERTS: Thank you,  
17 counsel.

18 Ms. Ellsworth.

19 ORAL ARGUMENT OF JESSICA L. ELLSWORTH

20 ON BEHALF OF PETITIONER

21 DANCO LABORATORIES, L.L.C.

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

24 In 2016 and 2021, FDA made certain  
25 changes to the labeling and use restrictions for

1 Danco's drug, Mifeprex. The decision below  
2 stops Danco from selling Mifeprex in line with  
3 that scientific judgment based on a highly  
4 attenuated claim that an unknown doctor could be  
5 called someday to an unknown emergency room  
6 after a series of decisions by third parties.  
7 No facts causally link that possible future  
8 encounter to a specific change FDA made in 2016  
9 or 2021.

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

15 Reversal is required for two reasons:

16 First, Article III standing is not an  
17 academic exercise in what's conceivable.

18 Respondents lack standing under every prong of  
19 the analysis.

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

24 I welcome the Court's questions.

25 JUSTICE THOMAS: The government, the



1 Solicitor General points out, would not be  
2 susceptible to a Comstock Act problem. But your  
3 -- in your case, you would be.

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

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

18 I think this Court should think hard  
19 about the mischief it would invite if it allowed  
20 agencies to start taking action based on  
21 statutory responsibilities that Congress has  
22 assigned to other agencies.

23 On the merits, this issue was not  
24 presented below -- excuse me -- was not ruled on  
25 below, and in any event, I would also point out

1 that in 2021, FDA's decision allows use of  
2 brick-and-mortar pharmacies, in addition to  
3 mail-order pharmacies.

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

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

17 This statute has not been enforced for  
18 nearly a hundred years, and I -- I don't believe  
19 that this case presents an opportunity for this  
20 Court to opine on the reach of the statute.

21 CHIEF JUSTICE ROBERTS: Counsel, I'd  
22 like to ask you the same questions I was posing  
23 to the Solicitor General. You know, our  
24 precedents, Clapper and Susan B. Anthony List,  
25 talk about requiring a substantial risk that

1       harm will recur, and you argue that's not  
2       present here.

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

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

14                      CHIEF JUSTICE ROBERTS: Right. I  
15      mean, we toss around a lot of adjectives, but  
16      I'm just trying -- as a practical matter, how do  
17      you figure out -- I mean, what percentage of  
18      adverse consequences would be enough? What  
19      percentage of emergency room visits would be  
20      enough?

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

1       happen.

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

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

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

17                   JUSTICE ALITO: And the Fifth Circuit  
18       decision does not prohibit you from continuing  
19       to produce and -- and sell that product, right?

20                   MS. ELLSWORTH: That is correct.

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

25                   MS. ELLSWORTH: Yes.

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

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

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

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

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

18 MS. ELLSWORTH: That -- that's  
19 correct.

20 JUSTICE ALITO: Do you think the FDA  
21 is infallible?

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

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

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

17 JUSTICE ALITO: But don't you think  
18 the FDA should have continued to require  
19 reporting of non-fatal consequences?

20 MS. ELLSWORTH: Your Honor, the FDA  
21 decided not to continue that reporting  
22 requirement in 2016 based on more than 15 years  
23 of a well-established safety profile when that  
24 reporting was required. There is no drug on the  
25 market today under any REMS that requires the

1 kind of reporting that the plaintiffs are saying  
2 should be reimposed here.

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

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

17 I think Your Honor's question, though,  
18 gets at concern I heard in some of the earlier  
19 questioning about who would have standing if  
20 these plaintiffs don't have standing. And one  
21 of the things I want to note is that drug  
22 manufacturers are very frequently subject to  
23 tort litigation, product liability suits,  
24 failure to warn suits, deceptive advertising  
25 suits, when someone is claiming harm from a

1 pharmaceutical manufacturer's product.

