UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF WASHINGTON

STATE OF WASHINGTON, et al., Plaintiffs, vs. U.S. FOOD AND DRUG ADMINISTRATION, et al., Defendants.	Case No. 1:23-cv-03026-TOR March 28, 2023 Spokane, Washington Preliminary Injunction Motion Hearing Pages 1 - 28

BEFORE THE HONORABLE THOMAS O. RICE
UNITED STATES DISTRICT COURT JUDGE

APPEARANCES:

For the Plaintiff State of Washington:	KRISTIN BENESKI COLLEEN M. MELODY NOAH G. PURCELL State of Washington Attorney General's Office 800 Fifth Ave., Ste. 2000 Seattle, Washington 98104
For the Defendants:	NOAH T. KATZEN MOLLY SMITH U.S. Attorney General's Office 450 Fifth St. NW Washington D.C. 20530 ARAVIND SREENATH FDA Office of Chief Counsel
Official Court Reporter:	Allison R. Anderson, RMR, CRR, CCR United States District Courthouse P.O. Box 700 Spokane, Washington 99210 (509) 458-3465

Proceedings reported by mechanical stenography; transcript produced by computer-aided transcription.

(Court convened on March 28, 2023, at 8:28 a.m.)

THE COURTROOM DEPUTY: The matter now before the Court is the *State of Washington, et al., versus the U.S. Food and Drug Administration, et al.*, Case No. 1:23-cv-3026-TOR. This is the time set for a preliminary injunction motion hearing.

Counsel, please state your appearances for the Court and record, beginning with the plaintiff.

MS. BENESKI: Kristin Beneski for the plaintiffs.

THE COURT: Good morning.

MS. MELODY: Colleen Melody for the plaintiff states, Your Honor.

THE COURT: Good morning.

MR. PURCELL: And Noah Purcell for the plaintiffs.

THE COURT: Good morning.

MR. KATZEN: Noah Katzen for the defendants, Your Honor. I have with me at counsel table Aravind Sreenath of FDA's Office of the Chief Counsel and Molly Smith of the U.S. Attorney's Office.

THE COURT: And good morning to all of you.

I've read all the materials in the file. I'll hear from the plaintiff first. Who will be speaking?

MS. BENESKI: I will, Your Honor.

THE COURT: Come to the podium and use the microphone, please.

MS. BENESKI: Can you hear me all right?

THE COURT: Yes.

MS. BENESKI: Thank you. Kristin Beneski for the state of Washington, on behalf of the 18 plaintiff states; and Attorney General Ferguson and Attorney General Rosenblum are with us in the courtroom today.

I understand from Ms. Fortenberry's email that I have 15 minutes, and I'd like to return after that for any rebuttal time that may be permitted.

The 18 plaintiff states in this case represent 87 million Americans with protected rights to reproductive freedom. A preliminary injunction is needed to preserve and protect that freedom.

This case is about Mifepristone, which is an FDA-approved drug that is part of the gold standard of care for abortion within the first ten weeks of pregnancy and for treating miscarriages early in pregnancy. This drug has been on the U.S. market since the year 2000. It has been used by over 5 million people in this country alone, and it has proven to be extremely safe and effective, safer even than Tylenol.

Access to Mifepristone has never been more crucial or more threatened. Restricted access to abortion care is a full-blown crisis, including in the plaintiff states, as health care refugees turn to our states for care that has been outlawed elsewhere. This includes life-saving and essential abortion and miscarriage care.

THE COURT: I'm going to interrupt you. The briefing indicates that the January 2023 is the decision that you're challenging; is that correct?

MS. BENESKI: That's correct.

THE COURT: What existed? What were the restrictions to this drug prior to January 2023?

MS. BENESKI: It was many of the same restrictions, including the provider certification requirement and the patient agreement form prior to --

THE COURT: So those existed.

MS. BENESKI: Those existed. And then prior to 2023, there was no pharmacy certification requirement. Instead, the drug had to be dispensed by the provider.

THE COURT: So the pharmacy couldn't dispense it at all.

MS. BENESKI: Correct, Your Honor. But the reason we're challenging these restrictions now is that in the wake of the *Dobbs* decision, as I mentioned, access to reproductive health care has become a full-blown crisis; and the impact of the REMS, the unlawful and arbitrary REMS restrictions, the impact of those is much more significant now than it ever has been when prior REMS restrictions were imposed.

