



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.            )  
17  - - - - -

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. But  
2 their theories rest on a long chain of remote  
3 contingencies. Only an exceptionally small  
4 number of women suffer the kind of serious  
5 complications that could trigger any need for  
6 emergency treatment. It's speculative that any  
7 of those women would seek care from the two  
8 specific doctors who asserted conscience  
9 injuries. And even if that happened, federal  
10 conscience protections would guard against the  
11 injury the doctors face. And there's no basis  
12 to conclude that any of that would be traceable  
13 to the incremental changes that FDA made in 2016  
14 and 2021 as opposed to the availability of  
15 mifepristone in general.

16 Respondents' theories are too  
17 attenuated as a matter of law. The Court should  
18 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  
22 of women. Respondents don't identify any  
23 evidence that the agency overlooked. They just  
24 disagree with the agency's analysis of the data  
25 before 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  
6 this Court has recognized that when the theory  
7 of 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 doctors -- the only one there on duty  
13 who 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 recognize that respect -- with  
21 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 -- 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.  
10 I 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 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 has  
7 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 -- and I'm looking for guidance  
3 from you.

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

9 JUSTICE GORSUCH: Should we?

10 GENERAL PRELOGAR: Well --

11 JUSTICE GORSUCH: I guess as a  
12 preliminary.

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

14 JUSTICE GORSUCH: No?

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

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



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

10                   JUSTICE GORSUCH: Thank you.

11                   CHIEF JUSTICE ROBERTS: Thank you,  
12                   counsel.

13                   Justice Thomas, anything further?

14                   Justice Alito?

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

25                   GENERAL PRELOGAR: I think the only

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

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

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

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

7 JUSTICE ALITO: Shouldn't the FDA have  
8 at least considered the application of 18 U.S.C.  
9 1461?

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

20 Now that doesn't affect other sources  
21 of law. FDA was not affirmatively approving  
22 mailing in violation of Comstock, even if you  
23 interpreted it that way. We don't think it  
24 means what Respondents suggest it means. But,  
25 at the very least, I don't think that it was

1 FDA's responsibility to consider that, nor could  
2 it have permissibly considered that under the  
3 statute.

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

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

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

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

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

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

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

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

25                   Does that really count as a reasoned

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

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

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

23 And, you know, at the end of the day,  
24 FDA carefully parsed those studies. It made  
25 specific determinations about the results to be

1 gleaned with respect to safety and efficacy. It  
2 fully explained its decision-making, and I think  
3 it falls well within the zone of reasonableness  
4 under arbitrary and capricious review.

5 JUSTICE ALITO: All right. Thank you.

6 CHIEF JUSTICE ROBERTS: Justice  
7 Sotomayor?

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

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

17 I also want to emphasize, Justice  
18 Sotomayor, that the studies were far from the  
19 only evidence FDA consulted. At the time it  
20 acted in 2021, it had real-world experience  
21 during the COVID-19 pandemic, a period of time  
22 when the in-person dispensing requirement was  
23 not enforced, and FDA started by looking at, as  
24 a comparative analysis, the two periods of time  
25 when you had in-person dispensing and when you

1 didn't and saw that there was no relevant  
2 increase in serious adverse events or a  
3 difference between those two time frames. So  
4 that further supported the safety conclusion.

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

8 GENERAL PRELOGAR: Yes, virtually all.

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

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

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

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



1 restriction in place to ensure safe use.

2 JUSTICE SOTOMAYOR: Thank you.

3 CHIEF JUSTICE ROBERTS: Justice Kagan?

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

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

22 JUSTICE KAGAN: Those two are who?

23 GENERAL PRELOGAR: Those are Dr. Skop  
24 and Dr. Francis. The relevant language for Dr.  
25 --

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

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

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

22 GENERAL PRELOGAR: I think that the  
23 fairest reading of the declarations is they are  
24 not objecting to that. Now I acknowledge that  
25 Respondents, in their red brief, have suggested

1 there's a broader conscience injury in play here  
2 and that there might be other doctors who have a  
3 broader concern about providing any care.