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

11           JUSTICE ALITO: Does --

12           JUSTICE KAGAN: Could you go --

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

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

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



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

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

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

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

14 JUSTICE KAGAN: Could you go back to  
15 Justice Alito's questions about adverse event  
16 reporting? And you said you were subject, your  
17 product, to higher standards, and now we're  
18 being brought down to the sort of regular --  
19 could you talk about that a little bit? What  
20 are the normal standards for adverse event  
21 reporting as you understand them? Why are they  
22 there? What instead were you subject to in the  
23 past?

24 MS. ELLSWORTH: May I answer the  
25 question?

1 CHIEF JUSTICE ROBERTS: Go ahead.

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

7 What changed was that from 2000 until  
8 2016, prescribers were obligated to report  
9 adverse events to Danco and then Danco then had  
10 its separate reporting obligation to FDA.

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

19 JUSTICE KAGAN: Thank you.

20 CHIEF JUSTICE ROBERTS: Justice  
21 Thomas?

22 Justice Alito, anything further?

23 Justice Sotomayor?

24 Justice Kavanaugh?

25 Justice Barrett?

1 Justice Jackson, anything further?

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

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

12 MS. ELLSWORTH: Yes, Your Honor, I  
13 think we have significant concerns about that.  
14 And there are two amicus briefs from the  
15 pharmaceutical industry that expand on why  
16 exactly that's so concerning for pharmaceutical  
17 companies who do depend on FDA's gold standard  
18 review process to -- to approve their drugs and  
19 then to be able to sell their products in line  
20 with that considered judgment.

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

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

25 I think the -- the reality is -- and

1 this Court is a -- this decision below is a good  
2 example of it. You have a district court that  
3 among other things relied on one study that was  
4 an analysis of anonymous blog posts.

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

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

16 That is why FDA has many hundreds of  
17 pages of analysis in the record of what the  
18 scientific data showed, and courts are just not  
19 in a position to parse through and second-guess  
20 that.

21 JUSTICE JACKSON: Thank you.

22 CHIEF JUSTICE ROBERTS: Thank you,  
23 counsel.

24 MS. ELLSWORTH: Thank you.

25 CHIEF JUSTICE ROBERTS: Ms. Hawley?

1 ORAL ARGUMENT OF ERIN M. HAWLEY

2 ON BEHALF OF THE RESPONDENTS

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

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

11 We've heard a lot this morning about  
12 standing. Article III is satisfied here  
13 because, one, the FDA relies on OB hospitalists  
14 to care for women harmed by abortion drugs.  
15 Two, the FDA concedes that between 2.9 and  
16 4.6 percent of women will end up in the  
17 emergency room. And, three, the FDA  
18 acknowledges that women are even more likely to  
19 need surgical intervention and other medical  
20 care without an in-person visit.

21 According to Guttmacher, nearly  
22 650,000 women take mifepristone every single  
23 year. It's no surprise that Respondents have  
24 experienced an increase in emergency room visits  
25 and, indeed, treated women suffering from

1 abortion drug harms tens of thousands of times  
2 -- excuse me, dozens of times, women have  
3 suffered tens of thousands of times.

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

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

18           On the merits, FDA failed to comply  
19 with basic APA requirements. In 2021, it  
20 eliminated the initial in-person visit based on  
21 data it says elsewhere is unreliable. And in  
22 2016, it failed to consider or explain the  
23 cumulative effects of its wholesale removal of  
24 safeguards. These actions fall far short of  
25 what the APA requires. This Court should

1 affirm.

2 I welcome the Court's questions.

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

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

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

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

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

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

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

1 this.

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

4 JUSTICE THOMAS: The Alliance.

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

15 In Havens, the Court looked to two  
16 things, whether -- whether there was an  
17 impairment of the organization's mission and,  
18 second, whether there was an expenditure of  
19 resources. Both things are satisfied here.

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

25 One of the primary reasons that that's



1 required is because, in 2016, FDA took away the  
2 requirement that abortion providers report  
3 adverse events --

4 JUSTICE THOMAS: Well --

5 MS. HAWLEY: -- aside from deaths.

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

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

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

24 They comb through Medicaid data, they  
25 comb through FAERS data, so they get at the true

1 nature of adverse events. And all those sorts  
2 of things are neither a prelude to litigation,  
3 nor would they have occurred but for FDA's  
4 unlawful conduct in this case.