THE COURT: Okay. I'm reading from your brief, and you indicate that there's three changes, and the first change was the patient agreement form, but that's always existed; is

that correct?

MS. BENESKI: That's correct.

THE COURT: So that wasn't a change in 2023.

MS. BENESKI: Well, we're challenging the REMS that were imposed in January 2023. We're challenging the FDA's decision to reimpose restrictions on Mifepristone. The FDA could have decided to lift those, and it should have given the crisis that we're facing; but instead, the FDA chose to reimpose those restrictions, and that's what we're challenging.

THE COURT: So you're seeking a mandatory injunction. You're not going back to the status quo. You're asking me to mandatorily enjoin the FDA from reimposing the patient agreement form.

MS. BENESKI: No, Your Honor. We're asking for a prohibitory injunction against the FDA's enforcement or application of the REMS restrictions, and this is the same form of relief that was issued in the *ACOG versus FDA* case in the District of Maryland, which enjoined the REMS restrictions during the COVID-19 pandemic. It's not a mandatory injunction.

THE COURT: Okay. The second issue that you raised in your brief was that this drug can only be prescribed by a health care provider who is specially certified. Didn't that exist prior to January 2023?

MS. BENESKI: It did, Your Honor, but, again, the impact of the REMS restrictions is far more significant now that

we're facing a crisis of care. People from other states that have outlawed abortion or restricted it heavily are coming to our states, to the plaintiff states, for care that they can't get in their home state, and the REMS restrictions limit the number of providers who can prescribe this medication, which overburdens our health care systems. This is something that the FDA itself has acknowledged elsewhere that when access to Mifepristone is restricted, it overburdens state health care systems, and it's a huge problem following the *Dobbs* decision.

THE COURT: And how long has that been in effect, the health care provider must be specially certified?

MS. BENESKI: I believe it's been in effect the entire time that Mifepristone has been approved, but it has always been arbitrary and capricious. It has always been unlawful. It's just that the impact of that is far more significant today than it ever has been when the REMS were previously imposed.

THE COURT: All right. And then the third item in your brief was that the FDA now allows pharmacies to distribute the drugs if they're specially certified; yet prior to January of 2023, pharmacies were never allowed. So what's -- how's that arbitrary and capricious?

MS. BENESKI: It's arbitrary and capricious, Your Honor, because Mifepristone ought to be available to the same extent as any other prescription drug. It's far, far safer than many drugs that do not have any REMS restrictions at all. The

pharmacy certification requirement is completely unique to Mifepristone. No other drug has this requirement; so it's arbitrary and capricious to restrict this drug to a much greater degree than drugs that are far less safe.

THE COURT: Okay.

MS. BENESKI: Thank you, Your Honor. I will go ahead and address the *Winter* factors, which are likelihood of success on the merits, irreparable harm and the public interest and equities.

Starting with likelihood of success, as the FDA is well-aware, the evidence of Mifepristone's safety and efficacy has only gotten more compelling as millions of people in the United States have used this medication over the last 23 years; and by statute, the restrictions the FDA has imposed on Mifepristone can only be applied to inherently dangerous drugs, opioids being one example. Opioids are highly addictive and deadly. They're responsible for an epidemic that has killed more than a million people in this country; and yet the REMS restrictions for opioids, it's not mandatory, and it requires nothing more than optional training for prescribers.

By contrast, Mifepristone has a better safety record than Tylenol, aspirin, insulin, penicillin, Adderall, Viagra, and just about every other commonly-used medicine. Mifepristone is extremely safe by any measure, and yet its REMS restrictions are mandatory and unduly burdensome. The FDA asks this Court for

near total deference to its decision, but the FDA cannot disregard the limitations Congress placed on its authority nor can it justify singling out an exceptionally safe drug for uniquely burdensome restrictions.

This is illustrated, I think, most clearly by the fact that the FDA does not impose any restrictions on Mifepristone when it's used for a purpose other than abortion and miscarriage care. For abortion and miscarriage care, you take one 200-milligram pill one time. That is subject to onerous REMS restrictions. If you take Mifepristone for Cushing's disease, it's a 300-milligram pill up to four times a day every single day over the long-term, and there are no REMS restrictions on that usage. This is the definition of arbitrary and capricious, and it also violates the statutory requirement that REMS -- excuse me, that ETASU, the type of REMS at issue here, can only be imposed on inherently dangerous drugs.

