

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.)

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11 DANCO LABORATORIES, L.L.C.,)

12 Petitioner,)

13 v.) No. 23-236

14 ALLIANCE FOR HIPPOCRATIC MEDICINE,)

15 ET AL.,)

16 Respondents.)

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19 Washington, D.C.

20 Tuesday, March 26, 2024

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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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P R O C E E D I N G S

(10:04 a.m.)

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

General Prelogar.

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

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

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

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

1 specific doctor who faces imminent harm.

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

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

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

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

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

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

18 I welcome the Court's questions.

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

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

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

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

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

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

1 are not the direct object of the agency's
2 regulation, it can be substantially more
3 difficult to establish 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 -- the patients will go to
6 the 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 -- at -- at some
12 point, does this analysis lead to the other
13 result?

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

1 GENERAL PRELOGAR: Certainly, we think
2 that these --

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

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

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

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

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

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

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

21 JUSTICE JACKSON: General --

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

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

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

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

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

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

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

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

25 GENERAL PRELOGAR: But I do want to be

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

7 JUSTICE SOTOMAYOR: All right.

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

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

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

1 misunderstand our arguments and Respondents have
2 repeated that misunderstanding here.

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

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

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

1 agreements with other hospitals.

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

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

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

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

24 Can you distinguish that from Havens
25 Realty?

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

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

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

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

1 theories of standing, including in the
2 immigration context.

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

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

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

21 JUSTICE BARRETT: I'm done.

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

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

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

16 JUSTICE GORSUCH: Well --

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

20 JUSTICE GORSUCH: -- let -- let me
21 just push back on that a little bit because
22 standing is standing. It's Article III, right
23 --

24 GENERAL PRELOGAR: Yes.

25 JUSTICE GORSUCH: -- that we're

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

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

10 JUSTICE GORSUCH: Should we?

11 GENERAL PRELOGAR: Well --

12 JUSTICE GORSUCH: I guess as a
13 preliminary.

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

15 JUSTICE GORSUCH: No?

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

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

1 that type of injury.

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

11 JUSTICE GORSUCH: Thank you.

12 CHIEF JUSTICE ROBERTS: Thank you,
13 counsel.

14 Justice Thomas, anything further?

15 Justice Alito?

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

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

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

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

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

8 JUSTICE ALITO: Shouldn't the FDA have
9 at least considered the application of 18 U.S.C.
10 1461?

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

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

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

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

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

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

1 to maintain a REMS program.

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

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

10 GENERAL PRELOGAR: In the 2021
11 decision, no. But the REMS was then modified in
12 2023, and this was part of the administrative
13 record for that.

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

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

1 use."

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

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

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

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

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

7 JUSTICE ALITO: All right. Thank you.

8 CHIEF JUSTICE ROBERTS: Justice
9 Sotomayor?

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

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

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

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

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

10 GENERAL PRELOGAR: Yes, virtually all.

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

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

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

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

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

5 JUSTICE SOTOMAYOR: Thank you.

6 CHIEF JUSTICE ROBERTS: Justice Kagan?

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

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

25 JUSTICE KAGAN: Those two are who?

1 GENERAL PRELOGAR: Those are Dr. Skop
2 and Dr. Francis. The relevant language for Dr.
3 --

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

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

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

25 GENERAL PRELOGAR: I think that the

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

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

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

22 GENERAL PRELOGAR: Yes.

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

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

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

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

25 GENERAL PRELOGAR: That is still to

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

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

12 JUSTICE KAGAN: Thank you.

13 CHIEF JUSTICE ROBERTS: Justice
14 Gorsuch?

15 Justice Kavanaugh?

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

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

1 brief.

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

8 JUSTICE KAVANAUGH: Thank you.

9 CHIEF JUSTICE ROBERTS: Justice
10 Barrett?

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

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

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

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

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

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

1 to JA 383 to 384 in particular --

2 JUSTICE BARRETT: Okay.

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

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

17 GENERAL PRELOGAR: So --

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

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

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

3 JUSTICE BARRETT: Yeah.

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

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

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

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

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

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

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

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

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

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

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

8 JUSTICE BARRETT: Thanks.

9 CHIEF JUSTICE ROBERTS: Justice
10 Jackson?

11 JUSTICE JACKSON: Good morning,
12 General.

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

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

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

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

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

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

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

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

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

13 GENERAL PRELOGAR: -- protections
14 under federal law.

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

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

20 JUSTICE JACKSON: Yeah.

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

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

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

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

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

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

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

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

22 JUSTICE JACKSON: Thank you.

23 CHIEF JUSTICE ROBERTS: Thank you,
24 counsel.

25 Ms. Ellsworth.

1 ORAL ARGUMENT OF JESSICA L. ELLSWORTH
2 ON BEHALF OF PETITIONER
3 DANCO LABORATORIES, L.L.C.

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

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

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

22 Reversal is required for two reasons:

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

1 the analysis.

