

1  
2  
3  
4  
5  
6  
7  
8  
9  
10  
11  
12  
13  
14  
15  
16  
17  
18  
19  
20  
21  
22  
23  
24  
25

UNITED STATES DISTRICT COURT  
NORTHERN DISTRICT OF TEXAS  
AMARILLO DIVISION

ALLIANCE FOR HIPPOCRATIC	)	
MEDICINE, et al.,	)	
Plaintiffs,	)	
	)	
VS.	)	CAUSE NO. 2:22-CV-223-Z
	)	
U.S. FOOD AND DRUG	)	
ADMINISTRATION, et al.,	)	
Defendants.	)	

-----

HEARING ON PLAINTIFFS' MOTION FOR PRELIMINARY INJUNCTION  
BEFORE THE HONORABLE MATTHEW J. KACSMARYK,  
UNITED STATES DISTRICT JUDGE

MARCH 15, 2023  
AMARILLO, TEXAS

-----

FEDERAL OFFICIAL COURT REPORTER: MECHELLE DANIEL, [REDACTED]  
[REDACTED]

PROCEEDINGS RECORDED BY MECHANICAL STENOGRAPHY; TRANSCRIPT  
PRODUCED BY COMPUTER-AIDED TRANSCRIPTION.

1  
2  
3  
4  
5  
6  
7  
8  
9  
10  
11  
12  
13  
14  
15  
16  
17  
18  
19  
20  
21  
22  
23  
24  
25

A P P E A R A N C E S

FOR THE PLAINTIFFS:  
ALLIANCE DEFENDING FREEDOM  
440 FIRST STREET NW  
SUITE 600  
WASHINGTON, DC 20001  
BY: ERIK CHRISTOPHER BAPTIST  
ERIN MORROW HAWLEY

FOR THE DEFENDANTS:  
UNITED STATES DEPARTMENT OF JUSTICE  
CIVIL DIVISION, FEDERAL PROGRAMS BRANCH  
1100 L STREET NW  
WASHINGTON, DC 20005  
BY: JULIE STRAUS HARRIS  
DANIEL SCHWEI  
KATE TALMOR  
CHRISTOPHER EISWERTH  
EMILY NESTLER

FOR THE INTERVENOR DEFENDANT,  
DANCO LABORATORIES LLC:  
HOGAN LOVELLS US LLP  
555 13th STREET NW  
WASHINGTON, DC 20004  
BY: JESSICA LYNN ELLSWORTH  
CATHERINE EMILY STETSON

\* \* \* \* \*

1  
2  
3  
4  
5  
6  
7  
8  
9  
10  
11  
12  
13  
14  
15  
16  
17  
18  
19  
20  
21  
22  
23  
24  
25

INDEX

PLAINTIFFS' ARGUMENT BY MS. HAWLEY.....	8
PLAINTIFFS' ARGUMENT BY MR. BAPTIST.....	29
DEFENDANTS' ARGUMENT BY MS. STRAUS HARRIS.....	61
DEFENDANTS' ARGUMENT BY MR. SCHWEI.....	91
INTERVENOR DEFENDANT'S ARGUMENT BY MS. ELLSWORTH.....	118
PLAINTIFF'S REBUTTAL ARGUMENT BY MS. HAWLEY.....	137
PLAINTIFFS' REBUTTAL ARGUMENT BY MR. BAPTIST.....	144

\* \* \* \* \*

## P R O C E E D I N G S

1  
2 THE COURT: The Court calls Civil Action  
3 Number 2:22-CV-223-Z, Alliance for Hippocratic Medicine,  
4 et al. vs. United States Food and Drug Administration, et al.,  
5 for a hearing on the pending motion for preliminary injunction.

6 Are the parties ready to proceed?

7 MS. HAWLEY: Yes, Your Honor.

8 THE COURT: And if counsel for plaintiffs will  
9 announce your team for the record and the attorneys who will be  
10 presenting argument.

11 MS. HAWLEY: Yes, Your Honor. I'm Erin Morrow  
12 Hawley, and this is my colleague Erik Baptist, and we will  
13 present for plaintiffs.

14 THE COURT: And if counsel for defendants will  
15 identify the counsel presenting argument to this Court.

16 MS. STRAUS HARRIS: Yes, Your Honor. Julie Straus  
17 Harris with the U.S. Department of Justice for the  
18 United States. My colleague--

19 MR. SCHWEI: Daniel Schwei, Your Honor, also from  
20 the Department of Justice, on behalf of the United States. And  
21 the two of us will be doing the argument.

22 We have some other colleagues here in the courtroom  
23 with us: Chris Eiswerth, Emily Nestler, and Kate Talmor. Just  
24 noting their presence as well.

25 THE COURT: Okay. Thank you for that

1 clarification.

2 And now counsel for defendant intervenor, if you'll  
3 represent your client and the attorneys presenting argument.

4 MS. ELLSWORTH: Certainly. Good morning, Your  
5 Honor. Jessica Ellsworth on behalf of Intervenor Danco  
6 Laboratories. I will be the only person presenting argument.  
7 My colleague, Kate Stetson, is here with me at counsel table.

8 THE COURT: Okay. Thank you for that  
9 clarification.

10 The Court is holding this hearing pursuant to the  
11 Northern District of Texas rules for live hearings during the  
12 COVID-19 coronavirus pandemic. Pursuant to the Twelfth Amended  
13 Special Order Number 13-9 signed by Chief Judge Godbey on  
14 March 9, 2023, this Court concludes and does hereby find that  
15 this hearing may be conducted in person without seriously  
16 jeopardizing public health and safety and cannot be further  
17 delayed without serious harm to the interests of justice.

18 This Court is open to the public, both here in the  
19 Amarillo Division and in an additional courtroom in the Earle  
20 Cabell Federal Building in Dallas, Texas, which is securely  
21 streaming the audio from this hearing.

22 Additionally, consistent with standard operating  
23 procedure for the Northern District of Texas, the Court  
24 reserved half of the gallery space for members of the media,  
25 half for the general public.

1           Also consistent with standard operating procedure  
2 for this Northern District of Texas, any disrupters will be  
3 immediately escorted from the courtroom by the United States  
4 Marshal's Service or Court Security Officers. In this regard,  
5 this hearing in this civil case does differ from a criminal  
6 case, where disruptive defendants are typically entitled to a  
7 warning for Sixth Amendment and Rule 43 reasons. Here today,  
8 disrupters will be immediately removed without warning or court  
9 intervention, and counsel need not await the Court's  
10 instruction on disrupters.

11           So before we begin, some brief housekeeping rules  
12 that we discussed during the status conference.

13           Because the hearing is simulcast, I'll instruct  
14 counsel to speak clearly into the microphone at the lectern.  
15 That will facilitate a better simulcast for anybody dialing  
16 into the Dallas Division. I'll ask that you do stand at your  
17 feet when addressing the Court from counsel table, and you may  
18 proceed from there in exchanging counsel for turns at the  
19 podium.

20           Water is allowed, but nothing else. And regarding  
21 courtroom technology, counsel, paralegals, and support staff  
22 may use their laptops and courtroom technology during court  
23 proceedings. And we do have IT support from the Dallas  
24 Division and the Lubbock Division present if there are any IT  
25 issues. So you may request that IT support from the Court.

1           Now, today's hearing will concern plaintiffs'  
2 pending motion for preliminary injunction--that document is set  
3 forth in ECF Number 6--and any issues raised by that motion.  
4 As we discussed at the status conference and in the order  
5 scheduling the hearing, the plaintiffs and defendants will each  
6 be afforded two hours to present their arguments. This time  
7 will include answers to any questions from the Court. And my  
8 clerks will keep time, along with the courtroom deputy. If you  
9 ever need a time check, you may request it from the Court.

10           Plaintiffs and defendants shall determine how their  
11 time will be allocated among each individual party and each  
12 attorney, and plaintiffs may reserve time for rebuttal.

13           So at this time, plaintiffs may proceed. And if  
14 you could advise the Court of any rebuttal time you are  
15 reserving.

16           MS. HAWLEY: Your Honor, and may it please the  
17 Court. My name is Erin Hawley, and with my co-counsel, Erik  
18 Baptist, we represent the plaintiffs. We would like to reserve  
19 30 minutes for rebuttal.

20           THE COURT: And do you want a time warning on this  
21 portion of your argument?

22           MS. HAWLEY: Yes, Your Honor. At ten minutes, if  
23 possible. I'll have--we're splitting equally, so I'll have  
24 45 minutes.

25           THE COURT: Okay. You may proceed.

1 MS. HAWLEY: My colleague-- As I mentioned, we're  
2 dividing our argument, and my colleague is going to discuss the  
3 harms of mifepristone to women, why the FDA should never have  
4 granted approval of this dangerous drug, and why this Court  
5 should grant relief.

6 I will discuss why the doctors who have to deal  
7 with all of this fallout have standing to be here, why their  
8 claims are properly presented, and the Comstock Act.

9 So to begin with standing, plaintiffs possess it in  
10 at least three ways. They meet every requirement for  
11 associational, organizational, and third-party standing.

12 To start with associational standing, defendants do  
13 not contest that the plaintiff associations' interests are  
14 germane. Instead, they say that the individual doctors, the  
15 doctor members, do not have standing. This is incorrect for  
16 two reasons.

17 First, the declarations clearly show that the  
18 doctors have already suffered concrete harm. This is  
19 sufficient under *Lujan* and a slew of other cases. If we look  
20 at the declarations, Dr. Francis, Dr. Skop, and Dr. Jester all  
21 allege that they treated women who were presenting emergency  
22 medical situations and were required to perform either a D&C  
23 abortion or a suction aspiration in order to complete that  
24 abortion. These are concrete constitutional harms.

25 In addition, there are other examples. Dr. Francis



1 notes two instances in which she, and another instance in which  
2 a colleague, had to call additional doctors to cover their  
3 regular plaintiffs--one plaintiff was critically ill--due to  
4 the extra time and risk associated with treating women who have  
5 been seriously harmed by mifepristone.

6           In addition, this severely impacts the ability of  
7 doctors to practice medicine according to their medical oaths.  
8 It's risky, as the declarations say, both more risky to the  
9 doctors, as well as the patients. It's more time-consuming.  
10 It consumes an enormous amount of resources, including blood  
11 transfusions and the like, and comes with an onerous adverse  
12 reporting system.

13           The Supreme Court, in *Spokeo* and *TransUnion*, has  
14 noted that even emotional harm can suffice for Article III  
15 injury. That is unquestionably the case here, where we have a  
16 constitutional injury. And what the FDA has done, in illegally  
17 approving and then continually deregulating mifepristone, has  
18 resulted in doctors being forced, contrary to their most  
19 deeply-held ethical, medical, and religious convictions, to  
20 participate and finish elective abortions.

21           Defendants also argue that--and they point to  
22 *Clapper* and they say, well, any--you know, any future harm is  
23 merely speculative. That's dead wrong for two reasons.

24           First, *Clapper* did not involve any past harm. No  
25 one had spied on the plaintiffs in this case. Here, we have

1 testimony after testimony from doctors who have already been  
2 harmed by the FDA's approval and deregulation of mifepristone.

3 In addition, the fact that a third party might be  
4 involved is no barrier to Supreme Court review--or, excuse me,  
5 to federal court review when, in fact, that harm is imminent  
6 and concrete. We can take several cases to look at this. In  
7 the case *Texas vs. Becerra* just down the road, the plaintiffs  
8 presented the very same case involving third-party decisions to  
9 obtain an abortion. And in that case, the district court found  
10 harm.

11 Similarly, we can analogize to the abortion  
12 decisions from *June Medical*, to any of those cases in which  
13 plaintiff abortion providers were claiming standing based on  
14 third-party decisions that would be made by women in seeking an  
15 abortion. Third-party actions are not a barrier when the  
16 action of the defendant here is still fairly traceable. Again,  
17 we're not talking about a proximate causation standard, but  
18 merely that it be fairly traceable.

19 In addition, with respect to future harm, Your  
20 Honor, past really is prologue, and I think that that will even  
21 be seen with greater harm to plaintiffs here. If we look at  
22 the FDA's own numbers, the FDA's petition that approves the  
23 mifepristone at 2011--in 2011--and this is page ID 607--says  
24 that between 5 to 8 percent of women--so that's 5 to 8 of every  
25 100 women--will need a surgical abortion in order to complete

1 the chemical abortion by mifepristone.

2 This means that thousands of women will present to  
3 the doctors in these emergency rooms. There's no question. We  
4 know that, today, more than half of abortions take place by  
5 chemical abortion. These patients will end up with serious  
6 adverse consequences in the care of plaintiff doctors and their  
7 associations in this case.

8 To speak just a bit about organizational standing,  
9 organizational standing exists where the organizations  
10 themselves suffer harm. Under Fifth Circuit cases like *OCA*,  
11 this case really is on all fours. Plaintiffs here can show an  
12 organizational injury by alleging the diversion of resources,  
13 which it has done, from its usual activities in order to lessen  
14 the impacts of the challenged restrictions.

15 THE COURT: Let's discuss that Fifth Circuit  
16 precedent now. So must plaintiffs identify specific projects,  
17 which is the terminology the Fifth Circuit uses in that line of  
18 cases, from which they have diverted resources to assert  
19 standing under that precedent?

20 MS. HAWLEY: Absolutely not, Your Honor. I  
21 acknowledge that there's some language in *City of Kyle* that the  
22 defendant seized upon, but the Fifth Circuit's decision in *OCA*  
23 specifically rejects that argument. It says that the language  
24 in *City of Kyle* was not meant to heighten any requirement under  
25 *Lujan*, but merely to say that specific projects is, quote, one

1 example of a way in which harm may be shown.

2           So the harm here is the diversion of resources. If  
3 we look again at the declarations, we have all sorts of  
4 resource diversion. We have the efforts to educate member  
5 doctors, patients that these member doctors see, as well as a  
6 92-page petition, a 30-page response, in which Donna Harrison  
7 was--petitioned the FDA, and as she puts it, sort of mildly,  
8 that involved considerable effort.

9           THE COURT: So let's camp out on that Fifth Circuit  
10 jurisprudence for a while and what types of specific projects  
11 qualify for that diverted resource analysis.

12           So I cannot ascertain from that Fifth Circuit case  
13 law that my circuit or the Supreme Court has addressed citizen  
14 petitions and whether that constitutes nonlitigation-related  
15 expenses.

16           MS. HAWLEY: Yes, sir.

17           THE COURT: So can you argue for a different rule  
18 when it comes to citizen petitions versus complaints and the  
19 filings that you typically see in litigation? Are citizen  
20 petitions different for purposes of applying that Fifth Circuit  
21 precedent on standing?

22           MS. HAWLEY: So I think two responses, Your Honor.  
23 First, we don't need the citizen petition. As in the OCA case,  
24 the diversion of resources to educate and to make sure the  
25 mission is more successful, despite the defendants' actions, is

1 itself enough harm.

2 I do think, however, that citizens petitions are  
3 different from litigation expenses, which we acknowledge are  
4 not covered as a diverted harm. And the reason I think they  
5 are different is because, if you look at the FDA's regulation,  
6 21 CFR 10.45(b) and (c), those regulations require plaintiffs  
7 to file a petition if they want to contest the FDA's  
8 determination. This is the only way doctors have to tell the  
9 FDA they got it wrong.

10 THE COURT: Okay. I have your argument on that.  
11 You may continue with any points you want to make on standing  
12 to sue.

13 MS. HAWLEY: In addition, Your Honor, I would just  
14 like to remark that defendants note that the associations here  
15 may not have organizational standing because they are pro-life  
16 groups. But that would really read the mission out of  
17 missional standing. Every voting organization in these cases--  
18 there's *OCA*, there's *La Union*, there's *Texas State*, and each of  
19 these organizations possessed an interest in voting rights and,  
20 yet, were able to challenge, because of the harm to the  
21 organizational mission, the regulations involving voting. So  
22 we think organizational standing is met.

23 Just a word on third-party standing. That doctrine  
24 is prudential, as Your Honor knows. Here, we think it's  
25 clearly met. The Supreme Court, in *June Medical*, said that

1 courts have long permitted abortion providers to invoke the  
2 rights of their actual or potential patients in challenges to  
3 abortion-related regulations. It, quite frankly, would be  
4 passing strange to suggest that abortion providers have  
5 standing but the doctors in this case do not. They possess at  
6 least as close of a personal relationship, and patients here  
7 suffering from a mifepristone severe adverse consequence have  
8 at least as much of a hindrance to sue. So we would submit  
9 that third-party standing applies as well.

10 THE COURT: So you wouldn't take Justice Alito's  
11 dissent to presage or preview an exception for the goose but  
12 not the gander?

13 MS. HAWLEY: Absolutely not.

14 THE COURT: Okay.

15 MS. HAWLEY: In regard to zone of interest, Your  
16 Honor, the zone of interest test is not demanding. The benefit  
17 of the doubt goes to the plaintiff, such that a suit is  
18 foreclosed--and I'm quoting from the Supreme Court's decision  
19 in *Lexmark*--only when a plaintiff's interests are so marginally  
20 related to or inconsistent with the purposes implicit in the  
21 statute. And this lenient review is required, the Supreme  
22 Court has said, because of the presumption of reviewability of  
23 administrative action, something that implicates separation of  
24 powers concerns as well.

25 Here, these plaintiffs are clearly within the

1 FDA's--FDCA's, excuse me, zone of interest. The FDCA directs  
2 the FDA to make sure that drugs are, quote, safe.

3 When we're talking about the REMS provision of the  
4 FDCA, what those provisions direct the FDA to do is to assess  
5 drugs that are found to be effective but are unsafe unless they  
6 come with restrictions on their use and distribution. So  
7 again, the REMS provisions in particular say not only safe, but  
8 if they're not safe generally, then the FDCA needs to apply  
9 restrictions on those use.

10 Here, the doctors who treat adverse events--  
11 Again, 5 to 8 percent of every woman who has a mifepristone  
12 abortion will end up with surgery, according to the FDA's own  
13 numbers. Those doctors who treat the fallout from that  
14 absolutely have standing.

15 To take just one case example, in *Bennett vs.*  
16 *Spear*, the Supreme Court found that ranchers and irrigation  
17 districts had standing to challenge an administrative decision  
18 under the Endangered Species Act, even though the Endangered  
19 Species Act primary purpose was to protect endangered animals,  
20 not ranchers or other landowners.

21 If there are no further questions on standing or  
22 zone of interest, I can move to reopen.

23 THE COURT: Okay. Please do so at this time. And  
24 are different attorneys taking that portion of the argument?

25 MS. HAWLEY: No, Your Honor.

1 THE COURT: Okay. You may proceed.

2 MS. HAWLEY: With respect to reopening, the  
3 reopening doctrine really exists for situations just like this.  
4 It exists to prevent agency gamesmanship. And if you look at  
5 the timeline of this case, you see why the reopening doctrine  
6 is a really good idea. In 2002--or, excuse me, in 2000, the  
7 FDA, we submit, illegally approved mifepristone. In 2002, two  
8 years later and well within the statute of limitations, they  
9 filed--the plaintiffs here filed a citizen petition.

10 Then we wait and wait and wait until 2016, fourteen  
11 years later, before the FDA responds to that citizen petition.  
12 When they respond and have a blanket denial of the citizen  
13 petition, what they do on the very same day is issue their 2016  
14 major changes, getting rid of nearly every safeguard the FDA  
15 initially placed on the safe use and distribution of  
16 mifepristone.

17 Now, what this means, Your Honor, is that the FDA  
18 regulations, again pointing you to 10 CFR--or, excuse me,  
19 21 CFR 10.45(b) and (c), those regulations require a plaintiff  
20 to file a citizen petition--as the FDA acknowledges on page 17  
21 of its brief, they are required to file a citizen petition, and  
22 that action is not final until the FDA responds. And it has  
23 all the time in the world under its own procedural rules. So  
24 the action on the 2016 major changes was not final until the  
25 citizens petition was filed in 2019 and until the agency acted



1 on it in December of 2021.

2           So what the major questions doctrine does-- In a  
3 series of cases, from *National Biodiesel vs. EPA* to  
4 *Sierra Club vs. EPA*, you see cases that say time starts anew.  
5 The statute of limitations clock starts afresh when an agency  
6 takes an action, either explicitly or implicitly, that  
7 reexamines its former choice.

8           So, here, I think one case that's particularly  
9 instructive is *Sierra Club vs. EPA*. And in *Sierra Club vs.*  
10 *EPA*, what happened was the agency approved a rule in 1994.  
11 Then, not unlike this case, it changed that rule in 2006 and it  
12 took away the major safeguards, the necessary safeguards the  
13 Court had said that were inextricably tied to the initial  
14 decision in two thousand--excuse me--in 1994. And because of  
15 that, because these necessary safeguards were taken out of the  
16 initial action in 1994, the D.C. Circuit said that reopens the  
17 initial decision and starts the statute of limitations anew.

18           THE COURT: So let's apply that *Sierra Club* case to  
19 the facts here. I know this has been briefed by both parties.  
20 Do I take your argument to be this, that the FDA reopened the  
21 2000 approval when it conducted a full review of the  
22 mifepristone REMS program in 2021 and decided to remove that  
23 in-person dispensing requirement? That is something that was  
24 deemed an element to assure safe use. ETASU is the  
25 abbreviation that shows up in the briefing. Is that the

1 reopening event the Court should focus on?

2 MS. HAWLEY: So I think there's two reopening  
3 events, Your Honor. And I agree completely the 2021 event does  
4 reopen, because, as you said, it was a review of the entire  
5 proceeding, and it stripped away, in *Sierra Club's* words, one  
6 of the necessary safeguards. An in-person visit was absolutely  
7 found to be a safeguard in 2000, because this gives an  
8 attending physician the ability to diagnose ectopic  
9 pregnancies, to gather information on gestational age or other  
10 contraindications. So a crucial safeguard was stripped away.

11 In addition, Your Honor, we also identify the 2016  
12 major changes as being an agency action that triggers the  
13 reopening doctrine. The agency itself categorized those  
14 changes as major. And if you look at them, it took the  
15 in-person visits from three to one. It got rid of the  
16 requirement that only physicians could dispense. It said  
17 nondoctors were also allowed to do so. It increased the age  
18 from seven to ten weeks at which mifepristone can be taken, the  
19 gestational age. And it removed adverse reporting requirements  
20 unless death resulted. It also changed the timing and the  
21 dosage and the administration. So it's hard to imagine, you  
22 know, really, what is left, except that one in-person visit,  
23 from 2016. So we submit that's also a reopening event.

24 And how the timeline works, Your Honor, we think,  
25 is that it's reopened in 2016, but then because of the FDA

1 rules, that reopening was not final until December of '21. So  
2 the statute of limitations does not actually begin to run until  
3 that time period.

4 THE COURT: Okay. I understand that argument.

5 Let's turn to agency decision-making and the  
6 multiple references in both briefs to various studies; which  
7 elements to assure safe use were dropped, which conditions  
8 appeared and then disappeared as you move from the 2000  
9 approval to the 2016 major changes to the '21 decision that is  
10 a triggering event for a reopening analysis.

11 It appears that there is a matching theme, this  
12 concept of clinical studies matching the elements and that  
13 being a recurring problem as you're moving through that  
14 chronology over two decades. Specific to the FDCA, does  
15 Section 355(d) require that FDA's post-approval restrictions  
16 match the clinical safety conditions and protocols in the  
17 studies that FDA relied upon in its approval?

18 And here, because we're discussing those two data  
19 points, the 2000 approval and the 2016 major changes, is that a  
20 linchpin of your argument, that 355(d) requires that those  
21 clinical conditions, which are cited in the studies relied upon  
22 by the FDA, must then match the elements for safe use and any  
23 other conditions that are imposed? Must we have a one-to-one  
24 matching, or is there any flex in the joints for purposes of  
25 agency decision-making?

1 MS. HAWLEY: Absolutely, Your Honor. Our position  
2 is that the FDA was required to follow the congressional  
3 mandates.

4 Now, my colleague, Erik Baptist, is going to  
5 discuss the merits. Would you prefer for us to switch? I'm  
6 also ready to discuss *Heckler* or *Comstock*, if you would like to  
7 do those first.

8 THE COURT: Okay. So let's reserve time for  
9 Mr. Baptist to ask what I've deemed a study-match problem  
10 that's been raised by the plaintiffs. I'll put a pin in that,  
11 allow Mr. Baptist to continue during his portion. But you may  
12 move on to the *Comstock* Act and the arguments relevant to that.