The REMS is causing irreparable harm in our states every single day because it prevents patients from accessing Mifepristone for no good reason. This is much more harmful, as I mentioned, now than it was the last time the FDA imposed a REMS because now there is an access crisis across this country. Because of the REMS restrictions, there are only a limited number of specially-certified providers who can write a prescription for Mifepristone, and that's not because other providers aren't qualified. Primary care providers, OB/GYNs,

and others have the basic skills needed to safely prescribe medication abortion, but the REMS prohibits otherwise qualified providers from prescribing an extremely safe drug.

THE COURT: I need to interrupt you. I need clarification here. Ever since this drug's been on the market, though, it's been required to have specially-certified providers; isn't that correct?

MS. BENESKI: That's correct, Your Honor.

THE COURT: All right.

MS. BENESKI: And again, the reason that we're challenging it now is because a situation that might have been tolerable at a time in this country when everyone had a constitutional right to access abortion care within the ten-week window, for which Mifepristone is available, that world no longer exists. Now we have extremely restricted access to care that is overburdening our health care systems, and so the REMS restrictions that limit the universe of prescribers that can prescribe this drug causes and exacerbates this access crisis.

The harms that are caused by the REMS are detailed extensively in our briefing, and I won't spend too much time going over them here. All of these harms are well substantiated by the undisputed record evidence that we've submitted, but I would like to spend just a few minutes talking about the impacts of the REMS on real people who rely on access to Mifepristone.

The people who are most hurt by the REMS restrictions are

those who live in rural medically-underserved areas, including right here in eastern Washington. The FDA was required by statute to consider these impacts on rural and underserved patients, but it did not do so. In fact, it explicitly said in its 2021 review that it would not consider these impacts.

The REMS hurt people who have the least available time and resources to navigate complex and unusual pathways to care or to travel to get care. The REMS hurt people who already suffer the worst disparities in health care outcomes at a time when maternal mortality is rising in this country. The REMS hurt people who are the most vulnerable, such as people living with domestic abuse, as amici in this case explain. In this country, a black woman is three to four times more likely than a white woman to die a pregnancy-related death.

In states that protect the right to choose to end a pregnancy, medication abortion offers the promise of broader access to care that reduces disparities. If the REMS restrictions are lifted, which they should be, Mifepristone could be prescribed by any qualified provider and dispensed by any qualified pharmacy just like any other prescription medication subject to all the same safeguards. But the FDA's decision to single out Mifepristone for disfavorable treatment right now when we're -- they're experiencing the worst crisis in access that has occurred in generations, this blocks people from accessing this essential medication and causes widespread

irreparable harm.

Lastly, the public interest, which merges with the equities here, overwhelmingly favors preserving and expanding access to a safe, effective, and essential medication that's been available for a generation and that people rely on as the gold standard of care.

Turning to the plaintiff states' request for relief, the Ninth Circuit has held that courts have broad discretion to fashion equitable relief that addresses the specific needs of the parties before them and the specific facts and circumstances of the case; and here, our request for relief has two layers.

First, we seek an order prohibiting the FDA from taking Mifepristone off the market or otherwise harming access to the drug in our states. This is a pure preservation of the longstanding status quo, and it's crucial in part because the FDA is a party to a case in Texas that seeks to undue its longstanding approval of this extremely safe and effective drug. The plaintiff states are not parties to that case, and the FDA agrees, as I mentioned, that the states will suffer enormous irreparable harm if the nationwide relief sought in the Texas case were to be granted.

The REMS restrictions are bad enough, but losing access to Mifepristone would be a catastrophe. That is why we need a court order protecting access in our states. Our claims in this case depend upon the FDA's correct determination over

twenty years ago that Mifepristone is safe and effective, and our claims rely on the drug's continued availability.

The FDA opposes this relief but fails to offer any assurances that the status quo will be preserved. To the contrary, the FDA's opposition to this relief and the dire threat posed by the Texas lawsuit and other threats to access to Mifepristone show why a court order is needed to protect access in our states.

