IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF NORTH CAROLINA

AMY BRYANT, M.D. Plaintiff, vs. JOSHUA STEIN, in his official capacity as Attorney General for the State of North Carolina, et al., Defendants, and TIMOTHY K. MOORE and PHILIP E. BERGER, Intervenor-Defendants.	CASE NO. 1:23CV77 Greensboro, North Carolina January 17, 2024 9:30 a.m.

TRANSCRIPT OF THE **MOTIONS HEARING**
BEFORE THE HONORABLE CATHERINE C. EAGLES
UNITED STATES DISTRICT JUDGE

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P R O C E E D I N G S

THE COURT: Good morning. We're here in Bryant against Stein, 23CV77, hearing on the Intervenor Defendants' motion to dismiss.

I had the clerk email you all a bunch of questions just so you would know I had read everything, which I did, and more. So I'm also -- you know, I don't know if I asked you this one or not, but it is a motion to dismiss on preemption. So if I grant the motion, I know what happens. You all appeal. If I deny the motion, we'll -- then what happens? Are there fact issues? Are you all just going to brief it again on summary judgment? I mean, this is it; right? This is what the case is about.

So is it -- you know, y'all can -- do we just need to convert it to summary judgment and not deal -- I don't know. You all can -- let me finish before you start talking to me about that. You can talk to me about it.

So I have that question. And then I just -- also, something else I didn't really cover, the complaint alleges what it alleges, and then it attaches a lot that's not specifically alleged -- you know, the details of which are not specifically alleged. Some of the regulatory stuff before 2016 didn't really have dates on it. It seems important to go through the regulatory history, and I don't know that it's disputed. But at some point I may need to, like, tell you what

I think it is and then let you tell me if I've, you know, inadvertently made a mistake.

I do want you to talk to me about how the REMS goals defined by the FDA play into the preemption analysis.

I don't know. I asked y'all about a million questions, it felt like. It really wasn't that many. What? Ten or fifteen? And some of them overlapped.

So I really was just thinking I would let you all talk to me and answer the questions in the course of your argument, unless there's some other way you all would rather do it.

So, first, why don't I get everybody to tell me who they are and make sure I remember all your names. And if there is any housekeeping thing you want to say, you can address that when you're introducing yourself.

So here for the Plaintiff?

MR. MEZZINA: Good morning, Your Honor. Paul Mezzina for --

THE COURT: Speak into the microphone.

MR. MEZZINA: Sorry, Your Honor. Paul Mezzina for Dr. Bryant.

MS. TEMKIN: Good morning, Your Honor, Eva Temkin for Dr. Bryant.

MS. COREY: And Chelsea Corey for Dr. Bryant.

THE COURT: I'm sorry. Say your last name.

MS. COREY: Corey.

THE COURT: And who's going to be arguing?

MR. MEZZINA: That would be me, Your Honor.

THE COURT: All right. And here for the -- well, let's just start with the Defendants.

MS. BOYCE: Good morning, Your Honor. My name is Sarah Boyce on behalf of Attorney General Josh Stein.

MS. NARASIMHAN: Good morning, Your Honor, Sripriya Narasimhan on behalf of Attorney General Josh Stein.

MS. O'BRIEN: Good morning, Your Honor, Elizabeth Curran O'Brien. I'm here on behalf of District Attorney Jeff Nieman who takes no position on this motion.

MR. BULLERI: Good morning, Your Honor, Michael Bulleri on behalf of the North Carolina Medical Board.

MR. WOOD: Good morning. I'm Michael Wood on behalf of Secretary Kody Kinsely from DHHS.

THE COURT: Any of y'all going to be arguing other than Ms. Boyce? No? Okay.

And here for the Defendant Intervenors?

MR. BOYLE: Good morning, Your Honor, Ellis Boyle from the Wake County Bar on behalf of the Intervenor Defendants.

And I would like to introduce Ms. Hawley who is pro hac from the New Mexico, Missouri, and District of Columbia Bar. She will be arguing on behalf of our clients.

THE COURT: Good morning.

And tell me your last name again.

MS. HAWLEY: It's Hawley.

THE COURT: So this is a pretty wonderful courtroom, but you can't hear if you don't speak right into the microphone. And so I apologize. I'm not even really particularly polite about it. I hope I'm not rude, but I will just tell you to speak into the microphone. You may get tired of hearing me saying that if you don't speak into the microphone. If you move -- if you have a tendency to move around when you talk, just please be aware of that.

Sometimes it works well to pull the second microphone over if only one of you is going to be arguing, and that may -- sometimes works a little bit. So if anybody wants to do that, you are free to -- might help a little, but don't count on it because you can only get them so close. They didn't build these courtrooms in 1928 for our technology.

So it is the Intervenors' motion. What I would propose to do, given how it all has fleshed out, is to let them go first. Then hear from the Plaintiffs. Then hear from the Defendants. And then I'll just let y'all go around in circles in that order until you start repeating yourselves.

Okay. Go ahead.

MS. HAWLEY: Good morning, Your Honor. May it please the Court, the challenge provisions here are ubiquitous in

state laws across the country. They are not preempted for three reasons.

First, the plain terms of the REMS statute expressly limits the FDA's authority. It does not supersede state laws that are regulating health and safety.

THE COURT: Where does it say that in the statute?

MS. HAWLEY: So, Your Honor, I'd point you to Section 355-1(f)(1) and (2). I have that right in front of me. And if you look at (f)(1), it says: "The Secretary, in consultation with offices," blah-blah blah, may "include such elements as are necessary to assure safe use..." So it's plainly directed to the Secretary.

THE COURT: Okay. But how does that explicitly -- you said, "It expressly limits the FDA's authority."

MS. HAWLEY: So I think that's the fairest reading of the statute, Your Honor. I would go so far to say expressly for the additional reason that if you look at Section (2), it says: "Such elements to assure safe use" -- those that are imposed by the Secretary -- "under paragraph (1) shall," and then, and only then, does it talk about the FDA considering whether a provision might be unduly burdensome.

So I think when you look at Section 355-1, it is clear what Congress was intending to do. The FDAAA was enacted in response to the Vioxx controversy in which FDA had approved a drug that essentially doubled the risk of heart disease and

stroke. Congress was not happy, so they enacted the REMS provision to allow the FDA to regulate high-risk drugs at a greater level.

THE COURT: Well, didn't they also enact it to -- I mean, there were lots of purposes to those amendments. And that's kind of one thing I want to ask you, because it looks like it incorporated, you know, requirements for post-clinical, post-approval complications and problems, increased reporting. It authorized the FDA to do -- require clinical studies, for example, after approval. And it made it clear that the FDA approval process not only for REMS, but for other drugs, too, was sort of an ongoing thing; that the FDA was empowered to constantly evaluate and reevaluate safety and efficacy, particularly for REMS drugs.

Would you disagree with what I just said?

MS. HAWLEY: So I agree that the REMS provision requires the FDA to look at those REMS again. In some cases the FDA does impose post-marketing studies and those sorts of things. But what I would quibble with Your Honor is I think all of those things are directed to the FDA's primary purpose here, which is safety. The Supreme Court told us that in *Wyeth*. It said that the FDCA was enacted to promote safety and efficacy.

If you look at the appendix, Appendix A, page 2, as you mentioned, Your Honor, it includes the REMS goals. Those

goals are to mitigate the safety risks. I think that is of a piece with the FDCA's purpose in promoting safety.

THE COURT: So if Congress is telling the FDA that's their job, giving them ongoing authority and responsibility, telling them for REMS drugs you have to look every one year, three years, seven years, unless you decide, FDA, that it's not necessary, why is the State allowed to further regulate for safety concerns?

MS. HAWLEY: Because, as the Supreme Court explained in *Wyeth*, the Federal Food, Drug, and Cosmetic Act has always allowed for complementary state regulation.

THE COURT: But that was enacted -- that was decided before the 2007 amendments, correct, so it was under previous law?

MS. HAWLEY: That's correct, Your Honor. But the direct arguments made there were the exact same as here. That, of course, concerned a labeling provision. When the FDA places a label on a drug, as the FDA acknowledged in *Wyeth*, it balances risks and benefits. It determines whether a particular provision is necessary. In *Wyeth*, the Supreme Court rejected the idea that that risk-benefit analysis meant that state regulation was preempted.

In addition, Your Honor, if you look at the express savings provision -- the court in Wyeth relied on that. And that savings provision says that state law is preserved unless

there is a direct and positive conflict.

There's no such thing --

THE COURT: So wouldn't there be one -- just imagine a slightly different scenario, which, I guess, is within the realm of the possible since it seems to have happened in other states. If you say it's not safe -- imagine that were the basis -- just pick a drug, not this drug, some other REMS drug. You know, there's something out there that treats thyroid cancer, I think. I don't know. There are some other drugs out there. Could North Carolina say, We don't think this drug is safe? Pick like an opioid, okay. This happened, right, in Massachusetts. So could North Carolina say, We don't care what you say about the safety; we don't think it's safe, and it's banned in North Carolina? Can the State do that?

MS. HAWLEY: So I think that's a much more difficult question.

THE COURT: Yeah, I agree. But I'm asking you for the answer because it does seem like it matters. If you can do that, then it's more likely you can do what North Carolina has done here.

MS. HAWLEY: So I would point Your Honor to the *Zogenix* case.

THE COURT: To what?

MS. HAWLEY: The *Zogenix* case that you're referring to. In that trilogy of cases, I actually think it absolutely

supports what North Carolina has done here. The reason being, if you look at *Zogenix I*, what the Court held in that case was a ban was preempted. Then you look at *Zogenix II*, and what the Court said was that actually a pharmacist-only requirement was fine. Then you look at *Zogenix III*, and it was a motion to dismiss stage. The plaintiffs had put in additional evidence alleging that the pharmacist-only along with pharmacy handling requirements meant that it was an effectual ban. So the district court in that case said that because I have to accept plaintiff's allegations as true, I'm going to accept their allegations that no pharmacist will stock this. That means that is effectually a ban, so it's preempted.

But of note, Your Honor, if you look at Footnote 7 of that opinion, it concerns two other regulations that the Court allowed to stand. Those regulations were the BORIM regulations and the BORPA, B-O-R-A-P-A [sic], regulations. The BORIM regulated physicians. The BORPA regulated physician assistants. Those provisions did things like requiring an in-person exam, evaluation of risk factors of substance abuse history, discussing the risks and benefits, informed consent with the patients, entering into a pain management treatment agreement, requiring a letter of medical necessity, things very similar, or perhaps even more restrictive, than what North Carolina is doing here.

Again, the district court found that those things

were not problematic and that states, as they traditionally can do, were allowed to complement the safety purpose of the FDCA.

THE COURT: Does it matter that that case did not involve REMS drugs?

MS. HAWLEY: It did, Your Honor.

THE COURT: It did?

MS. HAWLEY: Yes.

THE COURT: Okay. Thank you for clarifying that.

Go ahead.

MS. HAWLEY: Your Honor, in addition, if we look at this preemption analysis, I think one thing that is important from the *Geier* case is FDA's view of preemption. FDA, of course, is not in this case, but we know what they think of preemption from a couple of different places. I would point you to Footnote 3 of our reply brief, and in that note we point out an FDA website. It's their fact section on REMS -- or, excuse me, on mifepristone REMS.

And what that provision --

THE COURT: If you could slow down. It's kind of hard to follow because you're talking very fast.

MS. HAWLEY: Sorry. I have so much to say. So when you --

THE COURT: I have all morning, so you can slow down. You're only going to get 20 minutes at the Fourth Circuit. So there you can talk fast. Talk slow here.

MS. HAWLEY: So if you look at Footnote 3 in our reply brief, what that points to is an FDA website. It's mifepristone facts, and in that website it notes that even though the REMS have allowed since 2016 other healthcare providers aside from physicians to dispense the drug, that providers, quote, need to check their state law to determine whether nonphysicians can prescribe. That is echoed at Exhibit 4, page -- excuse me -- Exhibit D, pages 4 and 5, again directing providers to check their state law.

THE COURT: Exhibit D of your answer?

MS. HAWLEY: Of Plaintiff's --

THE COURT: Of the complaint?

MS. HAWLEY: Yes, ma'am.

THE COURT: Okay.

MS. HAWLEY: And so I think both of those things clearly indicate that the FDA considers state law imposing additional safety requirements to be complementary, rather than burdensome or contradictory.

In addition, Your Honor, I do think the statutory history is important here, and that's one thing that distinguishes this case from *Geier*. As you know, *Geier* was really the high-water mark of obstacle preemption.

As sort of an aside, we're only dealing with obstacle preemption here. Plaintiffs have disclaimed both impossibility as well field preemption.

And in the *Geier* case, one thing that the Court noted was that the extensive history was important. In *Wyeth*, the Supreme Court looked back at the *Geier* decision and said that the history came to the opposite conclusion.

THE COURT: So here, in light of that, I would also need to look at the history since 2007, the 2007 amendments, and everything -- the regulatory history of this drug since; correct? I mean, we don't stop looking at the history in 2006?

MS. HAWLEY: Correct, Your Honor. But I think that's correct only in part. I think we look at the statutory history. The regulatory history would be relevant to the question as to whether there was a direct conflict.

THE COURT: As to what?

MS. HAWLEY: As to whether there is a direct conflict, but would not be relevant to the statutory purpose, which is what the Supreme Court in *Wyeth* really focused on.