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

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

19 GENERAL PRELOGAR: Yes.

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

23 GENERAL PRELOGAR: Yes. And I think,  
24 on these declarations, they have not asserted a  
25 broader injury. But, even if they could

1 conceivably come forward with other doctors or  
2 try to adjust their declarations in some way,  
3 still that would not suffice.

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

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

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

1 to grant greater access to drugs when that  
2 overrides FDA's expert judgment about what's  
3 necessary to ensure safe use.

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

9 JUSTICE KAGAN: Thank you.

10 CHIEF JUSTICE ROBERTS: Justice  
11 Gorsuch?

12 Justice Kavanaugh?

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

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

24 The church amendments have the most  
25 comprehensive protection here, and we think that

1 those amendments guard against the kind of  
2 injury that Respondents are asserting. There  
3 are also state law protections that often apply  
4 in this context.

5 JUSTICE KAVANAUGH: Thank you.

6 CHIEF JUSTICE ROBERTS: Justice  
7 Barrett?

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

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

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

25 As I understand it, the serious

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

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

13 GENERAL PRELOGAR: So I want to be  
14 careful because there's a list of serious  
15 adverse events and I'm not sure that I have all  
16 of them down to be able to recite them to you,  
17 although they're in the record, but I do think  
18 the premise of the question is wrong. This idea  
19 that the change to in-person dispensing would  
20 necessarily increase the risk of those events,  
21 that was not reflected in the data that FDA  
22 consulted, and I would point you to JA 383 to  
23 384 in particular --

24 JUSTICE BARRETT: Okay.

25 GENERAL PRELOGAR: -- where FDA -- FDA

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

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

14 GENERAL PRELOGAR: So --

15 JUSTICE BARRETT: You know the JA way  
16 better than I do.

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

23 You know, I don't want to represent  
24 all of the different findings of the different  
25 studies because they varied a little bit, but



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

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

13 GENERAL PRELOGAR: That's right. And  
14 that dates all the way back to the initial  
15 approval of this drug in 2000. It has never  
16 been a required condition of use to have an  
17 ultrasound. FDA has always left that up to  
18 medical judgment. Now it is, of course,  
19 necessary for providers to be able to diagnose  
20 ectopic pregnancy and to date gestational age.  
21 That remains true under the REMS now.  
22 Prescribers still have to have that capability,  
23 and they have to deploy whatever mechanisms they  
24 believe 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. And if the woman has those kinds of  
18 risk factors, then imaging may be necessary, but  
19 that remains true under the 2021 REMS as well.  
20 The prescriber has to be confident that it has  
21 excluded those kinds of conditions before  
22 prescribing this drug.

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

1 JUSTICE BARRETT: Thanks.

2 CHIEF JUSTICE ROBERTS: Justice  
3 Jackson?

4 JUSTICE JACKSON: Good morning,  
5 General.

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

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

23 So I guess then what they're asking  
24 for in this lawsuit is -- is more than that.  
25 They're saying, because we object to having to

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

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

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

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

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

1 women all around the nation simply because of  
2 this conscience injury that's already directly  
3 addressed by other --

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

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

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

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

13 JUSTICE JACKSON: Yeah.

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

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

1 relief all over the country.

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

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

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

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

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

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

14 JUSTICE JACKSON: Thank you.

15 CHIEF JUSTICE ROBERTS: Thank you,  
16 counsel.

17 Ms. Ellsworth.

18 ORAL ARGUMENT OF JESSICA L. ELLSWORTH

19 ON BEHALF OF PETITIONER

20 DANCO LABORATORIES, L.L.C.

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

23 In 2016 and 2021, FDA made certain  
24 changes to the labeling and use restrictions for  
25 Danco's drug, Mifeprex. The decision below

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

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

14 Reversal is required for two reasons:

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

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

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

23 I welcome the Court's questions.

24 JUSTICE THOMAS: The government, the  
25 Solicitor General points out, would not be



1 susceptible to a Comstock Act problem. But your  
2 -- in your case, you would be.

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

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

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

22 On the merits, this issue was not  
23 presented below -- excuse me -- was not ruled on  
24 below, and in any event, I would also point out  
25 that in 2021, FDA's decision allows use of

1 brick-and-mortar pharmacies, in addition to  
2 mail-order pharmacies.