And for the second layer of relief, we seek an order enjoining the FDA from applying or enforcing the REMS. This is necessary to prevent all the irreparable harms I've just discussed and that are extensively detailed in our brief. Even though it's not a pure preservation of the status quo, courts have awarded similar injunctive relief to prevent irreparable harm during a crisis. For example, as I mentioned, prior Mifepristone REMS included an in-person dispensing requirement that was enjoined during the COVID-19 pandemic, and those restrictions were ultimately lifted.

The FDA did not create the current crisis in access to abortion care, but the FDA is responsible for exacerbating that crisis by deciding at this moment to impose the unlawful REMS restrictions without considering the harm they would cause in a post-*Dobbs* world. These useless and harmful restrictions should be enjoined while this case proceeds to the merits.

In conclusion, Your Honor, the REMS exacerbate the crisis

that is impacting reproductive rights every day, including in states where those rights are protected, and these restrictions must be enjoined to prevent further irreparable harm.

Additionally, an injunction is needed to keep Mifepristone on the market in our 18 states and to prevent the massive irreparable harm that would be caused by a radical departure from the status quo. If the Court has no further questions, I'll reserve my remaining time.

THE COURT: I have no further questions at this time.

MS. BENESKI: Thank you.

MR. KATZEN: Good morning again, Your Honor.

THE COURT: Good morning.

MR. KATZEN: Plaintiffs say that they seek an order that would preserve the status quo, but the reality here is far different. They seek a preliminary injunction that would -- that would set aside FDA's existing determination that Mifepristone is safe with particular restrictions and replace it with plaintiffs' own determination that Mifepristone is safe without any restrictions. Not only is that not the status quo, it has never been the status quo in the entire 22 years that the drug has been on the market.

Moreover, plaintiffs request this extraordinary relief despite never having properly presented their evidence and arguments to the agency and despite the fact that the agency action they challenge, the January 2023 REMS modification,

actually reduced restrictions on Mifepristone and made them less burdensome than they've been the entire time the drug has been on the market. The Court should deny the motion for a preliminary injunction because plaintiffs have met none of the factors; and even if they had met all of the factors, the relief that they seek is plainly beyond any permissible scope.

I'll begin first with irreparable harm, which is -- the plaintiffs' failure to show irreparable harm, which is in and of itself a basis for denying the motion for preliminary injunction and is also relevant because they assert irreparable harm as a basis for being excused from the exhaustion requirement. The easiest way to see why plaintiffs have failed to show irreparable harm is to ask how are they worse off as a result of the January 2023 REMS modification than they were before the January 2023 REMS modification? The answer is they're not.

Let's look at what the January 2023 modification did. It did three things. First, it retained two requirements, the prescriber certification requirement and the patient agreement form, that have been in continuous effect since the drug was approved in 2000. Plaintiffs cannot credibly claim irreparable harm from having to comply with two restrictions that they've been complying with for over twenty years and did not during that whole time seek relief from the agency through a citizen petition or filing an action in this court.

The second thing that the 2023 REMS modification did is it

eliminated the in-person dispensing requirement. Plaintiffs do not claim irreparable harm from that. In fact, they favor that.

And the third thing that the 2023 REMS modification did is that it permitted something that had previously been prohibited, namely dispensing the drug by pharmacy. Now, to be sure, FDA didn't go as far as plaintiffs would like. The pharmacies have to be certified to dispense Mifepristone. But nonetheless, FDA didn't burden any activity that states were permitted to engage in prior to January 2023. Prior to January 2023, no pharmacy could dispense Mifepristone under the REMS; and after January 2023, certified pharmacies can dispense Mifepristone under the REMS. That doesn't make plaintiffs worse.

THE COURT: Let me stop you there. What other drug requires pharmacy certification?

MR. KATZEN: I'm not -- pharmacy certification, I believe, is one of the possible -- one of the statutorily possible elements to assure safe use. I don't have another example off the top of my head of such a drug, but there are other drugs, including -- that have elements to assure safe use, including drugs where the -- where one drug product has a REMS and another drug product doesn't have a REMS, even though they have the same active ingredient, but I don't know of another -- there may be another drug. I'm just not aware of one, Your Honor.

THE COURT: Well, I'm trying to understand how

pharmacy certification provides any safety to the patient if the patient's already signed a patient agreement form and the certified health care provider is certified to prescribe the drug. So what role does the pharmacy certification play? It doesn't seem --

MR. KATZEN: It helps ensure that the provider certification -- the integrity of the provider certification requirement is maintained. Prior to January 2023, the drug could only be dispensed in person by the provider, who was certified. Now it can be dispensed by pharmacies; and to make sure -- and to help make sure that the integrity of that requirement is maintained, the pharmacies themselves have to be certified.