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

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

16 And so that's a very important  
17 distinction from here. Separate from the  
18 individual defendants' claims of -- of standing  
19 based on wasted resources, their resources, the  
20 organizations are not losing anything.

21 MS. HAWLEY: So --

22 JUSTICE SOTOMAYOR: Their job is to do  
23 exactly what you're talking about and they're  
24 doing it. They're investigating certain  
25 problems, but that's not an injury that's

1 redressable by this -- by vacating this rule.

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

11 With respect to our own injury, it's  
12 absolutely redressable. For example, if the  
13 regulations are put back in place, the  
14 protections whereby individual abortion  
15 providers need to provide information about  
16 adverse events, that would provide our  
17 Respondent organizations with more accurate  
18 information about the harms from abortion drugs.

19 JUSTICE JACKSON: Counsel --

20 CHIEF JUSTICE ROBERTS: Can --

21 JUSTICE JACKSON: -- can I ask you --

22 CHIEF JUSTICE ROBERTS: Go ahead.

23 JUSTICE JACKSON: -- about the remedy  
24 and sort of the way that I was talking with the  
25 SG. I mean, it makes perfect sense for the

1 individual doctors to seek an exemption, but as  
2 I understand it, they already have that, and so  
3 what they're asking for here is that in order to  
4 prevent them from possibly ever having to do  
5 these kinds of procedures, everyone else should  
6 be prevented from getting access to this  
7 medication.

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

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

14 One of this -- this is the emergency  
15 nature of these procedures. As the FDA  
16 acknowledges, many women do go to the emergency  
17 room, and if we just think about what that might  
18 look like, take Dr. Francis. She's on the labor  
19 and delivery floor, supervising --

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

25 MS. HAWLEY: She talks about, Your

1 Honor, being an --

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

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

14 In addition, the government simply  
15 cannot get its story straight on EMTALA. If you  
16 look at the district court brief in that case,  
17 we just heard that the Church Amendment applies,  
18 and while we would love for this Court to adopt  
19 that position, they told the district court the  
20 very opposite.

21 JUSTICE JACKSON: All right. Let me  
22 ask you this. If we were to find that there are  
23 conscientious objections that, say, hospitals  
24 take them into account and these doctors do have  
25 a way to not do these kinds of procedures,

1 should we end this case on that basis?

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

5 JUSTICE JACKSON: Why?

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

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

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

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

23 I think Justice Jackson's saying let's  
24 spot you all that, okay, with respect to your --  
25 your clients. Normally, in Article III

1 traditional equitable remedies, we issue and we  
2 say over and over again provide a remedy  
3 sufficient to address the plaintiff's asserted  
4 injuries and go no further.

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

16           MS. HAWLEY: Yes, Your Honor. Again,  
17 I have to say that I think it's impracticable to  
18 -- to raise a conscience objection. But, even  
19 spotting that, I think the -- the district court  
20 remedy here was perfectly appropriate under  
21 Section 705.

22           Section 705 grants the reviewing  
23 courts the authority to issue all necessary and  
24 appropriate relief. And as the government  
25 acknowledged in oral argument in *Corner Post*,

1 when the parties before the court are  
2 non-regulated parties, the only avenue in which  
3 they can possibly get relief -- and, of course,  
4 that's sort of the sine qua non of equitable  
5 relief, is that the parties before the court get  
6 it, and that's for, as in this case, a stay to  
7 issue or -- or another case is a vacatur, and  
8 that's because, without that sort of relief, the  
9 very parties before the court won't get it.

10 JUSTICE ALITO: I think --

11 CHIEF JUSTICE ROBERTS: Why can't  
12 you --

13 JUSTICE ALITO: -- something as --

14 CHIEF JUSTICE ROBERTS: Why can't the  
15 court specify that this relief runs to precisely  
16 the parties before the court, as opposed to  
17 looking to the agency in general and saying,  
18 Agency, you can't do this anywhere?

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



1 and day out.

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

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

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

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

1 more shot at that.