In addition, there's a few other things that distinguish this case from *Geier*.

THE COURT: So the 2007 amendments -- I mean, oh my gosh, you just look at the public law. It's slightly overwhelming. I think, what was it, over 200 pages long and a lot of it totally irrelevant to this case.

MS. HAWLEY: Yes, Your Honor.

THE COURT: You know, some things in the public law don't make it into the codified version, like the thing that

says all Subpart H drugs are REMS drugs, basically. That didn't make it into the codified statute that I saw.

So is there anything in that public law that specifically tells me the purpose or the intent for these REMS provisions?

MS. HAWLEY: So I think there's a couple of places to look for that.

First of all, it's still under the Food, Drug, and Cosmetic Act, and that act says -- I think it's at 393(b) -- that the purpose of the FDA is to preserve a health and safety -- or, excuse me, "safety and efficacy" is the term the statute uses. So I think we have to start there.

And then when we look at the 2007 provisions, they are all about safety for particularly high-risk drugs. These are drugs that the FDA has found cannot be approved without additional safeguards. My friends on the other side's argument is that these higher -- that the higher the risk the drug is, the less ability the State has to protect the health and safety of its citizens. And with respect, I don't think we can get that out of the text.

Of course, we are in the land of implied preemption, and we're also in the land where we have a presumption against preemption, because, as the Attorney General concedes, the states have traditionally had an important and complementary role in buttressing and coming alongside FDA regulations.

So given that we need a presumption against preemption, I think we have to find in this REMS statute a clear directive that Congress has enabled the FDA to preempt state law. I don't see anything approaching that. Instead, what I see is when that we look at the operative provisions --

THE COURT: Slow down.

MS. HAWLEY: -- 355-1(f)(1) and (2), we see that provision -- that Plaintiff's argument really hangs on this idea of access, that the access was magically added by the FDAAA. But we look at the statutory provision, and the only term -- the only place they can find that access are in specific statutory provisions that are directed to the Secretary and that say -- Judge Chambers in West Virginia found it particularly persuasive that when you look at (f)(2), it says: --

THE COURT: Slow down.

MS. HAWLEY: -- "Such elements to assure safe use under paragraph 1." Paragraph 1 is directing the secretary to set safe use standards.

THE COURT: Well, right. So if Congress will not let the FDA impose safety rules or restrictions that interfere with access, what makes you think that it would -- that Congress meant to allow states to do so?

MS. HAWLEY: Because, Your Honor, states have always had the police power to regulate for the health and safety of

their citizens. There is a presumption against preemption, and the way that presumption works is that Congress has to speak clearly the means to displace that traditional state authority.

THE COURT: Well, right, but it doesn't have to be explicit. I mean, it can be implicit, implied. That's what we're talking about here is implied preemption. So by definition, it does -- you don't have to have in the statute, We preempt state law.

MS. HAWLEY: That's correct, Your Honor. But you do have to have a pretty clear indication from Congress --

THE COURT: You do.

MS. HAWLEY: -- that that's what they intended, and I think that's wholly absent here.

Again, in comparison, Your Honor asked about the *Geier* case. Putting to one side that that case was, as I mentioned before, a high-water mark of obstacle preemption, in addition, that case was different for the statutory context that we've talked about. It was -- also, the regulation at issue was quite different because it involved a direct conflict.

What the Department of Transportation had said in that case was that the provision that -- that the NHTSA provision --

(Reporter requested clarification.)

THE COURT: If you use abbreviations -- you know, the

court reporter has not studied the briefs, so it would be helpful if you could say it. And, also, it would help me in case I don't remember the particular three-, four-, five-letter acronym in the moment.

MS. HAWLEY: Sure. NHTSA is the National Highway Traffic and Safety Administration, and what NHTSA said in that case was that it didn't want airbags. It had safety concerns with airbags and preferred a mix, a mix of passive restraint devices, so that it could allow additional time for safety concerns for airbags to be resolved, for functionality, for price concerns with airbags to be --

THE COURT: But in this case hasn't the FDA done something similar by saying certain things are not necessary for safety and efficacy, and we have waited and these things are not necessary? So isn't that similar to what happened in *Geier,* however you say it?

MS. HAWLEY: Absolutely not, Your Honor. In *Geier* you had DOT saying, You can't do this and the states saying, You must do this. That's classic impossibility preemption. In this case you have the FDA saying this is not necessary.

THE COURT: Well, I thought -- I didn't think they prohibited airbags, did they?

MS. HAWLEY: They did -- if you look at that case closely, what the Department of Transportation said was that they wanted a mix. They did not want airbags only. So they

had -- the state standard was imposing airbags.

THE COURT: Okay. But they didn't -- the FD -- the whoever acronym -- the government did not prohibit automakers from using airbags, did they?

MS. HAWLEY: So you're correct; they didn't prohibit automakers from using airbags, but they did prohibit the state requirement of only airbags --

THE COURT: Yes.

MS. HAWLEY: -- or airbags in every car. So that conflict is a lot clearer.

In this case what you have is FDA saying, you know, I don't think this is necessary for safety, even though we've required it for 20 years --

(Reporter requested clarification.)

MS. HAWLEY: So the FDA in this case is saying we don't require certain safety measures, even though those safety measures have been in effect for, some of them, nearly 20 years.

THE COURT: Well, exactly. I mean, that's the whole point of the act -- one of the points, not the whole point. One of the points of the act is to require the FDA to periodically reevaluate so that more restrictions can be imposed when necessary or restrictions can be removed when they are not necessary. So the fact that it's been the same for 20 years -- if you now have 20 years of data -- I mean, just

because -- I thought Congress explicitly rejected in the 2007 amendments the idea that just because something is approved by the FDA once, that that's the end of the story; you never look at it again. The 2007 amendments seem to, among other things, say, no, that's not the story; that's not the end of the story, Vioxx, among other things. We continue to look at what happens after we approve it, and then we reevaluate as we need to, either more restrictions or fewer restrictions.

So I'm not understanding your point about the 20 -- yeah, we've done it for 20 years, so we can't change it. That seems incorrect.

MS. HAWLEY: No, Your Honor, I'm not saying the FDA can't change it. I agree that the FDAAA -- that the 2007 amendment allows and, indeed, requires FDA to reassess its requirements for REMS drugs. What I'm saying is if the FDA thought something was crucial for 20 years, a state is entitled under standard preemption and under the FDCA to say, We think that's still necessary. We think it improves women's safety.

To take one example: If you look at the in-person requirement, back in August of 2020, the FDA submitted a brief to the United States Supreme Court in which they argued that the in-person requirement was crucially important for a few reasons: One, so that the doctor could personally inform the women of the serious risks of mifepristone; and, second, so there would be a minimization of delay after receiving the

pill.

Of course, mifepristone can get more dangerous with progressing gestational age. So the FDA thought those things important. It makes complete sense that North Carolina would still want to think those things are important. So I think the fact that the FDA is entitled, indeed obligated, to change the REMS in no way takes away from the State's traditional authority to regulate for health and safety.

THE COURT: So, under your view, you could have 50 different requirements, not just for this drug, but for any drug. So the states are free to come in and say for any prescription -- I will just say prescription drug because it's easier -- any prescription drug, we can do whatever we think necessary for safety reasons and nothing prevents us from doing that. So all 50 states could come in and have totally different rules about what physicians have to do, about telemedicine, about importing the drugs.

Florida wants to import -- I think the FDA just approved this, at least I read it in the newspaper or online, even less reliable -- I can't remember -- but importing drugs from Canada, I think. So you could have, if you count the territories, more than 50 different schemes that people -- that drug manufacturers would have to comply with and physicians, healthcare, hospitals, et cetera, would have to comply with.

Is that -- that's your view about how many drugs are

approved by the FDA? I think you all told me 10,000. I don't actually remember how many it is.

MS. HAWLEY: So I think it's 11,000.

But a couple of things, Your Honor. I think --

THE COURT: I mean, that seems a little (nonverbal sound.)

MS. HAWLEY: No, absolutely not, Your Honor. That's what the Supreme Court held in *Wyeth*, and that's what my friends on the Attorney General side say, except with respect to REMS. They are trying to carve out REMS as being unique, even when those are the most dangerous drugs.

In *Wyeth*, the Supreme Court acknowledged that the states have traditionally been the ones to regulate for health and safety. They are in charge of the requirements for physicians.

Again, as the Attorney General noted in his brief, the states have traditionally come alongside and supplemented FDA regulation. They called it an important part of the regulatory scheme. So I don't think that's odd at all, but how the system is designed. And we can see the benefits of that, as states can be more protective.

The Supreme Court in *Wyeth* rejected the very idea Your Honor is positing here and that's that the FDCA sets a federal ceiling. Instead, what the FDA does is set a floor, and in that case states are allowed to add to those

requirements and hold physicians to a standard, for example, requiring in-person informed consent or asking them to do an ultrasound before they prescribe mifepristone.

In addition, Your Honor, you asked what are the things you should think about in looking at preemption analysis. One thing that Justice Ginsburg found particularly persuasive in the *Riegel* decision was the fact that Congress in 1976 adopted the Medical Devices Act. Under the Medical Devices Act, that is an express preemption provision. It says that the states may not have anything different from or in addition to --

THE COURT: Right, they know how to do it if they want to.

MS. HAWLEY: Exactly. And Justice Ginsburg said they didn't do it with respect to prescription drugs, and I don't think they've done it with respect to the FDAAA.

In addition, Your Honor, that's an additional distinction with *Geier*. *Geier*, of course, had both the savings clause and an express preemption clause.

To talk a bit about *Wyeth*, Your Honor, I know, of course, as your questions indicated, that that did not involve the FDAAA. It did not involve REMS provisions.

THE COURT: Right. And as I was reading some of the scholarship, I will just say, about these issues, both -- some of which was written before *Dobbs*, okay -- so it was speaking

about it in a less politically charged way -- you know, said there is a pretty good argument that the 2007 amendments would change the result in *Wyeth*. And that was before *Dobbs*. And, you know, that does seem -- I don't know if that's so or not.

MS. HAWLEY: So I don't think that's correct. Again, as we talked about, Your Honor, you would have to find that clear intent to overcome the presumption in the text of the FDAAA. And in that text you see direction to the Secretary. As you noted, the Secretary has to reassess the REMS. The Secretary has to make sure that -- to mitigate the safety risks of these high-risk drugs. But nowhere does it direct the states to sort of stay out of their traditional sphere of regulating for health and safety.

THE COURT: Do you agree that I have to look at each disputed provision and say, Is this preempted? Is that preempted? Is this -- there's what -- one of my questions was what are we talking about here? What provisions?

But it seems to me that, when I read the cases, they all talk about fact-specific analysis of this implied preemption, obstacle preemption. So to me that seems to say, okay, this thing one, physician -- the requirement that only medical doctors can dispense it -- let me look at that one -- is that preempted?

Thing two, in-person, doctor must be physically present when the first drug is administered, is that preempted?

Do you agree that it is a provision-by-provision requirement, or is it something more general than that?

MS. HAWLEY: So I think under Plaintiff's theory of the case, you do need to go provision by provision because the question would be whether this interferes with Congress' purpose. We think Congress' purpose is safety. If they include access or some sort of other broad purpose, then we need to look and see whether there's that direct and positive conflict that the Court required in the express savings provision.

THE COURT: So what do you think?

MS. HAWLEY: I think, Your Honor, that you look at the text of the FDAAA. You look at *Wyeth*. You look at the text of the FDCA. You look at FDA's contemporaneous and longstanding statements that state law can supplement, and you say the purpose of the FDCA, including the FDAAA, is safety.

THE COURT: So your argument is that the State can do whatever it wants, and there is no implied preemption of anything? That's what I just heard you say. Is that right or wrong?

MS. HAWLEY: So I think you have to look at the statute and find out its purpose. That's what the Court required in *Hines* and in every sort of obstacle preemption case post-dating that one. So you look at the statutory purpose. We --

THE COURT: So you're saying to me that when you do that -- when one does that, then that means the State can do whatever it wants about imposing additional requirements on prescription drugs because it's not preempted?

MS. HAWLEY: So --

THE COURT: Is that you're saying, or are you saying, no, I have to look at each provision?

MS. HAWLEY: So with the caveat that not every problem is a preemption problem and there are all sorts of problematic laws and lots of constitutional provisions that you can look at those laws under. But as far as presumption goes --

THE COURT: That's what we are here about.

MS. HAWLEY: Yes, you are correct. You do not need to do, under our theory and analysis, provision by provision. But if the Court is inclined to adopt the Plaintiff's theory that you -- that there's some sort of access or something else that can be gleaned from the statutory text, then I think you do.

THE COURT: But the underlying premise of that proposition, that I don't need to examine it provision by provision, is your kind of basic point that the State is not preempted, and it can do whatever it wants in preemption terms.

So put aside, okay, First Amendment, you know -- I live with you all sometimes, it feels like. But, you know,

just preemption, the State can do what it wants because it's not --

MS. HAWLEY: So I think that's what the Supreme Court said in *Wyeth*, that the FDCA sets a federal floor, and if we're looking at preemption --

THE COURT: At least obstacle preemption for this drug.

MS. HAWLEY: Yes.

THE COURT: We could -- obviously, the State could do something that may be impossible --

MS. HAWLEY: Yes, of course.

THE COURT: -- or directly conflict. But as long as we're not talking about that --

MS. HAWLEY: Yes, I think that's correct, Your Honor.