THE COURT: So the pharmacy's --

MR. KATZEN: This was --

THE COURT: -- overlooking the health care provider's certification?

MR. KATZEN: The pharmacy has to receive the certification from the provider and verify that the provider is certified. This was essentially the trade-off that FDA decided was necessary in order for it to conclude that there was sufficient evidence of safety to remove the in-person dispensing requirement, which, of course, was more burdensome than the pharmacy certification requirement because it prohibited pharmacies from dispensing the drug altogether.

THE COURT: All right.

MR. KATZEN: So plaintiffs do not suffer any irreparable harm as a result of the January 2023 action.

Let me just turn to exhaustion. Plaintiffs don't claim that they filed a citizen petition, but they offer a number of reasons why it shouldn't matter, one of which is that they suffer irreparable harm. Well, for the reasons I just explained, they don't suffer irreparable harm from the January 2023 action. But even if they did suffer some irreparable harm from the January 2023 action, that still would not explain why they failed to exhaust administrative remedies before January 2023. Again, two of the requirements they challenge have been in effect for 20 -- for 22 years.

The third requirement, the pharmacy certification requirement, was first announced by FDA back in December, December 16th, 2021, which means that any time after December 16th, 2021, plaintiffs could've filed a citizen petition with FDA challenging all three requirements and asking FDA to refrain from approving a supplemental drug application proposing modifications to the REMS with those three requirements. They have offered no excuse for their failure to do so. Even assuming they could have done so until *Dobbs*, *Dobbs* was in June of 2022, with plenty of time to file a citizen petition, especially since they did not know at the time that the FDA was going to approve supplemental applications modifying

the REMS in January 2023.

The next excuse that plaintiffs offer for not exhausting their administrative remedies is they claim those remedies were effectively exhausted by the 2022 ACOG citizen petition. The ACOG citizen petition, however, was very different, Your Honor. It contained two requests to FDA besides its request for enforcement discretion.

The first request was that FDA direct the application holder from Mifeprex to submit a supplemental new drug application proposing miscarriage management as a new approved indication for Mifepristone. Miscarriage management is not an approved indication for Mifepristone. The second request -- and this is the key -- was to -- was that FDA modify the REMS so as not to unduly burden that new use, meaning miscarriage management.

So it makes perfect sense that when FDA denied the first request, because it is up to the application holder to decide what uses to seek approval for, it denied the second request relating to REMS modification as premature, not on the merits but as premature because miscarriage management was not and is not an approved indication for Mifepristone. So that response says nothing whatsoever about how FDA would've responded to a citizen petition that raised the issue that plaintiff raised in this case -- that raised -- that asked FDA to modify or eliminate the REMS to -- in light of, for instance, the burdens

of *Dobbs* or the recent evidence from 2022 or the expert declarations attached to plaintiffs' motion to modify or eliminate the REMS so as not to burden the existing approved use of abortion.

And even if FDA had substantively addressed ACOG's citizen petition request for modification of the REMS, that still wouldn't bear on the question here because when FDA considers scientific evidence, including evidence relating to the burdens of the REMS or the safety of Mifepristone or anything else, it views that evidence in the context of the specific question that's being asked; and since ACOG's citizen petition was asking a very different question, asking FDA to do very different things than what plaintiffs are asking here, any answer that FDA would've -- could conceivably have given, even if the ask by ACOG were not premature, would have no bearing on the issue in this case.

And the third and final excuse plaintiffs give for not exhausting their administrative remedy is they say that their claim just involves the same issues that were presented to the agency before 2022. Well, I think that's belied by the entire emphasis that plaintiffs put on the burdens that have arisen, they say, in the wake of the *Dobbs* decision, which was decided in 2022. It's also belied by the fact that they cite studies from 2022, including the Canadian study, that forms their primary evidence that Mifepristone's safety profile isn't at all

attributable to the fact that it has been operating with a REMS since its approval.