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

6 I welcome the Court's questions.

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

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

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

25 I think this Court should think hard

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

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

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

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

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

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

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

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

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

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

1 percentage of emergency room visits would be
2 enough?

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

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

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

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

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

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

2 MS. ELLSWORTH: That is correct.

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

7 MS. ELLSWORTH: Yes.

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

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

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

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

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

25 MS. ELLSWORTH: That -- that's

1 correct.

2 JUSTICE ALITO: Do you think the FDA
3 is infallible?

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

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

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

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

1 reporting of non-fatal consequences?

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

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

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

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

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

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

18 JUSTICE ALITO: Does --

19 JUSTICE KAGAN: Could you go --

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

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

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

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

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

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

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

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

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

6 MS. ELLSWORTH: May I answer the
7 question?

8 CHIEF JUSTICE ROBERTS: Go ahead.

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

14 What changed was that from 2000 until
15 2016, prescribers were obligated to report
16 adverse events to Danco and then Danco then had
17 its separate reporting obligation to FDA.

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

1 JUSTICE KAGAN: Thank you.

2 CHIEF JUSTICE ROBERTS: Justice
3 Thomas?

4 Justice Alito, anything further?

5 Justice Sotomayor?

6 Justice Kavanaugh?

7 Justice Barrett?

8 Justice Jackson, anything further?

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

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

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

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

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

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

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

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

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

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

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

3 JUSTICE JACKSON: Thank you.

4 CHIEF JUSTICE ROBERTS: Thank you,
5 counsel.

6 MS. ELLSWORTH: Thank you.

7 CHIEF JUSTICE ROBERTS: Ms. Hawley?

8 ORAL ARGUMENT OF ERIN M. HAWLEY
9 ON BEHALF OF THE RESPONDENTS

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

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

18 We've heard a lot this morning about
19 standing. Article III is satisfied here
20 because, one, the FDA relies on OB hospitalists
21 to care for women harmed by abortion drugs.
22 Two, the FDA concedes that between 2.9 and
23 4.6 percent of women will end up in the
24 emergency room. And, three, the FDA
25 acknowledges that women are even more likely to

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

3 According to Guttmacher, nearly
4 650,000 women take mifepristone every single
5 year. It's no surprise that Respondents have
6 experienced an increase in emergency room visits
7 and, indeed, treated women suffering from
8 abortion drug harms tens of thousands of times
9 -- excuse me, dozens of times, women have
10 suffered tens of thousands of times.

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

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

25 On the merits, FDA failed to comply

1 with basic APA requirements. In 2021, it
2 eliminated the initial in-person visit based on
3 data it says elsewhere is unreliable. And in
4 2016, it failed to consider or explain the
5 cumulative effects of its wholesale removal of
6 safeguards. These actions fall far short of
7 what the APA requires. This Court should
8 affirm.

9 I welcome the Court's questions.

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

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

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

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

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

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

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

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

11 JUSTICE THOMAS: The Alliance.

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

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

1 resources. Both things are satisfied here.

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

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

11 JUSTICE THOMAS: Well --

12 MS. HAWLEY: -- aside from deaths.

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

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

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

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

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

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

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

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

4 MS. HAWLEY: So --

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

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

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

1 information about the harms from abortion drugs.

2 JUSTICE JACKSON: Counsel --

3 CHIEF JUSTICE ROBERTS: Can --

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

5 CHIEF JUSTICE ROBERTS: Go ahead.

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

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

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

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

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

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

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

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

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

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

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

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

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

13 JUSTICE JACKSON: Why?

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

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

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

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

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

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

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

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

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

18 JUSTICE ALITO: I think --

19 CHIEF JUSTICE ROBERTS: Why can't
20 you --

21 JUSTICE ALITO: -- something as --

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

1 Agency, you can't do this anywhere?

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

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

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

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

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

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

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

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

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

19 Is that your theory?

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

1 are critical to the safe use of drug.

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

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

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

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

1 So you agree with that, yes?

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

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

6 MS. HAWLEY: Mm-hmm.

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

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

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

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

1 That echoes the CMDA declaration at 142 and 143.

2 It's also consistent with --

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

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

13 JUSTICE KAGAN: She herself performed
14 that?

15 MS. HAWLEY: That is correct, Your
16 Honor.

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

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

24 JUSTICE KAGAN: Well, usually --

25 MS. HAWLEY: -- emergency room table.

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

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

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

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

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

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

9 JUSTICE JACKSON: Counsel --

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

25 MS. HAWLEY: Absolutely. We agree

1 with that, Justice Alito.