THE COURT: All right. Go ahead.

MS. HAWLEY: But I'm happy to discuss these preemption provisions provision by provision because I think that there are some of them that, even under Plaintiff's theory, are clearly not preempted.

So if you look at the first one on their sheet here, in-person examination, administration, and dispensing, as I mentioned, the in-person exam was something that the FDA required up until a few years ago, had required it for 20 years. Again, we think that this is a federal floor and not something that -- or is something that states can build on.

If you look at the in-person -- that the -- Plaintiff's call it 72-hour advance consultation. So there's a couple of things in there. The Plaintiffs note that that's never been part of the REMS. Maybe they are referring to the wait period. It's certainly true that even today the REMS require informed consent. They require that doctors get a patient agreement that is signed.

Your Honor, do you have the chart that was prepared by Plaintiffs?

THE COURT: What chart?

MR. MEZZINA: Your Honor, so in light of your email, when you said the Attorney General's chart was important --

THE COURT: It was helpful is what I think I said.

MR. MEZZINA: Yes, you did, Your Honor.

We prepared a one-page summary chart listing provisions we're challenging. We shared that with the other parties in advance of the hearing, and if Your Honor would like a copy of that, we're happy to provide that.

THE COURT: Yeah, that would be great. Is it all right if he hands it up?

(Pause in the proceedings.)

THE COURT: Thank you. Go ahead.

MS. HAWLEY: So, Your Honor, to look at No. 2 here, just what I was talking about, it's certainly the case that the REMS even today require informed consent. So I take

Plaintiff's sort of protestation to be about the 72-hour advance notice.

Again, I'd refer Your Honor to the August 2020 brief filed by the FDA. In that brief, they note that waiting periods and in-person visits are minimally burdensome. That's the FDA's own words before the Supreme Court.

In addition, Your Honor, 28 states -- sort of getting to your point about can states do whatever they want, it's certainly true that states have exercised this authority to preserve health and safety. Twenty-eight of them currently require informed consent. Fifteen of them require that to be in person, something that Plaintiffs here say can't happen after 2007.

The in-person 14-day follow-up, Your Honor --

THE COURT: Well, they don't say it after 2007. They say it after -- whenever they most recently revised the REMS.

MS. HAWLEY: Sure. But because of 2007, yes, Your Honor.

The in-person 14-day follow-up -- when mifepristone was approved in 2000, it was contraindicated for women who were unable to follow up because the FDA believed that to be so crucial to preserving their health.

The current patient agreement -- I think this is Appendix A, page 11. Patients must sign and say that they agree that "I should follow up with the doctor." It does not

seem to be access or any other problem we can extrapolate to have patients -- to have -- actually, all that's required by this statute, Your Honor, is that the doctor schedule a follow-up. If a woman chooses not to make that follow-up, then that, I guess, is the woman's choice.

THE COURT: "The statute" being the North Carolina statute?

MS. HAWLEY: Yes, Your Honor.

So the statute only requires that the doctor schedule a follow-up. That can in no way inhibit access. And, again, the patient agreement tries to tell the patient that that would be especially important to her safety and well-being.

The physician-only restriction, I would point Your Honor to our reply brief, Note 3, where the FDA acknowledges that providers, quote, need to check their state law to determine if providers other than physicians can prescribe it. And that has been a REMS change since 2016. The FDA has continually maintained its view that providers have to comply with supplemental additional state law.

If you look at the ultrasound requirement, I would just note that in support of North Carolina's law, ACOG, which is the American College of Obstetricians and Gynecologists.

THE COURT: Usually you don't like what they say. That's been my general experience in these cases over the past however many years. Y'all are, like, nope, those people don't

know what they're talking about.

MS. HAWLEY: So that's why I'm particularly delighted to quote them to you today and to say that they say that an ultrasound is the, quote, best way to diagnose gestational age. Of course, gestational age is important, because, as the FDA admits in any number of these exhibits, there is an increase in complications with each passing week of gestational age.

In addition, to quote someone maybe a little less controversial, the Mayo Clinic notes that an ultrasound is, quote, required to determine whether an atopic pregnancy exists. That's why, Your Honor, that when a prescriber agrees to be part of the mifepristone program, is licensed under the REMS, they certify that they can diagnose an atopic pregnancy, and they certify that they can accurately diagnose gestational age.

North Carolina's admonition or requirement to physicians to use an ultrasound is plainly supported by science. It also exists in 15 states. Plaintiffs would wipe out all of those states' laws in one sweep.

A blood-type determination, Your Honor, I am hoping I can at least convince you of this one. On Exhibit P, page 18, of the record, Your Honor, the FDA states that testing for Rh type blood is, quote, the standard of care. If the FDA acknowledges that that's the standard of care, it certainly can't be true that North Carolina's requirement for that

particular procedure conflict with any sort of amorphous access or whatever Plaintiff suggests exists in the FDAAA.

And, finally, Your Honor, requirements to report nonfatal complications and adverse events, this exists in 28 states. So, again, all of those laws would be wiped out by Plaintiff's argument. And it's not at all about access. Again, this is a requirement that runs only to abortion providers.

THE COURT: This one actually seems -- the state requirement -- I'm not deciding -- I'm not deciding any -- none of my questions reflect a decision, but this one actually seems consistent with the way I've been thinking about the 2007 amendments because it is -- it provides more information and transparency for people who decide things to make decisions.

MS. HAWLEY: So I would agree with that statement as far as it goes, Your Honor. Absolutely, the more information we get about complications of any drug, including mifepristone, will allow the FDA greater ability to assess risks and to mitigate those risks, for sure.

So, Your Honor, do you have any questions for me on any of these?

THE COURT: No. Thank you for going over them.

MS. HAWLEY: So, again, I would just note, Your Honor, that if we look at the cases that are most relevant to this decision, I think those -- or to this case, I should

say -- those are obviously *Wyeth*, Your Honor has identified *Geier*, and also the *Zogenix* case, as well as the *GenBioPro* case out of West Virginia. Our position is that each of those cases either support or are readily distinguishable from what North Carolina has done here.

The *Wyeth* case tells us clearly that the FDCA is a federal floor. It does not impose a ceiling. And it says that a contrary interpretation would be an overbroad interpretation of preemption and misinterpret Congress' purpose in the FDCA.

As we've talked about with *Geier*, Your Honor, that involved an express preemption provision. It involved a direct and positive conflict, and the Supreme Court said the FDCA is different from the highway transportation bill at issue.

THE COURT: So Judge Chambers said the result of -- when he was talking about the FDA's REMS review process and this drug specifically: "The result of this heightened scrutiny and extensive review is a REMS which unambiguously assures the safety of the drug without any additional safeguards from the states. Defendants have not disputed the safety of mifepristone REMS, nor could they."

But here you seem to be disputing the safety of the REMS. You seem to say it's not enough. The State is entitled -- not only can the State say that, the State is saying that.

MS. HAWLEY: So I think two things, Your Honor.

First, we don't dispute in this case the validity of the REMS. That's obviously at issue in other cases. But in this case we don't dispute that the 2016 and the 2023 REMS were lawfully -- so we don't dispute the validity of them, but we do think that inherent in the provision of the REMS is FDA's acknowledgment that these are high-risk drugs. The mifepristone REMS, for example, includes a black box warning that tells patients that fatal infections and bleeding can occur.

The goal of the REMS -- I've already mentioned that, in terms of looking at what Congress' purpose here. The goal of the REMS is Appendix A, page 2, and that goal is to, quote, mitigate the serious risk of mifepristone.

So I think North Carolina's position here is consistent with the position of many states, that you can't entirely eliminate the risk from mifepristone. I think the FDA would say the same thing. That's why they have REMS.

THE COURT: That's true of like -- there's risk in walking down the street. There's risk in getting in a car. You can't remove all risk from any -- I mean, every drug has side effects or it wouldn't be regulated; right?

So you're not saying that the FDA can only approve drugs with no risks or side effects, are you?

MS. HAWLEY: Certainly not, Your Honor.

THE COURT: Okay.

MS. HAWLEY: But what we are saying is that there is a category of 61 drugs that have REMS. That category of drugs could not be approved unless they have these post-marketing restrictions that impose things to help protect women.

THE COURT: But that's both your problem and your argument. You know, you think that that means no preemption, but it seems like it just as easily supports preemption.

MS. HAWLEY: I don't think so, Your Honor. And the reason being is, again, I keep mentioning, but my friends in the Attorney General's Office acknowledge, that if we're talking about a random, one of the 11,000 drugs, then, of course, states can come alongside and help out and increase safety.

But what Plaintiffs and the Attorney General are saying here is if the drug is dangerous enough, then states can't step in and help out. And that's simply an untenable interpretation of the FDCA. At no point in time that I am aware of, Your Honor, has Congress indicated they wanted the states to step back in regulating and helping keep women safe.

THE COURT: Okay. Just to put aside this drug, I think I looked at -- I don't know how to say this drug -- vigabatrin. That's a drug that's used to treat thyroid cancer, and it's a REMS drug.

So, in your view, the state could say -- you know, if the FDA said any healthcare provider can do this over

telehealth, in your view, the state could say, nope, not in North Carolina, not in Alaska, not in New York, not in Massachusetts; in our state, you have to come in and do it in person?

That's your view, that that is not -- some of your arguments in your briefs seemed specifically directed to this particular drug, but your overall argument is any drug -- any REMS drug; right?

MS. HAWLEY: I think that's correct, Your Honor. But the reverse would also be true. If states are not allowed to come alongside and help support health and safety of their citizens, then potentially every drug. I don't see a great basis to limit this to only the 67 REMS. But because the FDA balances labeling, then the states just have to cede their traditional historic police powers. And in one fell swoop, 28 state laws that require informed consent or that require reporting requirements would be gone.

THE COURT: Can you talk to me about these two pending Supreme Court cases? I don't know. I mean, should I just wait around and see what they are going to do? Are those cases going to tell me anything?

MS. HAWLEY: So it's possible they could, Your Honor. I think with respect to the *AHM v. FDA* case, one -- the merits of the case involve the question of whether the 2016 REMS and the decision to remove in-person dispensing are lawful or

whether they violate the Administrative Procedure Act. If the Supreme Court decides that that was unlawful and the agency did not sufficiently explain itself or didn't follow the science, then that would mean that under Plaintiff's argument states could continue to impose those requirements.

Under our argument, Your Honor, we don't think there is any reason to wait. We think that the obstacle preemption cases tell this Court to look at the purpose of the statute. We think that the statutory text, we think that FDA's agreement, we think that *Wyeth*, we think that the express preemption provision all point to a safety purpose that is in no way impaired by North Carolina's law here.

THE COURT: And what about the *Moyle* case? I mean, it is a different federal statute, but it's a preemption case.

MS. HAWLEY: It's true, Your Honor, that the Idaho EMTALA case, E-M-T-A-L-A -- that the Idaho EMTALA case is a preemption case, Your Honor. It does involve a different statute. And my guess is that the arguments in that case are going to focus on what the statute means. The agency guidance in that case suggests that its interpretation is what the statute says.

So I think there's going to be a lot of discussion about whether that guidance is consistent with the statute. There may be some discussion of preemption, for sure. Again, I think it's a different statute, so unlikely to be super helpful

here.

THE COURT: All right. And can you talk to me, before I move on to let somebody else talk for a while, about just case management-wise -- you know, you've moved to dismiss. Are there factual issues? I know you think there aren't any. If I were to disagree with you, then what does that mean? Is this -- do I need to convert to summary judgment? I mean, where are we? What's the best way to think about this? Not that I have decided the motion to dismiss, because I haven't.

MS. HAWLEY: Yes, Your Honor. So Plaintiffs, Intervenors, and the State had a meet-and-confer on Monday afternoon, Your Honor, and each of those parties agreed that there was no factual development necessary to the legal issues in this case.

So, yeah, I think that's our position, Your Honor.

THE COURT: All right. So, in your view, there is no reason not to convert this to summary judgment and basically treat it as cross-motions?

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

THE COURT: Okay. Thank you. Anything else you want to say to wrap up?

MS. HAWLEY: So, Your Honor, the last thing I would note is, just to go back to your thyroid example, it really is the case that since the FDA was enacted in 1906, Congress has sort of viewed that as a supplement to pharmaceutical drugs.

So our position would be that a state can do that because it is a federal floor and not a federal ceiling, but that that would be something that would complement the safety rationale of the REMS statute.

Now, of course, if there weren't a safety rationale, then there would be other constitutional provisions that might be in play.

THE COURT: Well, we're -- one thing in this case.

Okay. Thank you.

For the Plaintiffs?

I'm going to give you about 30 minutes. Well, let's see. What time did we start? 9:30. In about 30 minutes, we'll take a short break. If you're not finished, we'll come back to you.

MR. MEZZINA: Thank you, Your Honor.

Like my friend on the other side --

THE COURT: You may need to pull that mic just a little closer. You can move the base of it so you don't have to slump over. Just pull the whole thing closer to you.

MR. MEZZINA: How is that?

THE COURT: That's much better?

MR. MEZZINA: I'm also a fast talker. So I am going to try very hard to keep that under control. If I get out of control, please slow me down.

THE COURT: Don't worry.

MR. MEZZINA: I want to respond to the arguments on the other side, but I think it might be helpful just to start first with Your Honor's logistical question.