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

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

16 This statute has not been enforced for  
17 nearly 100 years. And I -- I don't believe that  
18 this case presents an opportunity for this Court  
19 to opine on the reach of the statute.

20 CHIEF JUSTICE ROBERTS: Counsel, I'd  
21 like to ask you the same questions I was posing  
22 to the Solicitor General. You know, our  
23 precedents, Clapper and Susan B. Anthony List,  
24 talk about requiring a substantial risk that  
25 harm will occur. And you argue that's not

1 present here.

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

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

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

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

25 And in situations where there is this

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

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

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

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

18 MS. ELLSWORTH: That is correct.

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

23 MS. ELLSWORTH: Yes.

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

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

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

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

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

16 MS. ELLSWORTH: That -- that's  
17 correct.

18 JUSTICE ALITO: Do you think the FDA  
19 is infallible?

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

24 JUSTICE ALITO: Has the FDA ever  
25 approved a drug and then pulled it after

1 experience showed that it had a lot of really  
2 serious adverse consequences?

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

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

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

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

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

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

25 What is so, I think, revolutionary

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

9 JUSTICE ALITO: Does -- does --

10 JUSTICE KAGAN: Could you --

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

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

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

24 MS. ELLSWORTH: That's right. There  
25 are some lawsuits that have been brought by the



1 generic company that do make that argument. And  
2 I think that is for later courts to -- to sort  
3 out.

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

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

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

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

22 MS. ELLSWORTH: May I answer the  
23 question?

24 CHIEF JUSTICE ROBERTS: Go ahead.

25 MS. ELLSWORTH: Justice Kagan, what

1 changed was not Danco's adverse event reporting  
2 responsibility. Danco's adverse event reporting  
3 responsibility has been the same throughout this  
4 period.

5 What changed was that from 2000 until  
6 2016, prescribers were obligated to report  
7 adverse events to Danco and then Danco then had  
8 its separate reporting obligation to FDA.

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

16 So it is only one of seven that have  
17 that.

18 JUSTICE KAGAN: Thank you.

19 CHIEF JUSTICE ROBERTS: Justice  
20 Thomas?

21 Justice Alito? Anything further?

22 Justice Sotomayor?

23 Justice Kavanaugh?

24 Justice Barrett?

25 Justice Jackson? Anything further?

1 JUSTICE JACKSON: I just have one  
2 quick question.

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

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

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

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

24 I think the -- the reality is, and  
25 this Court is -- this decision below is a good

1 example of it, you have a district court that  
2 among other things relied on one study that was  
3 an analysis of anonymous blog posts.

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

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

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

20           JUSTICE JACKSON: Thank you.

21           CHIEF JUSTICE ROBERTS: Thank you,  
22 counsel.

23           MS. ELLSWORTH: Thank you.

24

25

1 CHIEF JUSTICE ROBERTS: Ms. Hawley?

2 ORAL ARGUMENT OF ERIN M. HAWLEY

3 ON BEHALF OF THE RESPONDENTS

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

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

12 We've heard a lot this morning about  
13 standing. Article III is satisfied here  
14 because, one, the FDA relies on OB hospitalists  
15 to care for women harmed by abortion drugs.

16 Two, the FDA concedes between 2.9 and  
17 4.6 percent of women will end up in the  
18 emergency room and, three, the FDA acknowledges  
19 that women are even more likely to need surgical  
20 intervention and other medical care without an  
21 in-person visit.

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

1 and, indeed, treated women suffering from  
2 abortion drug harms tens of thousands of times.  
3 Excuse me, dozens of times, women have suffered  
4 tens of thousands of times.

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

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

19           On the merits: FDA failed to comply  
20 with basic APA requirements. In 2021, it  
21 eliminated the initial in-person visit based on  
22 data it says elsewhere is unreliable.

23           And in 2016, it failed to consider or  
24 explain the cumulative effects of its wholesale  
25 removal of safeguards. These actions fall far

1 short of what the APA requires. This Court  
2 should affirm.

3 I welcome the Court's questions.

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

7 Isn't it just the cost of litigating,  
8 of pursuing this litigation?

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

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

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

21 Dr. Skop talks about these being  
22 heart-breaking situations and some of the most  
23 stressful work she's had to deal with, Your  
24 Honor.