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

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

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

22 When you did your 1, 2, 3 in your  
23 opening statement, it sounded very probabilistic  
24 to me. I mean, I don't remember exactly what  
25 the 1, 2, 3 are, but, you know, let's say it's

1 something along the lines of we represent a lot  
2 of doctors, and there are a lot of women out  
3 there taking mifepristone, and some fraction of  
4 them are going to have adverse events, and some  
5 fraction of those are going to come to the  
6 emergency room, and -- and so there's some  
7 probability or likelihood that one of our  
8 doctors who has a conscience objection is going  
9 to come face-to-face with one of these women who  
10 has an adverse event.

11 Is that your theory?

12 MS. HAWLEY: No, Your Honor. What we  
13 think really shows that Respondents have  
14 standing here is FDA's own acknowledgments. I  
15 would point you to JA 384. And in regulating  
16 mifepristone, FDA has continually said that  
17 emergency room doctors and OB-GYN hospitalists  
18 are critical to the safe use of drug.

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

1 theory, yes?

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

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

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

18 So you agree with that, yes?

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

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

23 MS. HAWLEY: Mm-hmm.

24 JUSTICE KAGAN: But, if you had to  
25 pick one and say go read that declaration and

1 that declaration is going to tell you why --  
2 why, you know, we're entitled to be up here,  
3 who's the person?

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

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

10 MS. HAWLEY: So, to speak to  
11 Dr. Francis, at the beginning, there's been some  
12 confusion, I think, about the precise nature of  
13 the conscience harm. But, if you look at JA  
14 155, paragraph 15, she talks about her and other  
15 AAPLOG members who object not only to taking the  
16 life of an unborn child during an elective  
17 abortion but also to "completing that process."  
18 That echoes the CMDA declaration at 142 and 143.  
19 It's also consistent with --

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

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

5 JUSTICE KAGAN: She herself performed  
6 that?

7 MS. HAWLEY: That is correct, Your  
8 Honor.

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

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

16 JUSTICE KAGAN: Well, usually --

17 MS. HAWLEY: -- emergency room table.

18 JUSTICE KAGAN: -- conscience  
19 objections, the way people with conscience  
20 objections do this is they make those objections  
21 known. And, you know, that may be harder. It  
22 may be easier in a particular context, but most  
23 hospitals have mechanisms in place, routines in  
24 place to ensure that doctors who are allowed to  
25 do this, you know, in advance, right, and are

1 allowed to do it at the moment, they say so.

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

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

15           And, again, I'd point Your Honor to  
16 the district court Fifth Circuit brief in EMTALA  
17 where the government says that neither the  
18 church nor any of the other sponsors of those  
19 federal conscience protections intended them to  
20 apply in emergency situations.

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

1 JUSTICE JACKSON: Counsel --

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

17 MS. HAWLEY: Absolutely. We agree  
18 with that, Justice Alito.

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

24 So it's certainly true that data is  
25 appropriate to consider in determining whether



1 there's a substantial risk under SBA List.  
2 Here, the FDA admits -- this is at 533 -- that  
3 between 2.9 and 4.6 percent of women will go to  
4 the emergency room. It acknowledges -- this is  
5 at 542 -- that up to 7 percent of women will  
6 need surgical intervention.

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

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

17 Now we can get into whether other  
18 people are illegally breaking the law and  
19 supplying it contrary to law, but what does that  
20 do to your probability, which is -- it's already  
21 infinitesimally small because there are  
22 thousands of hospitals in the country, 50  
23 states, I don't know how many territories,  
24 thousands and thousands of -- of -- of places  
25 where pregnant women go who may be suffering

1 from miscarriages or otherwise, to know or to  
2 even imagine how one doctor is going to ever  
3 actually see a patient that it's going to be --  
4 that he or she is going to be forced to  
5 intervene on their behalf, but then add to it  
6 that this is illegal in these states.

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

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

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

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

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

14 So, if that's right, I mean, I think  
15 the difficulty here is that at least to me,  
16 these affidavits do read more like the  
17 conscience objection is strictly to actually  
18 participating in the abortion to end the life of  
19 the embryo or fetus, and I don't read either  
20 Skop or Francis to say that they ever  
21 participated in that.