So we're obviously here on a motion to dismiss. The motion made what we understand to be cross-cutting arguments, that there can't be any preemption in this case, and that's why we didn't respond by going through each provision specifically. We responded to those arguments. But we're happy to talk through those provisions today.

If Your Honor wanted to convert this to summary judgment, we have no objection to that. And if it weren't converted, if the motion to dismiss were denied, we would anticipate moving promptly for summary judgment after that because we do agree that there is no need for discovery. The issues are purely legal.

THE COURT: Okay. Thank you.

MR. MEZZINA: So, Your Honor, in the REMS statute that was passed in 2007, Congress charged the FDA with striking a precise balance, with determining the precise combination of restrictions on distribution of REMS drugs, like mifepristone, that would be commensurate with the risks, sufficient to assure patient safety, but at the same time would not unnecessarily burden patient access to the drug or the healthcare system as a whole. And I think those objectives are very clear from the statute. So I want to start with the statute.

The key provision is Section 355-1(f). This is the REMS statute. That provision is titled "Providing Safe Access For Patients To Drugs With Known Serious Risks That Would Otherwise Be Unavailable." So right there in the title you have the goal of Congress is to provide safe access to these drugs. Congress is concerned that these drugs would otherwise be unavailable because if they couldn't be regulated under the REMS program, they wouldn't be approved, and, therefore, they wouldn't be available. So you have these twin goals right there at the outset of providing safety but also assuring access.

As you read through the statute, I think it is impossible to miss that one of Congress' objectives was to provide access to these drugs. The very next subsection, (f)(1), is called "Allowing Safe Access..."; the next subsection, "Assuring Access and Minimizing Burden." Throughout the statute there is this requirement: The FDA is directed to seek input from patients and providers on the burdens that are being created. It's directed to periodically reevaluate on an ongoing basis whether these burdens are excessive, and it's directed to modify the REMS whenever it concludes that the burdens are unnecessary or excessive. So clearly access is one of the goals here.

Now, it's true that this statute is directed to the FDA. It's talking about the burdens of the REMS. It's not --

it doesn't say in so many words that state law is preempted. If it did, this would be an express preemption case, not an implied preemption case.

THE COURT: Yeah, we wouldn't even be here probably on preemption.

MR. MEZZINA: I hope that's right, Your Honor. But, of course, we're not arguing express preemption, but we are arguing implied preemption. And I think in terms of implied preemption, we are squarely on all fours with *Geier*. So in *Geier*, similarly, the Department of Transportation was directed to promulgate federal motor vehicle safety standards. And, in doing that, the Department concluded that an all-airbag standard would be inappropriate. So the Department considered whether to mandate airbags in all the vehicles, and it said, We think that would be inappropriate, gave a variety of reasons for that, said it would be unnecessarily costly, and it wouldn't ultimately improve driver safety. And so the Department declined as a federal matter to impose that standard.

And just like here, in *Geier* the statute didn't expressly say, And states can go no further than the Department. It didn't have an express preemption provision. But the Court said when a federal agency that's charged with striking this balance has looked at the issue, evaluated the competing considerations, and determined that a particular

requirement shouldn't be imposed because it would be unnecessarily burdensome and appropriate, a state can't come in after the fact and impose that same burdensome requirement. And that's exactly what's going on here.

Now, I want to respond to some of the points my friend made about *Geier*.

So the only argument that the Intervenors made about *Geier* in their papers, and I think we heard it again today, is they tried to characterize *Geier* as an impossibility preemption case. And that's just not correct. *Geier* is an obstacle preemption case. There was no impossibility there. Although the Department -- the federal agency had chosen not to mandate airbags, it had in no way prohibited manufacturers from installing airbags. So it's perfectly possible for the manufacturer there to comply with both the federal and the state law. The issue was obstacle preemption where the federal agency had looked at an airbag requirement, decided it was inappropriate, chose not to impose it. Could the state then impose that requirement? And the Court said no.

My friend also referred a couple of times to *Geier* as the high-water mark of obstacle preemption, and I don't know if that's meant to sort of suggest that *Geier* is no longer good law. But it certainly is good law. It's been cited many times by the Supreme Court and lower courts over the years, and I certainly think it's controlling in this case.

And then I think my friend said that the history supporting the Department's rejection of the airbag standard was more extensive there. And I actually think exactly the opposite is true. So what the court said in *Geier* was that there was a sufficient record from the agency to show that the agency had actually looked at an airbag standard and decided that it was inappropriate, and it showed the reasons why the agency had made that decision.

We absolutely have that here in spades. Your Honor mentioned some of the documents we attached to our complaint. We didn't even attach the entire regulatory history. We attached some of the key documents. But there are hundreds of pages of the FDA over the years looking at these issues, analyzing them very carefully, both through the REMS process, which is, as Your Honor noted, this ongoing, meticulous detail review of the REMS, and also in response to citizen petitions that have been filed challenging various aspects of the REMS. The FDA has analyzed all of these issues at length. And just as in *Geier*, you can look at that record and see exactly why the FDA rejected the very same requirements that the State is trying to impose.

And I want to talk about *Wyeth* because I actually think, far from supporting the State, *Wyeth* is actually our case. The reasoning of *Wyeth* completely supports our preemption arguments here, and I think that's true for at least

two reasons.

So, first of all, as Your Honor noted, *Wyeth* did not involve REMS. The injury in that case arose before the REMS statute. Phenergan, the drug at issue there, was not a REMS drug. What the Court was considering there was basic FDA labeling approval. And at that time there were about, as the Court noted, 11,000 FDA-approved drugs. Today I think it's over 20,000. And what the Court said is FDA does not have the resources to monitor on an ongoing basis new safety information about more than 10,000 drugs. It relies on manufacturers to do that. And so the initial label approval at one point in time does not mean that FDA's rejecting that any additional warnings might be required in the future.

And related to that, the court distinguished *Geier* in that it said, I think, at least five different times in the opinion that unlike in *Geier*, FDA had never considered and rejected the state law warning at issue in that case. It said, in fact, the evidence was that the FDA had paid basically no attention to the issue. The issue had never come before it. It had approved the label at one point in time and that it had never revisited it and looked back at this issue of should an additional warning be imposed.

So there was no direct conflict between the state's decision to impose this warning and the FDA's initial labeling approval. The FDA had never actually considered and rejected

the warning, unlike here, where the FDA has specifically considered and rejected the requirements that North Carolina is imposing.

And, of course, *Wyeth* also said if there were clear evidence that the FDA either had rejected or would reject imposing that warning, then the state would be preempted from requiring it. And that's reaffirmed in the *Merck* case just a few years ago.

THE COURT: The what case?

MR. MEZZINA: *Merck*.

THE COURT: Okay.

MR. MEZZINA: Your Honor, my friend also mentioned the savings clause. I think it's important to note, as we point out in our brief, the -- let me say three things about the savings clause.

First of all, it does not apply to the REMS statute. The savings clause that was quoted in *Wyeth* was part of the 1962 amendments to the FDCA. And what it said is the changes made by those amendments won't preempt state law absent a direct and positive conflict. Those amendments were the basic labeling provisions at issue in *Wyeth*. There is no similar savings clause for the REMS statute that was enacted in 2007. And, in fact, if you look at the legislative history, Congress considered -- at one point there was in the draft bill a sort of saving clause or anti-preemption provision, and Congress

removed that from the final enacted bill.

Second point, even if you thought the savings clause applied, by its own terms, it says a direct and positive conflict is a basis for preemption. And that's exactly what we have here.

The third point, *Geier* itself involved a savings clause. There was a savings clause that --

THE COURT: A direct and positive conflict -- okay. You're equating that to obstacle?

MR. MEZZINA: I am, Your Honor. Obstacle preemption is a species of conflict preemption --

THE COURT: Yes.

MR. MEZZINA: -- that breaks down into conflict, breaks down into impossibility and obstacle. And I think courts looking at similar saving clauses that require a direct conflict have typically interpreted that as codifying the principles of conflict preemption, including obstacle preemption.

THE COURT: Go ahead.

MR. MEZZINA: And the third point I want to make about the saving clause is that there was a savings clause at issue in *Geier*. It actually applied, unlike here, and it was very broadly worded. It purported to save all state common law actions. And what the court said there is even in the face of that savings clause, it does not displace ordinary background

principles of obstacle preemption. And the court said it also doesn't create any special burden on the party asserting preemption.

So for all of those reasons, I don't think the savings clause helps.

And I think the ultimate takeaway from *Wyeth* is that in a situation like here, where FDA has specifically looked at the risks and the issues associated with a particular drug, has considered and rejected imposing a particular requirement, the State is preempted from coming in and imposing that same requirement in contravention of FDA's considered judgment.

I want to talk a little bit about the *Zogenix* case, Your Honor. So I think *Zogenix* also supports our preemption argument. There, as my friend noted, the main argument that was being made was that a state couldn't ban -- either de jure or de facto couldn't ban an FDA-approved drug. And the Court accepted that; held a state can't ban an approved drug. I think that shows that even under the FDCA more generally the court understood that ensuring access to a group of drugs is part of the congressional objective.

It is true, as my friend noted, Zohydro, the drug at issue in *Zogenix*, was a REMS drug, but there was no discussion of the REMS in the opinion. It seems like the manufacturer may not have relied on REMS; may have just made more general preemption arguments. And so the court treated -- I think

analyzed the issues as if it was just any other drug.

Not only the ban, but the court also held that specific restrictions imposed by Massachusetts on the prescribing of the drug were preempted when they were in conflict with the federal label. So the main one that was challenged was a requirement under Massachusetts regulations that physicians, before prescribing this drug Zohydro, had to try other methods of pain management, and those other methods had to fail. And the state imposed that as a requirement. That wasn't part of the federal label, and the court said that's preempted; you're restricting access to this drug in a way that FDA has rejected.

Some of the other -- my friend mentioned some other requirements. My understanding of the history of that case is that the manufacturer prevailed on essentially all of the preemption challenges that it pressed, and there were some other requirements imposed by the state that seemed not to have been challenged, or they were initially challenged and then that was dropped.

THE COURT: Yeah, it was kind of hard to follow it, partly because I think there were four or five decisions, and then the state kept changing the regulations. I needed a chart. I like charts as you can tell.

MR. MEZZINA: We'll keep that in mind, Your Honor.

THE COURT: That's all right. I'm joking.

Go ahead.

MR. MEZZINA: No, but I completely agree it is hard to follow the sequence of events there. As we parsed it, it seems like every argument that the manufacturer made for preemption and continued to press, it was ultimately successful.

I want to talk a little bit about the Chambers case in West Virginia, which I think also supports us. And I think it is important to note --

THE COURT: How does -- didn't it go the other way?

MR. MEZZINA: So, actually, no, Your Honor. I'm glad I have a chance to address this.

There were two different kinds of West Virginia laws at issue in Chambers. One was a total ban on abortion, which, of course, we don't have here. North Carolina does not ban medication abortion. It's legal in North Carolina. And the court said -- as to the total ban, the court said that is -- what Judge Chambers called upstream from the REMS; and, therefore, it's not preempted. We take no position on that. We don't have that issue in our case.

There was also at issue in that case a ban on telemedicine, effectively the same as North Carolina's in-person requirement. And Judge Chambers said, as to that ban, that is unambiguously preempted because it directly conflicts with FDA's judgment.

Now, what happened after that decision is GenBioPro amended its complaint to drop the challenge to the telemedicine ban. It only wanted to focus on the total ban. And so the case is now up on appeal in the Fourth Circuit, and it's only on appeal as to the total ban issue, which is not presented in our case.

But we completely agree with Judge Chambers' conclusion as to the telemedicine ban. What Judge Chambers said is restrictions that are not these sort of upstream, you know, total ban on abortion, but a restriction that is more granular and is applied specifically to the manner in which this drug is prescribed or dispensed -- he said those are unambiguously preempted if they conflict with FDA's judgment. And so that's the case we have here.

And just a brief word, Your Honor, about something I don't think we actually heard today, but a big focus of briefing on the other side, was the Supreme Court's *Dobbs* decision and the major questions doctrine. And my friend, I don't think, mentioned those, but just to sort of briefly address them --

THE COURT: I didn't ask any questions about that one, so that may be why she didn't talk about it.

MR. MEZZINA: Understood.

So *Dobbs*, I think, very clearly doesn't speak to the issues here. The Supreme Court there held there's no

substantive due process right to abortion, but it didn't otherwise displace the operation of ordinary legal principles like obstacle preemption. And, in fact, I think many of the things the court said support our view that these ordinary legal doctrines apply even in a case involving abortion.

So, for example, the court said abortion laws are, quote, governed by the same standard or review as other health and safety measures. It also said that courts should not, quote, engineer exceptions to longstanding background rules when abortion is at issue.

So I think the big picture message from *Dobbs* is you apply ordinary legal doctrines and principles when a law concerns abortion. And, of course, obstacle preemption is one of those ordinary legal principles.

As far as the major questions doctrine, I think that's not applicable here for two basic reasons. First, that doctrine has always been used as a way of determining whether a particular agency action is authorized. Here, I think my friend said in this case they are not challenging the validity of the FDA's actions concerning the REMS. So that's not at issue. I don't think the Supreme Court has ever applied the major questions doctrine to limit the ordinary preemptive effect of a concededly valid agency action.

