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]

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INDEX

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P R O C E E D I N G S

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

Are the parties ready to proceed?

MS. HAWLEY: Yes, Your Honor.

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

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

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

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

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

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

THE COURT: Okay. Thank you for that

clarification.

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

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

THE COURT: Okay. Thank you for that clarification.

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

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

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

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

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

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

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

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

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

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

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

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

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

THE COURT: Okay. You may proceed.

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

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

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

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

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

In addition, there are other examples. Dr. Francis

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

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

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

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

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

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

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

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

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

the chemical abortion by mifepristone.

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

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

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

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

example of a way in which harm may be shown.

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

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

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

MS. HAWLEY: Yes, sir.

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

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

itself enough harm.

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

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

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

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

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

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

MS. HAWLEY: Absolutely not.

THE COURT: Okay.

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

Here, these plaintiffs are clearly within the

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

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

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

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

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

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

MS. HAWLEY: No, Your Honor.

THE COURT: Okay. You may proceed.

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

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

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

on it in December of 2021.

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

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

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

reopening event the Court should focus on?

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

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

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

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

THE COURT: Okay. I understand that argument.

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

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

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

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

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

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

MS. HAWLEY: Absolutely, Your Honor.

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

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

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

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

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

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

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

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

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

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

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

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

General in the Office of Legal Counsel.

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

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

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

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

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

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

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

for producing abortion.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

THE COURT: And that--

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

Yes, Your Honor.

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

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

MR. BAPTIST: This is a pure textual application of

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

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

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

THE COURT: Could you spell Serono, please.

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

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

MR. BAPTIST: Yes, sir.

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

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

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

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

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

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

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

MR. BAPTIST: Yes.

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

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

wiggle room granted thereby?

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

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

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

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

discretion was arbitrary and capricious?

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

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

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

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

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

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

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

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

MR. BAPTIST: Thank you.

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

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

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

threefold.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

MR. BAPTIST: Yes.

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

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

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

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

MR. BAPTIST: Yes, Your Honor.

Plaintiffs' opening brief in support of their

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

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

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

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

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

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

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

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

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

THE COURT: Oh, no. You may proceed.

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

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

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

MR. BAPTIST: Correct.

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

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

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

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

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

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

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

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

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

You may proceed to your next topic.

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

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

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

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

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

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

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

operations also is an important factor as well.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

And as a textual matter, the mandatory language of

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

MR. BAPTIST: Yes, Your Honor.

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

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

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

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

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

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

THE COURT: Okay.

MR. BAPTIST: Thank you, Your Honor.

THE COURT: Thank you, Mr. Baptist.

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

MS. HAWLEY: Yes, Your Honor.

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

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

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

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

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

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

(RECESS TAKEN)

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

pending motion for preliminary injunction.

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

MS. STRAUS HARRIS: Yes, Your Honor.

THE COURT: You may approach.

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

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

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

MS. STRAUS HARRIS: Thank you, Your Honor.

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

relief until after a trial on the merits.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Second, they argue that there is an exception on

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

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

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

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

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

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

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

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

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

It's quite telling that no party raised the issue

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

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

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

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

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

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

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

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

THE COURT: Okay. And I know you mentioned the

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

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

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

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

invoking the delay to suggest that exhaustion should be excused.

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

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

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

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

to the Court.

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

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

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

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

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

years, not sixteen. You are correct.

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

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

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

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

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

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

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

MS. STRAUS HARRIS: Yes, he will.

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

MS. STRAUS HARRIS: Thank you, Your Honor.

THE COURT: You may continue.

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

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

injury for standing purposes.

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

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

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

MS. STRAUS HARRIS: Yes.

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

MS. STRAUS HARRIS: Yes. Correct.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

underlie their associational standing arguments.

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

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

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

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

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

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

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

THE COURT: And you mentioned a third reason.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

THE COURT: You may proceed.

