IN THE UNITED STATES DISTRICT COURT FOR THE

SOUTHERN DISTRICT OF WEST VIRGINIA, HUNTINGTON DIVISION

BEFORE THE HONORABLE ROBERT C. CHAMBERS, JUDGE

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GENBIOPRO, INC.,
Plaintiff,
vs. No. 3:23-cv-00058

MARK A. SORSAIA, in his official capacity as Prosecuting Attorney of Putnam County, and PATRICK MORRISEY, in his official capacity as Attorney General of West Virginia,
Defendants.
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REPORTER'S TRANSCRIPT OF PROCEEDINGS

MOTION HEARING

TUESDAY, MAY 23, 2023, 1:30 P.M.

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HUNTINGTON, WEST VIRGINIA

TUESDAY, MAY 23, 2023, 1:23 P.M.

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THE COURT: Good afternoon.

MR. MAJESTRO: Good afternoon, Your Honor.

MR. FREDERICK: Good afternoon, Your Honor.

THE COURT: All right. We're here today for the Court to hear arguments on the remaining issues and motion to dismiss. So who is going to be presenting on the defense side?

MS. HAWLEY: Your Honor, Erin Hawley for West Virginia.

THE COURT: All right. Are you ready?

MS. HAWLEY: Yes, ma'am -- or yes, sir.

THE COURT: All right. Go ahead.

MS. HAWLEY: Sorry.

May it please the Court. Erin Hawley for defendant West Virginia.

GenBioPro makes the counterintuitive argument that the FDA's imposition of additional safeguards on especially dangerous drugs means that states cannot also help regulate the safety of those drugs, even though the Supreme Court has called this an area of historical and especially local concern. This means that the graver the risk from a drug, drugs like opioids and chemical abortion, the less states can

do to protect their citizens.

GenBioPro's three preemption claims fail. First each of them fails to overcome the presumption against preemption. Congress does cavalierly preempt state law particularly where, as we discussed, states have traditionally regulated.

As for field preemption, Your Honor, under Fourth Circuit precedent, field preemption is not available, whereas here there is an express preemption clause -- or, excuse me -- an express savings clause.

I'm sorry, Your Honor.

In addition, Your Honor, field preemption is impossible in this case to rebut because it cannot rebut the presumption against preemption as the Supreme Court found in *Wyeth*. In that case, also involving the FDCA, also involving regulation of the pharmaceutical market, the Court noted that this is precisely an area of historic state concern, and, therefore, field preemption was impossible. In fact, *Wyeth* is a case didn't even argue for field preemption.

With respect to conflict preemption, there are two sorts of preemption that GenBioPro alleges. First, GenBioPro speaks about impossibility preemption. But impossibility preemption, Your Honor, applies when it is literally impossible, not possibly impossible, but literally impossible to comply with both federal and state law. This applies in a situation like *PLIVA* or like *Bartlett*, where it was impossible

for the drug manufacturer to comply with FDA's label while having a contrary state label. The requirements did not overlap; they contradicted. It was physically impossible for the drug manufacturers to do that.

That is not the case here. I'm aware of no case, and I don't believe plaintiffs cite one, Your Honor, where a court has found impossibility preemption in a situation like this, where the different regulations, the different statutes act on different entities.

THE COURT: Act on different --

MS. HAWLEY: Different entities.

So the FDA here, of course, regulates drug manufacturers, the drug sponsors. In contrast, West Virginia is regulating abortion, and it acts on abortion providers, so completely different entities. I think there is no logical way to say that it is impossible for GenBioPro to comply with both federal and state law.

So that leaves us, Your Honor, with the third bucket of preemption, and that's the sort of purpose preemption or the idea that West Virginia's laws here frustrate the purpose of Congress in the FDCA. Again, we have that clear presumption against preemption. In fact, it applies with special force in this area. As the Supreme Court has noted, even Justice Stevens acknowledged that when you're looking at this sort of preemption, we want to be careful to tailor our

preemption analysis to the text of the statutes rather than to do a deep dive into purpose.

Here, we don't have to dive very far for purpose at all. The FDCA plainly says that its purpose is to protect the safety of consumers as well as to make sure that drugs are efficacious. So --

THE COURT: Well, but in the additional act, the agency was charged with addressing accessibility, too, which admittedly is different from the FDA review undertaken before.