And the second reason it doesn't apply is just this case does not involve a major question. The Supreme Court has

applied that doctrine in a very narrow set of cases; said they have to involve assertions of agency power that have vast economic and political significance. And as important as the restrictions at issue are here to Dr. Bryant and the patients, I think that the relatively granular questions of, for example, does a doctor have to administer this lawful drug in person or can a patient pick it up from a pharmacy is not anything approaching what the Supreme Court has considered to be a question of vast economic and political significance.

THE COURT: Of course, on that point, major questions doctrine is not that old, it seems like. It's hard to know whether they are going to expand it to include anything that they think is important. I mean, they have not -- it's new. They don't appear to have completely worked out the details of it yet.

MR. MEZZINA: I would agree with that, Your Honor. I think it's a somewhat amorphous doctrine.

THE COURT: Much criticized, generally, I mean, by lots of people. I don't know. It's a little hard to know exactly -- you know, is it just going to start applying to anything they think is important? It certainly has that possibility. And if it ends up being a broader standard, then maybe this would apply -- would fall within it.

MR. MEZZINA: Your Honor, I can't predict where the court is going, but I think if the court gets to the point

where it says that the kind of very specific granular administrative questions here are major questions, I think the doctrine would really spiral out of control.

THE COURT: Disappear.

MR. MEZZINA: I certainly don't think that's where we are now. At this point the court has applied it to things like a national vaccine mandate, a national eviction ban, a regulation that empowered FDA to ban cigarettes nationwide, things that clearly would cause a political uproar.

THE COURT: You don't think that a decision prohibiting states from imposing additional safety and efficacy requirements on REMS drugs counts?

MR. MEZZINA: I really don't, Your Honor.

THE COURT: Because isn't that what we're talking about here?

MR. MEZZINA: Your Honor, this is -- it's important to note, this is a procedure -- this medication abortion -- using this drug, it is legal in North Carolina. So we're not talking about --

THE COURT: Under limited circumstances.

MR. MEZZINA: Under limited circumstances, yes, but --

THE COURT: I mean, it's not --

MR. MEZZINA: That's right.

THE COURT: Timing, et cetera.

MR. MEZZINA: Right, right.

But I think it is very hard to see treating as a major question, a question of vast economic and political significance, the question of whether a woman can take this lawful drug for a lawful purpose at home or at a doctor's office.

THE COURT: I mean, that's -- is that how I'm supposed to look at the entire issue -- entire preemption issue?

I mean, isn't -- maybe I'm wrong, but this is a case where it seems like I should be looking at the 2007 amendments and the effect that they have on state regulation of REMS drugs -- that is the first question -- this drug, any drug that's a REMS drug.

And then, of course, I have to look at the specifics of, as you say -- I think I have to do this -- what has the FDA actually done with this statutory authority, the *Geier* argument you were talking about earlier?

But, I mean, this is not a case that's just about this drug, right, or is it?

MR. MEZZINA: No, I completely agree, Your Honor, the arguments are not specific to this drug. If the State were correct, then other REMS drugs could similarly be subject to state restrictions consideration that directly contradict the REMS.

So I forget the name of the drug Your Honor mentioned, but --

THE COURT: Oh, well, you know, I have actually no idea about what restrictions those other drugs have and whether -- I mean, that is why it is important to look at this drug. Has the FDA explicitly considered this particular restriction and rejected it? I mean, that can vary from drug to drug. And that matters, correct --

MR. MEZZINA: Yes, Your Honor.

THE COURT: -- under *Geier*?

MR. MEZZINA: Yes.

THE COURT: I'm sorry. I keep you interrupting you. I apologize.

MR. MEZZINA: No, thank you, Your Honor.

THE COURT: Though I interrupt everybody. That's why we're here.

MR. MEZZINA: Your Honor, I think what you said is exactly correct. This is a very small number of drugs. There's only a few dozen drugs that have REMS, and even a fewer of those have what we call the ETASU, E-T-A-S-U, which stands for elements to assure safe use.

But for that small set of drugs, the FDA has gone through this very meticulous, statutory-mandated process. And as part of that, it may have said for other drugs -- you know, I'm not familiar with all of the REMS for other drugs, so I

don't want to make any representations. But it's easy to imagine that the FDA could have similarly made judgments about where should this drug be administered, who should be allowed to administer it. And I think, similarly, states, under *Geier*, would not be allowed to come in and impose requirements that FDA has considered and rejected because it deems them unnecessarily burdensome and inappropriate.

THE COURT: So under your argument, it would be okay or probably okay, if you don't want to go firm on this, if you have a REMS drug and there's some safety restriction or requirement, labeling, warning, in-person, whatever, that the FDA has not explicitly considered and rejected, that it's just still out there kind of being talked about -- the State could impose that?

MR. MEZZINA: And I want to be precise in answering this, Your Honor. I think that for REMS drugs specifically, unlike the broader 20,000 drugs that were at issue in *Wyeth*, the nature of the process under the REMS statute is that FDA is mandated to consider on an ongoing basis whether or not certain types of requirements should be imposed.

And so even if we couldn't point to a specific place where FDA has said in writing, We looked at whether to require X and we decided not to, I think you would be able to tell from the statutory scheme that the FDA had considered and rejected that.

Here, of course, for almost all of the requirements we're challenging -- and if we go through them, we can talk about this -- but almost every individual single one, with the exception of the blood-type determination, we can point to places -- many places where FDA has specifically said, Here's why we didn't impose this requirement. We considered it; we rejected it, and here's our reasoning.

THE COURT: I mean, maybe I don't have to reach that. There's lots of questions I've asked y'all that I probably don't have to reach. It just seems like the new drug -- if you had a new drug with REMS, there might not be the same reasons for the states to not be able to impose some additional requirements early on in a drug's post-approval life because that would be more consistent with sort of the general -- one of the overarching purposes of the 2007 amendments.

MR. MEZZINA: Right. Your Honor, I don't think I have to persuade you on this point for us to win here, but I would say if it were a new drug, but a new REMS drug, and so FDA had gone through the REMS process and necessarily considered all of the statutory factors and ultimately come out -- came out with the REMS that said these are the requirements that we think are necessary to make the drug safe without being unduly burdensome on patient access or the healthcare system, that would necessarily represent FDA's balancing of risks and benefits, and it would be inappropriate

for a state to come in and impose more restrictions.

THE COURT: Okay. Go ahead. Don't forget to address these two Supreme Court cases.

MR. MEZZINA: Yes, so I will do that.

If Your Honor doesn't mind, I will make one more point before I move on from this.

So just as to FDA's position on preemption, because I think my friend mentioned the frequently-asked-questions document and some places where FDA has talked about state law -- and we don't disagree with that. It's certainly true; FDA has not displaced all state law. It's left some state law to operate. Where it's done that is on the broader question of professionally licensing. So FDA says to become a certified prescriber under the federal REMS, you have to be either a licensed physician in your state or a licensed nonphysician healthcare practitioner who, under the state law licensing laws, is allowed to prescribe medication.

I couldn't get a federal REMS -- a federal prescriber certification under the REMS because -- probably for many reasons, but one of those reasons is that I'm not a licensed doctor in any state. Similarly, if you're a nurse in a state where nurses are not allowed to prescribe medication, you can't become a certified prescriber.

The FDA is not getting involved in that broad general question of professional licensing. I don't think that that

then allows the State to come in and say, As to this specific drug, we are disagreeing with FDA's judgment. So we have nurses and nonphysician practitioners who are generally licensed to prescribe medication, but we're not going to let them prescribe this specific drug, even though the FDA has looked at the issue and said that type of practitioner should be allowed to prescribe this type of drug. And that is directly conflicting with FDA's considered judgment.

So as to the Supreme Court cases, Your Honor, I think we're largely in agreement on that. The Idaho case, which is also the *Moyle* case, I think, although it does sort of at a high level of generality involve questions of preemption and questions related to abortion, the specific issues in that case I think are very unlikely to be relevant here. We looked at the briefs. It seems like that case is going to turn on some very specific questions about the meaning of that statute, the EMTALA statute.

THE COURT: That one was just granted. So I guess, in theory, they could get it decided this year; is that right?

MR. MEZZINA: That would be my expectation, Your Honor.

THE COURT: When you address the other one, tell me the status. I think I forgot to ask counsel for the Intervenors about that.

MR. MEZZINA: Sure. My -- obviously, the Supreme

Court can do what it wants, but my expectation, based on the timing, would be that both of those cases would be argued and decided this year.

But, again, the Idaho case we don't think is going to be particularly relevant here. The *Alliance for Hippocratic Medicine* cases are relevant, but -- I agree with my friend -- not a reason to hold up proceedings here.

So depending on what happens in those cases, it could affect, I think, the scope of our preemption challenge. There's some -- you know, some of the provisions might not be preempted, depending on what the Supreme Court does. If the Supreme Court -- for example, if the Supreme Court were to roll back FDA's recent actions and say, We're reinstituting the in-person administration requirement, then we wouldn't have a conflict with the similar state requirement.

But at least for some of the requirements we're challenging, the challenge would still be live even if, I guess, the challengers in that case won in the Supreme Court. So just, for example, the ultrasound requirement, that's something the FDA has rejected consistently going all the way back to 2000. And so that would continue to be a conflict regardless of the outcome of that case.

THE COURT: Has the *AHM* case been fully briefed or arguments set, or do you know? I'm sure I can look it up.

MR. MEZZINA: As far as I know, and I haven't checked

the docket recently, but I believe the opening briefs are due in a few weeks. And so I think it will be briefed over the course of the spring and most likely argued in potentially April, I guess.

THE COURT: Okay.

MR. MEZZINA: My cocounsel tells me argument is in March.

THE COURT: All right. Let's take a 15-minute recess, and we'll come back and finish.

(Proceedings recessed at 11:00 a.m.)

(Proceedings called back to order at 11:17 a.m.)

THE COURT: All right. Mr. Mezzina, you can continue.

So as you get started, you know, it seems like a pretty good deal for Congress to say to the states, There's a category of drugs where you cannot act. That seems like a pretty good deal. You agree it has to be clear. It has to be -- it's a pretty high standard that you have to meet here to show obstacle preemption; correct? I mean, it seems like that's a big deal.

MR. MEZZINA: Well, Your Honor, I don't want to quibble too much with the characterization. I'm not sure that I would consider -- I don't know if Your Honor is getting at the major questions issue. I think I've already made clear I don't think it comes anywhere close to that level.

In terms of the question of preemption, I think *Geier* really shows what the standard is here. In *Geier*, the Court was very clear that we don't need an express statement of preemptive intent because we assume that obstacle preemption is always a background principle. The default assumption is that when Congress has legislated an area, when it authorized a federal agency to act with the force of law in that area, we assume -- the courts assume Congress does not want states to interfere with that scheme; does not want courts to -- does not want states to countermand the agency's considered regulatory decisions.

So I think *Geier* basically supplies the roadmap for how to approach this issue.

THE COURT: Okay. Go ahead.

MR. MEZZINA: So I think what's left, Your Honor, if it would be helpful to the Court, is that I can go through that chart sort of line by line and talk about each one.

THE COURT: Yes.

MR. MEZZINA: So start with the in-person examination, administration, and dispensing. This is -- North Carolina law requires the physician providing the drug to be physically present in the same room as the woman when --

(Reporter requested clarification.)

MR. MEZZINA: I'm sorry. I will start that sentence over.

It requires the physician to be physically present in the same room as the woman when the mifepristone is administered. It also requires the physician to examine the woman in person. And although it doesn't speak expressly to dispensing, it has provisions in Section 14-44.1. It provides strict liability penalties for supplying an abortion-inducing drug which is then administered outside of the presence of the physician, and those penalties apply regardless of whether the person who supplied the drug knew or intended that that would be the case. And so what that effectively does is says the only way to safely dispense this drug, meaning the only way to dispense this drug without risk -- the risk of strict liability, is to dispense it in person. So, effectively, North Carolina has mandated in-person examination, administration, and dispensing.

These all are things that the FDA has specifically deliberately rejected. It updated the federal REMS in 2016 to eliminate the requirement of in-person examination and administration. At that point it kept the in-person dispensing requirement. Then in 2023, it updated the REMS again to eliminate the requirement of in-person dispensing and allow pharmacy certification, and it created under the REMS an entire program where pharmacies could now become certified federally to dispense this drug.

And there are many places in the record where you can

look to see FDA's views on this. But we just, for example, point to Exhibit P to the complaint at page 36 where the court -- the FDA explained its conclusion that, quote, the REMS must be modified to remove the in-person dispensing requirement, which would allow, for example, dispensing of mifepristone by mail and by certified prescribers or pharmacies. And the FDA has many pages in that exhibit where it goes through its reasoning for why in-person is not required for safety and would be unduly burdensome on both patient access and the healthcare system.

Going on to the second line, the in-person 72-hour advance consultation, my friend is correct; we're not challenging that there has to be informed consent. Informed consent is part of the REMS. We are challenging both the requirement that it has to be in person and the requirement that it has to be 72 hours in advance.

So the in-person is something the FDA, again, has specifically rejected. Of course, requiring in-person consultation would frustrate FDA's efforts to facilitate access through telemedicine, because even if you could dispense the drug by mail or through a pharmacy without in-person administration, if you have to come in for an in-person consultation, then that sort of defeats the purpose.

And the FDA addressed this -- one place it addressed it is Exhibit P at page 13 where it talked about this exact

issue, and it concluded that: "A certified prescriber can also review the Patient Agreement Form with the patient, fully explain the risks of the mifepristone treatment regimen, and answer any questions, as in any consent process, without physical proximity." So this is another instance of direct conflict.

