

1 IN THE SUPREME COURT OF THE UNITED STATES
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3 FOOD AND DRUG ADMINISTRATION,)
4 ET AL.,)
5 Petitioners,)
6 v.) No. 23-235
7 ALLIANCE FOR HIPPOCRATIC MEDICINE,)
8 ET AL.,)
9 Respondents.)
10 - - - - -
11 DANCO LABORATORIES, L.L.C.,)
12 Petitioner,)
13 v.) No. 23-236
14 ALLIANCE FOR HIPPOCRATIC MEDICINE,)
15 ET AL.,)
16 Respondents.)
17 - - - - -

18
19 Washington, D.C.
20 Tuesday, March 26, 2024

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

25

1 APPEARANCES:
2 GEN. ELIZABETH B. PRELOGAR, Solicitor General,
3 Department of Justice, Washington, D.C.; on behalf
4 of the Federal Petitioners.
5 JESSICA L. ELLSWORTH, ESQUIRE, Washington, D.C.; on
6 behalf of Petitioner Danco Laboratories, L.L.C.
7 ERIN M. HAWLEY, ESQUIRE, Washington, D.C.; on behalf
8 of the Respondents.
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P R O C E E D I N G S

(10:04 a.m.)

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

General Prelogar.

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

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

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

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

1 specific doctor who faces imminent harm.

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

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

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

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

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

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

18 I welcome the Court's questions.

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

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

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

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

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

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

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

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

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

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

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

1 of these doctors.

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

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

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

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

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

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

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

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

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

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

25 GENERAL PRELOGAR: No. We think the

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

25 GENERAL PRELOGAR: Certainly, we think

1 that this --

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

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

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

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

25 JUSTICE ALITO: I mean, so your

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

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

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

20 JUSTICE JACKSON: General --

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

1 lack of an in-person --

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

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

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

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

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

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

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

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

6 JUSTICE SOTOMAYOR: All right.

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

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

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

1 repeated that misunderstanding here.

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

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

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

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

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

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

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

23 Can you distinguish that from Havens
24 Realty?

25 GENERAL PRELOGAR: Yes. So I think

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

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

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

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

1 immigration context.

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

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

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

20 JUSTICE BARRETT: I'm done.

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

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

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

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

15 JUSTICE GORSUCH: Well --

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

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

23 GENERAL PRELOGAR: Yes.

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

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

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

8 JUSTICE GORSUCH: Should we?

9 GENERAL PRELOGAR: Well --

10 JUSTICE GORSUCH: I guess as a
11 preliminary.

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

13 JUSTICE GORSUCH: No?

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

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

25 And, here, our argument is that the

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

9 JUSTICE GORSUCH: Thank you.

10 CHIEF JUSTICE ROBERTS: Thank you,
11 counsel.

12 Justice Thomas, anything further?

13 Justice Alito?

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

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

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

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

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

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

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

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

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

1 it have permissibly considered that under the
2 statute.

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

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

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

25 But the other thing I would say,

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

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

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

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

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

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

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

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

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

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

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

4 JUSTICE ALITO: All right. Thank you.

5 CHIEF JUSTICE ROBERTS: Justice
6 Sotomayor?

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

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

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

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

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

7 GENERAL PRELOGAR: Yes, virtually all.

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

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

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

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

1 JUSTICE SOTOMAYOR: Thank you.

2 CHIEF JUSTICE ROBERTS: Justice Kagan?

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

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

21 JUSTICE KAGAN: Those two are who?

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

25 JUSTICE KAGAN: The other five don't

1 refer to conscience objections?

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

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

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

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

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

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

18 GENERAL PRELOGAR: Yes.

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

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

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

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

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

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

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

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

8 JUSTICE KAGAN: Thank you.

9 CHIEF JUSTICE ROBERTS: Justice
10 Gorsuch?

11 Justice Kavanaugh?

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

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

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

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

4 JUSTICE KAVANAUGH: Thank you.

5 CHIEF JUSTICE ROBERTS: Justice
6 Barrett?

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

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

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

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

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

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

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

23 JUSTICE BARRETT: Okay.

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

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

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

13 GENERAL PRELOGAR: So --

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

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

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

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

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

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

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

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

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

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

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

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

1 an ultrasound.

2 JUSTICE BARRETT: Thanks.

3 CHIEF JUSTICE ROBERTS: Justice
4 Jackson?

5 JUSTICE JACKSON: Good morning,
6 General.

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

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

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

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

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

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

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

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

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

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

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

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

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

14 JUSTICE JACKSON: Yeah.

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

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

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

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

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

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

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

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

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

15 JUSTICE JACKSON: Thank you.

16 CHIEF JUSTICE ROBERTS: Thank you,
17 counsel.

18 Ms. Ellsworth.

19 ORAL ARGUMENT OF JESSICA L. ELLSWORTH

20 ON BEHALF OF PETITIONER

21 DANCO LABORATORIES, L.L.C.

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

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

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

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

15 Reversal is required for two reasons:

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

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

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

24 I welcome the Court's questions.

25 JUSTICE THOMAS: The government, the

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

1 happen.

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

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

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

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

20 MS. ELLSWORTH: That is correct.

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

25 MS. ELLSWORTH: Yes.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

1 pharmaceutical manufacturer's product.