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

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

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

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

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

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

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

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

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

THE COURT: Okay. You may proceed.

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

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

health conditions.

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

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

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

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

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

You may proceed.

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

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

MR. SCHWEI: I appreciate that, Your Honor.

THE COURT: Mr. Schwei, you may proceed.

MR. SCHWEI: Thank you.

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

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

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

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

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

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

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

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

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

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

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

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

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

approved.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Cosmetic Act.

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

THE COURT: Please proceed with that next part.

MR. SCHWEI: Thank you, Your Honor.

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

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

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

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

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

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

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

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

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

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

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

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

THE COURT: Okay. You may proceed.

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

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

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

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

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

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

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

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

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

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

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

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

MR. SCHWEI: So I'm not--

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

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

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

MR. SCHWEI: Correct, Your Honor.

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

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

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

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

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

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

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

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

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

And so even if the Court has some questions about

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

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

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

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

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

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

were still good law and the Comstock Act was unenforceable.

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

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

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

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

Subsection 2 talks about unlawful abortion.

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

This is just a straightforward reading of Section 1461.

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

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

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

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

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

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

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

not constitute an adoption of a previous administrative construction.

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

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

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

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

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

But in 2007, when Congress deemed mifepristone to

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

extend any deadlines for supplemental briefing--

MR. SCHWEI: Thank you, Your Honor.

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

MR. SCHWEI: Thank you, Your Honor.

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

MR. SCHWEI: I appreciate the reassurance.

THE COURT: Okay. Thank you.

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

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

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

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

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

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

impending harm to them.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

The FDA is tasked with enforcing the FDCA's rules

on drug approvals, and, by statute, Congress specifically told FDA what it may consider in approving or denying an NDA. We've been talking about those requirements this morning. Section 505(c) sets out the fact that the FDA must approve an NDA if none of the grounds are--none of the grounds for denying it apply. The language is very explicit. Quote, FDA shall issue an order approving the application. That's in 21 U.S.C. 355(d).

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

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

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

Subpart H.

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

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

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

leaves your system in eight hours.

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

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

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

MS. ELLSWORTH: Thank you, Your Honor.

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

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

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

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

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

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

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

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

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

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

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

including, if necessary, on remand from this Court.

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

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

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

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

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

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

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

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

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

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

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

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

MS. ELLSWORTH: Than this case, yes.

THE COURT: Just trying to be clever.

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

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

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

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

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

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

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

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

MS. ELLSWORTH: Yes, Your Honor.

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

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

MS. HAWLEY: Is it okay if we--

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

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

half? Would that be permissible?

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

MS. HAWLEY: Yes, sir.

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

MS. HAWLEY: Can we--

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

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

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

MS. HAWLEY: Okay.

THE COURT: You may proceed.

MS. HAWLEY: Thank you, sir.

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

And then if you look at the Supreme Court's

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

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

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

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

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

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

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

MS. HAWLEY: Absolutely.

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

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

well-supervised under the new rules is simply untrue.

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

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

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

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

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

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

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

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

MS. HAWLEY: Thank you, Your Honor.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

MR. BAPTIST: Yes, Your Honor.

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

MR. BAPTIST: With regards to their drug approval?

I'm sorry.

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

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

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

MR. BAPTIST: Yes, Your Honor.

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

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

If you were to decide to grant the entire relief

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

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

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

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

necessarily need to run the table to prevail at all?

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

THE COURT: Okay. Anything else from the plaintiffs?

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

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

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

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

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

And I want to note--

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

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

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

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

THE COURT: Okay.

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

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

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

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

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

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

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

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

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

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

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

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

Thank you, Your Honor.

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

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

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

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

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

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

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

We are adjourned.

(END OF HEARING)

I, Mechelle Daniel, Federal Official Court Reporter in and for the United States District Court for the Northern District of Texas, do hereby certify pursuant to Section 753, Title 28, United States Code, that the foregoing is a true and 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.

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

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