As to the 72-hour advance requirement, that's something the FDA has never required, and it would effectively shorten the FDA-approved period in which the agency determined a woman could receive this treatment. So the FDA modified the labeling of the REMS in 2016 to allow mifepristone up through 70 days of gestation; but if the informed consent has to happen 72 hours in advance, that period is effectively shortened to 67 days. So we think there is a conflict there as well.

Moving on to line 3, the in-person follow-up, again, this is something the FDA has specifically rejected.

Oh, and just on the question of what North Carolina law requires, I think my friend said, and she's right, that the follow-up doesn't actually have to happen. But North Carolina law is very clear that the physician has to schedule the follow-up visit and has to also make all reasonable efforts to ensure that the woman returns before the in-person follow-up. And, yes, the physician actually has to document those efforts specifically in the medical records and in the report that he or she files with the State after the fact.

Now, this is all contrary to the FDA's judgment. The FDA updated the federal REMS in 2016 to eliminate the requirement of in-person follow-up. And, for example, again, Exhibit P, at pages 14 to 16, FDA said follow-up can be performed by telephone. It said: "We disagree that medical abortion always requires in-person follow-up with a healthcare provider." And it went on to say: "....the way in which post-treatment follow-up is performed may be determined by the healthcare provider and the patient."

So the FDA specifically concluded that follow-up does not have to be in person. And, of course, that in-person requirement would frustrate the FDA's attempt to provide access through telemedicine.

THE COURT: So the access point which Intervenors' counsel made a big point of discussing, you know, is that new in the 2007 amendments? I mean, is access -- access doesn't seem like it was historically a goal of these statutes. It was a consumer protection statute basically to be sure you're getting drugs that are safe and drugs that do what they are promised to do.

So access is new in 2007?

MR. MEZZINA: So it's certainly much, much clearer and more explicit in the REMS statute. I think there's a -- I think it's always been -- part of Congress' objective under the FDCA more generally is to provide access to these safe drugs,

and that's why you get the question of can a state ban a federally-approved drug. Of course, the *Zogenix* court held no, and that was a REMS drug, but the court held that without considering that it was a REMS drug. I think the holding in *Zogenix* is a state can't ban an FDA-approved drug because part of the purpose of FDA approval is to provide access to that drug. But setting aside the FDCA more generally, the REMS statute could not be clearer that part of the purpose of that statute is providing access.

In fact, just to go back to it, I mentioned several provisions before, but one that I didn't mention is under the heading of "Assuring Access and Minimizing Burden." The statute specifically directs the FDA to consider the burdens on particular types of patients, including "patients who have difficulty accessing healthcare (such as patients in rural or medically underserved areas)."

THE COURT: That's in the statute?

MR. MEZZINA: That's in the statute.

THE COURT: Where is that?

MR. MEZZINA: That's 355-1(f)(2)(C).

So those are exactly the type of patients who benefit from telemedicine and who are burdened by the type of in-person requirements that North Carolina is imposing. So this was clearly a specific, explicit concern of Congress was providing access to these drugs to patients who might have difficulty

accessing them if unnecessary burdens are imposed on prescribing and dispensing the drugs.

So continuing with the chart, the next challenged North Carolina law is the physician-only restriction.

This is probably a good time for me to mention, Your Honor, a sort of caveat about this chart, which is that we have done our best to be comprehensive in identifying these sections of North Carolina law that embody these requirements. But to the extent we've missed any, we would intend -- or challenge to encompass any provision that embodies one of these requirements.

And physician-only is a particular issue where we have cited in the chart the two sections that we think most clearly impose a physician requirement. But, of course, there are references throughout the statute to the physician. And to the extent any of those are understood as requiring the person to be a physician, that's the requirement we're challenging.

So, here again, we have a direct conflict with the FDA. The FDA updated the federal REMS in 2016 to specifically eliminate the restriction that only physicians could become certified prescribers. Now, as I said, the nonphysician prescriber still has to be somebody who is licensed under state law to provide prescribed medicines. The FDA is not getting into that question of general licensing. But once you're licensed under state law to prescribe medicines generally, the

FDA says it is perfectly appropriate for you to prescribe mifepristone.

THE COURT: What are the additional elements? What -- is it still REMS drug? Has the FDA -- is it really just treating it like the other 20,000 drugs out there, or does it still have some specific restrictions?

MR. MEZZINA: It does, Your Honor. So it is absolutely still a REMS drug. There's still a REMS that requires, among other things, a prescriber agreement. So not just anyone can prescribe these. You have to be federally certified. You have to sign a prescriber agreement, which means you have to agree to various things the FDA requires. You to show that you have various competencies that the FDA requires.

Similarly for pharmacies -- this is new under the 2023 changes -- not just any pharmacy can dispense. Again, you have to be federally certified. So there's a pharmacy agreement that you have to sign, and that, similarly, has requirements with it. And there's also a patient agreement form that includes various disclosures to the patient that the patient has to sign, and the physician has to get the patient to sign that.

So there is a REMS, and it still has a variety of requirements, but the FDA has looked at these specific requirements and concluded that they are unnecessarily

burdensome.

THE COURT: Okay. Go ahead.

MR. MEZZINA: So just to finish up on the physician-only restriction, I will give you one example. And as with all of these, there are many different places in the record I can quote, but I will quote Exhibit P at pages 10 to 12. The FDA goes through this in some length. And it says: "In 2016, we determined that available data support that Mifeprex is safe and effective when prescribed by mid-level providers such as physician assistants and nurse practitioners as well as by physicians."

And then the same Exhibit P at 24, the FDA says: "We do not agree," dot dot dot, "that the healthcare provider needs to be a licensed physician..." So the FDA specifically disagrees with this requirement imposed by the State.

Moving on to No. 5, the ultrasound requirement, North Carolina requires in every case of medication abortion that the physician has to get an ultrasound of the patient to determine gestational age. This is something the FDA has rejected going all the way back to the original 2000 approval decision. So, for example, Exhibit D at 6 -- that's the 2000 approval memo -- the FDA says the role of ultrasound was carefully considered, and what the FDA concluded is that it would recommend ultrasound evaluation as needed, leaving it to the medical judgment of the physician.

Exhibit E at 19 -- this is in 2016 -- the agency denied a citizen petition on this topic, and it said: "...the Agency carefully considered the role of ultrasound." And: "We determined that it was inappropriate to mandate how providers clinically assess women for duration of pregnancy and for ectopic pregnancy."

And, again, Exhibit P at 12, in 2021, FDA reiterated: "...the determination of gestational age does not always require an ultrasound." So this is another requirement North Carolina is imposing that the FDA has specifically and repeatedly rejected.

No. 6, the blood-type determination requirement, I mentioned earlier in candor with the Court that this is the one requirement we're challenging where we can't point to a specific place where the FDA has considered and rejected this, but we think that the statute itself shows that the FDA considered and rejected this.

So in Section 355-1(f)(3)(D), one of the elements to assure safe use that the FDA is required to consider imposing is a safe use condition such as laboratory test results. So if the FDA thought that blood testing was required, that would have been imposed as part of the ETASU. It wasn't, and so you can tell from that that the FDA rejected this as unnecessary. And, again, our view is imposing anything that could have been part of the REMS but wasn't is necessarily going beyond what

the FDA determined was commensurate with the risks and more than necessary to provide safety.

My friend mentioned a discussion of Rh testing in Exhibit P. I think if you look at that paragraph -- first of all, it is clear that the FDA is not requiring that. The FDA refers to Rh testing as being part of the standard of care in some cases. I actually think that's no longer true, but that's certainly neither here nor there. The fact is the FDA didn't require it.

THE COURT: Did or did not?

MR. MEZZINA: Did not require it. And what I think that paragraph says as a whole is that the FDA does not think this is something that has to be done by the prescriber of mifepristone.

The final requirement on the chart is the requirement to report nonfatal complications and adverse events. So North Carolina requires reporting of both: Any complications the woman experienced as well as written reports of adverse events. It defines complications and adverse events both extremely broadly to encompass essentially any physical or psychological condition or any untoward medical occurrence that's in any way associated with use of the drug.

And I should say it requires reporting of this not only to North Carolina, but it also requires reporting of adverse events to the FDA. That might be the most clearly

preempted of any of these, because as the Supreme Court said in *Buckman*, states are not supposed to interfere in that federal relationship between the regulator and the regulated party. Here, North Carolina is requiring the FDA to receive reports that the FDA itself has said it doesn't want or need. So it's actually directly burdening the federal agency. I think that's preempted under *Buckman*.

As to the reporting requirements more generally, the FDA again has rejected this. In 2016, the FDA updated the federal REMS to eliminate the requirement to report anything other than fatal adverse events. What the FDA said -- in Exhibit P at 21, the FDA said it assessed 15 years of adverse event reports and determined that certain ongoing additional reporting requirements were not warranted.

And it's true, as my friend said, this is not specifically about patient access. It's about burdens on the prescribing physician, but that, too, is part of what the FDA is required to consider under the REMS statute. So as we talked about when we went through the statute, it's both assuring access and minimizing burden, and the agency is directed to consider both burdens on patient access as well as burdens on the healthcare system.

Now, having to file reports for every single minor complication or adverse event that comes up is a clear burden on the healthcare system. It's a burden on the prescribing

physicians, and it's one that the FDA specifically rejected as unnecessary based on the long history with this drug and it's well-characterized safety profile.

THE COURT: It's well-characterized what?

MR. MEZZINA: Safety profile.

So we have a couple of notes at the bottom of the chart that I'll mention. First, just to sort of clear the air about this, in our complaint we talk about the facility requirement. North Carolina previously had a requirement that facilities where mifepristone would be administered had to be specially licensed, and they had to meet particular requirements. We conferred, and we agree that that is no longer part of the law. That's been repealed, and so that's no longer at issue.

Second, as to risk disclosure requirements, so Section 90-21.83A of the North Carolina law requires the consent form that's used with the patient to include various risk disclosures. We've looked at the consent form that was put out by the Department of Health and Human Services. We decided that, based on how the agency has implemented those requirements, we're not challenging it at this time. But if that implementation were to change in the future or if the consent form were to be modified in ways that brought it more into conflict with the federal REMS, we would reserve the right to challenge that.

THE COURT: Okay. Thank you.

MR. MEZZINA: Thank you, Your Honor.

THE COURT: For the Attorney General?

MS. BOYCE: Yes, good morning, Your Honor.

THE COURT: Ms. Winchester, is there something you can put underneath that microphone so it can be a little bit higher so Ms. Boyce doesn't have to ruin her back.

MS. BOYCE: My mother would be very offended if my posture were poor.

THE COURT: Thank you, Mr. Boyle.

MS. BOYCE: Thank you, Your Honor.

Just a few points on behalf of the Attorney General.

The first point I would like to respond -- counsel for the legislature has made several emphases about the Attorney General's position with respect to preemption, and it is certainly true that in our brief we reiterate that ordinarily states have great latitude to regulate in the area of health and safety. That's precisely why in this particular case the Attorney General has advocated a cautious approach from this Court, that is, a middle road between the physicians that are being advocated by the parties here today.

The Attorney General would urge this Court to adopt the rule that where the FDA has imposed and then subsequently withdrawn a restriction as part of a REMS, that is preempted, and a state regulation that attempts to reimpose a requirement

that has been withdrawn cannot stand and must be struck down.

That position takes us to the exact same place in terms of the state laws that need to invalidated, as the Plaintiff's rule does, but it avoids some of the more difficult questions that Your Honor has gestured at today, including that it seems like a big deal to completely shut states out of the game of regulating drugs.

It avoids the question of whether ordinarily the 20,000 or more drugs that the FDA regulates can have additional requirements superimposed by the states. It avoids the Court having to grapple with how clearly the FDA has to have considered and then rejected a particular requirement, because it simply allows the Court to look at the regulatory record and see where a requirement has been imposed, and then, after additional information and evidence has come light, the FDA has then subsequently rescinded the requirement. Where that has happened, a state cannot come in and second-guess whether a particular requirement is still needed. Instead, that particular requirement is preempted.

And I think, given this helpful chart that the Plaintiffs put together, it's relatively obvious why that means that these restrictions need to fall. The only ones that I wanted to touch on in particular are the ultrasound and blood-type determination requirements. Insofar as those requirements are read to require a patient to come into the

doctor's office, which certainly for an ultrasound requirement it would, those would fundamentally conflict with the FDA's considered judgment that an in-person examination is no longer required. And so while it is true that there has never expressly been an ultrasound requirement imposed, it is in fundamental conflict with the requirements that have been imposed and rescinded. So that, too, would fall under the Attorney General's rule that we've advocated.

THE COURT: So the second one on this chart, the in-person 72-hour advance consultation, according to the Plaintiff's chart, that was never required. So how would that be evaluated under your approach?

MS. BOYCE: Your Honor, I think it depends on what piece of that you focus on exactly. We read that to be a requirement that has to be read collectively. And it is certainly the case that in-person consultation with the provider was previously imposed and then rescinded. And so because North Carolina law seems to require a patient to come in person to a doctor, then wait 72 hours and come back, that is fundamentally inconsistent with the REMS as it stands today, because, of course, as Your Honor knows, it was previously required that a patient in come, meet with the doctor in person, and then come back a couple days later for the dose of misoprostol. And now the FDA has concluded that those in-person touchpoints are not required.