22 So do you want to address that?

23 MS. HAWLEY: Sure. So, first, Justice  
24 Barrett, I think Dr. Francis's, combined with  
25 CMDA, can be read for the broader conscience

1 harm. Again, that's how the district court  
2 understood that. I'd point you to pages 7 and  
3 8. That's how both the state panel and the  
4 Fifth Circuit understood Respondents' conscience  
5 harms to extend beyond simply requiring the  
6 ending of an unborn life.

7           And with respect to even the more  
8 narrow conscience harm, to whether a doctor may  
9 need to end a life, we think there's still a  
10 substantial risk of that occurring. If you look  
11 at the numbers of the increase from 7 to 10  
12 weeks in gestational age, that means that  
13 3.1 percent of pregnancies will be ongoing,  
14 requiring a D&C. We know at JA -- or, excuse  
15 me, ROA 870, that 55 percent of those D&Cs occur  
16 in the emergency room.

17           This is a substantial number of women  
18 suffering abortion drug harm. Again, Guttmacher  
19 says 650,000 women took the drug in 2023.

20           JUSTICE BARRETT: But not all of those  
21 D&Cs will involve a pregnancy that would  
22 otherwise be viable or an embryo or a fetus that  
23 would otherwise be living, because you can have  
24 complications or excessive bleeding even after  
25 the abortion is complete in that respect, but

1 there's pregnancy tissue remaining?

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

4 JUSTICE BARRETT: Is ongoing  
5 pregnancies?

6 MS. HAWLEY: Yes. And FDA says at JA  
7 542 that up to 7 percent will need surgeries to  
8 stop either bleeding or ongoing pregnancies or  
9 failures.

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

17 MS. HAWLEY: There are hundreds of  
18 them, Your Honor. But I think -- may I finish?

19 CHIEF JUSTICE ROBERTS: Sure.

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

25 JUSTICE JACKSON: Ms. Hawley, can you

1 clarify the broader conscience harm from the  
2 narrow one? Because I had understood the  
3 conscience harm as Justice Barrett does, but you  
4 suggest that there's a broader one. So what --  
5 what is that?

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

14 JUSTICE JACKSON: That's what I  
15 understood the narrow one to be, right? I'm  
16 participating in a procedure that is ending the  
17 life.

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

20 JUSTICE JACKSON: That's narrow?

21 MS. HAWLEY: Yes.

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

24 MS. HAWLEY: So the broader one, Your  
25 Honor, is being complicit in the process that

1 unnecessarily leaves -- takes an unborn life,  
2 such as performing a D&C and abortion. And it's  
3 really not that hard to -- to see.

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

9 MS. HAWLEY: So this Court, of course,  
10 takes religious beliefs and conscience beliefs  
11 --

12 JUSTICE JACKSON: Yes.

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

15 JUSTICE JACKSON: Yes.

16 MS. HAWLEY: But what harms our  
17 doctors, Your Honor, is being involved in  
18 completing in the terms of our declaration an  
19 elective abortion, and it's really not that hard  
20 to see why that might be a conscience harm if  
21 you think about what's involved in a D&C.

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

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

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

14                  JUSTICE KAGAN: So --

15                  MS. HAWLEY: -- and remove placental  
16                  tissue.

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

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

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

23                  MS. HAWLEY: So I would point Your  
24                  Honor to JA 155, paragraph 15, where, again, she  
25                  talks about completing an abortion. The CMDA



1 declaration at pages 142 and 143 also describe  
2 this sort of complicity harm from being involved  
3 in -- in an elective abortion, Your Honor.

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

10 JUSTICE JACKSON: May I --

11 JUSTICE KAGAN: No, go ahead.

12 JUSTICE JACKSON: It's -- sorry. It's  
13 my understanding that sometimes the completion,  
14 it doesn't involve surgical intervention. Do  
15 you have a sense of how often? I mean, we -- we  
16 may get all the way down the chain to the  
17 doctor's there, the person is having an  
18 emergency procedure. My understanding is, with  
19 some of these chemical abortion scenarios, the  
20 completion occurs by prescribing additional  
21 medication.