MS. HAWLEY: I think that's a great point, Your Honor, and GenBioPro's brief points out that it is relying exclusively, as you suggest, on the 2007 amendments, the REMS statute which is codified at Section 355-1. But when you look closely at that statute, Your Honor, the very title is 355-1(f), and it says that the REMS provision is allowed to assure safe access, which GenBioPro focuses on, but it leaves off the second part of that title, which is the drugs that would not otherwise be available.

So I think when you look at Section 355-1, what you see is that this provision, too, is all about approval. The FDA is approving drugs that are especially dangerous. The FDA cannot use this section unless it finds that these drugs have severe and known consequences, severe adverse events like hospitalization and death, so we're talking about a narrow category of drugs that are particularly dangerous. And in

that narrow category, the FDCA -- these amendments instruct the FDA to look at patient access, but only in terms of its own regulations on that access.

So if you look at Section 355-1(f)(2), it says assuring access and minimizing burden. That's something that GenBioPro highlights, but then it goes on "such elements to assure safe use under paragraph (1)," so referring back to those REMS provisions. So I think it's clear from the structure, as well as the text of 355-1, what Congress did in those amendments is to say, when you have these really dangerous drugs, we're going to put additional restrictions on them. We realize some people might need them, so, FDA, don't go overboard, don't put restrictions on that aren't necessary. We still want people to get them. But it in no way suggested that complimentary state regulations would be preempted. That would be contrary to the entire history of the FDCA.

As my esteemed colleague on the other side argued successfully in the *Wyeth v. Levine* case, the FDCA has long set a federal floor. It has never been interpreted to set a federal ceiling. The Supreme Court in *Wyeth* called that sort of an astounding idea, that the FDCA might do that. And especially coupled with the presumption against preemption, I don't think you can get that access purpose out of Section 355.

THE COURT: Isn't it significant that at the time

Congress passed this act, that abortion was a constitutionally protected right, and so in every state there was already the availability of abortion? And isn't the clearing accessibility as one of three things that the agency has to look at, doesn't that give it significance for the discussion we're having today?

MS. HAWLEY: I don't think so, Your Honor, especially when we look at the congressional history here.

The 2007 amendments were a reaction to the Vioxx controversy. The Vioxx controversy involved a very popular drug that turned out to be quite dangerous. It increased risk of stroke and heart disease, essentially about doubled it. So Congress -- the public was upset about this. In the 2007 amendments, Congress strengthened the FDA's authority make sure drugs are safe.

But that statute, Your Honor, was passed, signed by the first President Bush. It passed the House overwhelmingly, 400 and some to a handful, and it passed the Senate by unanimous consent. I don't think you can read from that a congressional direction that abortion should be available everywhere.

THE COURT: Okay. So in *Wyeth*, we know that the Court focused on the fact that, at common law, there were remedies for defective products, and the Court found that that was not preempted by the terms of the FDA. And all that focus was on

labeling, and it seems to me the cases that have come up since generally have been cases involving labeling more than anything else.

So does the State claim that its abortion ban here is based upon its determination that this is not a safe drug?

MS. HAWLEY: No, Your Honor.

The State here is not taking issue -- it's the subject of other litigation --

THE COURT: Okay. So it does seem to me, then, there's a pretty good argument that with regard to safety and efficacy, the FDA decision is preempted; that that is what the agency is charged with doing. There's a long history of this agency being responsible for making determinations about pharmaceuticals, what's approved, what's not approved, I mean, for a hundred years, I guess more now.

So at least are those things not preempted?

MS. HAWLEY: So I think that's correct, Your Honor, but how the Supreme Court in *Wyeth* and in *PLIVA* and *Bartlett* as well, found this to operate is that the FDCA has always operated with complimentary state regulation.

Since it was passed in 1906, Congress has worked to ensure state regulation and even state tort laws --

THE COURT: Well, I think I agree with that. And it seemed to me in *Wyeth*, the Court in particular reviewed the FDA requirements for when you can change labels and so

forth --

MS. HAWLEY: Yes.

THE COURT: -- and found because there is a mechanism --

MS. HAWLEY: Yes.

THE COURT: -- within the statute itself to allow for a label change as the drug is used and more information is gathered and so forth.