13 MS. HAWLEY: Absolutely, Your Honor.

14 So one argument raised in response to the *Comstock*  
15 Act is that this claim is unexhausted. But as Your Honor  
16 knows, there are a number of exceptions to the exhaustion  
17 doctrine, and we submit that at least three apply here.

18 First of all, it would have been entirely futile  
19 for the plaintiffs here to raise *Comstock*. If you look at  
20 page ID 2266--that is the FDA's December 2022 memorandum--it  
21 specifically mentions this case by name. It adopts the OLC's  
22 interpretation of the *Comstock* memorandum--or *Comstock* law,  
23 excuse me, as, quote, controlling advice. And it notes that,  
24 even if the FDA would have considered the *Comstock* Act, it  
25 would not have changed its regulatory decision-making one iota.

1 So under the futility test, it is hard to imagine the agency  
2 being any more clear that it would have been absolutely futile  
3 to raise Comstock.

4 In addition, another futility--or, excuse me,  
5 another exhaustion exception comes into play when the agency  
6 action is patently unlawful. The agency has no discretion  
7 simply to ignore the law. The Comstock Act plainly prohibits  
8 the mailing of drugs that are designed, manufactured, or  
9 intended for use as abortions. We submit that plainly applies  
10 to the FDA's actions here.

11 If you look at the 2000 approval, the Danco  
12 distribution plan includes shipping. It talks about packages.  
13 It includes the idea that these will be shipped, in direct  
14 contravention to the Comstock laws. In addition, if you look  
15 at the 2021 petition, that clearly strips away any of the  
16 in-person requirements and expressly authorizes mail-order  
17 abortions, really. It dispenses with the in-person dispensing  
18 requirement, allowing and directing that those drugs be mailed  
19 vis-a-vis the U.S. Postal Service and other common carriers,  
20 thereby patently violating the Comstock Act.

21 In addition, Your Honor, there are exceptions to  
22 the exhaustion requirement when the interests of justice  
23 require. We submit here that the FDA's practice of delaying  
24 and then mooting out claims filed by citizens petitions is  
25 another reason that any of its claims, including its Comstock

1 Act claim, are unexhausted. The 2000 petition, we submit, is  
2 open for this reason, in addition to the Comstock Act claim,  
3 because here, you've got undue delay, the fourteen years where  
4 the petitioners simply had to sit on their petition, waiting  
5 and hoping that the FDA would, at some point, act.

6 And if you look at Federal Practice and Procedures  
7 Section 8363, in that section, the authors write that  
8 irreparable injury can be harm due to delay, which can, itself,  
9 be an equitable exception.

10 So we think that there are at least three  
11 exceptions to futility for the Comstock Act. We think a number  
12 of those exceptions also would apply to defendants' other  
13 exhaustion arguments vis-a-vis the other specific claims.

14 As to the merits on Comstock, Your Honor had asked  
15 whether the OLC's memorandum was specifically clear.

16 THE COURT: Well, and here, I want to make sure for  
17 record purposes--because Department of Justice attorneys  
18 reference OLC memoranda all the time. I want to make sure that  
19 we have identified for the record the memo that is referenced  
20 here.

21 So this is the memorandum dated December 23rd,  
22 2022, Application of the Comstock Act to the Mailing of  
23 Prescription Drugs That Can Be Used for Abortion. It is styled  
24 as a Memorandum Opinion for the General Counsel, United States  
25 Postal Service, and it is signed by the Assistant Attorney

1 General in the Office of Legal Counsel.

2 So this is what we're referring to as the OLC memo.

3 MS. HAWLEY: Yes, Your Honor. Thank you.

4 THE COURT: Okay. All right. You may proceed.

5 MS. HAWLEY: So the OLC memo itself is a broad  
6 application. It is applied to the U.S. mails because the  
7 request for legal advice was made by the United States Postal  
8 Service. But the memorandum itself is a broad application that  
9 would apply both to Section 1461 and 1462 in its legal  
10 reasoning.

11 In addition, the memo is quite broad in trying to  
12 absolve any person from shipping abortion drugs, even contrary  
13 to state law. The memorandum's conclusion is that there is no  
14 liability under the Comstock laws where the sender, quote,  
15 lacks the intent that the recipient of the drugs will use them  
16 unlawfully.

17 So we think that that memorandum is sufficiently  
18 clear to trigger futility. It is unquestionably clear to  
19 trigger futility when you couple it with the FDA's own December  
20 2022 memorandum, again, at page ID 2266 of the FDA's own  
21 attachment.

22 And on the merits of Comstock, you know, what is  
23 the OLC's rationale for really rewriting the Comstock law?  
24 Section 1461 of the Comstock law prohibits the, quote, knowing  
25 mailing of any article, quote, designed, adapted, or intended

1 for producing abortion.

2 OLC says, you know, we're going to supplement that  
3 knowing requirement with actually an intent, that you know that  
4 the person will use it for unlawful activity.

5 But there are a number of reasons this fails.  
6 First, congressional text. Second, what OLC relies on here is  
7 really congressional acquiescence based on a smattering of  
8 Federal Court of Appeals decisions, I think four Federal Courts  
9 of Appeals. Acquiescence is always a tough sale, as this Honor  
10 knows, but especially here where it involves a minority of  
11 circuits.

12 In addition, only one of the cases cited by the OLC  
13 memorandum involves abortion at all. The others involve  
14 contraceptives. And that case, *Bours vs. United States*,  
15 recognizes a, quote, national policy of discountenancing  
16 abortion as inimical to national life.

17 So it's hard to find in those cases any sort of  
18 uniform national federal court policy that would be able to  
19 override clear congressional text.

20 THE COURT: So you would agree with the amicus  
21 brief of the Ethics and Public Policy Center that there is no  
22 emergent consensus supporting OLC's position?

23 MS. HAWLEY: Absolutely, Your Honor. And I think  
24 the final nail in that--and not to put too fine of a point on  
25 it, but Congress rejected this very limitation in 1972. So the



1 idea that we can rely on congressional acquiescence when  
2 Congress itself rejected this, I think, does not fit within the  
3 acquiescence doctrine.

4 THE COURT: Okay. And in *Brown vs. Gardner*, the  
5 Court explained, when dealing with acquiescence arguments,  
6 reenactment, ratification style arguments, that you can't  
7 invoke those doctrines where the law is plain and subsequent  
8 reenactment does not constitute an adoption of a previous  
9 administrative construction.

10 Are we far afield of those reenactment arguments  
11 where the construction of the Comstock Act remains disputed and  
12 there just is no emergent consensus among the circuits?

13 MS. HAWLEY: I think that's correct. And I think  
14 what those cases you cited, as well as the *SWANCC* decision,  
15 would suggest is that when you have clear text, congressional  
16 acquiescence really can't get around that at all. But it  
17 certainly can't get around it in cases where you only have four  
18 circuits making decisions that might impact or--under the  
19 Comstock laws but certainly have nothing approaching a uniform  
20 federal court rationale for narrowing the Comstock law,  
21 contrary to its very text.

22 THE COURT: Okay. And you believe, under Supreme  
23 Court precedent and circuit precedent, this question of  
24 Comstock Act construction has been raised with sufficient  
25 clarity so that this Court can decide based on plain text and

1 tools of textualism and typical canons of construction, like,  
2 this has been raised with clarity; it's been percolating  
3 through the circuits; and this is an exception to any  
4 reenactment acquiescence doctrines that would give additional  
5 weight to that OLC memo?

6 MS. HAWLEY: Absolutely, Your Honor. This is  
7 really bread-and-butter statutory interpretation. Your Honor  
8 has the OLC memorandum. Your Honor obviously has the text of  
9 Section 1461 and Section 1462, and I agree that it's properly  
10 presented.

11 THE COURT: What do you perceive to be the  
12 defendants' best argument for ratification, and how would you  
13 respond?

14 MS. HAWLEY: Again, I think ratification is a  
15 really hard sale. I think the only thing OLC has to argue on  
16 and rely on here, and what defendants rely on as well, is these  
17 lower court decisions. But the lower court decisions I think  
18 would be a slim read. Even if they said what OLC says they  
19 say, I don't think it's enough. OLC cites Justice Scalia's  
20 book, but, of course, later on, Justice Scalia talks about a  
21 minority of circuits and that not being sufficient.

22 In addition, I think you would have a really  
23 difficult time finding ratification when we have a House  
24 committee report that specifically recommends the change that  
25 the OLC memorandum says happened by ratification and, yet,

1 that's defeated in Congress. If Congress had actually intended  
2 to change the language through the sort of implicit sort of  
3 ratification, then surely it would have done that formally when  
4 asked to do so in 1972.

5 THE COURT: Okay. And so back to your argument on  
6 important public policy and exceptions that apply where  
7 important public policies are implicated. In addition to the  
8 arguments of the plaintiffs in this case, we have 22 states  
9 joining as amici, arguing that FDA's action is a harm to the  
10 public interest and it does undermine their ability, as  
11 sovereign states, to enforce their own laws regulating abortion  
12 in the post-*Dobbs* era. So this is an intervening event that  
13 has sort of changed the field of federal-state relations  
14 vis-a-vis regulation of abortion.

15 Is your case to this Court that the public policy  
16 arguments on reviewability and exhaustion are supported by that  
17 briefing, and how would you pair your arguments against  
18 ratification, against exhaustion to those 22 states and how  
19 should the Court give weight to those 22 states who have filed  
20 briefs in this case?

21 MS. HAWLEY: Absolutely, Your Honor. I think there  
22 are a couple of things going on here. One, if, you know, the  
23 OLC memorandum is correct, you really are seeing a sea change  
24 in federal-state relations. The *Dobbs* decision said that it  
25 left to the people, the elected representatives the power to

1 protect life. The OLC memorandum says that unless a shipper  
2 knows that it's going to be intended for an unlawful purpose--  
3 which it can't know, the OLC memo says, because there's  
4 different ways-- Mifepristone can be used for treating a  
5 miscarriage, for example. So it's virtually unknowable, so it  
6 strips Comstock entirely of any effect.

7 I think this is an affront not only to  
8 congressional texts and enactments and a separation of powers  
9 sort of analysis, but, as well, it's an affront to the states  
10 in being denied the ability to exercise their traditional state  
11 powers to protect the health and welfare of women and children  
12 within their boundaries.

13 And I think the way this relates to the exhaustion  
14 arguments is a couple of fold. First, I think that it's  
15 absolutely clear, given the FDA's memo, the 2022 memo, that it  
16 would have been futile to raise Comstock. The FDA says it  
17 wouldn't have changed its mind at all.

18 Second, I think it's patently--that Comstock Acts  
19 patently apply, that there's no provision that gives the FDA  
20 the power to ignore federal law.

21 And, third, there is this irreparable injury  
22 exception, which I think you can talk about in terms of  
23 federal-state relations, you can talk about federalism and the  
24 need for clarity when a federal agency is changing that  
25 dynamic.

1           In addition, Your Honor, I think the delay here  
2 really does come into play. Again, if you look at Federal  
3 Practice and Procedure 8363, what that says is that an agency's  
4 delay--and here, the FDA's own regulations require a citizen to  
5 file; then require them to wait fourteen years before an action  
6 is even final; and then, on that same day, they moot out the  
7 challenge. So I think that, itself, would be an exhaustion  
8 exception for Comstock, as well as our other claims.

9           THE COURT: Okay. Thank you, Counselor. I have  
10 your argument.

11           At this time, I'll direct Mr. Baptist to begin his  
12 portion of plaintiffs' argument to the Court. Mr. Baptist, you  
13 may proceed.

14           MR. BAPTIST: May it please the Court. Your Honor,  
15 my name is Erik Baptist with Alliance Defending Freedom on  
16 behalf of plaintiffs.

17           Now that my colleague has discussed the procedural  
18 questions of this case, I'm going to proceed to the merits of  
19 plaintiffs' motion for preliminary injunction. I'll start off  
20 talking about the merits, the substantial likelihood of success  
21 on the merits; then proceed to the final two factors under  
22 preliminary injunction: irreparable harm and public interest.  
23 And then finally, if the Court were inclined to grant  
24 plaintiffs' motion for preliminary injunction, I will discuss  
25 the remedies available to the Court.

1           I want to jump right in and go--answer your  
2 question that you asked Ms. Hawley. Yes, that is our--exactly  
3 our position under 21 U.S.C. Section 355(d). The FDA had a  
4 requirement to study and evaluate the safety of mifepristone  
5 under the labeled conditions of use, or, as Congress wrote,  
6 under the conditions prescribed in the proposed labeling.

7           That--complying with the requirements from Congress  
8 is not a matter of agency deference. There is no discretion to  
9 ignore congressional directives, but that's exactly what the  
10 defendants are arguing here. And it's important to see how it  
11 played out in the 2000 approval, and again in the 2016 major  
12 changes; finally, in the 2021 petition response in the initial  
13 approval, with this--then the taking away of basic protections  
14 of women and girls who do take mifepristone. And I'm going to  
15 start with the 2000 approval.

16           The clinical investigations upon which the FDA  
17 relied all required the women subject in that trial to go  
18 through an ultrasound before she took mifepristone and  
19 misoprostol to have a chemical abortion. That was important  
20 for two reasons. One, ultrasounds are vital. They are the  
21 best way to determine gestational age of the baby inside the  
22 woman. That's important because, initially, the FDA only found  
23 it to be safe for seven weeks, and secondarily, in 2016, they  
24 expanded to ten weeks. But everybody agrees the further along  
25 a woman is in her pregnancy and, if she has a chemical

1 abortion, the more likely she will have complications, and it's  
2 important to get that age correct.

3           Secondarily, ultrasounds help identify and they are  
4 the best means to identifying a life-threatening ectopic  
5 pregnancy. Ectopic pregnancies occur in 1 in 50 pregnancies,  
6 and, if not diagnosed, they can rupture and end with the life  
7 of the woman as well.

8           And the problem here is, when a woman is not  
9 properly screened with an ultrasound for an ectopic pregnancy  
10 and she takes mifepristone while having an ectopic pregnancy,  
11 one, mifepristone will not treat and resolve her ectopic  
12 pregnancy; but, two, she will exhibit the same symptoms as a--  
13 with mifepristone as with a ruptured ectopic pregnancy. So she  
14 is going to have severe bleeding and severe pain, and she will  
15 not know, necessarily, that she has an ectopic pregnancy,  
16 because she did not have that lifesaving ultrasound at the end  
17 of the day.

18           And there's evidence in the record, I believe an  
19 amicus brief submitted, that told the story of a woman who was  
20 misdiagnosed, did not have a proper ultrasound, and died  
21 because she had an ectopic pregnancy.

22           That's important, because these are essential  
23 safety protocols that were in the studies. And so when the FDA  
24 relies on studies, it must--those--it must include the  
25 essential safety protocols that were embedded in those studies

1 on the approved label regimen. Otherwise, the FDA is  
2 evaluating oranges and then declaring apples to be safe. This  
3 apples-to-oranges analysis is simply inappropriate and,  
4 frankly, contrary to the congressional mandate to review the  
5 labeled conditions of use and then determine safety.

6 We're not necessarily going after the safety  
7 finding but the parameters and the guardrails that FD--that  
8 Congress set for the FDA in how to determine a drug is safe.  
9 And they fail to do that here, and they went off the rails and  
10 off the cliff here, because they failed to include lifesaving  
11 protocols at the beginning that were in the investigations and  
12 not transferred over to the label.

13 And again, the same thing happened in 2016. My  
14 colleague talked about at least nine different changes that the  
15 FDA did in 2016 to the chemical drug regimen. But there is not  
16 a single study in the record that the FDA relied upon that  
17 evaluated the regimen pre-2016 changes versus the nine changes  
18 after 2016. There is not a single study. Those studies also  
19 didn't match other conditions too. They had safety protocols  
20 embedded in them as well.

21 And that, again, is contrary to the direct  
22 congressional mandate to the FDA to have those guardrails, to  
23 follow the labeled conditions of use on necessary safety  
24 protocols, which at least evaluate whether those safety--those  
25 changes are safe--



1 THE COURT: And that--

2 MR. BAPTIST: --and the FDA took a piecemeal  
3 approach.

4 Yes, Your Honor.

5 THE COURT: That's the crux of my question which I  
6 have labeled the study-match thesis or problem. The Court can  
7 do the work of matching apples to oranges, study to label and  
8 things of that sort. Do I understand your argument to be a  
9 textual or statutory argument?

10 You have used the terminology of congressional  
11 mandate. So where we're construing Section 355(d) and we find  
12 that there is this mismatch between the safety protocols and  
13 conditions that were part of the clinical studies underlying  
14 the FDA's action, and those are arguably mismatched with  
15 labeling regimes and the dispensation of that drug through  
16 subsequent FDA action, is that a textual statutory FDCA  
17 violation so that this Court can use tools of textualism to  
18 judge that question, or is it your position that the FDA may  
19 depart from those clinical safety conditions and protocols but  
20 may not do so arbitrarily and capriciously in violation of  
21 administrative law principles that apply? So am I applying the  
22 rules of textualism to a statutory violation, or am I applying  
23 agency law, administrative law to something that is arguably  
24 arbitrary and capricious? So which toolkit am I using?

25 MR. BAPTIST: This is a pure textual application of

1 the law. Looking at the directive from Congress, it says, if  
2 the FDA lacks sufficient information, adequate testing,  
3 substantial evidence in indicating the safety and effectiveness  
4 of these drugs under the labeled condition of use, the FDA must  
5 reject those--excuse me--must refuse those applications.

6 And that is exactly what other courts have done in  
7 different contexts, not with this specific provision under  
8 355(d), but there are cases out there where the district courts  
9 have reviewed, under 35--excuse me, let me--35(j)--Court's  
10 indulgence, please--35(j)(4), where, again, it says, when  
11 approving generic drugs, or otherwise known as abbreviated new  
12 drug applications, or ANDAs, and ANDA has to tell the  
13 Secretary--under subpart (4) there, "The Secretary shall  
14 approve an application for a drug unless the Secretary finds,"  
15 and there's a list of things the Court has to find, and if they  
16 don't exist, the Court--I'm sorry--the FDA must reject it. And  
17 there's a subpart (H) there that says, information submitted in  
18 the application or any other information available to the  
19 Secretary shows that the inactive ingredients of the drug are  
20 unsafe for use under the conditions prescribed, recommended, or  
21 suggested in the labeling proposed for the drug.

22 Now, there is a case I'll cite for the record  
23 today, because it's not before the Court right now in the  
24 briefings. It is *Serono Labs, Inc. vs. Shalala*--

25 THE COURT: Could you spell Serono, please.

1                   MR. BAPTIST: Yes. S-e-r-a-n-o, *Laboratories,*  
2 *comma, Incorporated vs. Shalala.* That's found at  
3 974 F.Supp. 29.

4                   THE COURT: It's Donna Shalala, the previous HHS  
5 Secretary?

6                   MR. BAPTIST: Yes, sir.

7                   THE COURT: Okay. Spelled like that. Okay. You  
8 may proceed.

9                   MR. BAPTIST: It's a district court from the  
10 District of Columbia, a 1988 decision. In that case, there was  
11 similar language, which I just read to you, where the Court  
12 found that the FDA was required to reject the ANDA because it  
13 did not have the information required under this provision.

14                   And in that case--we'll talk about remedies at the  
15 end, but as a preview, the Court there enjoined the FDA and  
16 compelled the FDA to take the designation for that approval off  
17 the marketplace.

18                   THE COURT: Okay. Going back to Section 355(d)--  
19 I have your argument on subsection (j), but going back to the  
20 Court's initial question on 355(d) and working through a very  
21 lengthy paragraph of conditional clauses and phrases, it begins  
22 with, "If the Secretary finds." I'm assuming here, to apply  
23 rules of textualism to the facts and exhibits in the  
24 administrative record, where I see that word "finds" in the  
25 first opening sentence, you would direct the Court to ECF

1 Number 1, Attachment 124. That's the FDA letter dated  
2 February 18, 2000, where there are findings that are relevant  
3 to the subclauses that require that the Secretary, quote, shall  
4 issue an order refusing to approve.

5 So as I apply the text of subsection (d), that  
6 finding which is relevant to adequate testing, methodology,  
7 et cetera, occurred with ECF Number 1, Attachment 124, FDA  
8 letter dated February 18, 2000, and thereby triggered what  
9 follows, subpart (7), he shall issue an order refusing to  
10 approve the application.

11 I take it that is how you think this should have  
12 been applied all the way back to the 2000 approval?

13 MR. BAPTIST: Yes.

14 THE COURT: Okay. Now, in looking at amicus briefs  
15 filed in support of the FDA actions from the 2000 approval  
16 forward, some of those briefs make reference to language in  
17 subpart (4), where there appears to be some discretion in the  
18 language, "or upon the basis of any other information."

19 How would you respond to the terminology, "or upon  
20 the basis of any other information," when drug approval and  
21 labeling rulemaking and agency decision-making does involve  
22 continued study? Is that not the sort of any other information  
23 that would obviate the mandate that the Secretary shall issue?  
24 Does any other information weaken your argument in any other  
25 way, and what construction would you give to that potential

1 wiggle room granted thereby?

2 MR. BAPTIST: Two responses to that. That  
3 subclause (4) still is tied to "under such conditions." That's  
4 going to be in the conditions under the approved label. So  
5 they can't--whatever other information is out there, the FDA  
6 still has to demonstrate that it was evaluating the safety  
7 under the approved label conditions.

8 But plaintiffs also have a broader focus. It's not  
9 just that subsection that we are bringing this claim. It's  
10 all--well, it would be (1), (2), (4), and (5), not just (4).  
11 So--and again, this is--the FDA needs to find all of these or  
12 it must refuse. It's not just one of the others and the FDA  
13 can approve. This is mandatory requirements for approval of  
14 the new drug.

15 THE COURT: Okay. I have your argument, and I did  
16 want further clarification on whether this argument sounds in  
17 statutory construction and the tools of textualism apply or  
18 it's just a strict agency administrative law argument that  
19 requires a finding that certain actions were arbitrary and  
20 capricious and that certain clinical studies were not properly  
21 applied or ignored.

22 So I take it that you're making the statutory  
23 argument and then, in the alternative, an agency administrative  
24 law argument that even if there was textual authority using any  
25 of the language of those subparts, the exercise of that

1 discretion was arbitrary and capricious?

2 MR. BAPTIST: Yes, Your Honor. That's precisely  
3 our argument.

4 THE COURT: And even if-- Okay. All right. You  
5 may proceed.

6 MR. BAPTIST: I'll finish with one other--on 2021.  
7 The same applies there. The FDA relied on two data sets for  
8 approving or taking away the in-person dispensing requirement.  
9 One was the FDA's adverse event reporting system. Again, this  
10 is 2021, five years after, as my colleague noted, the FDA took  
11 away a significant reporting requirement for reporting nonfatal  
12 adverse events, rendering even more useless the FAERS, what we  
13 call the F-A-E-R-S, or the FDA's Adverse Event Reporting  
14 System.

15 And, secondarily, they rely on literature that--to  
16 support that finding as well. That was problematic for  
17 multiple reasons but in violation of the FDCA, because that  
18 literature--the FDA, in its own words, was unable to prove the  
19 safety on its own, and therefore, the FDA had to rely on the  
20 inadequate FAERS data.

21 But either way, it does not meet the strict  
22 standards of Section 355(d) of the FDCA, and it definitely does  
23 not meet the substantial evidence that Congress required the  
24 FDA have when approving an application.

25 I'm going to travel back in time to the year 2000,

1 because I want to talk about Subpart H and how the FDA first  
2 went about approving mifepristone for use in the United States,  
3 unless Your Honor has questions further on the FDCA  
4 Section 355(d) argument.

5 THE COURT: I'll follow you into the time machine.  
6 Go ahead.

7 MR. BAPTIST: Thank you.

8 In 2000, the FDA used its Subpart H approval  
9 authority to approve the Population Council's application for  
10 mifepristone use in the United States for chemical abortion  
11 purposes. Subpart H reads in the text--and that's  
12 21 CFR Section 314.500. It says that the scope only applies to  
13 certain drugs that treat serious or life-threatening illnesses  
14 and that provide a meaningful therapeutic benefit to patients  
15 over existing treatment.

16 The text, again, is clear on its face. It only  
17 deals with illnesses. What the FDA did in 2000 was use this  
18 drug and this mechanism to approve this drug. Mifepristone is  
19 to terminate a pregnancy, and pregnancy is not an illness. And  
20 chemical abortion drugs don't provide a meaningful therapeutic  
21 benefit over surgical abortion. Frankly, mifepristone doesn't  
22 treat anything.