25 JUSTICE THOMAS: Well, I -- I

1 understand that, but I'm talking about the  
2 injury of having to divert resources to litigate  
3 this.

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

6 JUSTICE THOMAS: The Alliance.

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

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

22 If you look at how our organizations  
23 have been harmed, they've been forced to divert  
24 resources from speaking and advocating for their  
25 pro-life mission generally to explaining the



1 dangers of the harm from abortion drugs.

2 One of the primary reasons that that's  
3 required is because in 2016 FDA took away the  
4 requirement that abortion providers report  
5 adverse events.

6 JUSTICE THOMAS: Well --

7 MS. HAWLEY: Aside from deaths.

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

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

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

1           They comb through Medicaid data, they  
2           come through FARE's data so you get at the true  
3           nature of adverse events. And all those sorts  
4           of things are neither a prelude to litigation  
5           nor would they have occurred but for FDA's  
6           unlawful conduct in this case.

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

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

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

24          MS. HAWLEY: So --

25          JUSTICE SOTOMAYOR: Their job is to do

1 exactly what you're talking about and they're  
2 doing it. They're investigating certain  
3 problems, but that's not an injury that's  
4 redressable by this -- by vacating this rule.

5 MS. HAWLEY: So a couple of things,  
6 Your Honor. This Court's opinion in Havens did  
7 not rely on the economic nature at all. Again  
8 I'd point Your Honor to the line in Havens where  
9 the Court says the non-economic nature of  
10 Respondents' interest in housing. They were  
11 speaking broadly.

12 Again, you have to dig to the  
13 underlying briefs to find the economic interest  
14 that this Court did not rely on. With respect  
15 to our own injury, it's absolutely redressable.

16 For example, if the regulations are  
17 put back in place, the protections whereby  
18 individual abortion providers need to provide  
19 information about adverse events, that would  
20 provide our Respondent organizations with more  
21 accurate information about the harms from  
22 abortion drugs.

23 JUSTICE JACKSON: Counsel --

24 CHIEF JUSTICE ROBERTS: Can --

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

1 CHIEF JUSTICE ROBERTS: Go ahead.

2 JUSTICE JACKSON: -- about the remedy  
3 and sort of the way that I was talking with the  
4 SG. I mean, it makes perfect sense for the  
5 individual doctors to seek an exemption, but as  
6 I understand it, they already have that.

7 And so what they're asking for here is  
8 that in order to prevent them from possibly ever  
9 having to do these kinds of procedures, everyone  
10 else should be prevented from getting access to  
11 this medication. So why isn't that plainly  
12 overbroad scope of the remedy the end of this  
13 case?

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

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

24 JUSTICE JACKSON: No, I don't -- I'm  
25 sorry. I don't want to hypothesize. Tell me in

1 her declaration where she talks about not being  
2 able to object or pose a conscientious  
3 objection.

4 MS. HAWLEY: She talks about, Your  
5 Honor, being -- and --

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

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

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

25 JUSTICE JACKSON: All right. Let me

1 ask you this. If we were to find that there are  
2 conscientious objections that, say, hospitals  
3 take them into account and these doctors do have  
4 a way to not do these kinds of procedures,  
5 should we end this case on that basis?

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

9 JUSTICE JACKSON: Why?

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

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

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

25 JUSTICE GORSUCH: Counsel, let -- let

1 me interrupt there. I'm sorry.

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

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

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

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

14           JUSTICE ALITO: I think --

15           CHIEF JUSTICE ROBERTS: Why can't  
16 you --

17           JUSTICE ALITO: -- something as--

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

23           MS. HAWLEY: So I think, Your Honor,  
24 that might be impracticable. If we're thinking  
25 again about the emergency room situation, would



1 Dr. Francis, again, have to know when she's in  
2 the emergency room whether this is a  
3 miscarriage, an ectopic pregnancy, or an  
4 elective abortion? This is what she does day in  
5 and day out.

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

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

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

22 And over the last four years or so,  
23 the number is something like 60 and -- maybe  
24 more than that, and they're -- they're a  
25 relatively new thing. And you're asking us to

1 extend and -- and pursue this relatively new  
2 remedial course, which this Court has never  
3 adopted itself. Lower courts have kind of run  
4 with this. And I -- I just want to give you one  
5 more shot at that.