So here there is no claim by the State that this drug is not as safe or not as effective as the FDA determined. Why is it not then in conflict with the FDA's determination that this is a drug that ought to be accessible throughout the healthcare industry in the country?

MS. HAWLEY: So I think a couple of things there, Your Honor.

So I don't think it -- again, if we focus on Section 355-1, I don't think that gets us to an access mandate. I think when we're talking about Section 355, what Congress is saying is that these are dangerous drugs. They're like Vioxx, they're like opioids, and we want them to have additional restrictions.

THE COURT: And that's what the FDA was charged with determining.

MS. HAWLEY: Yes, Your Honor.

THE COURT: So you keep coming back to that as though

the State is somehow complimenting, adding to the FDA's decision about what is safe or effective, but that's not the purpose of this statutory bar on using the drug.

MS. HAWLEY: So I think that actually helps the State here, Your Honor.

If you look at -- and, again, we're talking about the bucket here of purpose preemption cases, and so there's --

THE COURT: I'm sorry. Of what?

MS. HAWLEY: Of purpose preemption, where it frustrates the purpose.

THE COURT: Right.

MS. HAWLEY: And so there's a series of three cases from the Supreme Court that I think really illustrate why what West Virginia had done here is not preempted.

The first one of those is *Virginia Uranium* mining. In that case, Congress had, of course, regulated extensively in the field of mining; it had regulated for health and safety. And what Virginia was allowed to do is say we're not going to allow mining. We realize that the federal regulations speak to what is permissible with milling, what is permissible with tailing, but the Supreme Court said Virginia was operating in a different purpose, Your Honor, and so the different purpose is key here.

It's important to note that West Virginia does have a different purpose. It's not disagreeing with safety and

efficacy. It's saying instead West Virginia citizens have determined that life is worthy of protection no matter how small.

If you look at the *Harris* case, this is the meat packing case, and what the Supreme Court said in that case was, California, you can't interfere with slaughter standards, you can't say stuff about non-ambulatory pigs, but what you can do is you can disallow horses from being slaughtered entirely.

Similarly in a case called *PG&E*, this involved nuclear regulation, nuclear safety, again an area in which Congress is heavily invested, a heavily regulated area. And the Supreme Court in *PG&E* said Congress could institute a moratorium on building. Even though Congress heavily regulated the design and safety, California could say, no, we're not going to build because that determination was an economic one.

Similarly here, West Virginia's determination is one about unborn life, about maternal health. It's different than FDA safety and efficacy. And for that reason, Your Honor, I think that this case fits squarely within that line of cases that say when a state regulates for a different purpose, it is entitled to do so, and it would be an affront to state sovereignty to read congressional -- the FDCA or the 2007 amendments to take away those validly enacted state laws.

So, Your Honor, to talk -- we've talked about field

preemption. We've talked about how express savings clauses, as we find in the FDCA, are incompatible with field. We've talked about --

THE REPORTER: I'm sorry, incompatible with field?

MS. HAWLEY: Field preemption, yes, ma'am. I will speak more slowly.

So we've got the conflict impossibility preemption. We just talked about purpose preemption.

And to look again at the text of Section 355-1, what that text says is that such elements, the elements for the REMS under paragraph (1) are not to be unduly burdensome. So, again, we're talking about what FDA can do, not about what states can do under their complimentary authority.

In fact, in *Wyeth*, the Supreme Court said that to find that the FDCA was both a ceiling and floor would be an untenable interpretation of congressional intent and an overbroad view of agency power to preempt.

Again, we talked about the different purposes here, and how the West Virginia law being aimed at unborn life is something that is completely different from the FDA's prerogative, as Your Honor noted, in determining whether something is safe and effective. I would note, Your Honor, that that also distinguishes the *Zogenix* case from the District of Massachusetts. In that case, Massachusetts had determined that a particular opioid was unsafe. It had

directly disagreed with the FDA's safety determination.

Here, West Virginia is doing something completely different. What West Virginia is doing is saying we think -- that we want to protect unborn life and maternal health in this way. We're not disagreeing that mifepristone does what it says, we're not disagreeing in this lawsuit about its safety, but we're still entitled to protect life under the State's health and safety authority.