23 And so the FDA and the other defendant, Danco  
24 Laboratories, has to rely on nontextual language or arguments  
25 to justify the approval in 2000, and those arguments are

1 threefold.

2 First, they say the FDA is afforded deference under  
3 *Kisor vs. Wilkie*. But that's Step 2 under *Kisor*. *Kisor's*  
4 first step is that the language actually has to have ambiguity.  
5 Neither defendant has alleged or demonstrated that "illnesses"  
6 is an ambiguous term. And, as *Kisor* noted, if uncertainty does  
7 not exist, there is no plausible reason for deference.

8 And defendants' interpretation here is not even  
9 reasonable. The FDA knew how to write conditions into its  
10 regulatory text if it had wanted to include conditions, and  
11 that's how the FDA justified it. They said, we said illnesses,  
12 but we really meant conditions; we should be afforded  
13 deference. But again, the FDA knows how-- Under standard  
14 canons of interpretation, if the FDA wanted to include both  
15 terms, it would have done so.

16 Second, the FDA relies on the preamble and says  
17 that broadened the interpretation or the definition of  
18 illnesses, despite what the regulatory text said. Again, we  
19 noted in our briefing, a preamble can never override a  
20 regulatory text, nor does it actually give the broader  
21 definition. We don't see the same reading that they did where  
22 they argue the FDA expanded the scope. We just don't see that.  
23 There's some discussion of diseases, illnesses, and a couple of  
24 references to conditions, but it doesn't give any clarity that  
25 that's what the FDA intended to do.



1           And finally, the FDA relies on the 2007 Food and  
2 Drug Administration Amendments Act, or I'm going to refer to  
3 the FDAAA. And they say that codified and ratified the  
4 previous 2000 approval, so whatever infirmities were associated  
5 with that approval, the FDA was cured by Congress.

6           Nothing could be further than the truth. This law,  
7 the 2007 FDAAA, merely grandfathered in previous restrictions  
8 under Subpart H, and different Subpart E, which is located at  
9 21 CFR Section 601.42, and other voluntary restrictions agreed  
10 to by the sponsor.

11           Congress did not ratify the FDA's approvals, let  
12 alone even the FDA's decisions to impose those post-marketing  
13 restrictions on those drugs that were affected. It was merely  
14 saying, in 2007, if there are post-marketing restrictions on  
15 drugs, under these provisions, where, voluntarily, they can be  
16 carried over and grandfathered and deemed to have a risk  
17 evaluation and mitigation strategy--in other words, a REMS,  
18 R-E-M-S-- And that's it. It made no decision, no  
19 determination in terms of the--on whether it was right for the  
20 FDA to approve those drugs or it imposed those post-marketing  
21 restrictions. So the 2007 FDAAA does not provide the  
22 defendants with an out as well.

23           If Your Honor does not have any other questions  
24 with regard to the Subpart H approval, I want to move over to  
25 talk about the Pediatric Research Equity Act of--

1           THE COURT: I do have one follow-up. So as we walk  
2 through this chronology and, using your time machine, we go  
3 from Subpart H, FDAAA to REMS and then ETASU, going back to  
4 that time period when Subpart H was the operative regulation--I  
5 believe this was 1992 to 2008. Is there anything in the  
6 briefing by plaintiffs or any of the amicus briefs that  
7 identify the categories of drugs that were approved under  
8 Subpart H and whether those provide any analogues to this  
9 Court's determination whether that 2000 approval was a proper  
10 exercise of Subpart H regulatory authority?

11           What other types of drugs in those preceding years,  
12 roughly eight years, received that sort of accelerated  
13 Subpart H treatment? Were these pregnancy-related? Were any  
14 of these related to other naturally-occurring physiological or  
15 biological conditions, or were these primarily fast-tracked HIV  
16 drugs and things affecting things like cancer?

17           MR. BAPTIST: There's one amicus brief in  
18 particular I'll point your attention to. It's filed by  
19 Judicial Watch. It's located at Docket 65-1 beginning  
20 page ID 2999. In that, it describes what the FDA did prior to  
21 the 2000 approval in terms of approving other new drugs under  
22 Subpart H, and then it also discussed the drugs post-2000 that  
23 were approved under Subpart H, as well.

24           And that analysis, which is also found on the FDA's  
25 own website, was that prior to the 2000 approval of

1 mifepristone, the FDA granted accelerated approval, pursuant to  
2 Subpart H, 37 times. Of these 37 accelerated approvals,  
3 21 related to HIV drugs, and 10 related to cancer drugs. The  
4 remaining approvals related to chronic low blood pressure,  
5 tuberculosis, leprosy, and bacterial infections.

6 And then going further, beyond the 2000 approval,  
7 the FDA granted Subpart H approvals 26 times. Of those  
8 26 approvals, 9 related to HIV drugs, 10 related to cancer  
9 drugs, 3 related to hypertension, and 2 to blood disorders.  
10 The remaining approvals related to a problem with a pituitary  
11 and narcolepsy.

12 The contrast between these illnesses and the FDA's  
13 jamming of pregnancy into Subpart H cannot be more stark.  
14 There is simply no correlation between the two.

15 THE COURT: Okay. And so in giving construction to  
16 314.500 and that terminology of serious life-threatening  
17 illness, you would direct the Court to the agency's own  
18 decisions and actions in approving drugs. In those prior  
19 categories, you would ask the Court to give some adjudicative  
20 weight to--almost like a canon of construction, give weight to  
21 all of the other drugs that were approved under that  
22 accelerated program, that this Court should deem one of these  
23 not like the others?

24 MR. BAPTIST: Yes, Your Honor. The plain text is  
25 clear that it applies to illnesses, and everything the FDA did

1 before 2000 and after 2000 showed that it was intended to deal  
2 with illnesses, and not pregnancy.

3 THE COURT: Okay. I think I have your argument on  
4 that. And I did recall that there was an amicus brief that set  
5 out that history of other approved drugs under Subpart H, and I  
6 just wanted to clarify that you do endorse that analysis.

7 MR. BAPTIST: Yes.

8 THE COURT: Okay. And now you may proceed, I  
9 believe to remedies. Is that next in the queue, or what were  
10 you going to address next?

11 MR. BAPTIST: I was going to discuss the Pediatric  
12 Research Equity Act of 2003, which is an amendment to the FDCA,  
13 but it wasn't the complete part. When I talked about the FDCA,  
14 I didn't finish that part. Then I'm going to talk about  
15 irreparable harm and the public interest and then get to  
16 remedies. But, Your Honor, I'm happy to go in whatever order  
17 you--

18 THE COURT: No, we'll take your order of operation.  
19 It tracks the elements for injunction nicely.

20 I do want to make clear for record purposes that  
21 PREA here is a reference to the Pediatric Research and Equity  
22 Act. That's 21 U.S.C. Section 355(c). But you may refer to it  
23 as PREA from this point forward.

24 MR. BAPTIST: Yes, Your Honor.

25 Plaintiffs' opening brief in support of their

1 motion for preliminary injunction highlighted how the FDA  
2 ignored the potential impacts of this hormone-blocking regimen  
3 on developing bodies of adolescent girls. But because  
4 plaintiffs did not brief this requirement for the FDA to assess  
5 the safety of mifepristone in adolescent girls, if it's okay  
6 with Your Honor, I'm going to spend a little more time just  
7 going over the history and background of this requirement and  
8 how the FDA failed to comply with it.

9           The FDA, in the late 1990's, issued a rule called  
10 the Pediatric Rules, a regulation that was issued in 1998 and  
11 required an assessment specifically powered to determine the  
12 safety and effectiveness of a new drug on pediatric patients.  
13 This rule allowed for full or partial waivers of its pediatric  
14 assessment requirement if certain conditions were met.

15           This was the rule that was operating and governing  
16 the FDA at the time of its decision to approve mifepristone in  
17 2000, and the FDA explicitly and expressly told the Population  
18 Council that it was waiving this requirement. And, again, the  
19 waiver factors were to--these were to-- For necessary studies  
20 that are impossible or highly impractical, which does not  
21 apply, there is evidence strongly suggesting that the drug or  
22 biological product would be ineffective or unsafe in all  
23 pediatric age groups--the FDA didn't take that position--or the  
24 drug does not represent a meaningful therapeutic benefit over  
25 existing therapies for pediatric patients and is not likely to

1 be used in a substantial number of pediatric patients. Again,  
2 clearly, that would not apply based on how the FDA approved and  
3 justified its approval in 2000.

4 We would note that this requirement was imposed  
5 on--the FDA imposed it through its rule in 1998, carried over to  
6 2000. The district court vacated that rule and set it aside.  
7 In 2003, in response, that's when Congress passed PREA  
8 codifying that previous rule and said, any waivers granted  
9 between a certain time period, including the approval of  
10 mifepristone, would be deemed to be a full or partial waiver.  
11 So that waiver carried over.

12 Again, that waiver was illegal under PREA. It was  
13 illegal under the FDA's own regulations. And again, what the  
14 FDA did, in 2016--they didn't waive it this time in 2016 for  
15 the major changes. The FDA justified it by saying, we're going  
16 to extrapolate, and extrapolate that we are going to assume  
17 that a 13-year-old girl will have the same safety and  
18 effectiveness outcome as a 35-year-old woman who takes this  
19 drug.

20 We simply don't think that's true, but it's not  
21 plaintiffs' obligation to demonstrate that. It was incumbent  
22 and required by Congress for the FDA to determine that  
23 assessment. But the FDA made that extrapolation. That  
24 extrapolation provision, in and of itself, is inapplicable to  
25 the FDA. That is going to be found at

1 21 U.S.C. Section 355c(a)(2)(B)(i). And that discusses when  
2 the FDA may extrapolate the safety and effectiveness of a drug  
3 for safety and effectiveness on pediatric populations.

4 If Your Honor would want me to wait for you to--

5 THE COURT: Oh, no. You may proceed.

6 MR. BAPTIST: And this says--the statute says: If  
7 the course of the disease and the effects of the drug are  
8 sufficiently similar in adults and pediatric patients, the FDA  
9 may conclude that pediatric effectiveness can be extrapolated  
10 from adequate and well-controlled studies in adults, usually  
11 supplemented with other information obtained in pediatric  
12 populations.

13 Your Honor, again, for the same reasons the  
14 Subpart H approval was inappropriate, the extrapolation in 2016  
15 was inappropriate, because pregnancy is not a disease. This  
16 provision is not available for mifepristone. It could be  
17 available to other medications that actually treat and cure  
18 diseases, but it's not this one.

19 THE COURT: And so between the pediatric rule and  
20 President Bush signing PREA into law, there was an intervening  
21 D.D.C. case; is that correct?

22 MR. BAPTIST: Correct.

23 THE COURT: So this is a little bit like RFRA,  
24 where Congress passes federal RFRA; *City of Boerne* is decided;  
25 and then Congress responds with RLUIPA. So it's a little bit

1 of a similar trajectory where there's a pediatric rule in  
2 place; that's deemed violative of law for various reasons; and  
3 then Congress acts.

4 Did the 2000 approval happen within that gap period  
5 between a pediatric rule and then the codified statute later?

6 MR. BAPTIST: No. The approval in 2000 occurred  
7 before the Court vacated the pediatric rule, and then Congress  
8 came back and codified that time period for waivers and said  
9 those waivers can be deemed, moving forward, full or partial.

10 THE COURT: Okay. I recall that there was a D.D.C.  
11 case in between those two events triggering congressional  
12 action. I couldn't recall the precise chronology, but your  
13 brief correctly states the chronology of those events and how  
14 the pediatric rule migrates from rule to statute and then  
15 through further FDA legislation.

16 MR. BAPTIST: Correct. I would point you to our  
17 complaint located at page ID 26 through 28, 57 to 58, 59,  
18 page 60, 97 through 100, 104 through 105, and then again at  
19 106, where we discuss this chronology and the events that  
20 unfolded for mifepristone--

21 THE COURT: Okay. And then that intervening case  
22 was *Physicians and Surgeons vs. FDA*, 226 F.Supp.2d 204. That  
23 was a D.D.C. case from 2002. This prompted Congress to enact  
24 PREA, which was signed into law I believe in 2003. Is that  
25 correct?



1 MR. BAPTIST: That sounds correct to me, Your  
2 Honor.

3 THE COURT: Okay. So I'll double-check all the  
4 dates there, but as I'm walking through the time machine and  
5 all these various chronologies, start with pediatric rule; then  
6 we have D.D.C. intervention; PREA; and then everything from  
7 there follows as far as which rules have to apply to pediatric  
8 determinations and sub-populations. But thank you for  
9 reminding me of that D.D.C. case. I wanted to make sure that  
10 chronology was correct in my mind.

11 You may proceed to your next topic.

12 MR. BAPTIST: Thank you, Your Honor. If Your Honor  
13 is done discussing substantial likelihood of success on the  
14 merits, I want to move to the next preliminary injunction  
15 factor of irreparable harm.

16 In Administrative Procedure Act cases, the Fifth  
17 Circuit has stated that complying with an agency order later  
18 held invalid almost always produces irreparable harm of  
19 nonrecoverable compliance cost. When determining whether  
20 injuries are irreparable, it is not so much the magnitude, but  
21 the irreparability that counts. That's *Texas vs. EPA*,  
22 829 F.3d 405, a Fifth Circuit decision from 2006.

23 And other district courts have said, it is well  
24 established in the Fifth Circuit that injuries are irreparable  
25 only if it cannot be undone through monetary damages. Where

1 the costs are nonrecoverable because a government defendant  
2 enjoys sovereign immunity from monetary damages, irreparable  
3 harm is generally satisfied.

4           Here, because if the Court were to find that any or  
5 all of the plaintiffs are injured, it is inevitable that they  
6 will suffer irreparable harm under the APA. And whether it's  
7 the organizational harm to the plaintiff medical associations  
8 or the harms to plaintiff doctors or their patients, as my  
9 colleague outlined, the courts have recognized these harms are  
10 also irreparable, as well.

11           And then the Fifth Circuit has also allowed medical  
12 doctors to assert the irreparable harms of their patients,  
13 recognizing third-party irreparable harm, and that's *Deerfield*  
14 *Medical Center*, a Fifth Circuit case from 1981 referenced in  
15 our reply brief.

16           If Your Honor doesn't have any questions, I want to  
17 make sure I address everything within my remaining time. The  
18 public interest factor as well. Everybody agrees that the  
19 third and fourth preliminary injunction factors balancing the  
20 harms and public interest merge together when the defendant is  
21 the government. And public interest favors holding agencies  
22 accountable for failing to follow the law. Indeed, there is  
23 generally no public interest in the perpetuation of unlawful  
24 agency action. And the public interest in having governmental  
25 agencies abide by federal laws that govern their existence and

1 operations also is an important factor as well.

2           And the FDA is not entitled to deference when it  
3 ignores statutory mandates established by Congress and the will  
4 of the American people. Courts have recognized that the public  
5 interest has an interest in preventing dangerous drugs from  
6 entering the marketplace. And as you discussed with my  
7 colleague earlier, 22 states filed an amicus brief, led by the  
8 State of Mississippi, demonstrating why the public interest  
9 favors granting an injunction here as we restore the proper  
10 balance of police power for the states to determine how best to  
11 protect the health and welfare of their citizens.

12           Finally, granting the plaintiffs' motion here helps  
13 stop the federal government from illegally subverting these  
14 states' laws and regulations designed to protect their people  
15 from dangerous chemical abortion drugs and promote life.

16           THE COURT: Okay. So moving back to  
17 irreparability. So defendants argue and some amicus argue that  
18 there's a type of reliance interest that has developed over a  
19 two-decade period of time where practitioners and patients have  
20 used mifepristone as part of clinical practices across the  
21 country.

22           Can you point the Court to analogue cases where  
23 other drugs on the shelf for similar periods of time have been  
24 subject to court intervention and either suspended, withdrawn,  
25 set aside, vacated--whatever remedy, which we'll discuss next,

1 can you point to analogues where courts have intervened in such  
2 a way where a drug has been in use for so long?

3 MR. BAPTIST: My answer to your question is, no, I  
4 can't. But the answer to those briefs that say that is because  
5 this is the FDA's own doing. As my colleague highlighted, the  
6 FDA stonewalled our clients for, combined, over 16 years. This  
7 drug has been on the marketplace and maybe created reliance  
8 interest, but that was because of the FDA's own delay tactics  
9 and strategic denials of our petitions over time. So the  
10 reliance interest that may have been created, again, is not due  
11 to any fault but the FDA's, and they can't assert that argument  
12 now.

13 THE COURT: What is your best case for application  
14 of the reopening doctrine where there have been a series of  
15 agency actions and a long duration of time and the Court did  
16 intervene under principles of administrative law and did grant  
17 relief despite these long gaps of time between actions and then  
18 final court action?

19 MR. BAPTIST: The best case would be  
20 *Sierra Club vs. EPA*. That one was starting from the 1990's  
21 into the 2000's. And so there was a long period where a  
22 regulation was on the books, and there may have been reliance  
23 interest by industry for those regulations. And that was  
24 subsequently vacated by the D.C. Circuit.

25 THE COURT: Okay. And I know Ms. Hawley made

1 reference to *Sierra* earlier in her portion of the argument.

2           So at this time, are we ready to discuss my  
3 questions on remedies?

4           MR. BAPTIST: Yes, we are, Your Honor.

5           THE COURT: Okay. So I will sort of reframe your  
6 complaint as follows.

7           Here, you have six claims regarding different  
8 stages of FDA action, as that's understood at administrative  
9 law. And by my inventory, that includes the 2000 approval, the  
10 2016 major changes, the 2019 ANDA generic approval-- And for  
11 record purposes, ANDA is Abbreviated New Drug Application, as  
12 that's applied to generic drugs under 21 U.S.C. Section 355(j).  
13 The 2021 removal of in-person dispensing requirement, and then,  
14 of course, the responses to the citizen petition.

15           So those are six claims that are structured that  
16 way in your prayer for relief. Working in reverse  
17 chronological order, can the plaintiff discuss each action,  
18 starting with that 2021 removal of in-person dispensing  
19 requirement, all the way back to the 2000 approval, and inform  
20 the Court of a proper remedy per action? Or is this Court  
21 dealing with a domino effect, where it makes a decision on the  
22 2000 approval and there's this cascading effect of court  
23 intervention on each one?

24           Can you address each one and identify a remedy for  
25 each FDA agency action in backwards, reverse chronological

1 order? If so, make your argument there, or if you need to  
2 argue that, instead, this Court must definitively decide that  
3 the 2000 approval was against law for the various reasons  
4 briefed by the parties. Which approach should this Court take  
5 in fashioning remedies, should plaintiffs prevail?

6 MR. BAPTIST: Sure. I'll start in reverse  
7 chronological order, as you requested.

8 So the 2021 removal of in-person dispensing  
9 requirements, there are multiple options available to the Court  
10 to, we would say, set aside and vacate under the APA. And that  
11 would be our preferred and recommended approach, that that  
12 REMS, or the Risk Evaluation and Mitigation Strategy, REMS,  
13 changes in 2021 to remove in-person dispensing requirement  
14 because it violated the Comstock Act, it violated the FDCA, and  
15 it violated the PREA of 2003 should be set aside.

16 And this is going to be a general theme throughout  
17 my discussion, so I just want to make sure we're on the same  
18 page, just because 706 under--Section 706 under the APA  
19 requires a Court to hold unlawful and set aside agency action  
20 found to be arbitrary, capricious, and abuse of discretion or  
21 otherwise not in accordance with law. Our claims are saying  
22 that the FDA acted not in accordance with law in 2021,  
23 through--and all the previous agency actions that we'll go  
24 over, each individually.

25 And as a textual matter, the mandatory language of

1 the APA has led the courts to make remand and vacatur the  
2 default remedy for courts where they find that an agency action  
3 violates the APA. And we would submit to the Court that would  
4 be the easiest lift, because I think--I would say the Fifth  
5 Circuit has generally observed that vacating an agency action  
6 is the less drastic approach versus injunctive relief and  
7 enjoining. But both are available here.

8           And so again, for 2021, if the Court were not to  
9 want to use its authority under the Section 706 of the APA and  
10 set aside and vacate the 2021 removal of in-person dispensing  
11 requirement, it can also compel the agency to take an action,  
12 as well, to take down the changes and remove the actions that  
13 perpetuated the 2021 removal of in-person--

14           THE COURT: And, Mr. Baptist, I have been advised  
15 that you have ten minutes remaining in your portion.

16           MR. BAPTIST: Okay. Thank you for that reminder.

17           That is going to be true throughout. So I will  
18 say, for the challenge to the 2019 ANDA, again, set it aside or  
19 vacate it, because it was in violation of the law, because the  
20 underlying approval upon which it relied lacked the necessary  
21 safety studies under 735--I'm sorry--355(d) of the FDCA. But  
22 again, the Court can compel the agency to withdraw or suspend  
23 that approval as well. That has been done in other contexts.  
24 I'll give you a couple of examples, and I should have given you  
25 an example for vacatur of a drug approval by the FDA as well.

1           The first case for demonstrating that there's  
2 precedent for both of these types of remedies is *American*  
3 *Bioscience, Incorporated vs. Thompson*, found at 269 F.3d 1077.  
4 It's a D.C. Circuit case from 2001. In that case, the  
5 D.C. Circuit-- Again, this is at the preliminary injunction  
6 stage. The D.C. Circuit directed the district court to vacate  
7 the FDA's order approving a drug and remanded it back to the  
8 agency.

9           So there is precedent for such an action here. But  
10 also, as I just described, there is also precedent to suspend  
11 or withdraw an approval of a new drug by the FDA. And I can  
12 give you a couple of examples of that. And there's *Bayer*  
13 *Health--that's B-a-y-e-r--Healthcare, LLC vs. FDA*. That can be  
14 found at 942 F.Supp.2d, page 17. That is a district court of  
15 D.C. case from 2013. And then the Court found that the FDA has  
16 shown no attention to the congressional mandate that it  
17 withhold approval of a drug. This is in the animal drug  
18 context. But it also found that you can suspend there.

19           And another suspend case is *Mova Pharmaceutical*  
20 *Corporation vs. Shalala*. *Mova, M-o-v-a, Pharmaceutical*  
21 *Corporation vs. Shalala--that's S-h-a-l-a-l-a--found at*  
22 *955 F.Supp. 128, D.D.C. 1997*. There again, the Court ordered  
23 that the FDA suspend its approval of a drug.

24           So there's a couple of ways to address an illegal  
25 approval of a new drug by the FDA that the courts within the



1 D.C. Circuit have found. They have both done vacatur on the  
2 APA and compelling the FDA to withdraw or suspend those drugs  
3 at that preliminary stage.

4 THE COURT: I've been to the Supreme Court and back  
5 on those APA sections, so I'm familiar with the developing  
6 jurisprudence on what vacatur is and isn't and what those  
7 sections confer upon the district court and what those sections  
8 do not confer.

9 But I do want to focus my last line of questions on  
10 suspension versus withdrawal. So, here, are you making  
11 reference to 21 U.S.C. Section 355(e) as this Court's statutory  
12 authority to order suspension or withdrawal?

13 MR. BAPTIST: That is a provision within FDCA.  
14 It's entitled Withdrawal of Approval. That gives the grounds  
15 for the FDA to withdraw, on its own accord, a drug that is not  
16 shown to be safe under the conditions of used, prescribed,  
17 recommended, or suggested in the labeling. I've kind of  
18 paraphrased and culled down what those provisions may be. Or  
19 if there's an imminent hazard to the public health, and it can  
20 suspend that approval as well.

21 So that authority is available to the Court. I  
22 would say that if you compel the agency to do it, you have that  
23 authority to do it. Courts have done that in other contexts.  
24 But I believe there is some briefing on this where--that limits  
25 the Court's power to--you just can, say, initiate this

1 proceeding, which could take many years, and frankly, given the  
2 claims in this case and the harms that our doctors have seen  
3 firsthand in the emergency rooms across the country treating  
4 women and girls who have been harmed by these dangerous drugs,  
5 that the time cannot last, and that cannot be an appropriate  
6 remedy in this case.

7 THE COURT: Okay. So at this stage, at this  
8 preliminary injunction stage, what is your reading of  
9 Section 355(e) jurisprudence that the appropriate remedy under  
10 that provision--is it suspension or withdrawal?