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

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

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

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

15                   Is that your theory?

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

23                   JUSTICE KAGAN: Well, I think then it  
24 is your theory. I mean, you're just saying even  
25 FDA admits that there are going to be some

1 adverse events, people are going to show up in  
2 emergency rooms, people are going to come  
3 face-to-face with one of our doctors who objects  
4 to some aspect of the treatment. That's the  
5 theory, yes?

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

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

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

22 So you agree with that, yes?

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

25 JUSTICE KAGAN: Okay. So who's your

1 person? I know you have seven of them.

2 MS. HAWLEY: Mm-hmm.

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

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

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

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

24 JUSTICE KAGAN: Has she ever been --  
25 because I -- I read that declaration pretty

1 carefully. Has -- what actual emergency  
2 treatment has she participated in that she  
3 objects to and that -- and that she has stated  
4 an be objection to?

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

9 JUSTICE KAGAN: She herself performed  
10 that?

11 MS. HAWLEY: That is correct, Your  
12 Honor.

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

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

21 JUSTICE KAGAN: Well, usually  
22 conscience objections, the way people with  
23 conscience objections do this is they make those  
24 objections known. And, you know, that may be  
25 harder. It may be easier in a particular

1 context, but most hospitals have mechanisms in  
2 place, routines in place to ensure that doctors  
3 who are allowed to do this, you know, in  
4 advance, right, and are allowed to do it at the  
5 moment, they say so.

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

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

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

25 So it's a lot to ask our Respondent

1 doctors to go up to the top floor and litigate  
2 this with the general counsel when the federal  
3 government's telling them they don't have a  
4 conscience protection.

5 JUSTICE JACKSON: Counsel --

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

21 MS. HAWLEY: Absolutely. We agree  
22 with that, Justice Alito.

23 In particular, you can look at the  
24 Geertson Seed Farms case, which also involved  
25 non-regulated parties, and this Court looked at



1 the distance that bees might fly in order to  
2 pollinate seed farms.

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

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

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

21 Now we can get into whether other  
22 people are illegally breaking the law and  
23 supplying it contrary to law, but what does that  
24 do to your probability, which is it's already  
25 infinitesimally small because there are

1 thousands of hospitals in the country, 50  
2 states, I don't know how many territories,  
3 thousands and thousands of -- of -- of places  
4 where pregnant women go who may be suffering  
5 from miscarriages or otherwise, to know or to  
6 even imagine how one doctor is going to ever  
7 actually see a patient that it's going to be --  
8 that he or she is going to be forced to  
9 intervene on their behalf, but then add to it  
10 that this is illegal in these states.

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

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

22 We've had that happen with both  
23 Dr. Jester, where a woman went to New Mexico and  
24 returned to Texas, as well as Dr. Johnson, where  
25 a woman went to Illinois and returned to

1 Indiana. Indeed, according to Guttmacher, one  
2 in five abortions take place out of state in  
3 certain states, like New Mexico, like Illinois,  
4 the border states in which our doctors reside.

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

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

18 So, if that's right, I mean, I think  
19 the difficulty here is that at least to me,  
20 these affidavits do read more like the  
21 conscience objection is strictly to actually  
22 participating in the abortion to end the life of  
23 the embryo or fetus. And I don't read either  
24 Skop or Francis to say that they ever  
25 participated in that. So do you want to address

1 that?

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

11 And with respect to even the more  
12 narrow conscience harm, to whether a doctor may  
13 need to end a life, we think there's still a  
14 substantial risk of that occurring. If you look  
15 at the numbers of the increase from 7 to 10  
16 weeks in gestational age, that means that  
17 3.1 percent of pregnancies will be ongoing,  
18 requiring a D&C. We know at JA -- or, excuse  
19 me, ROA 70, that 55 percent of those D&Cs occur  
20 in the emergency room.

21 This is a substantial number of women  
22 suffering abortion drug harm. Again, Guttmacher  
23 says 650,000 women took the drug in 2023.

24 JUSTICE BARRETT: But not all of those  
25 D&Cs will involve a pregnancy that would

1 otherwise be viable or an embryo or a fetus that  
2 would otherwise be living, because you can have  
3 complications or excessive bleeding even after  
4 the abortion is complete in that respect, but  
5 there's pregnancy tissue remaining?