Moreover, it includes the declarations that contain expert opinions that plaintiffs cite as evidence going to the merits of this dispute appended to their motion for a preliminary injunction, which were obviously not before the agency before 2022. And this is important because FDA's exhaustion requirement, part of it, at 21 CFR 10.45(f), says that one thing a plaintiff has to do before relying on information and views that were not before the agency at the time of its initial decision is if they want to rely on such information or reviews, they have to put it before the agency in a new citizen petition, and it is indisputable that plaintiffs failed to do so here. So failure to exhaust administrative remedies, apart from their failure to show irreparable harm, is another reason to deny plaintiffs' motion for a preliminary injunction.

I'll move next to standing, and I'm going to make one point about standing here going to the redressability point. Then I'm going to tie it into plaintiffs' broader request for relief, and then I'll get to the merits. As I said, plaintiffs have a broad request for relief that goes well beyond enjoining the action that they say was unlawful, the final agency action they're challenging, namely the January 2032 REMS modification. They're also asking for an injunction that would preclude future decisionmaking by FDA on the REMS or anything else, whatever it

could be, that would in their view make the drug less available than it currently is.

They're not entitled to that relief under basic principles of injunctive relief and under the APA. Their relief would have to run against the final agency action. They've challenged the final agency action that they say is unlawful; so the question for redressability on standing is would an order that runs solely against the agency action that they are challenging here redress their injuries? They have offered no theory as to how it would. They have not alleged that it would.

And in fact, in their reply brief on Page 16, they say that the minimum relief that they would need in order to have their injuries redressed would be an order that goes beyond the final agency action here and precludes future agency decisionmaking with regard to the REMS. Since they can't get that relief and the only relief that they could get if they met all four preliminary injunction factors is not relief they say would redress their injuries, they fail to show redressability for any of their injuries, and that is an additional basis for they lack standing and that their motion for preliminary injunction should be denied.

Now I'll turn briefly to the merits. I'm not sure how much time I have. I'll just start with kind of a broad point about what it is that the agency was doing in 2021 when it undertook its REMS review, which culminated in the January 2023 action

that plaintiffs challenge. Contrary to what plaintiffs have suggested, FDA was not deciding whether on a tabula rasa to impose a REMS with elements to assure safe use. FDA originally imposed the elements to assure safe use in this case under its subpart (h) regulation before the REMS statute was enacted.

When Congress enacted the REMS statute in 2007, it ratified FDA's decision to impose elements to assure safe use by providing that drugs with existing subpart (h) restrictions like Mifepristone would be deemed to have in effect a REMS with elements to assure safe use. So the question for FDA by 2021 was whether, in the language of the REMS statute's modification provision at 355-1(g)(4), to add or modify or remove any of the existing elements to assure safe use that were part of the existing REMS, and FDA came ultimately to a mixed decision on that point. It decided two of the requirements should be retained, it decided a third should be omitted, and it decided a fourth should be added.

The question is whether -- and FDA undertook its analysis by asking whether since its last REMS modification in 2016 there was any evidence that justified taking such a step. That is the window through which FDA's decision in 2023 to approve a REMS modification in its decision in December of 2016 that the REMS must be modified, as it eventually was, should be judged, and we submit that FDA's decision on that point was reasonable and not arbitrary and capricious.

THE COURT: I have one question. Your briefing indicates that you've expanded the use of this drug by allowing pharmacies now to distribute it, but that doesn't take away the health care provider's ability to provide it directly to the patient, does it?

MR. KATZEN: No. A provider can still dispense the drug in person. The states and pharmacies still have every option that they had prior to January 2023 to dispense first; they just have a new additional option now.

THE COURT: All right.

MR. KATZEN: Thank you, Your Honor.

THE COURT: All right. I'll hear a couple minutes of rebuttal.

MS. BENESKI: Thank you, Your Honor. I'd like to touch briefly on the exhaustion issue. These same issues that we're raising in this case have been raised at least a dozen times since 2015. If you look at the Hughes declaration, Exhibit M, there's a chronology of all the times these same issues have been raised, and it's not just the ACOG petition from last fall. The FDA conducted what it described as a full review of the Mifepristone REMS in 2021; and as part of that, the FDA received multiple letters from leading health care organizations and professional organizations in this country, including the American Medical Association, representing the nation's obstetricians, gynecologists, family physicians and

others.