11 MR. BAPTIST: The case law has said suspension,  
12 but--I mean, sorry--but I think the better textual reading is  
13 withdrawal.

14 THE COURT: Okay. So, here, plaintiffs would argue  
15 first that 355(e) confers upon this Court the right to order  
16 withdrawal and, in the alternative, a suspension of agency  
17 action, in that sequence? That is how plaintiffs are arguing  
18 that particular remedy under that particular statute?

19 MR. BAPTIST: Yes, Your Honor.

20 THE COURT: Okay. I have your argument on that.  
21 You have four minutes remaining. Is there any additional  
22 argument plaintiffs seek to make, or are they reserving the  
23 rest of their arguments for rebuttal?

24 MR. BAPTIST: I'll spend a couple of minutes-- Any  
25 relief that you grant, Your Honor, it must be complete. The

1 scope of plaintiffs'--of this relief needs to be universal and  
2 nationwide. The harms of chemical abortion drugs know no  
3 bounds.

4 Dr. Jester, one of our named individual plaintiffs  
5 in this case, had to save the life of a woman who obtained  
6 these drugs in New Mexico, who came and had an emergency  
7 situation here, back near this courthouse.

8 Dr. Johnson, who is another named plaintiff here in  
9 this case, needed to treat a woman who took the drugs in  
10 Chicago, drove back to his Indiana hospital, and then he had to  
11 save her life there.

12 The four medical associations--three of the four of  
13 these medical associations have members in every country--I  
14 mean every state in this country. The only practical and  
15 reasonable way to grant relief in this is to provide complete  
16 relief and make it universal.

17 THE COURT: Okay.

18 MR. BAPTIST: Thank you, Your Honor.

19 THE COURT: Thank you, Mr. Baptist.

20 Ms. Hawley, I have your argument, and you have  
21 reserved 30 minutes for rebuttal; is that correct?

22 MS. HAWLEY: Yes, Your Honor.

23 THE COURT: Okay. So at this time, the Court will  
24 recess for 15 minutes to allow the defendants and intervenor to  
25 reconfigure the courtroom, to make ready any IT technology that

1 they deem necessary. I'll instruct the parties to reappear for  
2 continuation of this hearing at 10:50, and at that point, we  
3 will begin with the defendants FDA and HHS, to be followed by  
4 the intervenor in the time segments that have been announced to  
5 the Court: 45 minutes total for Ms. Straus Harris, 45 minutes  
6 total for Mr. Schwei, and then, for intervenor, 30 minutes  
7 total.

8           So that will be the sequence the Court anticipates.  
9 If there's any deviation from that, just notify the Court if  
10 there's any substitution of counsel.

11           And you may take your breaks. You may make your  
12 phone calls during this period. I just ask that you obey the  
13 instructions of the marshals and the court security officers at  
14 all times, since we do have many people moving in and out of  
15 the building.

16           I'll also caution that the magistrate court also  
17 has prisoner hearings today, so there will be prisoner  
18 transport in and out of this building. So be especially  
19 careful to mind those rules and obey the marshals and the CSO's  
20 at all time, less you run into a prisoner in the hallway.

21           So at this time, we stand in recess. Parties are  
22 instructed to reappear at 10:50 for resumption of the hearing.

23           (RECESS TAKEN)

24           THE COURT: The court is back on the record in Case  
25 Number 2:22-CV-223-Z for continuation of the hearing on the

1 pending motion for preliminary injunction.

2 At this point, the defendants may proceed with  
3 their arguments. And it's my understanding that Ms. Straus  
4 Harris will begin for the government. Is that correct?

5 MS. STRAUS HARRIS: Yes, Your Honor.

6 THE COURT: You may approach.

7 MS. STRAUS HARRIS: Good morning, Your Honor, and  
8 may it please the Court. I will be addressing the government's  
9 threshold defenses, including all of the topics listed in the  
10 Court's order next to standing and reviewability, with the  
11 exception of *Heckler v. Chaney*. I will also address the  
12 equitable factors, including all of the topics listed next to  
13 harm and public interest.

14 Then I will turn the podium to my colleague,  
15 Mr. Schwei, who will address all other merits issues, including  
16 Subpart H and agency decisions, plus *Heckler v. Chaney* and all  
17 of the topics listed under remedies.

18 THE COURT: Okay. Thank you for being so organized  
19 and for that preview, and you may proceed according to plan.

20 MS. STRAUS HARRIS: Thank you, Your Honor.

21 Plaintiffs seek the extraordinary relief of a  
22 preliminary injunction that upends the status quo by banning a  
23 drug that has been on the market for 22 years. That relief is  
24 not available for a host of reasons, including that the  
25 plaintiffs themselves ask the Court to hold off on entering any

1 relief until after a trial on the merits.

2 Congress authorized the Food and Drug  
3 Administration to determine, based on its scientific expertise,  
4 whether drugs are safe and effective. More than two decades  
5 ago, the FDA approved the drug mifepristone as safe and  
6 effective for the medical termination of intrauterine pregnancy  
7 under certain conditions.

8 In this unprecedented action, plaintiffs ask this  
9 Court to overturn that longstanding scientific determination  
10 based on speculative allegations of harm offered in support of  
11 claims and arguments that are untimely, unexhausted, and  
12 without merit. Plaintiffs' motion for a preliminary injunction  
13 satisfies none of the requirements for the extraordinary relief  
14 they seek and should be denied.

15 First, plaintiffs cannot demonstrate a likelihood  
16 of success on the merits of their claims, because they fail for  
17 several threshold reasons. As I will explain, with one  
18 possible exception, review of their claims is barred, because  
19 their claims are unexhausted, time barred, or both. Further,  
20 as I will discuss, plaintiffs fail to demonstrate a cognizable  
21 injury sufficient to establish standing to bring their claims,  
22 let alone a substantial threat of irreparable injury sufficient  
23 to justify the extraordinary relief they seek today.

24 Second, in contrast with plaintiffs' failure to  
25 show irreparable harm, the government has demonstrated that the

1 balance of harms and the public interest would be irreparably  
2 injured by a preliminary injunction here. As the Fifth Circuit  
3 has cautioned in *City of Dallas vs. Delta Airlines*, the purpose  
4 of a preliminary injunction is to preserve the status quo  
5 during the pendency of litigation.

6 But an injunction here would upend the status quo  
7 and the reliance interest of patients, doctors, and businesses  
8 involved in the pharmaceutical industry. An injunction would  
9 cause significant public harm, depriving patients and doctors  
10 of a safe and effective drug that has been on the market for  
11 more than two decades.

12 I'll begin by discussing the statute of limitations  
13 and exhaustion issues. First, all of plaintiffs' claims are  
14 untimely or unexhausted except their challenge to the FDA's  
15 December 16th, 2021, response to the 2019 citizen petition.  
16 The statute of limitations plainly bars their challenge to  
17 FDA's underlying approval of mifepristone, including its  
18 response to the 2002 citizen petition, because the initial  
19 approval and the response to the citizen petition each occurred  
20 more than six years before plaintiffs brought suit.

21 As to the ANDA approval for the generic version of  
22 mifepristone, plaintiffs fail to exhaust this claim because  
23 they did not file a citizen petition on it.

24 Plaintiffs have invoked the reopening doctrine to  
25 put the original approval of mifepristone back on the table,

1 but that doctrine does not apply here, where FDA did not  
2 undertake a serious substantive reconsidering of its 2000  
3 approval of mifepristone. And that language comes from  
4 *Texas vs. Biden*, 20 F.4th 951.

5 Plaintiffs assert that the *Sierra Club* case is  
6 particularly relevant to their reopening claim, but there are  
7 key differences between that case and the case here. In  
8 *Sierra Club*, the D.C. Circuit said that the agency there, the  
9 EPA, had constructively reopened an earlier decision because it  
10 had completely--and "completely" is italicized in the case  
11 decision--changed the regulatory context. It went from a  
12 situation where prior approval from the agency was required to  
13 one in which no approval from the agency was required.

14 Here, the agency did not alter that the drug was  
15 approved with conditions. It simply altered some of those  
16 conditions. That does not constitute a complete change in the  
17 regulatory context that the D.C. Circuit found was sufficient  
18 for constructive reopening.

19 Plaintiffs argue that there are reasons to excuse  
20 their failure to exhaust claims to the agency. There are two  
21 different types of exhaustion that are relevant here. One is  
22 exhaustion as to challenging a particular agency action; here,  
23 the 2019 ANDA approval. Plaintiffs never filed a citizen  
24 petition, and so that--any claim related to that petition is  
25 unexhausted and cannot be brought to this Court.



1           But there are also issues related to issue  
2 exhaustion with respect to whether the plaintiffs or the--in  
3 their posture as petitioners to the agency, raised particular  
4 issues in the citizen petition that they filed, and that  
5 specifically relates to their effort now to challenge the 2000  
6 approval.

7           In their citizen petition to the 2016 decision by  
8 the agency, plaintiffs never asked the agency to reconsider or  
9 withdraw the 2000 approval, and so that decision cannot be a  
10 basis for reopening the 2000 approval decision. It also means  
11 that any challenge to the 2000 approval decision would be  
12 unexhausted on the basis of the 2016 citizen petition.

13           Plaintiffs argue that there are three reasons why  
14 the exhaustion requirement should be excused here, and I'll go  
15 through and explain why each of them does not apply.

16           First, they argue that it would have been futile to  
17 raise certain of the issues; in particular, the Comstock issue.  
18 And specifically, they say that the 2022 OLC decision makes  
19 clear why it would have been futile. But in a case cited by  
20 plaintiffs in their brief, the *Tesoro Refining* case vs. *FERC*--  
21 and plaintiffs cite this in ECF Number 120 at 22--the  
22 D.C. Circuit made clear that a subsequent decision by an agency  
23 cannot be the basis for invoking the futility exception to  
24 exhaustion.

25           Second, they argue that there is an exception on

1 the basis of the agency's action being patently unlawful.  
2 There, they cite a case that, itself, cites--that, itself, only  
3 acknowledges a single time when this excuse was used to excuse  
4 exhaustion. It was a 1952 case. But what the Court explained  
5 there was that the agency had to be acting fully outside its  
6 authority.

7           And what the agency did here, the action that  
8 plaintiffs challenge, is the agency's determination to grant  
9 pre-market approval on the basis of safety and effectiveness to  
10 a drug. That is precisely the authority that Congress has  
11 vested in the FDA, and so this idea that the agency acted so  
12 far afield from its authority given by Congress is simply  
13 inapplicable here.

14           Third, they argue that the interests of justice  
15 require excusing exhaustion. And on this, they say that it was  
16 the FDA's delay in deciding their 2002 citizen petition that  
17 requires excusing exhaustion in order to overcome the--what  
18 they say was injustice from that delay.

19           The problem with this argument is that, first of  
20 all, they do not point to a specific case where, after a party  
21 has allowed the agency administrative process to conclude,  
22 exhaustion was excused on the basis of the time that it took  
23 the agency to decide a case.

24           And if the delay was a true concern for the  
25 petitioners that submitted that citizen petition, the law

1 provides a mechanism for them to remedy that alleged harm by  
2 the agency. And that is in 5 U.S.C. 706(1), which allows a  
3 party, under the APA, to seek relief for agency action  
4 unlawfully withheld or unreasonably delayed.

5 They did not invoke that here, so to now, more than  
6 six years later, after the agency completed review of that  
7 citizen petition, to now come in and say that justice requires  
8 excusing any exhaustion requirement on the basis of the FDA's  
9 delay is simply--simply can't be credited in this case.

10 THE COURT: So let me go back to futility briefly,  
11 because in December of 2022, the OLC issued the memorandum  
12 opinion on the Comstock Act. What is this Court to make of the  
13 government's reliance upon that OLC memorandum and the fairly  
14 definitive reading of that statute? How should the Court weigh  
15 your agency's reliance on the OLC memorandum in determining  
16 this exception for futility?

17 MS. STRAUS HARRIS: Your Honor, as I just  
18 explained, the D.C. Circuit has held that a subsequent decision  
19 by the government cannot excuse futility for failing to present  
20 an issue to the government in an earlier action. So the  
21 plaintiffs here presented arguments to the agency in 2019.  
22 They did not present any argument on the basis of Comstock.  
23 They similarly did not present any argument on the basis of  
24 Comstock in 2002.

25 It's quite telling that no party raised the issue

1 of Comstock with the FDA for all of those 22 years following  
2 the agency's approval of mifepristone as suggestion that,  
3 perhaps, it was not the impediment to the agency's action that  
4 plaintiffs suggest it is.

5 But most important is that plaintiffs have not  
6 pointed to a single case in which a subsequent action by the  
7 federal government could excuse an agency requirement to  
8 exhaust an issue before the agency. And, in fact, the case  
9 that plaintiffs cite actually says the opposite, which is that  
10 a subsequent decision by the agency cannot excuse presenting  
11 the issue on the basis of futility.

12 THE COURT: Okay. I have your argument on that.

13 Now, regarding that same category of the Comstock  
14 Act, so the Fifth Circuit, in *Myron vs. Martin*--I believe this  
15 is cited by both parties--670 F.2d 49, the Court there held  
16 that courts can review for the first time a particular  
17 challenge to an agency's decision which was not raised during  
18 the agency where it is contrary to important public policy.

19 So it's been variously referred to during this  
20 hearing as public interest, public policy. So what weight does  
21 the government give to roughly half the states filing an amicus  
22 brief in a post-*Dobbs* environment citing important state  
23 interests and the balance of the federal government and state  
24 police powers? What weight should this Court give to roughly  
25 half the states joining the plaintiffs in arguing that this is

1 a matter of important public policy and, therefore, might be an  
2 exception to exhaustion?

3 MS. STRAUS HARRIS: Your Honor, with respect to  
4 that argument about important public policy, I think it's  
5 important to step back and think about what is the specific  
6 action that the agency took here. What the agency did was  
7 grant pre-market approval to the drug mifepristone in a  
8 particular regimen as safe and effective under certain  
9 conditions. In doing so, the agency did not obligate or  
10 require anyone to prescribe or take mifepristone. It did not  
11 impose any penalty on a person for not prescribing or taking  
12 mifepristone. It simply said, we are giving it our grant of--  
13 that it is safe and effective.

14 And the argument that the states proffer and that  
15 the plaintiffs here also, you know, seem to be agreeing with  
16 today is simply beside the point of the action that the  
17 plaintiffs are challenging. The plaintiffs here--the states  
18 argue that somehow the FDA's determination of safety and  
19 effectiveness imposes some obligation on states or their  
20 residents. But, in fact, it does not. It does not, in that  
21 regard, set any national policy that affects their state  
22 powers. But the plaintiffs are the ones here who are trying to  
23 dictate national policy by asking this Court to withdraw the  
24 agency's determination as to safety and effectiveness.

25 THE COURT: Okay. And I know you mentioned the

1 statutory provision governing citizen petitions. Can you point  
2 the Court to any jurisprudential authority on what sort of  
3 duration constitutes a permissible delay in responding to a  
4 petition?

5           So it is true that both parties come to this Court  
6 citing chronology spanning over two decades, but a portion of  
7 that chronology is attributable to a delayed response to a  
8 petition that sat for sixteen years. So can you point to some  
9 circuit precedent, Supreme Court precedent that advises this  
10 Court on how long that response may be delayed under the  
11 relevant statutes or regs?

12           MS. STRAUS HARRIS: Your Honor, the courts that  
13 have addressed the question of unreasonable delay have done so  
14 when presented with a claim under that provision of the APA,  
15 706(1). Plaintiffs never brought that claim to this court or  
16 any other court with respect to the agency's action,  
17 suggesting, perhaps, that they didn't believe it was an  
18 unreasonable delay at the time. It is incumbent upon the  
19 plaintiffs to assert what government action they believe was  
20 unlawful, and that action was never asserted while the agency  
21 was working to determine the 2002 citizen petition.

22           The case law under that statute shows that there  
23 are a variety of circumstances that a court would consider, and  
24 it is often very fact specific. But plaintiffs here have  
25 simply not presented that question to the Court. They are

1 invoking the delay to suggest that exhaustion should be  
2 excused.

3           The problem is that-- Well, there are several  
4 problems with that. The first is that by sitting on this  
5 decision from the agency for more than six years, plaintiffs  
6 really undercut their suggestion that the delay by the agency  
7 was causing a substantial harm that must be addressed  
8 immediately now, more than six years after that decision by the  
9 agency.

10           But I think the more important point is that the  
11 agency decided the citizen petition more than six years ago, in  
12 March of 2016, more than six years before plaintiffs filed  
13 their suit. They are out of time to challenge that decision.  
14 So it's not a matter of exhaustion; it's a matter of the  
15 statute of limitations.

16           When the plaintiffs presented a separate citizen  
17 petition to the agency in 2019, they did not raise any  
18 arguments to the agency with respect to the initial approval.  
19 In fact, they asked the agency specifically to restore the  
20 conditions under which the agency approved the drug in 2000.

21           So the agency's decision in 2016, for which it is  
22 now also too late for them to bring a new claim-- They never  
23 argued to the agency that that decision should undo the initial  
24 approval, which is what they are asking this Court to do.  
25 Having never raised that to the agency, they can't raise it now

1 to the Court.

2 And if you were to excuse exhaustion, you would  
3 simply get back to the fact that the agency made the decision  
4 more than six years before they filed suit. So excusing  
5 exhaustion, plaintiffs would just run headlong into a statute  
6 of limitations problem.

7 THE COURT: Well, this entire case is something of  
8 a nightmarish law-school question on tolling. I know that's a  
9 more generic phrase. But one party has a backward tolling  
10 problem under reopening doctrine and various administrative law  
11 theories. Another party has a forward-looking sort of approval  
12 action tolling problem. Specific to pediatric care, the  
13 pediatric rule starts at this time; then it's incorporated by  
14 reference into PREA, and then REMS, and then ETASU.

15 So what is your best case on the reasonableness or  
16 unreasonableness of the delay for that 16-year period? I  
17 understand all the parties have briefed to this Court various  
18 intervals and where lines can be drawn. But from 2016 back to  
19 2000, what the plaintiffs have termed the 2016 major changes,  
20 what is your best argument explaining the delay for that  
21 16-year interval for the pendency of that original petition?

22 MS. STRAUS HARRIS: Just to be clear on the record,  
23 the citizen petition wasn't filed until 2002, and the agency's  
24 decision on that petition was in 2016.

25 THE COURT: Fourteen years. I'm sorry. Fourteen



1 years, not sixteen. You are correct.

2 MS. STRAUS HARRIS: So I--rather than pointing to a  
3 particular case, I will say that the problem is really one of  
4 plaintiffs' own inaction. There are remedies that federal law  
5 allows for a party that believes that they have been harmed by  
6 an agency's delay, and the plaintiffs didn't invoke that--  
7 those remedies in a timely way. They could have referenced the  
8 delay before the agency issued its decision.

9 And that is actually similar to the *Bracco* case  
10 that the plaintiffs cite. There, the Court found that the  
11 irreparable harm that would accrue to the plaintiffs in that  
12 case excused the plaintiffs' obligation to complete an  
13 administrative process that they had begun but that the agency  
14 had not yet concluded.

15 But that's not the situation here. The plaintiffs  
16 here let the agency complete its process, however long that  
17 took. Plaintiffs had mechanisms before then to go in, and they  
18 did not invoke those. And then once the agency made that  
19 decision, the plaintiffs had six years to challenge it. They  
20 could have challenged it perhaps on the basis that the agency  
21 took too long and maybe there was some impropriety there, but  
22 they didn't do that.

23 And it's not really argued here that the delay,  
24 like, exposed some other impropriety. They just are arguing  
25 that the delay in that decision should excuse exhaustion for a

1 later argument that they didn't make or should somehow allow  
2 the Court to reopen the original decision.

3 But because they have sort of two fatal defects in  
4 their claim laid on top of each other, they do not satisfy an  
5 excuse for the exhaustion requirement, and they are too late to  
6 bring their claims in the first instance. They simply can't--  
7 they simply haven't offered a basis for the Court to do what  
8 they are asking it to do in terms of revisiting that original  
9 decision.

10 THE COURT: Okay. And I took it from your  
11 introduction that Mr. Schwei is going to address whether this  
12 decision-making was committed to agency discretion and the  
13 *Heckler* line of cases?

14 MS. STRAUS HARRIS: Yes, he will.

15 THE COURT: So I'll reserve those cases for  
16 Mr. Schwei.

17 MS. STRAUS HARRIS: Thank you, Your Honor.

18 THE COURT: You may continue.

19 MS. STRAUS HARRIS: Yes. I'll turn now to  
20 plaintiffs' standing.

21 So plaintiffs assert several bases on which they  
22 argue that they have standing. As to the organizational  
23 plaintiffs, plaintiffs cannot proceed on an associational  
24 standing theory for the same reasons which I'll discuss in a  
25 moment, that none of their complaining physicians have alleged

1 injury for standing purposes.

2 But I'll talk now about specifically organizational  
3 standing, their organizational standing theory. The problem  
4 with their organizational standing theory arguments is that  
5 they have simply not alleged the type of diversion of resources  
6 that's necessary to satisfy Article III. And the separate  
7 informational injury that they allege in the briefing, but I  
8 don't think was discussed much today, is not cognizable. And  
9 absent a cognizable injury, in fact, there is no irreparable  
10 harm.

11 As to diversion of resources, the plaintiffs focus  
12 on the language about needing to identify specific projects to  
13 which they would be spending their resources but the resources  
14 would have allegedly been diverted. And--

15 THE COURT: And I think that specific projects  
16 terminology comes from the Fifth Circuit--

17 MS. STRAUS HARRIS: Yes.

18 THE COURT: --itself. That's the terminology that  
19 they use for this diverted resource concept.

20 MS. STRAUS HARRIS: Yes. Correct.

21 I think the problem with thinking about how  
22 plaintiffs have pled their claim and the allegations that they  
23 have asserted as relates to diversion of resources is that  
24 while, in the briefing, the parties might have focused on this  
25 language about there's not a need to identify specific

1 alternative projects, the problem here is that the plaintiffs  
2 have not identified specific--have not identified sort of an  
3 overarching mission projects that they generally engage in that  
4 are different from the activities to which they claim they have  
5 diverted their resources here.

6           What I mean by that is that they allege to have  
7 diverted resources to activities that are right in the  
8 wheelhouse and right within the basic mission of the  
9 organization. They speak about needing to educate physicians,  
10 their physician members, educate the public or, you know,  
11 potential plaintiffs about the harms of abortion generally, and  
12 they speak specifically about mifepristone. But that is  
13 specifically the mission, as they describe their own mission in  
14 the declarations that they provide.

15           I'll just give one example here of the alignment  
16 between what they claim to have diverted their resources to and  
17 what they say is their specific--the core of their mission.  
18 The ACOP group, A-C-O-P, says that its purpose is to educate  
19 doctors, their patients, and the public about dangers of  
20 chemical abortion. This is in ECF Number 1-7 at 6. But then  
21 they complain that they are spending resources on their, quote,  
22 public advocacy and educational activities, exposing the risk  
23 of harm to women from FDA's unlawful approval and deregulation  
24 of chemical abortion drugs. That's in ECF Number 1-7 at 6  
25 to 7.

1           They are perfectly aligned. So there's simply no  
2 diversion of resources here. The activities that they have  
3 engaged in, including preparation of citizens petition and the  
4 educational efforts, are right within the core of their  
5 mission.

6           THE COURT: So I take your argument to be, on  
7 diverted resource concepts, if the Court ascertains that an  
8 identifiable specific project also allies with an item listed  
9 in the core mission statement of the organization, if those  
10 lists match-- Here's yet another matching problem. If those  
11 match, we don't have the sort of diversion of resources that  
12 would allow for organizational standing. Is that basically the  
13 government's argument?

14           MS. STRAUS HARRIS: Generally. It's that the--if  
15 the agencies--if the activities that the agency claims it is  
16 engaging in by virtue of the agency action that they are  
17 challenging are the very activities that the agency describes  
18 as their core activities generally, there's no diversion of  
19 resources for the purposes of organizational standing.

20           THE COURT: Okay. I have your argument on that.

21           And then I could not find Fifth Circuit authority  
22 on whether a citizens petition is like a complaint that is  
23 often prepared in litigation, other filings that are submitted  
24 to the district court, or whether a citizen petition, for some  
25 sort of regulatory compulsion reason, may be counted as a

1 diverted resource event. What's the government's position on  
2 that?