In addition, Your Honor, I think the presumption against preemption is particularly powerful here. My friends on the other side try to say that the presumption against preemption doesn't apply because this is an area of pharmaceuticals in which the federal government has long regulated. That is for sure true, the federal government has long regulated in the pharmaceutical field, but, again, *Wyeth* firmly forecloses GenBioPro's argument.

At footnote 3, *Wyeth* says rejecting an argument -- it rejects the argument that the presence of federal regulation means that there is not an inherent state authority to regulate for health and safety. It says that that misunderstands the argument. It says that the presumption against preemption is built upon the idea that Congress respects states in our federal system, and as a result -- and this is a quote -- the presumption "does not rely on the absence of federal regulation."

So *Wyeth* clearly said in this precise context that the presumption against preemption applies because states have historically regulated on health and safety matters. Indeed, there's nothing really more local than health and safety matters like the West Virginia statute at issue here.

With respect to the Commerce Clause claim, Your Honor, when we look at that claim, GenBioPro has conceded under the *Pork Producers* case their extraterritorial argument doesn't -- doesn't work. So that's putting to one side. GenBioPro also argues that the West Virginia laws here are an abortion ban. That's incorrect factually and also irrelevant legally.

As a factual matter, Your Honor, as we discussed, the purpose here is not to ban mifepristone. The statute that passed the West Virginia Legislature says nothing about mifepristone or about any other drug at all. What it does is it says that, in West Virginia, subject to certain exceptions like emergency situations, incest, rape, those sorts of things, that providers are not allowed to perform abortions and take the unborn life of a child. So it does not operate at all in the -- on mifepristone, is not an abortion -- or, excuse me -- is not a ban on mifepristone. Instead, it regulates abortion --

THE COURT: Well, the plaintiff characterizes it as a functional ban because the restrictions so great. I mean, I think you noted them, there are very limited exceptions of the

West Virginia Act. So is that not a functional ban?

MS. HAWLEY: So I think two things, Your Honor. A, it has nothing to do with mifepristone any more than it has to do with scalpels or masks or other things that might be used in an abortion. What West Virginia law is concerned about is with preventing the primary conduct of abortion, not with any particular drug. So I think it's incorrect to call this a ban on mifepristone. That is just not accurate.

Your Honor's correct that there are limited exceptions, but the availability of limited exceptions does mean that this is not a ban even on all abortions.

THE COURT: I think you all argued in your briefing that there was still the possible use of mifepristone in West Virginia as an off-label use, but it strikes me that that's really kind of immaterial to all of this.

The preemption argument is premised upon what the FDA has said is an allowable use and circumstances for its use consistent with the label essentially, and so it doesn't seem to me being able to use it off-label somehow alleviates what would otherwise be -- perhaps as they've argued, stand as an obstacle to the federal accessibility decision.

MS. HAWLEY: So I think, Your Honor, that that actually highlights why the purposes are different here. The fact that the West Virginia law does have exceptions -- it has exceptions for saving the life of the mother, for medical

emergencies, for fetal abnormalities that are quite severe, for rape and for incest. And in all of those situations, West Virginia allows mifepristone to be used if it's medically appropriate. So I think these exceptions show affirmatively that West Virginia is not questioning the safety or efficacy.

THE COURT: You know, as a sort of -- this is almost like a footnote to our discussion, but as my law clerks and I have gone through this, we know that West Virginia passed an earlier act. It is in essence suspended pending --

MS. HAWLEY: Yes, Your Honor.

THE COURT: -- determinations as to whether or not this act is constitutional. And if this act is deemed to be unconstitutional, then these prior provisions go in.

But as we've looked at it, it seems to us that the restriction on telemedicine, using telemedicine for this purpose, for this type of prescription, it is not sidelined by the current statute and that it might still be in effect.

Is that your understanding? Or have you thought about this aspect of it? Am I being clear about what I'm trying to say?

MS. HAWLEY: Yes, Your Honor.

I think that's correct in the instances in which the exception would apply. I think there would still be the requirement under West Virginia law for an in-person visit, and this, again, highlights how West Virginia law aids and

comes alongside federal law.