So for that reason, we also believe that the in-person 72-hour advance consultation is consistent with our theory of preemption.

THE COURT: And does your theory flow from the statutory language or is it just a practical approach or what's the theoretical -- not theoretical. That's not a good word. How do you get to that argument other than just it's pretty clear and fairly easy to apply?

MS. BOYCE: Yes, Your Honor. We get there in much the same way that the Plaintiffs arrive there, and that is by looking at the statutory language. I would quote back to you almost the exact same sections of the statute as my friend Mr. Mezzina pointed to that reference this balancing that the FDA is tasked with doing between access for patients, minimizing burden on the healthcare system, and at the same time mitigating safety risks. I think that makes clear that the FDA has been the agency that's tasked with calibrating that balance. But, in our view, the only way to know for certain that the FDA has actually tried to calibrate the balance by eliminating particular requirements or not is to look at the record and see where they have expressly decided to alter their calibration or their balance by rescinding a particular requirement.

And I think it's -- go ahead, Your Honor.

THE COURT: So you disagree with counsel's argument

that it has implicitly rejected these other additional requirements -- I think that's the way that he said it -- you know, that they had to reject them because they don't require them?

MS. BOYCE: It's not that we disagree with them, Your Honor. We have not taken a position on whether, if it were the case that they had implicitly considered them, that would also be preempted. We just simply don't think that the Court needs to go that far. And given that there are 66 other drugs at issue here that also have REMS and given the significance of some of those drugs, in particular opioid drugs, that are regulated by the REMS to the states and the significant public interest in those drugs, we urge the Court to take a cautious approach and adopt the most moderate rule that it could in determining whether these rules have been preempted.

So I do want to be clear that we have not argued that. That is incorrect. We don't disagree with them, but we have taken a different approach that is a slightly more moderate one that avoids answering certain questions and that would bar states in any instance from imposing additional requirements where those were not in conflict with the decisions and the considered judgment of the FDA.

THE COURT: Okay.

MS. BOYCE: Next, I would like to briefly touch on *Wyeth* because we agree, I think, with all of the parties here

today that that's a critical case. We agree with the Plaintiff that *Wyeth* is a good case for us. And I'd just like to touch on two key points about *Wyeth*.

The first is to reiterate the fact that the statutory scheme at issue in *Wyeth* is a different one than the one here today. *Wyeth* did not involve the REMS. It involved labeling requirements, which are part of the same statutory regime but are distinct and separate parts of that statute, and that matters for two reasons.

First, it means that the congressional objective is not necessarily the same. And here, of course, as Mr. Mezzina has walked you through, we think that the congressional objective of delegating this calibration task to the FDA is clear. And, secondarily, it imposes a different process. In *Wyeth*, it mattered a great deal to the Supreme Court that the onus was on the manufacturer to continue updating the labels, and it mattered that under the 2007 amendments the manufacturer could unilaterally change the label so as long as it did so at the same time as it submitted a supplement application to the FDA.

Here, of course, the regime is entirely different. A manufacturer cannot unilaterally change the REMS and, in fact, cannot do anything to alter the requirements that govern the prescription, administration, or dispensation of a drug without first obtaining the approval from the FDA. And we think that

that's a critical difference.

Of course, as counsel for Plaintiff also pointed out, the Supreme Court in *Wyeth* goes out of its way to make clear that it may well have been a different case had the FDA actually considered a modification to the label and decided not to adopt that modification to the label. That, of course, is the case that we have here where the FDA has considered certain modification -- or, excuse me, has considered certain requirements and opted not to impose them or withdrawn them, as we've urged this Court to focus on. And in that instance, we think *Wyeth* is clear that the preemption is -- the preemption doctrine applies.

One extremely minor point on *Geier*, counsel for the legislature pointed out that there was an express preemption clause in *Geier*. That is true, of course, Your Honor, but the court held in that case that the express preemption clause did not apply given the savings clause that was also present in that conflict. So *Geier* is not a case in which the Court relied on the fact that there was an express preemption clause in the statute to arrive at its holding of preemption. It was an implied preemption case focused on obstacle preemption, and the fact that there was an express preemption clause in the statute was not relevant to the ultimate holding in that particular case.

Fourth, I wanted to just underscore a point that

Mr. Mezzina made, and that is that we believe the *GenBioPro* case out of West Virginia is a good case for us, and that's precisely for the reason that he pointed to. On pages 24 and 25 of that opinion, the Court focuses on a restriction very similar to the ones that have been put in place here in North Carolina. West Virginia attempted to say that mifepristone could not be prescribed via telemedicine. And the court said: "There is one provision which is unambiguously preempted by the 2023 REMS." And that was the telemedicine restriction.

So our position is that for exactly the reasoning that the court then walks through on pages 24 and 25, the state laws here in this case are preempted.

Just two more minor points, Your Honor.

First, counsel for the legislature seemed to suggest that for requirements where the FDA had imposed them at one point, that was more license for a state to then come in and superimpose those requirements after they had been rescinded. We, of course, believe exactly the opposite is true. And that's in part because, as Your Honor has pointed out, the REMS regime is set up such that the FDA hopes additional information will lead to better decisions about what the appropriate balance is between access and safety.

And so where the FDA has previously thought that a particular requirement was necessary to get that balance right and then decided, no, in fact, that is not the right balance,

we think that is a strong case against the State imposing that regulation, not evidence that the State should be able to go in and second-guess the FDA's better-informed and later judgment.

And then, lastly, just a brief point about the major questions doctrine. We certainly agree with Your Honor that that doctrine continues to evolve, and I don't know that any of us would be eager to make predictions about where it's headed. But the core of that doctrine is the question of whether Congress truly meant to confer the power that the agency has asserted or whether, in fact, the agency is looking to ambiguous language and exaggerating the authority that Congress, in fact, meant to confer.

Here, of course, it could not be clearer that Congress intended for the FDA to have precisely the authority that it has exercised here. In 2007, Congress not only gave the FDA authority to enact these REMS plans, it specifically told the FDA to convert the Subpart H regulations in mifepristone into a REMS plan. So not only does the FDA have the general authority to enact REMS plan, it has specifically for mifepristone and has been authorized to enact requirements about the prescription administration and dispensation of that drug.

So we don't think that this is a close case on the major questions doctrine, irrespective of where that doctrine goes, and we would ask the Court to reject that argument.

Thank you, Your Honor.

THE COURT: Thank you.

Further argument from the Intervenors?

MS. HAWLEY: Thank you, Your Honor. I will try to be quick.

To begin, I think we've heard today from my friends on the other side that Section 355-1 transforms the FDCA from what the Supreme Court in *Wyeth* said was a safety and efficacy purpose into something that includes not only safety and efficacy, but we heard also access and then a burden on physicians.

THE COURT: Isn't that in the statute?

MS. HAWLEY: Yes, Your Honor. But those are directed plainly to the FDA. It talks about the Secretary, and it says the Secretary shall not employ REMS that are unduly burdensome. It says nothing about the states' historic police power to protect its citizens.

So, absolutely, the FDA has to consider access. It has to consider whether those are unduly burdensome. But there is nothing in the statute that suggests that the states cannot exercise their historic ability to protect for health and safety.

I think it would be quite strange for the 2007 amendments to broaden the statutes so much. Again, this was an amendment enacted to increase safety. Congress was concerned

about Vioxx. And in doing so --

THE COURT: Well, that wasn't the only purpose; right? I mean, that wasn't the only reason. That statute covered a lot of different things and a lot of different concerns.

MS. HAWLEY: But the animating purpose, Your Honor, was that the FDA needed to do more to preserve safety. And so I think it would be -- I don't see, you know, burdens on physicians as being something that Congress was particularly concerned about.

THE COURT: But they put it in the statute.

MS. HAWLEY: Not as opposed -- or not as applied to states, Your Honor. There's nothing in Section 355-1 that we've heard today that says anything about states not having the ability; nothing that says states need to consider that; nothing that says because the FDA has, states can't.

With respect to the Attorney General, I think everybody's argument on the other side is that the rejection does something important here. I think that doesn't make a lot of practical sense.

If, for example, you had a North Carolina statute that says you need to bring a pink balloon to the visit, clearly, the FDA has not forbidden that -- or has not considered -- excuse me, I shouldn't have said "forbidden" -- the FDA has not considered, required, and then removed that

requirement. But why should North Carolina be able to enact something like that or something that says, you know, maybe more realistically, you have to get a physical, even though the FDA hasn't said anything about that?

But what they can't do is rely on FDA's decades-long history of regulation requiring some of these things to say, We think they are still important to women's health. So I don't think the rejection rationale works practically. I also don't think you can get it anywhere from the statute.

Your Honor, there have been something like 300 REMS. As you mentioned, those REMS are required to be updated. I think there have been 700 updates. That's most recently from the FDA's website. So I'm not sure it would even cabin too much a ruling from this Court just limited to rejections.

And to get back to the statutory language, I don't see anything anywhere in the FDCA that says states are preempted when the FDA has considered something but not when they are not.

To talk just briefly about *Geier*, as the Attorney General expressed, there was an express preemption clause in that case. I think my friend on the other side may have misspoke. What the Court said in that case was that the express preemption clause canceled out the savings clause. Here, we do not have an express preemption clause. Justice Stevens in the dissent talked about this. Justice Ginsburg in

Riegel talked about this.

And the fact of the matter is what Congress said is important, and what it didn't say is important as well.

Here, we have a savings clause --

THE COURT: Do you agree that the savings clause was enacted with the 1962 amendments and that it said that it was as to those amendments? So, I mean, I think the argument was it doesn't really even apply here because it was limited to the '62 amendments.

MS. HAWLEY: So I think *Wyeth* is controlling on that question, Your Honor. In *Wyeth*, the Court applied it to a general labeling statute that I don't believe was part of the 1962 amendments, to the best of my ability to decipher. So I think *Wyeth* applied it more broadly.

And the reason that makes sense is, as the *Wyeth* Court explained, that's of a piece with the congressional determination that states can always supplement. From 1906 on, states have been able to supplement.

For the *Wyeth* case, Your Honor, I do want to point out that the considered and rejected language, that comes from the impossibility part of the court's opinion, not the portion of the opinion dealing with obstacle preemption the Court mentioned, sort of in an offhand manner, that the district court had found that the FDA had considered and rejected. So I think that that is not a sufficient basis to rely on or to get

that sort of principle out of *Wyeth*. It was not in the obstacle preemption analysis, Your Honor.

In addition, with respect to *Zogenix*, my friends on the other side suggested that basically the district court enjoined everything that was challenged.

THE COURT: Well, just the telemedicine thing is what I think they were talking about.

MS. HAWLEY: *Zogenix*, Your Honor.

THE COURT: Oh, *Zogenix*. Opioids. Sorry.

MS. HAWLEY: No worries.

Yes, Your Honor. So with *Zogenix*, I think instructive on that point is the middle opinion that was issued in August of 2014. In that opinion, the district court said that he was not going to enjoin what he called the physician-only -- it was actually pharmacist-only, but he called it the physician-only requirement, that only pharmacists could dispense this drug. He said he would not enjoin that because there was insufficient evidence.

Then in *Zogenix III*, he did enjoin it based on the motion to dismiss standard, that they had to accept plaintiff's allegations as true; that it was akin to a ban, that it was a de jure -- excuse me -- a de facto ban.

So what the Court looked at in *Zogenix* was if something was a ban, then the Court found it preempted. If there was anything less, like informed consent, like in-person,

all of the things listed in Footnote 7 of *Zogenix III*, the Court did not preempt those.

Your Honor, on the major questions doctrine, I agree with all that has been said, that it is a doctrine that is in flux. I think the best understanding of that doctrine and the one that we are seeing up here most recently from the United States Supreme Court is as a canon of statutory interpretation. And I think there are a couple of ways that that doctrine could apply here, perhaps to the express savings clause or to the preemption analysis itself.

We agree completely with Your Honor that it is a big deal when you wipe out 28 states' laws. As Justice Stevens said in his dissent in *Geier*, this is a case about federalism. It's a case about whether the states' historic powers to protect the health and safety of their citizens can be done away with in statutory language that is certainly less than clear.

Finally, Your Honor --

THE COURT: I mean, essentially that argument is you can't have implied preemption if it concerns the state's health and safety -- historic health and safety authority. I mean, that sounds like what you're saying. Is that what you're saying?

MS. HAWLEY: So I don't think that's true. I think there are some justices that would probably take that position,

but that's not our position, Your Honor. If you look at the case law, it's clear that implied preemption can exist. As you said earlier, there does not have to be an express preemption clause. But in this case we have a savings clause that requires a direct and positive conflict.

In my preparation for this, I came across a Fourth Circuit case. My apologies that it's not in our briefing. But the case is called *Southern Blasting*. It's at 288 F.3d 584. It's a case written by Judge Wilkinson, and he's undertaken an analysis of an explosive statute, a statute that governs explosives, and that statute is subject to a savings provision that requires a direct and positive conflict. And what Judge Wilkinson says is direct and positive conflict means something close to impossibility preemption. It does not apply when the states add on additional requirements. So in that case, he upheld -- I think it was a Wilkes County regulation that added on additional permitting requirements that were not included in the federal law, again, this idea that certain federal laws serve as a floor, but not a ceiling.