3 MS. STRAUS HARRIS: Your Honor, I don't believe  
4 that there is specific Fifth Circuit authority on that. I do  
5 think that what's relevant here is why the mechanism of the  
6 citizen--how the mechanism of the citizen petition fits into  
7 the overall structure of the agency action and judicial review  
8 here.

9 The agency regulations require submission of a  
10 citizen petition as a precursor to judicial review. And in  
11 that regard, it is the very definition of a prelitigation  
12 activity, because it is a necessary precursor to bringing an  
13 action in court.

14 And in that way, the plaintiffs here, by filing  
15 citizens petitions, are directly aligned with the plaintiffs in  
16 the *City of Kyle* case that the Fifth Circuit described--the  
17 Fifth Circuit decided that case but also describes that case in  
18 the *OCA-Greater Houston* case in contrasting why the plaintiffs  
19 in the *City of Kyle* case lacked organizational standing but the  
20 *OCA-Greater Houston* plaintiffs possessed it.

21 THE COURT: Okay. Thank you for that  
22 clarification. I understand the government's argument on that.  
23 You may continue.

24 MS. STRAUS HARRIS: Sure. I'll move now to the  
25 individual physicians' standing arguments, which would also

1 underlie their associational standing arguments.

2           Here, no individual physician plaintiff or  
3 association member has standing for at least three fundamental  
4 reasons. The first is that a past exposure to harm cannot  
5 support standing to obtain prospective injunctive relief. This  
6 is clear from the *City of Los Angeles vs. Lyons* case from the  
7 Supreme Court. And the allegations that plaintiffs present in  
8 the declarations all relate to past examples of times when  
9 individual physicians allegedly experienced harm by virtue of  
10 the agency's action.

11           The second reason they lack standing is because  
12 continuing or threatened future effects must be certainly  
13 impending, and allegations of possible future injury, including  
14 what the Supreme Court has called a someday injury, are not  
15 sufficient. And here, I refer the Court specifically to the  
16 *Clapper* case from the Supreme Court.

17           The plaintiffs' argument that they have standing on  
18 this basis is based on what they call the likelihood of  
19 complications from a patient consuming mifepristone. This is  
20 at ECF Number 120 at 13. But this idea, the likelihood of  
21 complications, runs counter to the clear precedent as explained  
22 in *Clapper*.

23           And specifically, the Supreme Court, in *Clapper*--  
24 and this is at pincite 410 of that case--explained that an  
25 objectively reasonable standard is inconsistent with the

1 requirement to show that threatened injury must be certainly  
2 impending to constitute injury in fact.

3 But that objectively reasonable standard is  
4 precisely what plaintiffs seek to rely on here. They are using  
5 sort of a statistical argument or a likelihood argument to  
6 suggest that their members could be forced to care for a  
7 patient experiencing complications. And the "could be forced"  
8 language comes, for example, from ECF Number 1-5 at 13, but it  
9 appears in several of their declarations.

10 This is an argument that, on the basis of, really,  
11 the law of large numbers, they are likely to experience harm.  
12 And that's precisely the type of objectively reasonable  
13 standard that the Supreme Court has said does not suffice to  
14 establish standing in *Clapper*.

15 THE COURT: And you mentioned a third reason.

16 MS. STRAUS HARRIS: The third--yes, thank you, Your  
17 Honor--is that any alleged injuries must be fairly traceable to  
18 the challenged action of the defendant and not the result of  
19 the independent action of some third party that's not before  
20 the Court.

21 And here, the plaintiffs' contention is that they  
22 would be injured in some roundabout way because a different  
23 doctor would prescribe mifepristone to a patient; that patient  
24 would experience an adverse event; that patient would then seek  
25 care from one of the physicians that's complaining in this



1 case; and then that complaining physician would have to divert  
2 their time and resources from other patients; that they may  
3 then be subjected to some sort of liability exposure or  
4 increased insurance costs and maybe cause them some--what they  
5 allege are emotional--is emotional harm.

6 THE COURT: Okay. I wanted to give you your  
7 15-minute warning. And then I've got your arguments on  
8 post-exposure, future effects, and then traceability. I wanted  
9 to ask a follow-up question. It might need to go to defendant  
10 intervenor. But I already addressed this during plaintiffs'  
11 argument-in-chief that Justice Alito, interpreting *Powers v.*  
12 *Ohio*, that the second prong of third-party standing, which  
13 requires the litigant to have a close relationship, might need  
14 to be reevaluated in light of the actual facts of abortionist/  
15 patient relationships. Specifically in *June Medical*, in his  
16 dissent, he says: A woman who obtains an abortion typically  
17 does not develop a close relationship with the doctor who  
18 performs the procedure. On the contrary, their relationship is  
19 generally brief and very limited.

20 Obviously this is written in dissent. This hasn't  
21 been dogmatized in any sort of new rule or exception to  
22 third-party standing.

23 If a doctor doesn't have a close relationship with  
24 the patient, how can that possibly reconcile with the cases  
25 finding third-party standing in so many other abortion cases?

1 So beginning in 1973, moving forward, we don't see litigants  
2 struggling to establish third-party standing in *June Medical*,  
3 the *Whole Woman's* line of cases. So what is the Court to take  
4 from intervenor's argument that we don't have the requisite  
5 close relationship between doctor and patient?

6 MS. STRAUS HARRIS: Your Honor, I'll point the  
7 Court specifically to what the Supreme Court--the majority in  
8 *June Medical* did find was the basis for third-party standing,  
9 because that is the governing rule at this time. And in that  
10 case, the Court found that on the basis of a very specific set  
11 of factual circumstances that are not present here, that there  
12 was third-party standing for the physicians.

13 The laws at issue in that case directly regulated  
14 the physicians themselves and imposed criminal penalties that  
15 ran directly against the physicians. Here, the physicians are  
16 not, themselves, regulated by FDA, and there is no criminal or  
17 civil penalty that flows to them from the agency. They also  
18 don't purport to prescribe the drug, the approval of which they  
19 challenge here.

20 Second, in *June Medical*, it is very relevant to the  
21 Court's decision and important to the Court's decision was that  
22 the plaintiff physicians and the patients in that case had  
23 interests that were directly aligned. The physicians there  
24 wanted to provide a specific type of care, and the patients  
25 there wanted to receive that specific type of care. And so the

1 patients that were at issue there actively wanted and were  
2 deprived of the exact same thing that the physician plaintiffs  
3 there actually wanted and were deprived of, and that was what  
4 the relief sought.

5 The plaintiffs here seek to prevent access to a  
6 form of health care that the group of affected patients wants  
7 to receive. And so their interests are not only unaligned, but  
8 they are actually diametrically opposed.

9 That is the governing law on third-party standing  
10 that, you know, must govern this case. And we argue, on the  
11 basis of this case, it's clear that the plaintiffs have not  
12 established that third-party standing would apply here.

13 THE COURT: Okay. And then briefly back to your  
14 second argument on associational standing, what you have termed  
15 and, I think, other circuit courts have used the language of  
16 the prospective someday injury. With mail-in abortion now  
17 approved under the FDA actions at issue, does the government  
18 assert that it continues to be unlikely that plaintiff  
19 physicians will be harmed in the way described in the  
20 complaint, in the declarations? Now that that mail-in protocol  
21 has been approved by agency action, how should this Court apply  
22 *Lyons*, L-y-o-n-s, to that future harm or someday-injury  
23 inquiry? Is that a game-changer for that particular  
24 associational argument now that that intervening event has  
25 occurred, or are you still arguing that these are the sort of

1 someday injuries that are noncognizable under the PI standards  
2 that we must apply?

3 MS. STRAUS HARRIS: Your Honor, these are still the  
4 same sort of someday harms, potential someday harms that are  
5 not sufficient. And the reason for that--

6 THE COURT: So *Clapper*--your *Clapper* argument still  
7 applies?

8 MS. STRAUS HARRIS: *Clapper* still applies. The  
9 agency, in its recent--more recent decisions adjusting the  
10 conditions under which--the conditions that would apply to the  
11 approval of mifepristone, in doing so, the agency's  
12 determination was that the use of mifepristone for a  
13 termination of intrauterine pregnancy was safe and effective  
14 under the different conditions that they--you know, the change  
15 in the conditions that they implemented with that recent  
16 decision.

17 The prior decision had been that, similarly, the  
18 drug was safe for that indication under certain conditions.  
19 The agency determined that the conditions--those conditions  
20 could change but didn't--but in order to do that, the agency  
21 determined that the safety and effectiveness would be  
22 maintained with a different set of conditions.

23 And in that regard, the agency's decision doesn't  
24 actually alter the idea that, while there--you know, like  
25 with--when the agency--when the FDA approves a drug as safe and

1 effective, it is not making a determination that no patient  
2 will ever experience a complication from that drug. That's not  
3 what the standard is that's applied. And that continues. They  
4 have simply determined that these new conditions maintain the  
5 requisite safety and effectiveness.

6 So plaintiffs here have not suggested that there  
7 would be some--they don't have a basis for saying--a basis in  
8 fact or in past experience for saying that their harms would  
9 certainly inure to them under these current conditions.

10 THE COURT: But understanding, from *Clapper* and  
11 other cases, that you can't just do a probabilistic analysis  
12 and throw statistics at the Court to prove the necessary harm,  
13 here, we have intervening events that might have changed some  
14 of the probabilities. So in 2000, we have all of the in-person  
15 dispensation requirements, the follow-up visits. Moving into  
16 2016, those are suspended or removed, and then now we have a  
17 mail-in option that's available.

18 When there isn't this intervening physician  
19 monitoring on the back end or on the dispensation side, does  
20 that not alter your analysis of whether those harms are purely  
21 speculative? Now that there's a regime by which this  
22 medication can be distributed, absent end physician  
23 dispensation and absent subsequent visits for monitoring, does  
24 that not change the calculation on what is and isn't  
25 speculative?

1           When things were monitored by doctors in each  
2 instance, I can see where, you know, just playing the law of  
3 averages isn't inadequate under *Clapper* and other cases, but  
4 doesn't mailing and the removal of that conduit of a physician  
5 change those laws of averages, and is that the sort of delta  
6 that this Court may consider in considering whether alleged  
7 harms are speculative?

8           MS. STRAUS HARRIS: It doesn't change that the  
9 plaintiffs are still relying on a law of averages. There may  
10 be-- I do not concede that there's any change in the  
11 likelihood of complications that may occur. But if you were to  
12 credit plaintiffs' suggestion that there are, they are still  
13 relying on statistics, and the Supreme Court has been  
14 completely clear that that is not a sufficient basis to find  
15 standing. So they don't--the Supreme Court doesn't draw a line  
16 in saying, well, if the probability is this amount versus this  
17 amount, when you're relying on the law of averages, then you  
18 have reached standing. They say definitively that you cannot  
19 rely on an objectively reasonable standard such as that.

20           THE COURT: Okay. And the declarations attached to  
21 the complaint and part of the record are inadequate to allege  
22 particular harm because these are past exposures to harm, and  
23 that's argument number one. Correct?

24           MS. STRAUS HARRIS: Yes. And I'll just add one  
25 additional point, which is that the FDA approved this drug as

1 safe and effective for use more than two decades ago. And  
2 plaintiffs assert that they have members throughout the  
3 country, thousands of members. The plaintiffs' declarations  
4 cite just a handful of examples of situations in which they  
5 allege to have experienced harm from this.

6           And over that full amount of time, there's just a  
7 tremendous body of evidence and experience showing that, in  
8 fact, the numbers are not likely to create the overwhelming  
9 sort of burden on their practice or on the healthcare system  
10 that they allege is there. That's simply belied by the number  
11 of examples that the thousands of members of plaintiffs groups  
12 could even amass.

13           THE COURT: I know you're well acquainted with the  
14 Courts of Appeal. Unfortunately we don't have the light  
15 system; red, yellow, green. So you are now at your 5-minute  
16 warning.

17           MS. STRAUS HARRIS: I'll turn then to public  
18 interest.

19           THE COURT: You may proceed.

20           MS. STRAUS HARRIS: Before I say public interest,  
21 I'll just note that all of the arguments that I've made with  
22 respect to standing go to irreparable harm. And to the extent  
23 that a party has not alleged injury for standing purposes, they  
24 certainly have not alleged the requisite harm, irreparable harm  
25 that's necessary to invoke the Court's powers to grant a

1 preliminary injunction. So for that reason, the relief that  
2 they seek is not warranted here.

3           Turning to the public interest, an injunction here  
4 would interfere with the interests of every state in the  
5 country, for in every state, since 2000 and through today,  
6 abortion is lawful under circumstances where mifepristone may  
7 be the best treatment option, including cases of fetal  
8 nonviability or cases of a pregnancy resulting from rape. It  
9 may differ, the circumstances, from state to state, but every  
10 state has an allowance under which mifepristone would be  
11 lawfully used in that state.

12           The public interest here would be dramatically  
13 harmed by effectively withdrawing from the marketplace a safe  
14 and effective drug that has lawfully been on the market for  
15 22 years. And the public interest is paramount when an  
16 injunction would deprive the public of an important medical  
17 benefit. That's from the *Pharmacia Corporation vs. Alcon Labs*  
18 case that we cited.

19           Removing access to mifepristone would cause worse  
20 health outcomes for patients who rely on the availability of  
21 the drug to safely and effectively terminate their pregnancies,  
22 including, as I noted, cases of fetal nonviability or rape  
23 victims.

24           And our declarants cite examples of this. The  
25 Kieltyka declaration, the Lindo declaration, the Glaser



1 declaration are just some examples citing cases where the  
2 specific medical indication for mifepristone is based on a  
3 patient's unique needs that cannot be satisfied as well by a  
4 different option for that plaintiff.

5 THE COURT: Okay. I take that as your response to  
6 the 22 states that have filed an amicus brief supporting the  
7 plaintiffs in this case. This isn't an instance where we're  
8 comparing 22 to 28, but instead, that there's an overarching  
9 public policy interest in all 50, because, in some of those  
10 earlier term procedures, this drug would affect all 50 states?

11 MS. STRAUS HARRIS: Precisely. There is an  
12 interest throughout the country.

13 THE COURT: Okay. You may proceed.

14 MS. STRAUS HARRIS: A preliminary injunction here  
15 would also undermine the capacity of state healthcare systems,  
16 because it would lead to overcrowding and delays at both  
17 surgical abortion clinics, and also general practitioners who  
18 would be servicing patients. And the Lindo declaration  
19 provides evidence for this.

20 An injunction would interfere with the reliance  
21 interests of businesses that are involved in the sale and  
22 distribution of mifepristone. But, more generally, it would  
23 leave pharmaceutical companies unable to confidently rely on  
24 FDA approval decisions to develop the pharmaceutical drug  
25 infrastructure that Americans depend on to treat a variety of

1 health conditions.

2           Finally, a preliminary injunction would interfere  
3 with Congress's decision to entrust the FDA with the  
4 responsibility to make determinations about the safety and  
5 effectiveness of drugs. And allowing the plaintiffs to  
6 supplant the FDA's considered judgment here with their cursory  
7 and speculative allegations of harm would undermine the  
8 administrative framework that Congress designed for the  
9 pre-market approval of pharmaceutical drugs.

10           I'll note specifically, as to public interest, if  
11 the Court grants the relief that plaintiffs seek, there will be  
12 a significant disruption. There have been reports that some  
13 providers may have begun considering taking alternative actions  
14 to ensure lawful access in the event that this Court grants the  
15 relief that plaintiffs seek. Indeed, one of our declarants,  
16 Maine Family Planning, has articulated publicly that it started  
17 considering an alternative protocol. But even as to Maine  
18 Family Clinic, they make clear that it's unclear to them  
19 whether such a protocol would be practical or available if the  
20 Court entered an adverse order.

21           What we know for certain is that even if there were  
22 an alternative protocol, an order along the lines that  
23 plaintiffs seek would significantly disrupt lawful access,  
24 access that is lawful under certain circumstances in every  
25 state in the country.

1 THE COURT: Okay. And, Ms. Straus Harris, you are  
2 at the close of your time. Thank you for your argument.

3 At this time, I'll invite Mr. Schwei to approach  
4 the podium. And for time management, I do intend to ask  
5 questions on the *Heckler* line of cases, and then also what was  
6 revealed today as a textual statutory argument that plaintiffs  
7 present construing Subpart H. So if we reach a point, I may  
8 interrupt for those questions.

9 You may proceed.

10 MR. SCHWEI: Understood, Your Honor. And just one  
11 housekeeping matter. My name is pronounced actually Schwei,  
12 so--

13 THE COURT: Schwei. Okay. With my last name, I'm  
14 sensitive to mispronunciations, so I apologize for that.

15 MR. SCHWEI: I appreciate that, Your Honor.

16 THE COURT: Mr. Schwei, you may proceed.

17 MR. SCHWEI: Thank you.

18 The FDA has approved mifepristone for medication  
19 abortion for over two decades based on extensive scientific  
20 data confirming the drug's safety and efficacy. Plaintiffs now  
21 seek to overturn the FDA's expert judgments, contrary to  
22 fundamental principles of administrative law.

23 Plaintiffs' case is built upon portraying  
24 mifepristone as a dangerous, unproven drug. But as FDA has  
25 repeatedly explained, that is simply not true. The current

1 label for mifepristone highlights that it is extremely  
2 effective. In U.S. trials, the success rate is over  
3 97 percent. And in terms of safety, serious adverse events are  
4 rare. Hospitalization related to medical abortion occurs in  
5 less than one percent of all cases.

6 Plaintiffs now ask this Court to second-guess FDA's  
7 judgments, arguing that the numerous studies relied upon by FDA  
8 simply were not good enough. But there is absolutely nothing  
9 in the Food, Drug and Cosmetic Act limiting the Secretary's  
10 discretion to approve drugs only when the clinical trials are a  
11 perfect match to the full set of approved conditions.

12 And I think, with that, I'll turn directly into the  
13 plaintiffs' arguments about the FDCA, because I think this  
14 Court asked them a question to capture essentially the thrust  
15 of their argument, which is, are they claiming that there needs  
16 to be a one-to-one match between the protocols in the clinical  
17 trials and the ultimate set of conditions approved by FDA.

18 And their answer was, yes, there needs to be an  
19 identical set of conditions, but there is nothing in the  
20 statute that can plausibly be read as imposing such a mandate.  
21 And I think turning to the actual text of 355(d) underscores  
22 that.

23 First, as the Court noted, the very first words of  
24 355(d) are, quote, if the Secretary finds. That is a  
25 delegation of discretion to the Secretary for him or her to

1 make fact finding. It is a grant of wide discretion, not a  
2 ministerial duty simply to compare, are these conditions  
3 exactly the same as what was in any of the clinical trials.

4 And if you go beyond even just the opening  
5 language, it becomes even more clear--

6 THE COURT: Let's stay with that first sentence on  
7 that opening language. So during the plaintiffs'  
8 argument-in-chief, I read aloud that exact opening sentence and  
9 focused on the word "finds." And from what I can ascertain,  
10 plaintiffs allege that that finding was made in Attachment 124,  
11 which is the FDA letter dated February 18, 2000.

12 Are those findings not adverse to your argument as  
13 applied to the subparts that follow? In other words, has that  
14 finding not happened in a way that supports plaintiffs'  
15 argument?

16 MR. SCHWEI: I think the finding here is that  
17 mifepristone is safe and effective under the conditions  
18 imposed. It depends obviously on, you know, what moment in  
19 time we're talking about. But, I think, regardless of what  
20 moment in time, it's the finding under 355(d) that it's safe  
21 and effective under the conditions imposed.

22 But to understand what that finding means, it  
23 requires looking at the various subparagraphs within 355(d).  
24 The ones relevant here all confirm that there's no mandate for  
25 an identity of clinical trials and ultimate conditions

1 approved.

2 THE COURT: And here, the plaintiffs identified  
3 with particularity subpart (1), which is what I'll call the  
4 adequate test; subpart (2), which relates to tests showing the  
5 drug is unsafe for use, or do not show that it's safe, kind of  
6 a floor-ceiling concept; and then Subpart (4), which I called  
7 particular attention to the "any other information" language.

8 If you could just respond to plaintiffs' arguments  
9 that these subparts in particular give this Court authority to  
10 order either suspension or withdrawal and that these subparts  
11 support their case that that work was not done by statutory  
12 mandate.

13 MR. SCHWEI: Certainly, Your Honor. So with  
14 respect to paragraph (1), I think Your Honor highlighted the  
15 important language. It's about whether the investigations  
16 include adequate tests by all methods reasonably applicable.  
17 That language cannot be understood as requiring every single  
18 protocol to match perfectly. That language, again, is  
19 consistent with the grant of discretion to the Secretary to  
20 determine, are these studies sufficient to make the finding I  
21 need to make under 355(d).

22 I would note that the only case cited in  
23 plaintiffs' PI motion about this is the Seventh Circuit's  
24 decision in *United States vs. One Article--or One Device of*  
25 *Diapulse*. And that case itself confirms that plaintiffs'

1 argument is wrong, because there, the Seventh Circuit framed  
2 the inquiry as simply whether the studies were, quote, similar  
3 to the ultimate conditions imposed. And so whatever the--  
4 whatever the studies show, plaintiffs' argument that there  
5 needs to be a one-to-one match cannot be correct, even under  
6 their own cited authority.

7 But returning to the statutory text,  
8 subparagraph (2) talks about, quote, the results of such tests.  
9 So, again, it's a delegation of authority to the Secretary to  
10 interpret the results. It's not simply the Step One imposition  
11 of, are the clinical trials the same. It's Step Two, are the  
12 results adequate to support a finding.

13 And then in subparagraph (4), I think Your Honor  
14 again highlighted the key language, which is, the first part of  
15 it acknowledges that the Secretary can make a decision upon the  
16 basis of the information submitted to him as part of the  
17 application, which would include all of the clinical trials.  
18 But then it goes on to say, or upon the basis of any other  
19 information before him with respect to such drug.

20 THE COURT: So I think the parties are in agreement  
21 that the record accurately reflects the first part, the  
22 information that was submitted as part of the application. I  
23 asked a specific question on what that second part, after "or,"  
24 that "any other information." How would the government  
25 construe that language and how that defeats plaintiffs'

1 argument that they can continue to review and not necessarily  
2 match all the clinical conditions and preconditions  
3 study-by-study in the sort of apple-orange way described by  
4 plaintiffs?

5 MR. SCHWEI: I think that language disproves  
6 plaintiffs' argument about there needing to be a one-to-one  
7 match, because if that was the sole inquiry, the only  
8 information the Secretary would need is in that first part  
9 about the information submitted as part of the application.  
10 And so the fact that the Secretary can consider additional  
11 information proves that Congress was not contemplating a  
12 mandate of just asking a simple question, is there a one-to-one  
13 match.

14 And then I also want to point out subparagraph (5),  
15 which talks about substantial evidence. And this is again a  
16 long paragraph of statutory text, but the term "substantial  
17 evidence" is later defined, and it includes an acknowledgement  
18 that data from one adequate and well-controlled clinical  
19 investigation may be sufficient to establish effectiveness  
20 under the substantial evidence standard.

21 And the terms "adequate and well-controlled  
22 clinical investigation" are terms of art within the FDCA. They  
23 are defined by regulation at 21 CFR 314.126. And there's an  
24 extensive list of what must be shown for a clinical trial to be  
25 adequate and well-controlled, and that requirement is not



1 simply a one-to-one match. And so their statutory argument  
2 here on the FDCA has to be wrong based on the text of 355(d)  
3 and their own case.

4 I read the PI motion as presenting solely a  
5 statutory argument. I think they try to build in some level of  
6 arbitrary and capricious review in response to the Court's  
7 question, but even if that claim is properly presented, it  
8 would have to be an extraordinarily deferential type of review,  
9 given that what is essentially at issue is FDA's scientific  
10 judgment. And I think each of the issues that they flag as  
11 warranting that type of review just demonstrate how in the  
12 weeds they are trying to second-guess FDA's expert judgments.

13 And one that I'd like to touch on, because the  
14 plaintiffs discussed on it this morning, is the imposition of  
15 an ultrasound requirement. They say that the clinical trials  
16 required an ultrasound but the ultimate conditions imposed by  
17 the Secretary did not.

18 As a factual matter, that's not correct. There  
19 were three clinical trials at issue supporting the 2000  
20 approval of the drug. The two French clinical trials actually  
21 did not require an ultrasound. Only one of the three clinical  
22 trials did require an ultrasound. And the cite for that  
23 proposition is ECF Number 1-28 at page 19, footnote 47.