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

8 JUSTICE BARRETT: Is ongoing  
9 pregnancies?

10 MS. HAWLEY: Yes. And FDA says at JA  
11 542 that up to 7 percent will need surgeries to  
12 stop either bleeding or ongoing pregnancies or  
13 failures.

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

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

23 CHIEF JUSTICE ROBERTS: Sure.

24 MS. HAWLEY: I think, in particular,  
25 that the named plaintiffs are OB-GYN

1 hospitalists who spend most of their time on the  
2 labor and delivery floors but also are called to  
3 the OR to treat these sorts of emergencies.

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

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

18 JUSTICE JACKSON: That's what I  
19 understood the narrow one to be, right? I'm  
20 participating in a procedure that is ending the  
21 life.

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

24 JUSTICE JACKSON: That's narrow?

25 MS. HAWLEY: Yes.

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

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

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

13 MS. HAWLEY: So this Court, of course,  
14 takes religious beliefs and conscience beliefs  
15 --

16 JUSTICE JACKSON: Yes.

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

19 JUSTICE JACKSON: Yes, yes.

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

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

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

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

17 JUSTICE KAGAN: So --

18 MS. HAWLEY: -- and remove placental  
19 tissue.

20 JUSTICE KAGAN: Whether or not there's  
21 any live tissue?

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

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



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

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

13 JUSTICE JACKSON: May I ask --

14 JUSTICE KAGAN: No, go ahead.

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

25 Do you have a sense of how many times

1 the completion is that route and could be done  
2 by another physician as opposed to your clients  
3 and doing a -- a medical procedure?

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

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

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

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

25 In addition, Your Honor, if you think

1 about the numbers, again, it says 3.1 percent at  
2 10 weeks. And this has only gone up. In 2020,  
3 FDA told this Court that the in-person visit was  
4 both, quote, "necessary and minimally  
5 burdensome" and necessary to preserve women's  
6 health, precisely so these sorts of situations  
7 occur less frequently.

8 CHIEF JUSTICE ROBERTS: Thank you,  
9 counsel.

10 Justice Thomas.

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

15 I'd like you to comment on their  
16 answers.

17 MS. HAWLEY: Sure, Justice Thomas. We  
18 don't think that there's any case of this Court  
19 that empowers FDA to ignore other federal law.  
20 With respect to the Comstock Act as relevant  
21 here, the Comstock Act says that drugs should  
22 not be mailed through the -- either through the  
23 mail or through common carriers.

24 So we think that the plain text of  
25 that, Your Honor, is pretty clear.

1 JUSTICE THOMAS: When did you first  
2 raise it, the Comstock Act?

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

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

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

22 CHIEF JUSTICE ROBERTS: Justice Alito?  
23 Justice Sotomayor?  
24 Justice Kagan?

25 JUSTICE KAGAN: May I ask about your

1 view of traceability? And, you know, on -- on  
2 -- on one understanding, and I want you to tell  
3 me if you agree with this, that even beyond  
4 proving whatever injury you're trying to prove,  
5 that you have to show that that injury is  
6 traceable to the 2016 and 2021 FDA actions --

7 MS. HAWLEY: Yeah.

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

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

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

23 JUSTICE KAGAN: But that -- I guess  
24 what I'm saying is that you have to link  
25 whatever injury your members have to that

1 increased risk. Do you agree with that?

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

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

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

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

25 MS. HAWLEY: I --

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

2 MS. HAWLEY: I think --

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

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

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

20 JUSTICE KAGAN: Thank you.

21 CHIEF JUSTICE ROBERTS: Justice  
22 Gorsuch?

23 Justice Kavanaugh?

24 Justice Barrett?

25 JUSTICE BARRETT: So General Prelogar

1 said that that initial in-person visit, didn't  
2 -- had no requirement of an ultrasound or, you  
3 know, any effort to detect fetal heartbeat. So  
4 it wouldn't necessarily give an accurate read on  
5 gestational age or detect an ectopic pregnancy.  
6 So why would that necessarily -- the elimination  
7 -- why would the elimination of the visit  
8 necessarily increase the risks?