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

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

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

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

25 Now we can get into whether other

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

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

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

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

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

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

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

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

5 So do you want to address that?

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

15 And with respect to -- to even the
16 more narrow conscience harm, to whether a doctor
17 may need to end a life, we think there's still a
18 substantial risk of that occurring. If you look
19 at the numbers of the increase from 7 to 10
20 weeks in gestational age, that means that
21 3.1 percent of pregnancies will be ongoing,
22 requiring a D&C. We know at JA -- or, excuse
23 me, ROA 870, that 55 percent of those D&Cs occur
24 in the emergency room.

25 This is a substantial number of women

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

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

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

12 JUSTICE BARRETT: Is ongoing
13 pregnancies?

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

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

25 MS. HAWLEY: There -- there are

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

3 CHIEF JUSTICE ROBERTS: Sure.

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

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

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

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

1 life."

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

4 JUSTICE JACKSON: That's narrow?

5 MS. HAWLEY: Yes.

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

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

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

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

21 JUSTICE JACKSON: Yes.

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

24 JUSTICE JACKSON: Yes.

25 MS. HAWLEY: But what harms our

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

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

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

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

24 JUSTICE KAGAN: So --

25 MS. HAWLEY: -- and remove placental

1 tissue.

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

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

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

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

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

20 JUSTICE JACKSON: May I --

21 JUSTICE KAGAN: No, go ahead.

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

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

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

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

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

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

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

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

7 In -- in addition, Your Honor, if you
8 think about the numbers, again, it says
9 3.1 percent at 10 weeks, and this has only gone
10 up. In 2020, FDA told this Court that the
11 in-person visit was both "necessary and
12 minimally burdensome" and necessary to preserve
13 women's health precisely so these sorts of
14 situations occur less frequently.

15 CHIEF JUSTICE ROBERTS: Thank you,
16 counsel.

17 Justice Thomas?

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

22 I'd like you to comment on their
23 answers.

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

1 that empowers FDA to ignore other federal law.

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

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

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

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

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

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

4 CHIEF JUSTICE ROBERTS: Justice Alito?
5 Justice Sotomayor?
6 Justice Kagan?

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

14 MS. HAWLEY: Yeah.

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

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

25 MS. HAWLEY: So we believe, Justice

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

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

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

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

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

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

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

7 MS. HAWLEY: I --

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

9 MS. HAWLEY: I think --

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

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

20 And, again, this is entirely
21 consistent with FDA's own numbers. Again, in
22 2020, FDA told this Court that the in-person
23 visit was necessary to preserve women's health
24 because an in-person exam -- visit is the best
25 opportunity to examine for things like ectopic

1 pregnancy and accurately assess gestational age.

2 JUSTICE KAGAN: Thank you.

3 CHIEF JUSTICE ROBERTS: Justice
4 Gorsuch?

5 Justice Kavanaugh?

6 Justice Barrett?

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

16 MS. HAWLEY: So I think, Your Honor,
17 FDA's own data shows that those risks did go up.
18 If you look at the Kerestes study, it shows a
19 nearly threefold increase in emergency room
20 visits when you have the in-person visit and
21 when you removed it. There was 5.8 percent with
22 an in-person visit, and it was also -- and about
23 2.1 without.

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

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

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

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

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

22 MS. HAWLEY: Mm-hmm.

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

1 satisfy Havens.

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

9 JUSTICE BARRETT: That it?

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

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

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

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

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

5 CHIEF JUSTICE ROBERTS: Justice
6 Jackson?

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

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

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

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

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

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

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

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

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

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

6 In 2016, what the FDA said was we're
7 going to look at individual studies and then,
8 even though we say they're interrelated at JA
9 298, we're going to take all of the protections
10 away at once.

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

13 JUSTICE JACKSON: Thank you.

14 CHIEF JUSTICE ROBERTS: Thank you,
15 counsel.

16 Rebuttal, General Prelogar.

17 REBUTTAL ARGUMENT OF GEN. ELIZABETH B. PRELOGAR

18 ON BEHALF OF THE FEDERAL PETITIONERS

19 GENERAL PRELOGAR: Thank you.

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

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

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

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

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

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

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

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

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

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

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

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

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

1 effective.

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

5 CHIEF JUSTICE ROBERTS: Thank you,
6 counsel.

7 The case is submitted.

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

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Official

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