There's a broad consensus in the medical field that the Mifepristone REMS are unsupported by scientific evidence and should be lifted, and the FDA was aware of all of this. Those letters that the FDA received as part of the 2021 full review cite the same evidence that we cite in our briefing, including the Canadian study that the FDA chose to disregard; so these issues are both exhausted and futile.

To touch on the point about why the harm is so much more salient now than it has been and why we didn't challenge the REMS previously, we had every reason to believe that the FDA was taking this crisis, this post-*Dobbs* crisis, seriously. Secretary Becerra, after the *Dobbs* decision, released a statement saying that, "Working to increase access to this drug," Mifepristone, "is a national imperative and in the public interest." As part of those same comments, Secretary Becerra recognized that Mifepristone is part of the gold standard of care for miscarriage. He also said, "If there's something we can do to protect access, we will find it and we will do it." So it wasn't until January 2023 that we realized that the FDA was in fact not going to take Secretary Becerra's comments seriously and reimpose -- reimpose the unlawful and arbitrary REMS restrictions.

The Court asked several questions during my initial comments about why we're harmed now if the REMS have been in

place for such a long time, and I want to emphasize again the prior REMS restrictions were issued under much different circumstances in which there was a universal constitutional right to abortion at the federal level. The FDA completely ignores the changed circumstances in which it reissued these REMS restrictions. The REMS have always been arbitrary and discriminatory, but now they are exacerbating the crisis that has emerged in the last year, a crisis recognized by Secretary Becerra himself.

Before the *Dobbs* decision, no one could be prosecuted for providing or facilitating an abortion or miscarriage care that might be characterized as an abortion. That is an irreparable harm by itself to our state providers who have to sign these forms and who have to get certified and identify themselves as abortion providers and put themselves in danger by getting certified. These harms are brand new in the wake of the *Dobbs* decision.

One thing I did not hear during Counsel's presentation was any discussion of the real public interests at stake here. I heard about the FDA's institutional concerns and its desire for deference, but Counsel did not even acknowledge the interests of real people who need access to this essential medication. For them, this issue is not an abstraction. It is their lives and their health, and the REMS restrictions are impacting their lives and their health every single day.

Again, it's not as though defendants are unaware of this. Secretary Becerra's comments, which are at Hughes Exhibit G to our reply and they're also cited in our complaint, they make very clear that Secretary Becerra believes that this is a crisis and that expanding access to Mifepristone is a national imperative. So it's inexplicable that the FDA would not take this into account when imposing senseless restrictions on a medication women need that is safer than Tylenol, aspirin, penicillin, and just about every other commonly-used drug, and it's inexplicable that the FDA is fighting so hard to remain free to pull this extremely safe medication off the market at a time when people need it more than ever.

Access to Mifepristone, the baseline of access that exists today, is a necessary predicate to the ultimate relief that we're requesting, and this Court has the power to enjoin the FDA from changing that status quo in order to prevent irreparable harm; in other words, to prevent the egg from being scrambled -- that's the terminology that courts addressing similar issues use -- to preserve the plaintiffs' ability to obtain ultimate relief.

These issues that we're addressing today can seem abstract from the inside of a courtroom, but the declarations we've submitted and the briefs filed by amici are powerful messages from people who care for patients every day and see the harmful impacts of the FDA's actions every day. The REMS restrictions

are exacerbating the crisis of scarce access to essential reproductive health care and the climate of fear and uncertainty surrounding it. The states ask that the Court grant their motion for a preliminary injunction.

THE COURT: All right. Thank you, Counsel. I'll take this matter under advisement and issue a written decision as promptly as I can. That concludes today's hearing.

THE COURTROOM DEPUTY: All rise.

(Court adjourned on March 28, 2023, at 9:10 a.m.)

C E R T I F I C A T E

I, ALLISON R. ANDERSON, do hereby certify:

That I am an Official Court Reporter for the United States District Court for the Eastern District of Washington in Spokane, Washington;

That the foregoing proceedings were taken on the date and place as shown on the first page hereto; and

That the foregoing proceedings are a full, true, and accurate transcription of the requested proceedings, duly transcribed by me or under my direction.

I do further certify that I am not a relative of, employee of, or counsel for any of said parties, or otherwise interested in the event of said proceedings;

DATED this 4th day of April, 2023.

ALLISON R. ANDERSON, RMR, CRR
Washington CCR No. 2006
Official Court Reporter
Spokane, Washington