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

11 JUSTICE ALITO: Does --

12 JUSTICE KAGAN: Could you go --

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

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

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

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

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

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

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

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

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

1 CHIEF JUSTICE ROBERTS: Go ahead.

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

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

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

19 JUSTICE KAGAN: Thank you.

20 CHIEF JUSTICE ROBERTS: Justice
21 Thomas?

22 Justice Alito, anything further?

23 Justice Sotomayor?

24 Justice Kavanaugh?

25 Justice Barrett?

1 Justice Jackson, anything further?

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

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

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

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

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

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

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

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

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

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

21 JUSTICE JACKSON: Thank you.

22 CHIEF JUSTICE ROBERTS: Thank you,
23 counsel.

24 MS. ELLSWORTH: Thank you.

25 CHIEF JUSTICE ROBERTS: Ms. Hawley?

1 ORAL ARGUMENT OF ERIN M. HAWLEY

2 ON BEHALF OF THE RESPONDENTS

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

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

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

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

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

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

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

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

1 affirm.

2 I welcome the Court's questions.

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

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

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

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

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

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

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

1 this.

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

4 JUSTICE THOMAS: The Alliance.

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

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

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

25 One of the primary reasons that that's

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

4 JUSTICE THOMAS: Well --

5 MS. HAWLEY: -- aside from deaths.

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

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

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

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

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

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

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

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

21 MS. HAWLEY: So --

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

1 redressable by this -- by vacating this rule.

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

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

19 JUSTICE JACKSON: Counsel --

20 CHIEF JUSTICE ROBERTS: Can --

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

22 CHIEF JUSTICE ROBERTS: Go ahead.

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

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

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

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

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

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

25 MS. HAWLEY: She talks about, Your

1 Honor, being an --

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

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

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

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

1 should we end this case on that basis?

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

5 JUSTICE JACKSON: Why?

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

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

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

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

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

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

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

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

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

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

10 JUSTICE ALITO: I think --

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

13 JUSTICE ALITO: -- something as --

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

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

1 and day out.

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

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

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

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

1 more shot at that.

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

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

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

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

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

11 Is that your theory?

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

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

1 theory, yes?

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

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

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

18 So you agree with that, yes?

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

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

23 MS. HAWLEY: Mm-hmm.

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

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

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

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

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

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

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

5 JUSTICE KAGAN: She herself performed
6 that?

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

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

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

16 JUSTICE KAGAN: Well, usually --

17 MS. HAWLEY: -- emergency room table.

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

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

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

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

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

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

1 JUSTICE JACKSON: Counsel --

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

22 So do you want to address that?

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

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

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

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

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

1 there's pregnancy tissue remaining?

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

4 JUSTICE BARRETT: Is ongoing
5 pregnancies?

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

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

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

19 CHIEF JUSTICE ROBERTS: Sure.

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

25 JUSTICE JACKSON: Ms. Hawley, can you

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

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

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

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

20 JUSTICE JACKSON: That's narrow?

21 MS. HAWLEY: Yes.

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

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

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

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

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

12 JUSTICE JACKSON: Yes.

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

15 JUSTICE JACKSON: Yes.

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

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

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

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

14 JUSTICE KAGAN: So --

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

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

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

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

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

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

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

10 JUSTICE JACKSON: May I --

11 JUSTICE KAGAN: No, go ahead.

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

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

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

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

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

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

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

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

5 CHIEF JUSTICE ROBERTS: Thank you,
6 counsel.

7 Justice Thomas?

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

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

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

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

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

25 MS. HAWLEY: So I believe the Comstock

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

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

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

19 CHIEF JUSTICE ROBERTS: Justice Alito?

20 Justice Sotomayor?

21 Justice Kagan?

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

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

4 MS. HAWLEY: Yeah.

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

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

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

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

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

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

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

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

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

22 MS. HAWLEY: I --

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

24 MS. HAWLEY: I think --

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

1 the -- the -- the original risk.

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

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

17 JUSTICE KAGAN: Thank you.

18 CHIEF JUSTICE ROBERTS: Justice
19 Gorsuch?

20 Justice Kavanaugh?

21 Justice Barrett?

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

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

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

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

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

1 pregnancies, diagnose or assess gestational age.

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

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

12 MS. HAWLEY: Mm-hmm.

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

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

24 JUSTICE BARRETT: Is that it?

25 MS. HAWLEY: Well -- well, those

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

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

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

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

20 CHIEF JUSTICE ROBERTS: Justice
21 Jackson?

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

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

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

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

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

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

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

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

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

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

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

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

3 JUSTICE JACKSON: Thank you.

4 CHIEF JUSTICE ROBERTS: Thank you,
5 counsel.

6 Rebuttal, General Prelogar.

7 REBUTTAL ARGUMENT OF GEN. ELIZABETH B. PRELOGAR

8 ON BEHALF OF THE FEDERAL PETITIONERS

9 GENERAL PRELOGAR: Thank you.

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

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

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

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

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

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

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

25 On remedy, Justice Gorsuch, Justice

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

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

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

1 harm has materialized.

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

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

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

20 CHIEF JUSTICE ROBERTS: Thank you,
21 counsel.

22 The case is submitted.

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

25

Official - Subject to Final Review

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