Without an in-person visit, a physician is not able to diagnose ectopic pregnancy, which could cost a woman her life, is not able to diagnose gestational age, and these sorts of in-person visits were once required by the FDA. Under the FDCA structure, they've clearly allowed states to supplement or compliment these. So I think this is an example of how West Virginia's laws, not UCPA, but the other laws are complimenting FDA's purpose, ultimate purpose in making sure that consumers are safe.

THE COURT: But it does seem that upholding the telemedicine restriction would pose an obstacle to the federal determination by the FDA that a telemedicine visit is sufficient to allow for this -- for a prescription.

MS. HAWLEY: I don't think so, Your Honor.

If you look back through the history of FDCA litigation, there are countless examples, like with the practice of law, where courts have allowed -- they found that the province, the regulation of medicine is something that is especially -- delegated especially to the province of state legislatures.

So, for example, even during the *Roe* regime, we had all sorts of things like informed consent, we had waiting periods, we had those sorts of restrictions on abortion even when there was a fundamental right to it under Supreme Court

law. The states were allowed to do that because it complimented FDA's safety and efficacy guidelines. It's not contrary to it, but built upon it.

Again, this goes back to the federal floor or the federal ceiling, and the Supreme Court was really clear in *Wyeth* that the FDCA sets a federal floor.

And I think as hard as you try, especially when coupled with the presumption against preemption, you just cannot get a right to access out of Section 355-1.

And to think just a bit about what that might mean in this and future cases, if REMS provisions mean that there's a right of access, that presumably would mean that GenBioPro must sell its drugs in every state. There's not a lot of evidence that it sold it here at all.

THE COURT: I don't know why it means that. It seems to me that one could easily say that's a matter for the private marketplace to determine. What the preemption would do is say states can't prohibit, which is pretty different than saying that preemption compels a producer to be in a market.

I agree, I don't think any court has ever said that. What we're talking about, though, is whether the state can prevent entry into the market.

MS. HAWLEY: But the core right of access, I think, is the same thing. As various commentators, even proabortion

commentators have noted, that when -- or at least to have access at a reasonable price, you know, the FDA has never said that these particular drugs need to be available at a price that most women can afford. But yet that would be directly tied to access as well, I believe, Your Honor.

In addition, if we think about Section 355-1, and if we're going to carve out from that provision a right of access that's unique to REMS, as my colleagues on the other side say, they tried to say it's state tort law, and that makes sense in this case because their client GenBioPro only has one drug, it only manufactures mifepristone. However, Your Honor, I don't think it's possible to say there is both a right to access and state tort law still exists.

Wyeth is clear -- I understand why the other side does this. *Wyeth* is clear that Congress viewed state tort law as a compliment. Otherwise there is absolutely no remedy for individuals who are harmed by these admittedly dangerous drugs.

But I don't think you can have your cake and eat it, too. I don't think you could say, states, you can't regulate notwithstanding the presumption of preemption, but we're also going to allow state tort law because we need some remedy when women or others are grievously injured. And the other side, I'm not sure how they can say that one exists and not the other, Your Honor.

THE COURT: All right.

MS. HAWLEY: So to come back to the Commerce Clause, there is no extraterritoriality after *Pork Producers*.

GenBioPro also talks, Your Honor, about a ban. As we've talked about it, I don't think it's a ban on mifepristone at least. Even if it's a functional ban on abortion, again we have serious exceptions in the statute, but it is not a ban on mifepristone.

In addition, as I mentioned before, I think even that fact, if it were true, would be legally irrelevant. Justice Gorsuch's opinion notes that all sorts of things are banned. Fireworks are banned. Shark fins are banned. Horse meat, as we've already talked about, is banned. And the fact that it is unavailable in a particular state does not trigger the dormant Commerce Clause.

As I believe Justice Roberts pointed out, if that were the case, that would mean that if something were available in one state, it would have to be available in every other state, which is an untenable interpretation of the dormant Commerce Clause. So there is not a per se rule against bans, so that doesn't work either.

So we're left with Pike balancing. My friends on the other side note that Justice Roberts' opinion controls. I'm not sure that that is correct. But, at a minimum, what we can get from *Pork Producers* is that five justices clearly found

that the allegations in that case did not rise to the level of a dormant Commerce Clause violation.