Your Honor, just to talk a minute about the specifics of the various provisions that are challenged by Plaintiffs, some of them plainly don't go to the access that really formed, I think, the basis for Plaintiff's briefs. They -- now we know that their argument also goes to sort of burdens on physicians. But I think that that's a broad purpose -- reading of the

statutory text.

If we look at the physicians-only restriction, I initially thought my colleague on the other side was saying that states could limit it to physicians. I think they're not saying that and distinguishing FDA's facts based on licensing requirements. But if you look at our reply brief on page 3, it quotes the FDA's language. And the FDA is not concerned about who's licensed. There's all sorts of healthcare providers that can be licensed, including nurses, including physicians' assistants. What it says is: "Some states allow healthcare providers other than physicians to prescribe medications." Again, that can be a nurse; it can be anyone. "Healthcare providers should check their individual state laws." It is not concerned with licensing. It's concerned with whether a state allows nonphysicians to prescribe.

Your Honor, just a small point, but it's not the case that FDA doesn't want to hear about these adverse events. That would be a strange thing for an agency to say, that we don't want to be bothered with any sort of adverse events. In fact, manufacturers GenBioPro and Danco are required to submit adverse event reports for everything -- every serious adverse reaction. The providers are limited by the REMS only to reporting fatalities, but there's nothing that suggests that the FDA meant to limit that information if providers wanted to voluntarily provide it. And, again, the manufacturers or

sponsors of those drugs are required to do so. So I think that the FDA does -- certainly can't be said to not want that information.

Lastly, Your Honor, I would just like to touch again on the breadth of the decision. The Supreme Court in *Wyeth* said that the absence of an express preemption provision -- again, we know Congress knows how to say it. They said it in the Medical Device Act -- speaks powerfully that Congress did not intend the FDA to be the exclusive means of ensuring drug safety. Depending on how narrowly you slice it, that is precisely the argument being made here, that at least for some drugs or some decisions, the FDA is the exclusive authority.

If you took at the --

THE COURT: Right. I mean, I don't disagree with you about that, but we do have these 2007 amendments, and their argument flows from the 2007 amendments.

So *Wyeth* does not say never ever can Congress limit a state's authority to impose additional requirements on health and safety -- on prescription drugs. It doesn't say that. I mean, you keep saying that, but the whole argument is the 2007 amendments change things; right? I mean, that's what they're saying. You disagree with that point.

MS. HAWLEY: So sort of. They also indicated that the FDCA has an access component inherent in it as well.

THE COURT: Oh, okay. I see what you're saying.

Thank you for clarifying that.

MS. HAWLEY: And I don't think, Your Honor -- to speak more directly to your concern here, I don't think that what the Congress did in 2007 was -- performed a 180. I think this is the historic powers of the states. Certainly, that much is true both, before and after the 2007 amendments. So I think we would need something clearer than what was in Section 355-1 to displace the states' traditional authority.

THE COURT: All right. Thank you.

Anything else for the Plaintiffs?

MR. MEZZINA: Thank you, Your Honor. I will try to be brief here and just respond to a few things that were said.

First, as far as the Attorney General's position, I think we have a bit of a conceptual disagreement that doesn't -- you know, as they said, doesn't really make a difference in this case because they end up in the same place as we do as far as what's preempted.

As far as the idea that the FDA has to have composed and then withdrawn a requirement to trigger preemption, we do disagree with that. We don't think there's any need for the FDA to have actually imposed an improper requirement. If the FDA concluded from the very beginning that this requirement would be improper, then that should be just as preemptive. And, of course, that was true in *Geier*. It's not the case in *Geier* that the Department of Transportation had imposed an

all-airbag standard and then withdrawn it. It just chose not to impose it and explaining why it thought it was inappropriate, and that preempted state law.

So we think that the rejection is sufficient regardless of whether it was ever actually imposed by the FDA, but, again, we end up in the same place on preemption in this case.

As to the Intervenors' (indiscernible) statute, I think where we are is that we all agree that assuring patient access and minimizing burden were important objectives under the statute. I think their argument, as I understand it, is that because the statute is only directed to the FDA and doesn't mention the states, it's only concerned about burdens imposed directly by the FDA. And I just think that's wrong as a matter of law. It's true the statute doesn't say anything about the states. If it said something about the states, this would be a case of express preemption, not implied preemption.

The statute in *Geier* didn't say anything about the states either. It said that the Department of Transportation should promulgate federal motor vehicle safety standards, but in doing that, when the Department struck a precise balance, rejected a broader requirement as inappropriate, that impliedly preempted the states from imposing the same requirement.

So I want to talk a little bit just about *Wyeth*, because I think my friend said that the language we were

quoting from *Wyeth* was in connection with impossibility rather than obstacle preemption, and that's not right. This language does occur many times throughout the opinion. It was a central point for the court that the FDA hadn't looked at the issue and hadn't rejected the warning.

But, specifically, in the section on obstacle preemption, this was discussed. And if you look particularly at pages 580 to 81 of the opinion, this is where the court discusses *Geier* and explains that *Geier* -- in *Geier*, the agency had rejected an all-airbag standard. And then in Footnote 14, the Court says -- I will just read it: "Wyeth's more specific contention--that this case resembles *Geier* because the FDA determined that no additional warning on IV-push administration was needed, thereby setting a ceiling on Phenergan's label--is belied by the record. As we have discussed, the FDA did not consider and reject a stronger warning against IV-push injection of Phenergan." And then: "A tort case is unlikely to obstruct the regulatory process when the record shows that the FDA has paid very little attention to the issues raised by the parties at trial."

So that's just one example. That entire section is all about the fact that under the basic labeling statute, there's many, many thousands of drugs. The FDA doesn't have the resources to monitor all of them, and so it puts the onus on the manufacturers to come forward and update those labels.

The exact opposite is true with the small number of drugs that are regulated under the REMS statute. The FDA has an ongoing obligation to look at REMS in detail and to strike a very precise balance. And as we discussed here, the FDA did consider and reject these requirements.

As to some of the specific restrictions that we're challenging -- just on the physician-only restriction, I think we're actually saying the same thing about what the FDA said in that frequently-asked-questions document on its website. It says that in order to become a certified prescriber under the federal REMS, if you're not a physician, you have to be a type of nonphysician practitioner who can prescribe medications under state law. The FDA is not getting into the question of who can prescribe medications generally. But if you are an authorized prescriber of medications generally under state law, then you can become certified to prescribe mifepristone.

And so it's one thing for a state to say, you know, nurse, nurse assistants, physician assistants, whoever it is, you know, we just don't want to give prescribing power to this category of practitioners. The FDA is not expressing a view on that. But once the state says nurses can prescribe, the FDA's view is -- and it's clearly stated in the record -- they are perfectly competent to prescribe mifepristone just like any other medication.

As to the requirement to report nonfatal adverse

events, the federal reporting requirements are very carefully calibrated by the FDA. It is true that the FDA gets one report annually -- I believe it's one annually -- from the drug sponsor that reports adverse events. That's very different from saying that the agency should be required to receive mandatory reports from every provider of every single complication. That would be a huge burden on the agency. That's something -- the agency has specifically said it doesn't want to mandate that level of reporting.

And I think that's just about all I have.

I guess just to close on the question of the states' police powers, I'll go back to the *Zogenix* case. And I do think -- I think there are limits to how much you can really get from parsing those decisions. As we said, it is a little bit confusing. But I think the reason why the court was focused on whether certain rules were a de facto ban is because that's how the manufacturer presented its argument and said these rules were, in fact, a de facto ban, and so the Court analyzed them that way.

There was one challenge that was not presented that way that was also successful where the manufacturer said the requirement to try other pain management treatments before prescribing this particular drug should be preempted because it conflicts with the FDA's judgment about when prescribing is appropriate. The Court also held that that was a ban. So it

was not limited to a total ban or a de facto ban.

And as to the police powers, I think we agree with what the *Zogenix* court said. It said: "The Commonwealth's police powers permit it to regulate the administration of drugs --

THE COURT: Slow down and speak into the microphone.

MR. MEZZINA: Thank you.

"The Commonwealth's police powers permit it to regulate the administration of drugs by the health professions. But it may not exercise those powers in a way that is inconsistent with federal law."

I think that's been the consistent holding of the Supreme Court. It's certainly the holding of *Geier*, and we think it applies here.

THE COURT: Thank you.

Anything else for the Attorney General?

MS. BOYCE: Just three quick points, Your Honor.

The first is just a point of clarification, which I hope was clear earlier, but I just want to clarify something that was slightly off in what my friend representing the Plaintiff said, and, that is, the Attorney General's position is not that a requirement must have been imposed and then withdrawn for something to be preempted. It is simply that where a requirement has been imposed and then withdrawn, it becomes an easy case; preemption becomes obvious.

So we take no position on the question of what might happen if states impose requirements that the FDA has not considered or has not imposed previously and then rescinded. But we think where a requirement has been imposed and then withdrawn, it falls squarely in the *Geier* land; it's controlled by *Geier*, and the question of preemption becomes quite clear. And so our position is simply that the Court should cue to that narrow rule because it eliminates and avoids many of the most challenging questions about state authority to act to regulate in the public interest.

Secondarily, my friend representing the legislature referenced the many state laws that might be at issue in this decision. And I do just want to underscore that Plaintiffs have not asked this Court to do anything about invalidating laws in other states, and I think looking at all of those other state laws would require the kind of individualized case-by-case analysis that we've done here today, looking at each one and comparing it to the decision that the FDA has made in its previous REMS plan.

And so we take no position on whether it's correct that there are 28 laws, but we certainly don't think anything that the Court does here today or in subsequent weeks would invalidate any laws but the ones here in North Carolina.

And, finally, just because I forgot to admit it, we do agree with the parties here today that no further fact

discovery is needed, and we would not object to the notion that this would be converted to a question of summary judgment.

THE COURT: Thank you for addressing that. I meant to ask you and I also forgot.

MS. BOYCE: Sure.

Nothing further, Your Honor.

THE COURT: So just as a housekeeping matter, the website that you have referred to -- so I have, like, a little problem with just referring to websites when they're not in the record. Whatever the website says, I personally like for it to be printed, made an exhibit, and then I can say, This is what the website said on this day, and it's part of the court record, and nobody has to guess about whether it's been changed or, you know, all that kind of stuff.

So I don't know if there is anything else other than the one that's been mentioned in -- I think you said Footnote 3 of your reply brief. But if there is any other website-type information that's referenced in the briefs that you all want me to take into account, I like -- you don't have to print thousands of pages, but I kind of need enough to be able to look at it not on the Internet, which changes daily or can change daily. I know the FDA is likely -- unlikely to change their frequently-asked-questions answers daily, but still I kind of like that.

So does anybody -- I think I am comfortable at this

point converting it to cross-motions for summary judgment. And I would be happy to give you a few thousand words if you want to say anything else in writing, like, I don't know, 3,000 words -- that's about what a reply brief would be -- if anybody has anything else they want to say, which would also give you a mechanism to attach your web evidence. But you don't have to write 3,000 more words if you don't have anything else to say.

So do people want a chance to, you know, reflect -- you know, I mean, I don't really mind giving you a fairly small number of words to tell me anything else that I might need to think about, you know, a clearer chronology or -- I don't know. Nobody is saying anything.

Okay. I will just be so generous and give you 3,000 words. You can file a supplemental brief in support of what I'm now considering to be cross-motions for summary judgment and evidence that's been -- I don't know that I need additional evidence that you all haven't already been talking about. But if there is some Internet evidence that you've been talking about, I'm fine with attaching -- I'm asking you to attach it because I think that makes a better record for me.

MS. HAWLEY: When would you like this, Your Honor?

THE COURT: I'm sorry. They have given me a new calendar that apparently you need a microscope to read.

How about February 5th? Is that all right? I'm unlikely to get anything decided by then. That's about three

weeks.

MS. HAWLEY: Your Honor, the transcript will be available before then; correct?

THE COURT: I don't know. You have to order it and pay for it. She wouldn't prepare it unless I ask for it, which I have a pretty good memory. But if you all want it, go ahead. And if she needs more time than that and you need another week -- I mean, I have a lot of other stuff to do. I'm going to give it attention. I know the motion has been pending for a bit.

I'm also going to think about what the Supreme Court is up to and think about that a little further, too. I'm not in the business of advisory opinions, so we'll see.

So I will authorize supplement briefs in support -- I am converting the motion to cross-motions for summary judgment, authorizing supplemental briefs by each of the three groups here up to 3,000 words, and allow you to attach to that physical copies of any Internet sites that were referenced in the earlier briefs.

Anything else for the Plaintiff today?

MR. MEZZINA: Sorry, Your Honor.

No, nothing else for the Plaintiff.

THE COURT: Okay. For the Defendant?

MS. BOYCE: No.

THE COURT: For the Intervenors?

MS. HAWLEY: No, Your Honor.

THE COURT: Thank you all very much. This was very helpful. I appreciate y'all's thorough and educated responses.

I have something else at 2:00, but you all are excused.

(END OF PROCEEDINGS AT 12:21 P.M.)

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UNITED STATES DISTRICT COURT

MIDDLE DISTRICT OF NORTH CAROLINA

CERTIFICATE OF REPORTER

I, Briana L. Chesnut, Official United States Court Reporter, certify that the foregoing transcript is a true and correct transcript of the proceedings in the above-entitled matter prepared to the best of my ability.

Dated this 25th day of January 2024.

Briana L. Chesnut

Briana L. Chesnut, RPR
Official United States Court Reporter