9 MS. HAWLEY: So I think, Your Honor,  
10 FDA's own data shows that those risks did go up.  
11 If you look at the Kerestes study, it shows a  
12 nearly three-fold increase in emergency room  
13 visits when you have the in-person visit and  
14 when you removed it. There was 5.8 percent with  
15 an in-person visit, and it was also -- and about  
16 2.1 without.

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

22 MS. HAWLEY: So -- so when the FDA  
23 removed the in-person visit, Your Honor, it took  
24 away the opportunity to do that. I think ACOG  
25 -- I think medical organizations agree that that



1 is best practice, so if a woman comes into a  
2 doctor's office, she's likely to get an  
3 ultrasound to accurately assess both ectopic  
4 pregnancies, diagnose, or assess gestational  
5 age.

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

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

16 MS. HAWLEY: Mm-hmm.

17 JUSTICE BARRETT: Explain to me what  
18 additional costs you might have incurred or how  
19 your resources were diverted in a way that would  
20 satisfy Havens.

21 MS. HAWLEY: Absolutely, Your Honor.  
22 So putting to the one side the citizen petition,  
23 the AAPLOG declaration is clear that Respondent  
24 organizations conducted studies and analyzed  
25 studies. This included going through the

1 Medicaid data. It included going through the  
2 FAERS data to the extent it was available.

3 JUSTICE BARRETT: Is that it?

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

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

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

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

24 CHIEF JUSTICE ROBERTS: Justice  
25 Jackson?

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

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

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

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

24 So what -- what deference do we owe  
25 them at all with respect to their assessment

1 that these studies establish what it is that  
2 they say they do about safety and efficacy?

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

10 JUSTICE JACKSON: I understand. But  
11 didn't the lower courts go beyond that? I mean,  
12 representations were made here today that the  
13 lower courts actually relied on studies that  
14 have since been found discredited and removed.

15 So they were obviously looking at not  
16 just what the FDA was looking at in order to  
17 make their assessment.

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

20 MS. HAWLEY: So, yes. That claim is  
21 not even before this Court. But, with respect  
22 to the two claims that are before the Court, the  
23 2016 and the 2021, we think the FDA's own  
24 statements here are arbitrary.

25 In 2016, what the FDA said was we're

1 going to look at individual studies and then,  
2 even though we say they're interrelated at JA  
3 298, we're going to take all of the protections  
4 away at once.

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

7 JUSTICE JACKSON: Thank you.

8 CHIEF JUSTICE ROBERTS: Thank you,  
9 counsel.

10 Rebuttal, General Prelogar.

11 REBUTTAL ARGUMENT OF GEN. ELIZABETH B. PRELOGAR

12 ON BEHALF OF THE FEDERAL PETITIONERS

13 GENERAL PRELOGAR: Thank you.

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

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

22 And, here, what is so telling is that  
23 Respondents don't have a specific example of any  
24 doctor ever having to violate this care in  
25 violation of their conscience. Instead,

1 Respondents have pointed to generalized  
2 assertions in the declarations that never come  
3 out and specifically say by one of their  
4 identified members: Here's the care I provided,  
5 here's how it violated my conscience, and here  
6 is why conscience protections were unavailable  
7 to me.

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

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

22           If that is enough, then every  
23 organization in this country has standing to  
24 challenge any federal policy they dislike.  
25 Havens Realty cannot possibly mean that. The

1 Court should say so and clarify it is at the  
2 outer bounds and Respondents don't qualify under  
3 that standard.

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

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

20 And I think it's worth stepping back  
21 finally and thinking about the profound mismatch  
22 between that theory of injury and the remedy  
23 that Respondents obtained. They have said that  
24 they fear that there might be some emergency  
25 room doctor somewhere, someday, who might be

1 presented with some woman who is suffering an  
2 incredibly rare complication and that the doctor  
3 might have to provide treatment notwithstanding  
4 the conscience protections. We don't think that  
5 harm has materialized.

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

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

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

24 CHIEF JUSTICE ROBERTS: Thank you,  
25 counsel.



1                   The case is submitted.  
2                   (Whereupon, at 11:37 a.m., the case  
3 was submitted.)  
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