That is a case in which California went out of its way to change the way pork producers in every pork-producing state produced hogs intentionally. Chief Justice Roberts notes that this would have imposed $368 million worth of compliance costs on pork producers. Contrast it to this case, Your Honor, where we have no allegations of interstate effects, no allegations of interstate economic effects at all. If *Pork Producers* failed the dormant Commerce Clause, Pike balancing, so too does this case.

And just to respond to a couple of things my friends on the other side note, they talk about derivative harms to women in West Virginia. In the *Pork Producers* case, the Court notes that no one thinks that harms from in-state -- derivative harms to in-state persons who voted for that particular provision are a dormant Commerce Clause harm. That is because they're intrastate, not interstate.

Chief Justice Roberts, who in my colleagues' opinion think is controlling, says that before you get to Pike balancing, you have to first find that there are economic interstate harms. These simply don't exist here. They're not even really alleged.

My friends point to paragraph 17, but that paragraph does not point to interstate economic harms, Your Honor. So,

here, we don't even get to balancing the economic harm of GenBioPro to these other derivative harms. As the Chief Justice said, when we're talking about the dormant Commerce Clause, we're talking about interstate, and we're talking about economic, neither of which are present here.

Is there anything else I can do to convince you, Your Honor, that --

THE COURT: Well, your argument is well. Do you want to address the major questions claim as well? Or if there is more you want to say on the Commerce Clause, go ahead. I don't like to interrupt lawyers when they're giving their presentation.

MS. HAWLEY: No. No, absolutely, Your Honor.

So with respect to the major questions doctrine, I really think it comes into play particularly when we're talking about that third preemption bucket, that purpose preemption bucket. And if the FDCA, the 2007 amendments are interpreted as you said -- and they were passed when *Roe* was the law of the land, when abortion was legal. If they're interpreted to require nationwide abortion access up until 10 weeks gestational age, there is no question that that is a significant, moral, economic, political question.

There is hardly any --

THE COURT: I don't doubt the significance or the importance of the question, but when you compare it to the

tobacco case and the other cases, the *EPA* case in West Virginia, it strikes me it's really not even in the same ballpark.

In those cases, you had major regulatory programs built upon long-standing statutes that had not been applied or interpreted that way or comprehensive regulation of some important topic. And while this is an important topic, all the plaintiffs are arguing here is not that there is a minimum -- or not that there are limits on abortion laws generally but, rather, with respect to an abortion law that conflicts with the federal approval of mifepristone, those state laws have to yield.

And that's really different, it seems to me, than some comprehensive regulation of abortion as a result of FDA decisions. It looks to me like there is really no comparison between the scope of the regulatory action undertaken in those major question cases versus here where it's important, but pretty narrow, even in the context of the abortion debate.

MS. HAWLEY: But it's not narrow in its effect, Your Honor. To think about -- you know, we're talking about bans and not bans. The functional effect of FDA's decision here, if interpreted the way GenBioPro does, is to require nationwide abortion access up until 10 weeks of age.

As the states' amicus brief points out, the FDA, of course, also regulates scalpels and other sorts of medical

equipment that is involved in abortion. But in order for the FDA to have that sort of authority, A, Congress would have to give it to them, and, B, Congress would have to have it.

Do we think Congress has the ability to pass a nationwide abortion law requiring access in each and every state up until 10 weeks of gestational age? I think that's a really difficult question, Your Honor.

THE COURT: Well, I guess I'm troubled by characterizing this as being, you know, some sort of congressional act broadly requiring abortion to be available. It is always -- in this case, it is limited to the approved drug that has gone through this process. And I guess it strikes me as kind of ironic that you're arguing that interpreting the FDA statute as guaranteeing access up to 10 weeks through the use of this drug for termination across the board, that that is the functional equivalent of legalizing abortion everywhere. Well, I don't think it is.

But it seems to me it's kind of ironic that you're claiming that -- you object to their characterization of the mifepristone limitation as the functionally equivalent --

MS. HAWLEY: Your Honor, I was playing on that, that framework. That's -- yes, Your Honor. So I think here a couple of things.

First, even if you think the major questions doctrine doesn't apply here, I think *Wyeth* is clear that the

presumption against preemption does, and that still requires a clear statement.