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

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

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

12 JUSTICE JACKSON: Yeah, no, I guess  
13 I'm just trying to get at -- we're still -- I'm  
14 still working on how many circumstances or how  
15 often it would be that your clients actually  
16 have to complete the procedure in the way that  
17 you are describing.

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

22 In addition, Your Honor, if you think  
23 about the numbers, again, it says 3.1 percent at  
24 10 weeks, and this has only gone up. In 2020,  
25 FDA told this Court that the in-person visit was

1 both "necessary and minimally burdensome" and  
2 necessary to preserve women's health precisely  
3 so these sorts of situations occur less  
4 frequently.

5 CHIEF JUSTICE ROBERTS: Thank you,  
6 counsel.

7 Justice Thomas?

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

12 I'd like you to comment on their  
13 answers.

14 MS. HAWLEY: Sure, Justice Thomas. We  
15 don't think that there's any case of this Court  
16 that empowers FDA to ignore other federal law.

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

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

25 MS. HAWLEY: So I believe the Comstock

1 Act was first raised at -- at the district  
2 court, Your Honor. But we think that exhaustion  
3 does not apply for two reasons.

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

12 This is consistent with this Court's  
13 case in *Darby*. The -- the lower courts have  
14 taken conflicting opinions. But we think the  
15 better reading of Section 704 is that there is  
16 no exhaustion required unless either a statute  
17 or agency rule stays the proceeding during  
18 judicial review.

19 CHIEF JUSTICE ROBERTS: Justice Alito?

20 Justice Sotomayor?

21 Justice Kagan?

22 JUSTICE KAGAN: May I ask about your  
23 view of traceability? And, you know, on -- on  
24 -- on one understanding -- and I want you to  
25 tell me if you agree with this -- that even

1 beyond proving whatever injury you're trying to  
2 prove, that you have to show that that injury is  
3 traceable to the 2016 and 2021 FDA actions --

4 MS. HAWLEY: Yeah.

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

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

15 MS. HAWLEY: So we believe, Justice  
16 Kagan, under the case law that -- that we need  
17 to show that -- that each of the 2016 action and  
18 the 2021 action increased the risk of harm. And  
19 we think the way --

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

24 MS. HAWLEY: We do, and we think we  
25 can do that for a couple of reasons. First of

1 all, traceability, of course, is de facto.  
2 We're not in the Palsgraf sort of world of -- of  
3 tort causation.

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

13 JUSTICE KAGAN: So there -- there  
14 might be some dispute between the two of you as  
15 to exactly how big the increased risk is, but  
16 let's even take your view that there is, you  
17 know, some measurable increased risk.

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

22 MS. HAWLEY: I --

23 JUSTICE KAGAN: I mean, it could be --

24 MS. HAWLEY: I think --

25 JUSTICE KAGAN: -- you know, the --

1 the -- the -- the original risk.

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

10 And, again, this is entirely  
11 consistent with FDA's own numbers. Again, in  
12 2020, FDA told this Court that the in-person  
13 visit was necessary to preserve women's health  
14 because an in-person exam -- visit is the best  
15 opportunity to examine for things like ectopic  
16 pregnancy and accurately assess gestational age.

17 JUSTICE KAGAN: Thank you.

18 CHIEF JUSTICE ROBERTS: Justice  
19 Gorsuch?

20 Justice Kavanaugh?

21 Justice Barrett?

22 JUSTICE BARRETT: So General Prelogar  
23 said that that initial in-person visit had no  
24 requirement of an ultrasound or, you know, any  
25 effort to detect fetal heartbeat, so it wouldn't

1 necessarily give an accurate read on gestational  
2 age or detect an ectopic pregnancy. So why  
3 would that necessarily -- the elimination -- why  
4 would the elimination of the visit necessarily  
5 increase the risks?