24 But in any event, setting aside their argument as  
25 just wrong, FDA specifically addressed this issue and explained

1 why they did not need to impose an ultrasound requirement. In  
2 the 2000 approval memorandum, they note that they had carefully  
3 considered the issue but that they noted in the clinical trial  
4 where, in order to gain certain data, it was really important  
5 to use the ultrasound. In practice, other clinical methods are  
6 adequate for dating gestational age and diagnosing an ectopic  
7 pregnancy.

8           And I think the way plaintiffs have framed this  
9 issue as, FDA simply imposed no requirements at all-- But  
10 that's not accurate. FDA still required as one of the  
11 conditions that prescribers must be able to accurately diagnose  
12 the gestational age and be able to diagnose ectopic  
13 pregnancies. The only thing that FDA did was leave it up to  
14 each individual prescriber's judgment about how exactly to do  
15 that. And so sometimes, that might require an ultrasound, but  
16 other times, it might not.

17           And again, the fact that we are at this level of  
18 minutia of the protocol highlights how this is far from  
19 arbitrary and capricious review, which simply requires the  
20 agency to adequately explain its reasoning, which they did  
21 here.

22           My colleagues also mentioned the *Serono Labs*  
23 decision as perhaps supporting this Court's ability to make  
24 safety and efficacy decisions. I appreciate their candor that  
25 it was not cited in the briefs, and so I say that only to say

1 that I'm not 100 percent familiar with the decision at this  
2 moment, but--

3 THE COURT: I'll afford you the same courtesy, by  
4 the way. If you have found good case law in these intervening  
5 days and weeks, you may submit them to the Court. It's not  
6 like the Fifth Circuit where you have to file a 28(j) letter or  
7 anything like that. Just let me have it. So I afforded them  
8 the courtesy to go beyond the four corners of the briefing. If  
9 there's any additional authority, you may present that to the  
10 Court and it will be considered, so--

11 MR. SCHWEI: I appreciate that, Your Honor. I  
12 would just note that on *Serono Labs*, as best I can tell in this  
13 moment, that decision appears to have been vacated by the  
14 D.C. Circuit. Vacatur appears at 158 F.3d 1313. So I don't  
15 think the decision stands for much of anything relevant here.  
16 But as I understand it, that case arose in the context of  
17 generic drugs and the separate approvals under 355(j).

18 And so the types of questions that the agency is  
19 answering in connection with approval of a generic drug, about  
20 whether the ingredients match the brand-name drug, that's far  
21 afield from the type of safety and efficacy decision that  
22 plaintiffs are challenging here, and so I don't think it  
23 supports their claim here. So whether it's a statutory or  
24 arbitrary and capricious claim, I don't think they have  
25 established any cognizable violation of the Food, Drug and

1 Cosmetic Act.

2 And I'll turn now to Subpart H, unless the Court  
3 has questions on the FDCA.

4 THE COURT: Please proceed with that next part.

5 MR. SCHWEI: Thank you, Your Honor.

6 So with respect to Subpart H, I think the most  
7 practically relevant thing here is that none of it really  
8 matters, because in 2007, Congress enacted a law that took  
9 mifepristone's approval out of the Subpart H framework.  
10 Congress deemed mifepristone to have a REMS, directed that REMS  
11 to continue, mandated that the parties submit--or that the  
12 manufacturer submit a proposed new REMS. They did, in fact, do  
13 that. The agency approved that new REMS. And since 2007,  
14 since that time period, everything regarding mifepristone's  
15 approval has been governed under REMS.

16 So even assuming, hypothetically, that there was  
17 some violation of--or some improper invocation of Subpart H  
18 initially, that error is clearly harmless in light of the new  
19 statutory framework.

20 THE COURT: And I have that argument and, as I have  
21 described, these sort of chain-reaction, domino events and this  
22 sort of law review, law school-type tolling question where both  
23 parties are sort of sequencing different events to retain their  
24 authority to decide or litigate a question. So I have that  
25 part of it, but let's go back to the hypothetical.

1           So assuming this Court must decide whether  
2 Subpart H was violated in any statutory way, that section, that  
3 Subpart H refers to serious and life-threatening terms. And  
4 the 1988 rulemaking explained that life-threatening disease or  
5 condition is, quote, defined as one in which the likelihood of  
6 death is high unless the course of the disease is interrupted.

7           They cite as an example progression from  
8 asymptomatic HIV infection to symptomatic HIV infection. Of  
9 course, HIV treatments are part of the reasons for this  
10 accelerated process under Subpart H. That's all codified at  
11 53 Federal Register at 41517.

12           Is this initial rulemaking and those definitions  
13 consistent with how defendants would ask this Court to  
14 interpret Subpart H if the Court must answer the statutory  
15 challenge? Is the determination first reached through the 2000  
16 approval and every FDA agency action since that? How would you  
17 reconcile the listing of mifepristone and what indications are  
18 prescribed for that with this definition, which preceded that  
19 2000 approval in a 1988 rulemaking?

20           MR. SCHWEI: Your Honor, I think there are a couple  
21 of parts to the Court's question. One is, is pregnancy a  
22 serious or life-threatening condition, and I think the answer  
23 is yes, as FDA explained. Pregnancy is not life-threatening  
24 for everyone, to be sure, but the important thing is that for  
25 some patients, it can be life-threatening. And there's no

1 requirement that a condition be life-threatening for everyone  
2 in which it presents, but FDA specifically noted the conditions  
3 of preeclampsia and eclampsia potentially developing that can  
4 threaten a pregnant person's life.

5           But then-- And I don't take plaintiffs really to  
6 be challenging whether pregnancy is serious or life-threatening  
7 for at least some patients. I think their challenge on  
8 Subpart H relates to the regulation's use of the word "illness"  
9 and not "conditions." And I think, looking at the NPRM and the  
10 final rule in appropriate context, it becomes clear that  
11 Subpart H encompasses life-threatening conditions regardless of  
12 whether they would colloquially be called illnesses.

13           And just to walk through the regulatory history of  
14 that, in the notice of proposed rulemaking, FDA listed some of  
15 the diseases and conditions that they thought would qualify.  
16 Some of those are things like HIV or cancer that sort of easily  
17 fall within the bucket of diseases or conditions. But some--

18           THE COURT: Could you give me a citation for that  
19 NPRM?

20           MR. SCHWEI: Yes, Your Honor. 57 Federal Register  
21 at 13235.

22           THE COURT: Okay. You may proceed.

23           MR. SCHWEI: And in addition to things like HIV and  
24 cancer, they also listed things like asthma, depression,  
25 psychosis, which perhaps not everyone considers to actually be

1 an illness. And, in fact, during the notice and comment  
2 period, one commenter challenged whether depression and  
3 psychosis were actually diseases that properly fall within  
4 Subpart H.

5 And FDA's response was that it doesn't really  
6 matter how people think of them, as whether they are diseases  
7 or conditions. They clearly fall within Subpart H. And this  
8 is at 57 Federal Register 58946. FDA states: Drugs for the  
9 treatment of depression and psychosis would be examples of  
10 those that could be covered by the accelerated approval  
11 program, referring to Subpart H. And later in the final rule,  
12 at page 58948, FDA says, quote: The drug in question must be  
13 for a serious or life-threatening condition and must provide  
14 meaningful therapeutic benefit over existing therapy.

15 And so I think the preamble here, read in context,  
16 does demonstrate that, regardless of how the term "illness" is  
17 colloquially used, things like pregnancy can be encompassed  
18 within that. And that's also consistent with FDA's regulation  
19 of other drugs under Subpart H.

20 In 2008, the Government Accountability Office  
21 undertook a review of FDA's approval of mifepristone under  
22 Subpart H and concluded that FDA acted consistent with its  
23 normal processes, and they noted other types of drugs that had  
24 been approved under Subpart H. I think plaintiffs mentioned  
25 one for low blood pressure, which I think most people do not

1 naturally think of as an illness as opposed to a condition. I  
2 believe some types of fentanyl were approved under Subpart H,  
3 and those are approved for pain management, which is sort of a  
4 condition associated with an illness but not an illness itself.

5 And so I think FDA's consistent practice reflects  
6 that it treated Subpart H as applying more broadly than  
7 colloquial usage. And Congress ratified that usage in 2007 by  
8 enacting the REMS provision, which uses diseases or condition.

9 So even if the Court is not convinced about  
10 harmless error, I think there still is statutory congressional  
11 ratification argument about why FDA's implementation of  
12 Subpart H was correct.

13 And there's no dispute here that FDA has statutory  
14 authority under the REMS to approve mifepristone. And so in  
15 that world, I don't think the plaintiffs' Subpart H challenge  
16 moves things forward or justifies going all the way back in the  
17 time machine to 2007--or 2000 to analyze the legality of  
18 something that doesn't matter post-2007.

19 THE COURT: Okay. And so I downloaded from the FDA  
20 website all of the Subpart H approvals from '92 to 2008.  
21 Obviously we move on into different statutory and regulatory  
22 regimes after that. And I'll read aloud--not the medications  
23 by name, but specifically the purpose or the disease treated.  
24 So HIV, tuberculosis, HIV, heart failure, cancer, AIDS, HIV,  
25 HIV, HIV, HIV, HIV, HIV, cancer, cancer, HIV, AIDS. Then we



1 get to orthostatic hypotension--low blood pressure--HIV, HIV,  
2 HIV, cancer. Then there's a wound treatment medication,  
3 tuberculosis, leprosy, HIV, HIV, cancer, HIV, HIV, cancer, HIV,  
4 HIV, brain tumors, strep, cancer, HIV, HIV.

5 And understanding that Subpart H was, in part,  
6 developed as an accelerated process specifically to address the  
7 HIV epidemics, it's not surprising that you see that disease  
8 featured so prominently. But your best argument for why  
9 mifepristone is not, unlike the others--is the depression  
10 psychosis medication--which one was that?

11 MR. SCHWEI: So I'm not--

12 THE COURT: Did that occur after 2000? After the  
13 2000 approval?

14 MR. SCHWEI: I'm not sure whether any Subpart H  
15 drug was actually approved for depression or psychosis. I  
16 think it was an example--

17 THE COURT: Right. But the regs do reflect that  
18 the FDA made the determination that it could qualify under the  
19 Subpart H nomenclature that we're adjudicating here.

20 MR. SCHWEI: Correct, Your Honor.

21 THE COURT: I'm only curious because, in private  
22 practice, I worked on the Seroquel docket, which was an  
23 AstraZeneca drug, and it treats sort of that category of  
24 psychosis, bipolar, mania, schizophrenia, things like that. So  
25 I was interested to see if that somewhat controversial category

1 of drugs was part and parcel of the drugs that were approved up  
2 until the 2000 approval for mifepristone, but I didn't see that  
3 listed.

4 But thank you for the reference to the Federal  
5 Register. The Court will review those. You can continue with  
6 your argument.

7 MR. SCHWEI: I'll turn next to the PREA argument,  
8 the Pediatric Research Equity Act argument, that has come up at  
9 today's hearing. I think, again, with-- I appreciate my  
10 colleague's candor that this issue--this claim was not  
11 addressed in their PI motion, and so our first response is, we  
12 don't think it's properly before the Court today. The Court  
13 should not rule on it. It's particularly inappropriate to do  
14 so because, to our knowledge, there's really no case law about  
15 PREA. It's a very complicated--it has a very complicated  
16 history about, as the Court was discussing, the rule, the  
17 injunction, the congressional action. I think unpacking all of  
18 that without briefing would be inappropriate, and so it  
19 doesn't--and so the claim is not properly before the Court.  
20 But I'll just say two points just to make sure that our  
21 position is clear that the claim is meritless.

22 The first is that, with respect to the 2000  
23 approval, the statute that is invoked as the basis for their  
24 claims did not apply to the 2000 approval. There was the  
25 regulation in effect. Of course, the regulation was later

1 enjoined and invalidated, so I don't think that regulation can  
2 meaningfully serve as the basis for a claim.

3           But with respect to the statute, in Public Law  
4 Number 108-155--Section 4 is the effective date--notes that it  
5 applies to applications submitted after--or on or after  
6 April 1st, 1999. And here, although the approval of  
7 mifepristone occurred in 2000, the application was submitted in  
8 1996, before the effective date of the statute itself. And so  
9 I don't think the 2000 Act--or the 2000 approval is even  
10 relevant to this claim. A citation for the application being  
11 submitted in 1996 is ECF Number 1-24 at 2.

12           With respect to the 2016 changes, PREA did apply.  
13 My colleagues on the other side attempt to characterize FDA's  
14 action as extrapolating from adult studies to justify  
15 adolescent data. I'm not sure that's actually right. I'm  
16 looking at ECF Number 28-1, pages 78 to 81, which includes  
17 discussion of this issue, and I'll just read a quote from  
18 page 81: Medical abortion in adolescents appears to be at  
19 least as safe, if not safer, as in adult women.

20           And that's based on four studies addressing  
21 adolescents. And so I'm not sure it's right to even consider  
22 it an extrapolation as opposed to just a determination that the  
23 necessary adolescent studies exist and support safety and  
24 efficacy data.

25           And so even if the Court has some questions about

1 this claim, it's not in the PI motion. There hasn't been full  
2 briefing on it. The parties haven't addressed the full record,  
3 and so I don't think the Court should consider it for purposes  
4 of today, an emergency preliminary injunction hearing.

5 THE COURT: I have your procedural argument. I  
6 have a preview of a substantive argument. You can move on to  
7 your next point.

8 MR. SCHWEI: Thank you, Your Honor. I'll turn next  
9 to the Comstock Act.

10 So the first and most fundamental point is that  
11 plaintiffs identify no reason why FDA should consider the  
12 Comstock Act as part of the agency actions challenged in this  
13 case. The Comstock Act is a federal criminal law. FDA's  
14 approval is about the safety and efficacy of the drug.

15 Under 355(d), as we discussed, it lists extensively  
16 what FDA should consider. If those factors do not exist,  
17 application denied. If they do exist, application approved.  
18 Nothing in the text of 355(d) explains why FDA needs to  
19 consider unrelated portions of the U.S. Code and then  
20 incorporate those unrelated portions into the drug approval  
21 decision that FDA makes under this highly structured statutory  
22 scheme.

23 And that argument makes particularly little sense  
24 here when all of the agency actions at issue occurred before  
25 *Dobbs*, so, in other words, when the framework of *Roe* and *Casey*

1 were still good law and the Comstock Act was unenforceable.

2           And so plaintiffs' argument is--that even when this  
3 law was constitutionally unenforceable, the agency was  
4 nonetheless required to consider that law and impose  
5 unconstitutional restrictions in the approval decision makes--  
6 is simply unfounded for these agency actions challenged, and  
7 the legality of the agency actions needs to be judged at the  
8 time of the decision, all of which occurred when *Roe* and *Casey*  
9 were still good law.

10           But setting aside sort of the procedural argument,  
11 turning to the substance of what does the Comstock Act mean,  
12 plaintiffs argue that OLC's interpretation is wholly atextual  
13 and just based on case law. Respectfully, I think that's  
14 incorrect.

15           And I think the basis for this is Footnote 6 of the  
16 OLC opinion, which talks about how, when Comstock Act was first  
17 enacted by Congress, there were three relevant sections.  
18 Section 1 had certain prohibitions for articles that applied to  
19 any article for producing an abortion. Section 2 had certain  
20 prohibitions applying to articles for producing unlawful  
21 abortion. And then Subsection 3 prohibited certain acts with  
22 respect to the, quote, hereinbefore mentioned articles.

23           And so there's obviously some question about what  
24 are the hereinbefore mentioned articles that are referred to in  
25 Section 3, given that Subsection 1 talks about abortion and

1 Subsection 2 talks about unlawful abortion.

2 THE COURT: Okay. And I recall that Footnote 6,  
3 and I'm tracking with you on that OLC memorandum. Let's go to  
4 the phrase, "nonmailable." So the Comstock Act declares  
5 nonmailable every, quote, article, instrument, substance, drug,  
6 medicine or thing which is advertised in a manner calculated to  
7 lead another to use it or apply it for producing abortion.

8 This is just a straightforward reading of  
9 Section 1461.

10 Is there-- And I understand your argument about  
11 these intervening years under *Roe* and *Casey*. But is there any  
12 dispute on just pure statutory construction that chemical  
13 abortion drugs at issue in this case and labeled as such by the  
14 FDA are drugs, quote, for producing abortion?

15 MR. SCHWEI: As a statutory matter, we dispute that  
16 the--as--statutorily, we think OLC's interpretation is correct,  
17 because the correct reading of those phrases in 1461 is about  
18 drugs intended to be used for unlawful abortions. And the  
19 statutory basis for that relates back to 1873 and the  
20 definition of hereinbefore mentioned articles, and then in  
21 1874, when Congress answered that question of what they were  
22 referring to by referring--by changing that phrase to be about  
23 articles capable of producing unlawful abortions.

24 So Congress itself textually said that the prior  
25 two subsections were about unlawful abortion. I believe it's

1 Subsection 1 that has now been codified over the years into  
2 1461, but I think that text from the 1874 Congress confirms  
3 that 1461 is intended to be read in a manner consistent with  
4 the OLC memo.

5           And that's also true based on, you know, not just  
6 the ratification of these Courts of Appeals decisions, which is  
7 an important part of the analysis, but also, Congress itself  
8 understood Comstock in this manner. That's clear from the 1948  
9 historical revision note that specifically called Congress's  
10 attention to these Courts of Appeals decisions that interpreted  
11 Comstock consistent with the OLC opinion. It cited a number of  
12 the Courts of Appeals decisions and said that this is what  
13 Comstock Act means, and Congress then recodified that  
14 provision. And I think that is, again, a clear basis for  
15 interpreting the current versions, as they have been recodified  
16 over time, consistent with the 1874 Congress's textual action.

17           THE COURT: Okay. So I wanted to give you a  
18 10-minute warning. I promised 15 minutes, but I didn't want to  
19 interrupt you, so you're at the 10-minute mark.

20           And I do understand Footnote 6, and also the  
21 government to rely upon that OLC memorandum. I'm also guided,  
22 however, by the Supreme Court in *Brown vs. Gardner* to this  
23 point of ratification or reenactment. There, the Court said,  
24 quote: There's an obvious trump to the reenactment argument.  
25 In the rule where the law is plain, subsequent reenactment does

1 not constitute an adoption of a previous administrative  
2 construction.

3           Back to my initial question on whether that  
4 Section 1461 language, which refers to producing abortion-- If  
5 I refer back to the FDA's own labeling regime, which this is  
6 the current post-2021 label, it just refers to spontaneous  
7 surgical and medical abortions. It refers to termination of  
8 pregnancy. It lists a series of contraindications affecting  
9 abortion. But it is the government's case that that Footnote 6  
10 should be given greater weight than FDA's own label?

11           MR. SCHWEI: Apologies for being unclear, Your  
12 Honor. I agree that mifepristone is a drug that can cause  
13 abortion, but I do not agree that that--

14           THE COURT: The "unlawful" qualifier is what you  
15 would add, pursuant to that OLC memo?

16           MR. SCHWEI: Right. I do not agree that it  
17 necessarily falls within the Comstock Act under--as properly  
18 understood and interpreted.

19           And I'll just make one last point on Comstock  
20 before turning to the other issues. You know, again, the 2007  
21 act is important here, because, as plaintiffs conceded, the  
22 2000 approval had a distribution scheme in place. That  
23 distribution system contemplated distribution in a manner that  
24 plaintiffs say violates the Comstock Act.

25           But in 2007, when Congress deemed mifepristone to



1 have a REMS and directed that the existing REMS and the  
2 existing distribution scheme continue going forward and be  
3 immediately enforceable, the legal effect of that was to  
4 require the distribution scheme to continue, and the legal  
5 effect of that forecloses plaintiffs' argument here. It is  
6 simply inconsistent with that congressional action for them to  
7 argue that every mailing of mifepristone is necessarily  
8 unlawful, because Congress affirmatively directed that result  
9 in 2007.

10 So, with that, I'm happy to turn--

11 THE COURT: Let's turn-- You were designated by  
12 co-counsel as the *Heckler* expert. And so, here, we needed to  
13 discuss whether this decision-making was committed to agency  
14 discretion and the administrative law consequences of that.  
15 Because you have just five minutes left or less, I want to get  
16 right to the Court's questions.

17 Section 355-1(f)(3) states the Secretary can  
18 determine, quote, elements to assure safe use may be required  
19 for drugs, quote, with known serious risks. And then among  
20 these elements is that the drug, quote, be dispensed to  
21 patients only in certain healthcare settings, such as  
22 hospitals. So this is subpart (3)(c).

23 Additionally, the Secretary must publicly explain,  
24 quote, how such elements will mitigate the observed safety  
25 risk. This is part (f)(2). And then the Secretary must

1 consider whether the elements would, quote, be unduly  
2 burdensome on patient access to the drug and must also, quote,  
3 minimize the burden on the healthcare delivery system.

4           Finally, 355-1(f)(3) specifies one or more goals to  
5 mitigate a specific serious concern.

6           Given what the Court has read aloud, which is  
7 reflected in that section, is there not law to apply, as we  
8 apply *Heckler* and other cases, to that 2021 nonenforcement  
9 decision? Do we not have law to apply such that the argument  
10 that it's fully committed to the agency discretion is  
11 undermined by the *Heckler* line of cases?

12           MR. SCHWEI: So two responses, Your Honor. The  
13 first is a procedural one, but the second, I promise, will  
14 answer the Court's question.

15           The first is procedural, that this claim is moot,  
16 because the policy of nonenforcement was with respect to an  
17 in-person dispensing requirement that now no longer exists.  
18 And so the enforcement discretion aspect no longer exists  
19 either, because it was with respect to a requirement that  
20 doesn't exist.

21           And even if the Court doesn't agree that it's moot  
22 right now, the claim is imminently going to become moot  
23 because, as even plaintiffs acknowledge, the April 2021  
24 statement was that this would last during the COVID public  
25 health emergency, which the Administration has announced is

1 currently scheduled to end in May of this year. And so I don't  
2 think it makes sense for this Court to issue an emergency  
3 preliminary injunction on a claim that, at a minimum, is  
4 imminently going to become moot.

5 But setting aside those threshold responses and  
6 answering the Court's question directly, the statutory  
7 framework regarding whether FDA should impose a REMS, that has  
8 a number of legal requirements. And, you know, plaintiffs here  
9 aren't challenging the imposition of the REMS. What this claim  
10 is about is whether FDA has to enforce those REMS against  
11 providers who may violate one of the previously imposed REMS  
12 during a public health emergency and for most of the time when  
13 FDA has determined that it will soon remove that dispensing  
14 requirement.

15 And so regardless of the structure of the--whether  
16 to impose the REMS, it's a wholly separate question whether to  
17 enforce the REMS against anyone else, which is what *Heckler v.*  
18 *Chaney*--when that comes into play.

19 And I would note that this is a pure passive  
20 enforcement policy. It's unlike some of the government  
21 programs that the Supreme Court or the Fifth Circuit have held  
22 to be reviewable that confer affirmative relief, such as in the  
23 immigration context. There's no affirmative benefits from this  
24 enforcement policy. It's a pure passive nonenforcement policy  
25 that remains nonreviewable under *Heckler*.

1           Recognizing that I have very little time, I did  
2 want to make sure we addressed remedies and just one point that  
3 I wanted to state at the outset. In our brief regarding the  
4 Court's question about consolidation, at the end, the  
5 United States did request that, hypothetically, if the Court  
6 does enter any sort of adverse order, that that order be stayed  
7 pending appeal or, at a minimum, for a short administrative  
8 stay for any appeal that's authorized. We recognize that the  
9 Court previously did that in the Remain in Mexico set of cases  
10 to allow some immediate appellate proceedings.

11           I think our brief suggested a minimum of 21 days  
12 for the administrative stay. I think the Court's time frame,  
13 as extended by Justice Alito in Remain in Mexico, was something  
14 like 11 days. But, at a minimum, we would request that if the  
15 Court gets to any sort of adverse order. So just wanted to put  
16 that on the record.

17           But to--but with respect to remedies, I think, you  
18 know, the Court needs to keep in mind the governing equitable  
19 principles that any remedy would have to be tailored to the  
20 precise harm that plaintiffs have established and the  
21 irreparable harm that they have established. I think, even if  
22 they can establish standing or some form of harm, it's for a  
23 select few plaintiffs that could not, under the equitable  
24 factors, govern nationwide, broad relief.

25           And I think, you know, even at final judgment, the

1 most that plaintiffs could obtain is remand without vacatur.  
2 And the types of remedies they are asking for here, as  
3 suspending, withdrawing, vacating, those go beyond what they  
4 could even obtain at final judgment, which is just  
5 fundamentally inconsistent with the purpose of a PI of  
6 maintaining the status quo.

7           And all of the cases that my colleague cited in his  
8 response to justify these extraordinary remedies, my  
9 understanding is that those arose in the context of generic  
10 drugs and a brand-name drug trying to keep the generic version  
11 off the market, which is fundamentally different than what  
12 plaintiffs are requesting here, which is the wholesale  
13 withdrawal of a safe and effective drug that has been approved  
14 for over two decades. And so those cases do not support any  
15 judicial action that would remove a class of drugs entirely  
16 from the market over the agency's objection.

17           THE COURT: Okay. I have your argument on  
18 remedies, and I'll also note that you have preserved the right  
19 to request stay in the event of an adverse ruling. So that is  
20 preserved for this Court and for the appellate review.

21           MR. SCHWEI: Your Honor, just to clarify, I think  
22 we would hereby request that stay if the Court enters it and  
23 have--we would prefer that the Court address that stay question  
24 in the order itself, but understand the--

25           THE COURT: If I require additional briefing, I'll

1 extend any deadlines for supplemental briefing--

2 MR. SCHWEI: Thank you, Your Honor.

3 THE COURT: --in such an event. Okay.

4 MR. SCHWEI: Thank you, Your Honor.

5 THE COURT: I just wanted to let you know that you  
6 have properly preserved it for my review and appellate review.

7 MR. SCHWEI: I appreciate the reassurance.

8 THE COURT: Okay. Thank you.

9 And at this time, I'll invite argument from  
10 Ms. Ellsworth. It's my understanding that you have 30 minutes.  
11 And which time warning did you request?

12 MS. ELLSWORTH: I requested ten minutes and five  
13 minutes, please, Your Honor.

14 THE COURT: Okay. Ten and five. You will have  
15 those warnings at those intervals. You may proceed.

16 MS. ELLSWORTH: Good afternoon, Your Honor, and may  
17 it please the Court. Jessica Ellsworth on behalf of Intervenor  
18 Danco Laboratories.

19 We have heard a lot today, and so I want to just  
20 take a step back to start and think about what the plaintiffs  
21 need to show here to get the relief that they are asking for.  
22 They need to run the table on a list of issues, each of which  
23 has significant questionable law supporting their arguments.

24 First, they need to show standing, despite having  
25 only an attenuated chain of independent actors and no certainly

1 impending harm to them.

2 Then they need to show that they are also in the  
3 zone of interest for FDA approvals, which no court has found a  
4 doctor who seeks to not prescribe a drug is in that zone of  
5 interest.

6 Third, they need to show that the reopening  
7 doctrine applies and they can overcome a statute of limitations  
8 defense, even though FDA never reconsidered the 2000 approval  
9 in making the 2016 REMS adjustments or the 2021 REMS  
10 adjustments.

11 They next need to show an exception to  
12 administrative exhaustion applies. And then we go on from  
13 there. Once they get past that, they need to show some sort of  
14 likelihood of success on the merits.

15 On their Subpart H argument, that's particularly  
16 difficult, because the approved REMS has set the distribution  
17 restrictions since 2008. And there's also nothing in the PI  
18 record--and I would note here we do not have the full  
19 administrative record. But there's nothing in the PI record  
20 that shows FDA would have ever denied the NDA if it was somehow  
21 foreclosed from using Subpart H during that time period of 2000  
22 to 2008.

23 On their arguments about the FDA's assessment of  
24 the scientific and medical evidence, their new argument today  
25 is that it somehow violated 355(d), which I don't think the

1 text supports at all. But beyond that, they would need to show  
2 a lack of reasoned decision-making, despite hundreds of pages  
3 of reasoned explanation that are already before the Court in  
4 the PI record.

5           On Comstock, they would need to show that FDA was  
6 somehow obligated to consider a criminal law it is not  
7 authorized to implement or enforce in assessing Danco's  
8 applications about the safety and efficacy of a drug during a  
9 time when the law was unconstitutional to enforce.

10           Once we get past that, we get to what this Court  
11 has identified as perhaps the most important requirement for a  
12 preliminary injunction: irreparable harm. Here, they would  
13 need to show that despite waiting all of this time to sue,  
14 really 22 years after this drug was approved, and despite  
15 having only an attenuated multistep claim of potential future  
16 harm, and despite having told this Court they're willing to  
17 wait a number of months for a ruling that would be based on  
18 administrative record, somehow they will be irreparably harmed  
19 by waiting for this Court to resolve this case on the merits.

20           Finally, they need to show that the harms to Danco,  
21 my client, and the 96-plus percent of women who take  
22 mifepristone for a medication abortion with no complications do  
23 not outweigh the delayed, attenuated, and speculative harms  
24 they assert.

25           I said finally, but there's one more. The public



1 interest. They would need to show that the public interest is  
2 served by judicially limiting the availability of a product  
3 that, at the end of this case, the only remedy available on the  
4 claims that have been brought would be a remand without vacatur  
5 for the agency to address and potentially cure any concerns  
6 with the agency's reasoned analysis.

7 To say this list out loud, Your Honor, is to show  
8 how improbable it is that the plaintiffs have made the  
9 necessary showing to get the especially disfavored remedy of a  
10 mandatory injunction here.

11 I'd like to start with the irreparable harm. And I  
12 know that this Court has identified it as perhaps the most  
13 important element of the PI inquiry, and yet, the plaintiffs  
14 spent less than one minute describing their irreparable harm to  
15 you. That's for good reason. They don't have any.

16 There are two sets of facts that completely  
17 undermine any asserted irreparable harm. Those facts relate to  
18 the delay in bringing this suit and the attenuated chain of  
19 events on which their speculative claim of potential harm  
20 depends.

21 So let's start with delay. They waited 22 years to  
22 sue. They waited 2,438 days after their citizen petition was  
23 denied. They waited 337 days after their second citizen  
24 petition was denied. And, as the government noted, there are  
25 remedies they could have pursued to bring these claims sooner,

1 had they chosen to, but they chose to delay. There is no case  
2 law I am aware of that would find irreparable harm in light of  
3 these facts of delay.

4 There's also the speculative chain that their  
5 argument depends on, and I'd like to just walk through those  
6 steps.

7 Step one, a hypothetical patient goes to another  
8 physician and decides, in consultation with that physician, to  
9 have a medication abortion.

10 Step two, the hypothetical patient taking  
11 mifepristone is one of the very small number of patients who  
12 does not have complete treatment success or who experiences an  
13 adverse event. And I'd like to just focus on how small a  
14 number this is. The average treatment success rate in the data  
15 is more than 96 percent. You can see that at ECF 28-1, page  
16 ID 2097 to 2101. The average rate of termination across more  
17 than twenty studies without surgical intervention is  
18 97.4 percent for the U.S. studies, and 96.1 percent for the  
19 ex-U.S. studies. Treatment without adverse events is even more  
20 rare. It's 99.9 percent of uses of this medication. You can  
21 see that at ECF 28-1, page ID 2116.

22 You can also see in the provider declarations that  
23 are in the PI record at ECF 28-3, ECF 28-5, 28-6 and 28-7, the  
24 consistent record of safety that this drug has had. Their  
25 argument to the contrary that there will, in fact, be patients

1 injured rests on their declarations which identify a handful of  
2 instances across all of these doctors and these medical  
3 associations and five studies, none of which conclude  
4 mifepristone is unsafe, and three of which expressly endorse  
5 mifepristone. Two of them found higher rates of complication  
6 in second trimester abortions. Those are not at stake in this  
7 case. One found a higher rate of complications with surgical  
8 abortions. Well, that undercuts their argument that somehow  
9 the medication abortion presents irreparable harm. And one  
10 found a rate at which the hospitalization rate was within the  
11 same percentage that's identified on the label. 3.6 percent of  
12 women look for some sort of follow-up.

13           So we have a hypothetical patient going to a  
14 hypothetical other doctor. We have a tiny number of those  
15 patients percentage-wise who will require follow-up. And at  
16 step three, we now have a hypothetical patient who chooses not  
17 to follow up with the prescribing doctor but to go to one of  
18 the hospitals where they will be treated by one of these  
19 plaintiffs on a day where one of these plaintiffs is working  
20 and that doctor is the one who treats her.

21           That, Your Honor, does not amount to anything other  
22 than speculative injuries that depend on independent actions of  
23 third parties.

24           THE COURT: So what is defendant intervenor's read  
25 of *Clapper* in this someday-injury concept that defense counsel

1 raised? In light of the falling limits and restrictions as you  
2 move from the 2000 approval to the 2016 major changes, there  
3 was previously a dispensation only by supervising physicians,  
4 previously in-person administration of a drug regimen. There  
5 was a follow-up in-person evaluation required, and then  
6 prescribers are required to report the data on nonfatal serious  
7 adverse events. This is then followed by the 2021 agency  
8 action which confirms all of these changes and then adds to  
9 that dispensation by mail.

10 At what point are we beyond the realm of playing  
11 with statistics and probabilities and approaching a level of  
12 certitude about reasonably foreseeable injuries?

13 MS. ELLSWORTH: Your Honor, I don't think we're at  
14 that level in any way. The language that Justice Alito used in  
15 the *Clapper* decision was very clear in rejecting the  
16 objectively reasonable likelihood standard that the Second  
17 Circuit had used.

18 We still have a highly attenuated chain of  
19 possibilities. We still have speculation about the decisions  
20 of independent actors, and we still have an approval that, at  
21 most, authorizes--this is a quote--but does not mandate or  
22 direct a particular action, which makes allegations based on  
23 that action, quote, necessarily conjectural. That's in *Clapper*  
24 at 412. As in *Clapper*, this Court would have to speculate  
25 about how some other person or entity will exercise their

1 discretion. None of that changes based on any of the facts  
2 that Your Honor asked about.

3 *Clapper*, I think, really does resolve the standing  
4 questions in this case. Standing requires a certainly  
5 impending injury. And I think it's worth noting that  
6 plaintiffs suggested at one point in their brief and at one  
7 point to you this morning that past harm was somehow enough.  
8 But that is not true when they are seeking injunctive relief,  
9 and that's the *Lyons* decision from the Supreme Court.

10 On organizational standing, they have put all their  
11 eggs in the *OCA* basket, but I think that really misreads the  
12 body of Fifth Circuit precedent that's relevant here. After  
13 the *OCA* decision was decided, in the *Tenth Street Residential*  
14 case in 2020 and the *Texas State LULAC* case from the Fifth  
15 Circuit in 2022, the Fifth Circuit found no standing where  
16 organizations failed to identify specific projects they had put  
17 on hold because of diverted resources.

18 In the Tenth Circuit Residential case, the Court  
19 also found no injury in fact where the organization's work  
20 aligned with its mission. That's similar to what the Fifth  
21 Circuit held in the *El Paso County vs. Trump* case also in 2020.  
22 There, the Fifth Circuit said that an organization must be  
23 engaged in something different from its routine activities.

24 And finally, the *OCA* case itself is  
25 distinguishable, because there, the organization was

1 complaining about the cost of complying with the law, the cost  
2 that it imposed on them to conduct their work. That is not  
3 what's being argued here.

4           Your Honor asked about citizen petitions and  
5 whether they are prelitigation costs. I don't think there's  
6 any way, under Fifth Circuit precedent, including *City of Kyle*  
7 and including *OCA*, that they are not prelitigation costs.  
8 Otherwise, literally anyone could file a citizen petition and  
9 somehow claim standing based on a self-inflicted financial cost  
10 of having had to do that.

11           On associational standing, the plaintiffs'  
12 arguments aren't any better. They rely on at least two  
13 independent third parties who are not before the Court and  
14 neither of which have sued in their own right. Under *Clapper*,  
15 that is not acceptable. No court has held that the past  
16 treatment of a patient or two who experienced a known side  
17 effect from a drug another doctor prescribed has standing to  
18 challenge a drug approval. All drugs have side effects.

19           On third-party standing, this Court asked about  
20 *June Medical*. For one thing, in *June Medical*, the providers  
21 themselves were also regulated, and they faced sanctions. So  
22 there was that separate component that's not here.

23           But in addition, these physicians, in their  
24 declarations, these plaintiffs, actually walk through their  
25 lack of existing relationship, their lack of close relationship

1 with patients. They express concern about patients not being  
2 forthright with them, and they do nothing to identify an  
3 obstacle for a patient to come forward.

4 Under the *Kowalski vs. Tesmer* case from the Supreme  
5 Court, I don't think there's any way that they can assert  
6 third-party standing where their interests deviate so much from  
7 that of the patients on whose behalf they would be suing.

8 The last standing-related issue is the zone of  
9 interest. The closest point--the closest case on point here is  
10 the *Association of American Physicians* case from D.C., from the  
11 D.D.C. in 2008, which found no prudential standing for  
12 physicians or pharmacists who were trying to challenge the  
13 FDA's approval of emergency contraception. That Court found--  
14 and I think it's exactly the same as in this case--that those  
15 physicians' interests were, at most, marginally related--that's  
16 a quote--to the purpose of the new drug approval provisions,  
17 and that put them outside the zone of interest.

18 If we could turn to Comstock briefly. The most  
19 important thing I think this Court needs to think about when it  
20 looks at Comstock is that the FDA is not charged with enforcing  
21 the Comstock Act or many other criminal prohibitions that apply  
22 to pharmaceutical manufacturers in the U.S. Code. There are  
23 customs laws. There are environmental laws. There are drug  
24 laws. There are employment laws.

25 The FDA is tasked with enforcing the FDCA's rules

1 on drug approvals, and, by statute, Congress specifically told  
2 FDA what it may consider in approving or denying an NDA. We've  
3 been talking about those requirements this morning.

4 Section 505(c) sets out the fact that the FDA must approve an  
5 NDA if none of the grounds are--none of the grounds for denying  
6 it apply. The language is very explicit. Quote, FDA shall  
7 issue an order approving the application. That's in  
8 21 U.S.C. 355(d).

9 Consider the consequences of plaintiffs' argument.  
10 It would require an agency like the FDA or the SEC or the EPA  
11 to reach far outside of its own lane and mandate or preclude  
12 action by a regulated entity based on other statutes assigned  
13 to other agencies where the acting agency has no interpretive,  
14 implementation, or enforcement authority over that statute.

15 The next point I'd like to address is Subpart H.  
16 As the government said, Subpart H is essentially irrelevant at  
17 this point in time, and it could not be a basis for any  
18 injunctive relief today. It has no impact today. The REMS  
19 governs. The REMS has governed since 2008 when it was deemed  
20 to be in effect, and since 2011 when it was approved.

21 I think the simplest way to see this, Your Honor,  
22 is that if Danco were to submit an NDA for Mifeprax today or if  
23 it had submitted it in 2008 or later, this approval would have  
24 run through the REMS approval authority in 355-1 without any  
25 reference or need to rely on the agency's regulations in



1 Subpart H.

2 We are not aware of any instance in which the FDA  
3 has used Subpart H as a basis to impose distribution  
4 restrictions since the FDAAA was enacted. And even in the 2000  
5 time frame, Subpart H was not the only way the distribution  
6 restrictions could be imposed. The letter from Danco to the  
7 FDA that plaintiffs submitted with their reply--you can see  
8 this at ECF 121, page ID 4185. It expressly says Danco was  
9 willing to voluntarily agree to distribution restrictions  
10 without the need to impose them through Subpart H.

11 At other times, FDA has put restrictions directly  
12 into a label, or it has reached some other kind of agreement  
13 with the sponsor. Without the administrative record, we don't  
14 know FDA's views on these alternative ways of approving  
15 mifepristone that would have led to the same restrictions even  
16 back in 2000. And in any event, it would not be a basis to  
17 question the drug's approval today, which depends on the REMS.

18 If I could turn to the FDCA. There is no  
19 requirement under the FDCA that clinical trials and other  
20 studies must mirror conditions of use in the approved labeling.  
21 That makes sense, Your Honor. Imagine someone applying for a  
22 new drug. It's unclear, for example, how long the drug stays  
23 in your system, so a clinical trial is set up that does blood  
24 testing every two hours for the first 24 hours after you take  
25 the drug. It turns out that clinical trial shows that the drug

1 leaves your system in eight hours.

2           There is no reason that the FDA would not have  
3 discretion to say in the label that drug testing every two  
4 hours for 24 hours is not required. They have achieved the  
5 answer to their question. They have gotten the information  
6 they need to make the medical and scientific judgment about  
7 what labeling is appropriate for a drug, and that is exactly  
8 what 355(d) suggests they should do.

9           In this case, just as one example, if you look at  
10 the CDER clinical review and the cross-discipline team leader  
11 review--that's ECF 28-1, page ID 2069 to 2264--that is  
12 200 pages of explanation for the 2016 changes. It walks  
13 through every study that the agency considered, the adverse  
14 event reports, and all of the other information the agency used  
15 to inform its judgment about whether the revisions were  
16 appropriate.

17           THE COURT: And, Ms. Ellsworth, you are at your  
18 10-minute mark.

19           MS. ELLSWORTH: Thank you, Your Honor.

20           One point on adverse events, because I think in the  
21 briefing, the plaintiffs suggest that, somehow, FDA has given  
22 mifepristone a free pass on adverse event reporting, and that's  
23 not true. In 2016, FDA changed the terms of the prescriber  
24 agreement form to require a more limited number of reports  
25 through that provider agreement form based on 15 years of the

1 agency's experience with how that provider agreement form  
2 worked and what those reports were.

3 But what the agency said in the very next sentence,  
4 the applicant--that's Danco--will still be required by law, as  
5 is every NDA holder, to report serious, unexpected, adverse  
6 events as 15-day safety reports and to submit nonexpedited  
7 individual case safety reports and periodic adverse drug  
8 experience.

9 THE COURT: And I know that we don't have the  
10 complete administrative record at this point in the litigation,  
11 but there were multiple references to the FAERS system, the FDA  
12 Adverse Event Reporting System. Do you know or can you point  
13 to any part of the trial record that reflects how many  
14 instances your client accessed that FAERS system to report  
15 adverse events?

16 MS. ELLSWORTH: I do not have the exact number of  
17 times. But the obligation--when a manufacturer, like Danco,  
18 receives an adverse event report, it is obligated to  
19 investigate that report, and it is obligated to pass certain  
20 information on in response to having received that. And in all  
21 honesty, that's why I think the agency requires this periodic  
22 reporting and then sort of reassessment based on what is there.

23 One of the other elements for a preliminary  
24 injunction is the consideration of harm to other parties and  
25 the balancing of the equities. Danco is a small pharmaceutical

1 company. It faces serious irreparable harm from a court order  
2 that does any of the things that plaintiffs are asking this  
3 Court to do on an expedited basis without waiting for the  
4 administrative record.

5 Danco's harm is certain, it is great, it is actual,  
6 and it is unrecoverable. There is no dispute of fact about  
7 that in the record that is before the Court.

8 The public interest is important here too.  
9 Granting a PI is not in the public interest. 99.9 percent of  
10 patients who take the drug will not experience an adverse  
11 event. That's Docket 28-1 at 2116. 96-plus percent of  
12 patients will have a completely successful treatment with no  
13 complications. That's at 28-1, page 2097 to 2101.

14 The public interest is always supported by allowing  
15 patients access to drugs FDA has found to be safe and effective  
16 in consultation with their doctors when they may choose to seek  
17 that treatment. Mifepristone is the standard of care for  
18 medical abortion in the United States and in 82 countries  
19 around the world. It has been on the World Health  
20 Organization's model list of essential medicines for more than  
21 15 years.

22 The public interest is supported here by allowing  
23 FDA to continue its medical and professional judgment to make  
24 determinations about how to review scientific evidence, whether  
25 to approve certain drugs, and under what circumstances,

1 including, if necessary, on remand from this Court.

2 That brings us to the remedies. In our view--

3 THE COURT: And here's where I do want to ask  
4 defendant intervenor about drawing lines around each of the six  
5 claims reflected in the plaintiffs' complaint. I've asked this  
6 question, I believe, of all attorneys at the podium.

7 So, here, we have prayers for relief for six  
8 claims: the 2000 approval, the 2016 major changes, the 2019  
9 ANDA generic approval, and then the 2021 agency action. This  
10 is followed by requested relief relevant to the petition  
11 responses.

12 Is there any reverse chronology where you could  
13 group relief for individual claims, or is it your reading of  
14 the complaint that this Court must begin and end its analysis  
15 with the 2000 approval and then there's just this cascading  
16 effect of injunctive relief or vacatur relief, withdrawal or  
17 suspension that follows from there? Do you perceive that the  
18 Court can draw any lines or parameters around each of those  
19 claims?

20 MS. ELLSWORTH: The line I think Your Honor has to  
21 draw is between a question of whether the ultimate merits  
22 conclusion on any of these claims would lead to remand with  
23 vacatur or remand without vacatur, because if the ultimate  
24 merits conclusion on all six of them would be remand without  
25 vacatur, which the Fifth Circuit has said is generally

1 appropriate where there is at least a serious possibility the  
2 agency will cure whatever the issue is and sustain its decision  
3 given an opportunity to do so-- That's the *Central and*  
4 *Southwest Services* case from the Fifth Circuit in 2000.

5 Here, there's no question that the agency has put  
6 considerable thought into this over the years, and I think  
7 there is no question that the agency would have the opportunity  
8 at that point in time, once we've had a full administrative  
9 record, once the Court has identified if it thinks there are  
10 flaws in the reasoning, on remand, without vacatur, it would be  
11 able to analyze those issues. But in the meantime, there would  
12 be no basis, on a preliminary injunction, to do anything that  
13 would give the plaintiffs greater relief than they would be  
14 entitled to at that time.

15 The *Allied Signal* decision from the D.C. Circuit I  
16 think is the case that I'm most familiar with that talks  
17 through the factors that courts look at in determining whether  
18 to vacate an agency decision and ultimately concludes that only  
19 if it is an uncurable error.

20 On top of that, what the plaintiffs are asking for  
21 is a mandatory injunction. Mandatory injunctions are even more  
22 strongly disfavored. And I don't think there is any question  
23 that this is not about preserving the status quo. They want  
24 very much to upend the status quo, and they want to do so by  
25 pointing this Court to cases that are patent cases, where there

1 really was no way to cure. Those cases are not like this one.  
2 The *Serono vs. Shalala* case, I agree with the government that  
3 the decision they cited to you was vacated. The preliminary  
4 injunction was vacated.

5 And I'd also note that, in that case, there was  
6 statutory language that actually required a, quote, same active  
7 ingredient for a generic. So that use of the word "same" is  
8 quite different from any of the statutory provisions that  
9 plaintiffs have cited to you this morning that don't use that  
10 term and, in fact, are much more discretionary about how FDA  
11 gets to exercise--

12 THE COURT: You agree with the government that the  
13 *Serono* opinion, which I did not have before this hearing, holds  
14 that "same" is different? That that terminology of "same"  
15 would be different than your case?

16 MS. ELLSWORTH: Than this case, yes.

17 THE COURT: Just trying to be clever.

18 MS. ELLSWORTH: That's why I had to stumble for a  
19 minute.

20 THE COURT: Yeah, sorry. That was a strange curve  
21 ball.

22 So you're at the end of your time, but because I  
23 did interrupt with a bad joke, any closing remark would be  
24 welcome.

25 MS. ELLSWORTH: Your Honor, as the government said,

1 this is a case about a drug that has been on the market for  
2 22 years. Preliminary injunctive relief should be denied in  
3 this case. It can move forward to an administrative record.  
4 It can move forward to a merits ruling. But at this point in  
5 time, the plaintiffs have not come close to meeting any, let  
6 alone all, of the requirements that they would need to meet for  
7 preliminary injunctive relief.

8 THE COURT: And if I recall, defendant intervenor  
9 did not oppose consolidation if it were summary judgment and  
10 not trial on the merits. Is that correct?

11 MS. ELLSWORTH: It is, Your Honor. I think summary  
12 judgment in an APA case is essentially trial on the merits, so  
13 yes.