6 MS. HAWLEY: So I think, Your Honor,  
7 FDA's own data shows that those risks did go up.  
8 If you look at the Kerestes study, it shows a  
9 nearly threefold increase in emergency room  
10 visits when you have the in-person visit and  
11 when you removed it. There was 5.8 percent with  
12 an in-person visit, and it was also -- and about  
13 2.1 without.

14 JUSTICE BARRETT: Is that because  
15 doctors were just kind of voluntarily saying,  
16 hey, it would be a good idea to give you an  
17 ultrasound or try to detect a fetal heartbeat or  
18 what?

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



1 pregnancies, diagnose or assess gestational age.

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

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

12 MS. HAWLEY: Mm-hmm.

13 JUSTICE BARRETT: Explain to me what  
14 additional costs you might have incurred or how  
15 your resources were diverted in a way that would  
16 satisfy Havens.

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

24 JUSTICE BARRETT: Is that it?

25 MS. HAWLEY: Well -- well, those

1 studies, Your Honor, I would point to you, one  
2 of them is at ROA 5 -- excuse me -- ROA 870 and  
3 before and after, and those are pretty  
4 comprehensive studies, Your Honor.

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

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

12 And one thing to note with the citizen  
13 petition is that is the only way in which anyone  
14 can raise a -- a concern to the FDA. These  
15 proceedings go on between Danco and the FDA  
16 behind closed doors. This is not a  
17 notice-and-comment process. The first time  
18 anyone can raise these objections is a citizen  
19 petition.

20 CHIEF JUSTICE ROBERTS: Justice  
21 Jackson?

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

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

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

13 JUSTICE JACKSON: I guess I don't  
14 understand how that scope of review is not  
15 second-guessing the agency. I mean, they're  
16 looking at studies and you're saying that the  
17 Court can look at studies, maybe different  
18 studies, maybe the same studies, and critique  
19 their conclusions about them.

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

24 MS. HAWLEY: I don't think that's an  
25 accurate portrayal of the -- the APA claim at

1 issue here, Your Honor, and the reason being,  
2 again, is we're just asking this Court to look  
3 at what FDA said. The FDCA says you have to  
4 have adequate tests and test results, as well as  
5 sufficient information.

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

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

16 MS. HAWLEY: So, yes. That claim is  
17 not even before this Court. But, with respect  
18 to the two claims that are before the Court, the  
19 2016 and the 2021, we think the FDA's own  
20 statements here are arbitrary.

21 In 2016, what the FDA said was we're  
22 going to look at individual studies and then,  
23 even though we say they're interrelated at JA  
24 298, we're going to take all of the protections  
25 away at once.

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

3                   JUSTICE JACKSON: Thank you.

4                   CHIEF JUSTICE ROBERTS: Thank you,  
5 counsel.

6                   Rebuttal, General Prelogar.

7                   REBUTTAL ARGUMENT OF GEN. ELIZABETH B. PRELOGAR

8                   ON BEHALF OF THE FEDERAL PETITIONERS

9                   GENERAL PRELOGAR: Thank you.

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

13                  One thing the Court has looked at is  
14 whether that harm has materialized in the past  
15 and how often. Now it doesn't always guarantee  
16 there will be a future injury, but it can be a  
17 source of information.

18                  And, here, what is so telling is that  
19 Respondents don't have a specific example of any  
20 doctor ever having to violate this care in  
21 violation of their conscience. Instead,  
22 Respondents have pointed to generalized  
23 assertions in the declarations that never come  
24 out and specifically say by one of their  
25 identified members: Here's the care I provided,

1 here's how it violated my conscience, and here  
2 is why conscience protections were unavailable  
3 to me.

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

13           On organizational standing, my friend  
14 has pointed to the fact that they invested time  
15 in preparing their citizen petition. She says  
16 they voluntarily conducted studies and then  
17 generally refers to diversion of resources.

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

25           On remedy, Justice Gorsuch, Justice

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

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

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

1 harm has materialized.

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

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

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

20 CHIEF JUSTICE ROBERTS: Thank you,  
21 counsel.

22 The case is submitted.

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

25



## Official - Subject to Final Review

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