14 THE COURT: I think you agreed with the Court on  
15 that concept, at least on the papers. Okay.

16 MS. ELLSWORTH: Yes, Your Honor.

17 THE COURT: So I have your argument. Thank you for  
18 your time at the podium.

19 At this time, we'll turn to the reserve rebuttal  
20 for plaintiffs. And who will be taking the rebuttal?

21 MS. HAWLEY: Is it okay if we--

22 THE COURT: So I do have questions on this  
23 study-match questions. I've got a hypothetical--

24 MS. HAWLEY: Your Honor, one question--one  
25 preliminary question. Is it okay if we split rebuttal half and



1 half? Would that be permissible?

2 THE COURT: That's fine. So 15/15?

3 MS. HAWLEY: Yes, sir.

4 THE COURT: Okay. So, Ms. Hawley, I do want to ask  
5 a question about this mirror imaging, the study-match  
6 hypothetical. We've bandied it about between counsel and  
7 Court. I have a hypo on that--

8 MS. HAWLEY: Can we--

9 THE COURT: --and then I have three questions on  
10 remedy. So how would you like to allocate attorney time?

11 MS. HAWLEY: So those, actually, questions all go  
12 to my co-counsel.

13 THE COURT: Okay. So you may begin with your  
14 15-minute segment, and unfortunately, Mr. Baptist is going to  
15 be hit with question after question after question.

16 MS. HAWLEY: Okay.

17 THE COURT: You may proceed.

18 MS. HAWLEY: Thank you, sir.

19 I wanted to respond briefly to each of the standing  
20 arguments made by my friends on the other side. To begin with  
21 *Clapper*, I would refer the Court to Footnote 5 of *Clapper*.  
22 Footnote 5 clarifies that in other cases, the Court has, in  
23 fact, found standing based on what is known as a substantial  
24 risk. So that is Footnote 5.

25 And then if you look at the Supreme Court's

1 decision--recent decision in *TransUnion*, the Court says that  
2 it--what qualifies for Article III standing purposes is a  
3 material risk of future harm. They say sufficiently imminent  
4 and substantial.

5           So I really think that the argument made on the  
6 other side rewrites the standing jurisprudence vis-a-vis  
7 injunctions. It is simply not the case that, in order to  
8 obtain a preliminary injunction, you have to have a certitude  
9 of harm. That's never been the case. If we go back to cases  
10 like *Bennett vs. Spear*, if we go back to cases like  
11 *Massachusetts vs. EPA* or *Babbitt and Farm Workers*, what the  
12 Court said in those cases, Your Honor, was actually equating  
13 the certitude of harm with imminence. And that makes abundant  
14 sense.

15           To sort of trace that line of cases on, if you look  
16 at the decision--2019 decision of the Supreme Court in  
17 *Department of Commerce*, what the Court says is that standing is  
18 permissible if the plaintiff can show that harm is either,  
19 quote, certainly impending or there's a substantial risk that  
20 harm will occur. *SBA List* from 2014 says the very same thing.  
21 So we just simply can't cherry-pick out this certainly  
22 impending harm and apply basically a certitude requirement.

23           THE COURT: What is your best case against  
24 defendant and intervenor's argument construing *Clapper*? I know  
25 that you've given me Footnote 5 and *TransUnion*. What is your

1 best case responding to that, whether it's D.C. Circuit,  
2 Supreme Court, or somebody who does administrative law?

3 MS. HAWLEY: I think it would be the *Department of*  
4 *Commerce vs. New York*. That's a 2019 case. It's also an  
5 administrative law case. That citation is  
6 139 S.Ct. Reporter 2551, and the standing quote is at 2565.

7 THE COURT: Okay. I'm familiar with  
8 *Massachusetts vs. EPA* and *TransUnion*, but I didn't recall that  
9 case, so thank you for that clarification.

10 MS. HAWLEY: Absolutely.

11 So under that proper standard, is there a  
12 substantial risk of harm, is it sufficiently imminent. There's  
13 various ways the Supreme Court has described it. But what the  
14 Court is looking at is, is there enough of a risk of harm.

15 Here, that is certainly true. As Your Honor noted,  
16 the 2011 medication protocol or approval noted that there were  
17 5 to 8 percent of women who would be harmed. The FDA has since  
18 removed nearly every restriction. There are no in-person  
19 doctor requirements, none. So a person-- We have several  
20 declarations noting that patients that have been treated from  
21 suffering adverse consequences of mifepristone--one received  
22 the drugs from India; another received it online without  
23 consultation with a doctor. Presumably someone was required,  
24 but these patients could not recall. In addition, there is no  
25 follow-up visit. So this idea that this is going to be

1 well-supervised under the new rules is simply untrue.

2           And again, I would point this Court to *Texas vs.*  
3 *Becerra*. In that case, we have the very same third-party  
4 issues. We have the very same issue with women ending up in  
5 emergency care due to taking mifepristone, and the Court found  
6 standing in that case.

7           To turn briefly to organizational standing, again,  
8 my friends on the other side really read missional harm--they  
9 read the mission out of missional harm. And it's perfectly  
10 okay, under the Fifth Circuit's organizational standing cases,  
11 in order for an organization to advocate against defendants'  
12 conduct that has harmed it in a related field.

13           So if you take the cases of *La Union*, if you take  
14 *Texas State LULAC*, if you take *OCA*, all of those were voting  
15 rights organizations that challenged various voting rights  
16 provisions. And the harm that was alleged there and the harm  
17 the Court found in *OCA* was that requiring more education was  
18 enough. It diverted resources from the plaintiff's ordinary  
19 activities to something else and made them less effective at  
20 that second work.

21           And I think the only way that we can say that the  
22 plaintiffs' harms here are the same or are routine, as the  
23 Court found in *City of Kyle* or *Tenth Street Residential*  
24 *Association*, is by looking to today, to 2023, rather than 2000.  
25 Today, we have the approval of mifepristone. But in 2000, we

1 did not. And what these missions have always been oriented  
2 toward is saving lives. The pro-life organizations, they state  
3 in their declaration that their missional purposes are to  
4 preserve life, to advocate against the dangers of surgical  
5 harm, in addition to advocating for conscience protectives--  
6 conscience protections. Excuse me, Your Honor.

7           Those three harms do not neatly overlap and are no  
8 different than the voting rights associations in these other  
9 cases.

10           Your Honor, with respect to AC PEDS, they do  
11 mention the danger of chemical abortion. If that's too closely  
12 aligned, there are three other organizations whose missions are  
13 not that closely aligned.

14           THE COURT: You have five minutes remaining,  
15 Ms. Hawley.

16           MS. HAWLEY: Thank you, Your Honor.

17           With respect to the zone of interest test, as Your  
18 Honor notes, it's a prudential test, and the Supreme Court, in  
19 *Lexmark* and other cases, has recently remarked that the federal  
20 courts have a virtually unflagging obligation to exercise  
21 jurisdiction.

22           Would refer the Court again to *Bennett vs. Spear*.  
23 This is the EPA case in which the Supreme Court found that the  
24 regulated entities in that case--well, the affected entities,  
25 ranchers and irrigation districts, were, in fact, within the

1 zone of interest of the Endangered Species Act. Very similar  
2 to this case and, again, from the Supreme Court.

3 On *Comstock*, Your Honor, the colleagues on the  
4 other side basically say that there's the sort of the standard  
5 that the FDA can ignore a statute if they think it might be  
6 unconstitutional. They refer, of course, to *Roe* and *Casey*,  
7 which were overruled in *Dobbs*. But as Judge Easterbrook noted  
8 in denying a petition for rehearing, what the undue burden  
9 standard means was really anyone's guess, and I don't think--  
10 I'm not aware of any case which says a federal agency may  
11 ignore a federal law because they think it is unconstitutional.

12 With respect to the specific text, I appreciate  
13 very much your *Brown vs. Gardner* citation. In addition, the  
14 best textual evidence that the other side puts forward has been  
15 relegated to a footnote in the OLC memorandum. And I would  
16 actually suggest the opposite. When Congress chose to keep one  
17 provision, they kept the abortion provision, not the unlawful  
18 abortion provision. And as we know, when Congress says  
19 something in one statute and not in another provision, it knows  
20 how to say what it means.

21 The only other thought on *Comstock*, Your Honor, is  
22 that the 2007 FDAAA amendments simply deemed them to have  
23 preexisting regulations, so it was a pass-through sort of to  
24 smooth the regulatory transition from Subpart H to the REMS  
25 provision. It in no way validated any particular REMS. It

1 just noted the fact and, quote, deemed them to have REMS. So I  
2 don't think the 2007 amendment in any way obviates the Comstock  
3 claim.

4           And then finally, on *Heckler vs. Chaney*, I did not  
5 address this in my first presentation, but we run, of course,  
6 into the APA's presumption of judicial review. In the  
7 *Weyerhaeuser* case from the Supreme Court, it said that the  
8 Section 701(a)(2) committed to the agency's discretion must be  
9 interpreted narrowly, or else it runs into 706(a)(2), which  
10 requires courts to review for an abuse of discretion. If that  
11 abuse of discretion review is nonexistent, then we read 706 out  
12 of there.

13           So for those reasons on standing, as well as  
14 exhaustion and *Heckler*, we submit plaintiffs in this case, and  
15 my colleague will address remedies now.

16           THE COURT: Okay. Mr. Baptist, you may approach.  
17 And because it's late in the hearing, why don't I begin with a  
18 question.

19           So I've referred to this as a study-match problem.  
20 I think defense counsel discussed a mirror image metaphor. So  
21 I devised a hypothetical to illustrate the problem, and I'll  
22 allow you to respond.

23           So suppose FDA clinical trials relied on by the FDA  
24 for an NDA approval involved a safety protocol requiring all  
25 1,000 study participants to have a follow-up physician visit,

1 and suppose FDA finds that all 1,000 patients had no negative  
2 symptoms warranting a follow-up.

3           Is it plaintiffs' position that Section 355(d)  
4 would still nevertheless require FDA to retain that follow-up  
5 requirement despite those findings?

6           MR. BAPTIST: Yes, only because, in the real world,  
7 we see the complications that are associated with ultrasound--  
8 the lack of ultrasounds being a requirement. In the  
9 hypothetical scenario that you have--and you said there's zero  
10 complications post those trials, with just a follow-up visit  
11 that shows that no one had a complication. I would posit maybe  
12 plaintiffs wouldn't have a case or standing because no one  
13 would actually be hurt in the real world.

14           But in the sense there's essential safety  
15 protocols, such as an ultrasound in this case, and the safety--  
16 Well, you just can't tell or know without having a test  
17 conducted at any point in time, since the beginning to the end,  
18 of whether the approved regimen is safe.

19           THE COURT: Okay. I think I have your argument on  
20 that.

21           So during your argument-in-chief, we discussed  
22 remedies. And both of my law clerks attended the University of  
23 Virginia. The preeminent expert here is Doug Laycock, so they  
24 may have to rush back and dust off their outlines. But, here,  
25 the Court is trying to ascertain plaintiffs' argument for



1 suspension or withdrawal under Section 355(e). And this has to  
2 be framed in light of the stage of litigation we're at, at the  
3 preliminary injunction phase.

4 So at that stage, why is the preferred remedy or  
5 the recommended remedy withdrawal, and not suspension? I think  
6 your practical argument was that you were wanting full relief,  
7 but from a statutory perspective, doesn't suspension seem more  
8 appropriate at the injunctive phase than withdrawal?

9 MR. BAPTIST: Your Honor, counsel takes your point  
10 on that, and, in theory, that would be correct in terms of  
11 imminent harm and irreparable harm. Those sound like similar  
12 terms. And so in our prayer for relief, we did say suspend or  
13 withdraw, but recognizing "suspend" at this stage sounds more  
14 like a preliminary injunctive-type of action and it would be  
15 consistent with the statutory text at this stage. But at the  
16 same time, as you know, the plaintiffs have a long-term goal of  
17 setting aside, vacating, or having this approval withdrawn, so  
18 that is why we put that forward as well.

19 THE COURT: Okay. And to make certain that I heard  
20 your argument correctly-- I have your prayer for relief. It  
21 uses the terminology we're all accustomed to for a vacatur, set  
22 aside, all these different concepts. But at the level of  
23 granularity on what this Court could order were you to receive  
24 the relief you request, is it that you expect this Court to  
25 order the FDA to begin a suspension or withdrawal, almost like

1 a writ-type scenario, or that the Court itself can withdraw or  
2 suspend on its own accord?

3 MR. BAPTIST: The latter. We take the position  
4 that the Court, on its own accord, can order the FDA to  
5 withdraw or suspend the approval of the drug.

6 THE COURT: Okay. And explain to me your argument  
7 on why this Court has that sweeping authority.

8 MR. BAPTIST: It goes back to the case law that we  
9 cite. I know we've talked about one case maybe has been  
10 vacated. I believe it was on other grounds. But it's the  
11 power of the Court to enjoin and take whatever action to  
12 prevent harm. And so it's with that to compel where--we have  
13 seen that in past cases where an FDA approval, whether under  
14 the ANDA context or not, is what we would do, but--

15 THE COURT: Okay. And it's also--I recall your  
16 argument that this is simply conferred as construction of the  
17 statute that's being applied here, 355(e)?

18 MR. BAPTIST: Yes, Your Honor.

19 THE COURT: Okay. Now, I think I have your case,  
20 your papers, your argument here today on an appropriate remedy  
21 vis-a-vis FDA and HHS and what I have termed the government  
22 defendants in this case. What is your full position on a  
23 remedy vis-a-vis Defendant Danco should the Court reach that  
24 result?

25 MR. BAPTIST: With regards to their drug approval?

1 I'm sorry.

2 THE COURT: With regard to the intervenor. So far,  
3 most of the briefing that you have submitted refers to  
4 intervenor and defendant agencies collectively as defendants.  
5 Are you requesting any different remedy vis-a-vis the  
6 intervenor here, who doesn't stand in the same sort of shoes as  
7 a governmental agency?

8 MR. BAPTIST: There's nothing that we are asking  
9 the Court to do specifically with regards to Danco. Danco may  
10 be affected by what we're asking the Court to do if their drug  
11 approval has been set aside, enjoined in some capacity.

12 THE COURT: Okay. So there's no specific order  
13 that you're requesting vis-a-vis the intervenor; you just  
14 assume, should you prevail on the motion for preliminary  
15 injunction, that it would apply with equal force to Danco and  
16 that there's no special relief specific to the intervenor  
17 defendant?

18 MR. BAPTIST: Yes, Your Honor.

19 THE COURT: Okay. You may proceed with whatever  
20 argument you wanted to make in the remaining 10 minutes of your  
21 rebuttal.

22 MR. BAPTIST: I wanted to go back to--just about  
23 remedies. You asked about the domino or the reverse domino,  
24 and I wanted to make sure I answered that one appropriately.

25 If you were to decide to grant the entire relief

1 from plaintiffs with regards to the 2000 approval and beyond,  
2 it would be important not just to rule on Subpart H and the  
3 unlawful approval that occurred in that year, because there  
4 were also other problems with it, whether it was under the  
5 FDCA, PRA. And, again, Comstock pervades throughout this  
6 entire drug's history. It would be important because if the  
7 FDA merely says we just--we can put you right back in line and  
8 approve you with the same flawed studies or irrelevant studies  
9 or without a pediatric assessment, that would be problematic  
10 from a practical standpoint and from our plaintiffs'  
11 standpoint.

12 And again, just to make sure I was clear, you  
13 have--plaintiffs would say, if you want to enjoin or vacate the  
14 2021 decisions, the 2019, 2016, it can be singular, separate,  
15 apart. It doesn't have to be all-encompassing where, if one  
16 domino falls, they all have to fall.

17 THE COURT: Okay. I understand your argument  
18 better there.

19 And as to intervenor's argument that you  
20 essentially have to run the table to get to the relief  
21 requested at the end of your complaint, I think that also  
22 answers that question. I know you're arguing for total relief  
23 on all six claims, but it is your case to this Court that,  
24 should claims be adjudicated differently for various reasons,  
25 this Court can draw lines around each claim? You don't

1 necessarily need to run the table to prevail at all?

2 MR. BAPTIST: That is correct, Your Honor. That is  
3 our position.

4 THE COURT: Okay. Anything else from the  
5 plaintiffs?

6 MR. BAPTIST: Yes. I want to briefly touch on  
7 public interest based on what defendants collectively said.  
8 It's important to remember that mifepristone actually does not  
9 provide a medical benefit. It is not a medication that treats  
10 any illness or disease. At best, what defendants characterize  
11 chemical abortion drugs or mifepristone is that it prevents  
12 complications in pregnancies from occurring because it ends the  
13 life of an unborn baby before those complications present  
14 themselves. Because there are other medications to treat  
15 underlying pregnancy complications or surgical procedures to  
16 treat related complications as well, mifepristone is not going  
17 to be diagnosed to treat any related issues with that.

18 So in terms of thinking about the public interest  
19 and who is relying on it and how to rely on it, there are--in  
20 the areas where abortion is legal, those other options are  
21 going to be available. And again, plaintiffs are only focusing  
22 on chemical abortion in this lawsuit. To the degree surgical  
23 abortion is legal in those countries and on the circumstances  
24 that defendants say are available in all 50 states, that will  
25 still be available.

1           To the degree it's going to constrain where those  
2 procedures occur because there are rural areas that may not  
3 have access directly within an hour's drive of a surgical  
4 abortion, that's exactly one of the reasons why plaintiffs  
5 maintain that mail-order abortion is dangerous, because those  
6 are exactly the women who should not be receiving those drugs,  
7 because that means they are likely to be far away from  
8 hospitals and emergency treatment. So that does not  
9 necessarily go in the government's favor.

10           And, as well, the congressional brief found at--and  
11 amicus brief found at page ID 3417 talks about the  
12 congressional interest and how it entrusted the FDA to serve as  
13 the nation's gatekeeper and protect Americans from dangerous  
14 drugs. Defendants talked about how this lawsuit could  
15 undermine Congress's confidence in the FDA.

16           One, that would be only because of FDA's own doing.  
17 But second, Congress filed the--the only congressional brief  
18 filed said they want to see FDA follow their instructions and  
19 their directives. So the public interest would weigh in favor  
20 of Congress here, as opposed to undermine it.

21           And I want to note--

22           THE COURT: Just real quickly, because of all the  
23 argument about public interest and which way that cuts, can you  
24 point me to any portion of your briefing or declarations or any  
25 part of the record thus far that would address the parade of

1 horribles raised by defendant intervenor, all 50 states--  
2 Actually, defendant made the point about all 50 states, and  
3 then intervenor made the point about some of these early-term  
4 procedures that would be jeopardized by an order specific to  
5 mifepristone.

6           Is there anything in your brief or in the  
7 attachments or the declarations or any part of the record that  
8 refer to alternatives? So any references to Title X, OPA  
9 programs, state programs, anything like Plan B or other drugs?  
10 Is there a reference point there so the Court can have a full  
11 view of what the public interest looks like vis-a-vis the  
12 alternatives available to patients in this category?

13           MR. BAPTIST: To my immediate knowledge, nothing in  
14 the plaintiffs' briefs or filings. But I again would direct  
15 your attention to the 22-state amicus brief where it talks  
16 about how states have crafted their laws and regulations to  
17 reflect certain types of exceptions to the laws and how they  
18 have defended their citizens on abortion in general. So they  
19 have highlighted certain parts of that. And I may have a  
20 specific reference, if I have your indulgence. But for the  
21 sake of time, I may want to keep moving as well.

22           THE COURT: Okay.

23           MR. BAPTIST: One thing I would note, there was a  
24 declaration in support of the FDA's opposition brief by Maine  
25 Family Planning. I believe it was the Kieltyka, or Kieltyka,

1 declaration. They talked today--the FDA talked about how they  
2 may be doing an alternative protocol in response to any type of  
3 decision in favor of plaintiffs here.

4 I'll note that that's a little change of a position  
5 than what the declaration stated. The declaration stated that  
6 17 of 18 clinics would close. But as of last week, there are  
7 public press statements by their executives at Maine Family  
8 Planning that that would not necessarily have to happen, that  
9 they would just go to a one-drug chemical abortion treatment  
10 and just focus on misoprostol as opposed to mifepristone.

11 So circumstances may change. I commend the FDA for  
12 discussing that and bringing it up as they're talking about an  
13 alternative protocol that may not happen. But that is at least  
14 something that I--was important to bring, because I believe  
15 that was the only declaration talking about what clinics may  
16 have to shut down in specificity--

17 THE COURT: I believe from 2000 approval, to 2016  
18 major changes, to the 2020 agency action, although the dosage  
19 changed from 400 to 800, misoprostol is a continuing  
20 requirement through all of those agency actions, and you are  
21 not challenging the FDA's treatment of misoprostol; is that  
22 correct?

23 MR. BAPTIST: That is correct, in the sense that  
24 the separate drug approval of misoprostol is not at issue here.  
25 I will note that Danco Laboratories' approval-- And GenBioPro



1 is the generic manufacturer of the drug. They have a labeled  
2 use of misoprostol. When FDA approved mifepristone for use in  
3 chemical abortion purposes, it had to necessarily include both  
4 drugs as the approved labeled regimen.

5 So to the degree that the FDA has approved it, we  
6 have asked, I think, in our briefs, with sufficient clarity--if  
7 not, I apologize--that we would want the Court to set aside,  
8 vacate, enjoin, withdraw, or suspend at this point that  
9 approval to the degree that those two drug manufacturers have  
10 approvals with both drugs in it.

11 But plaintiffs acknowledge misoprostol is used, you  
12 know, on label to treat gastric ulcers. It's one of the top  
13 ways to induce labor and delivery. Those uses are not within  
14 the scope of this lawsuit. But if Maine Family Planning  
15 tomorrow wants to go and start using misoprostol only, our case  
16 wouldn't necessarily directly impact that, but it may be  
17 implicating Comstock, in addition, if they have to comply with  
18 that, obviously, depending how they ship and transfer that  
19 drug.

20 THE COURT: Okay. You may wrap up with any final  
21 statement to the Court you deem necessary.

22 MR. BAPTIST: Your Honor, the FDA's unlawful  
23 actions have harmed women and girls for far too long. The  
24 agency has prolonged these harms by stonewalling plaintiffs on  
25 their citizen petitions and then removing necessary safeguards

1 on the same day each time the agency denied those petitions.  
2 How many more women must die or come close to death before the  
3 FDA takes mifepristone off the market? Plaintiffs need not  
4 keep asking this question. Therefore, plaintiffs respectfully  
5 request that the Court hold the FDA accountable for its actions  
6 and grant our motion.

7 Thank you, Your Honor.

8 THE COURT: Thank you, Counselor. I have your  
9 argument.

10 So, here, neither party requested this hearing.  
11 The Court held the hearing on its own accord to afford all  
12 parties an adequate opportunity to make arguments before the  
13 Court reaches a decision on the pending motion.

14 I do want to thank those who endured the necessary  
15 planes, trains, and automobiles to travel from D.C. to Dallas  
16 to Amarillo. I know there are considerable logistics to reach  
17 this courthouse at this destination. So thanks to all of you  
18 that endured that.

19 I also want to thank the parties for excellent  
20 briefing all around, and excellent argument. This was superb  
21 appellate-grade efficacy at the writing phase, and also at oral  
22 argument today. So thank you for excellent work product all  
23 around.

24 They are not here, I don't imagine, but I would  
25 also like to thank the 77 amici who have submitted additional

1 research from both sides, in support of plaintiffs and in  
2 support of defendant and intervenors. That, too, is excellent  
3 briefing. This is just a smorgasbord of excellent  
4 appellate-grade work from all involved. So I extend the thanks  
5 of the Court for that.

6 Now that I have your oral arguments, in addition to  
7 the written papers before the Court, the Court will take this  
8 matter under advisement and issue--this Court will issue an  
9 order and opinion as soon as possible. We are adjourned in  
10 this matter. Counsel are excused. You may return home, and  
11 you may do lunch now at 1:30. So I apologize for that late  
12 hour.

13 We are adjourned.

14 (END OF HEARING)

15  
16 I, Mechelle Daniel, Federal Official Court Reporter in and  
17 for the United States District Court for the Northern District  
18 of Texas, do hereby certify pursuant to Section 753,  
19 Title 28, United States Code, that the foregoing is a true and  
20 correct transcript of the stenographically reported proceedings  
held in the above-entitled matter and that the transcript page  
format is in conformance with the regulations of the Judicial  
Conference of the United States.

21 /s/ Mechelle Daniel **DATE** MARCH 17, 2023

22 MECHELLE DANIEL, CSR #3549  
23 FEDERAL OFFICIAL COURT REPORTER  
24  
25