I don't think that when you look at Section 355-1, we get a clear statement that Congress meant access, particularly when that means -- and I don't think there is -- if GenBioPro is correct, Your Honor, that means that every state's law that prohibits abortion before 10 weeks must fall. That's what preemption does. So, again, we can quibble and laugh about the semantics, but that means abortion will be legal up until 10 weeks in every single state.

I think we have to ask whether Congress has the power to do that. Under *City of Burney* I think that's a very open question. Then we have to ask did Congress give that authority to the FDA? If we're talking about the authority to mandate nationwide abortion access, then we are very much in the major -- or, excuse me -- the nondelegation doctrine question.

If Congress is giving an agency the authority to determine life and death, it has done so in the 2007 amendments without any guidance, Your Honor. There is no indication that the FDCA is allowed to even consider the unborn life or the other moral implications that even *Casey* acknowledged exist from the very earliest stages of pregnancy.

So I think, you know, A, does Congress have this power? Probably not. Did it delegate it to the FDA?

Probably not. And if it did, then we have a nondelegation problem because, even under *Gundy*, there's simply nothing approaching an intelligible principle.

Even putting all of that aside, Your Honor, we come back to the presumption against preemption, and it would require a clear statement in order to find that Congress meant the 2007 amendments to require access, you know, broad access to opioids, broad access to chemical abortion drugs, even though that means nationwide abortion, and I don't think when you look at Section 355 and you look at that test, and when it says such elements under section (1), I don't think it's talking about complimentary state regulations.

THE COURT: All right. Thank you.

MS. HAWLEY: Thank you, Your Honor.

THE COURT: All right. For plaintiff?

MR. FREDERICK: Thank you, Your Honor. May it please the Court. David Frederick for plaintiff GenBioPro.

Congressional intent is the touchstone of preemption under the Supremacy Clause. The Supreme Court has said that over and over, we do not decide cases on the basis of presumptions. We look at the words Congress enacted, and we determine whether or not what states are seeking to do conflicts with the words that Congress enacted.

Here, the defendants hardly say anything about the 2007 act that is at issue here, 355-1. They cite it once for

a passing reference in their reply brief. They hardly address the statutory construction arguments we have advanced at all. And today counsel offers a very interesting theory that, when you boil it down, doesn't add up. Because the theory that the State advances now is that notwithstanding that Congress knew mifepristone was one of 16 drugs that had been approved by the FDA under Subpart H when it enacted the 2007 act, and notwithstanding that Congress then told FDA for those drugs, go back to the sponsors, the makers of the drug and get updated risk management strategies for them, and the FDA did that.

Now, when Congress is giving specific directions to the FDA under a very comprehensive statute, it is really incumbent upon courts to evaluate what are the words that Congress enacted, and what are the implications. And what we're getting today is essentially an argument that you have to rely on a presumption against preemption in order to save a state statute that runs directly counter to Congress's words.

The words in the statute ensuring access most assuredly do not allow the State to not ensure access, and that's what the functional abortion ban does here. Counsel argues, well, there are these little exceptions here and there. But the point of the FDA's approval of mifepristone was to engage in the early termination of pregnancy by those patients who sought to do that.

THE COURT: If I look to the statute to discern what legislative intent was at the time, what's the significance of the fact that, at the time, there was a constitutional right to abortion that Congress could not control? It was not the author, it was a constitutional right. And so at the time this act passed, there was a right in every state to an abortion. And accessibility in that context doesn't mean guaranteeing that that right persists if the Court later determines that there is no such right, which is what's happened.

MR. FREDERICK: I think that the key language in the decision in the *Dobbs* decision, Your Honor, is returning the question of abortion to their elected representatives. The elected representatives here was Congress. When Congress enacted the REMS program in the 2007 act, it did so knowing that mifepristone affected the abortion right.

THE COURT: I understand that. I think what concerns me greatly about that statement is that we know at the time Congress understood the current law to guarantee a right to abortion in every state. So it's hard to read into that 2007 act an intent by Congress, in adding accessibility language to the statute, to be in effect legislatively guaranteeing that right that was determined by the Court to be a constitutional right.

MR. FREDERICK: And I think if you go back to first

principles, Your Honor, when the Court decided *Roe*, there was no medication abortion. There have been obvious technological developments in the provision of medication since *Roe versus Wade* was decided. But the core question for you is, when Congress made its enactment, and it had a clear intent and effect on mifepristone, is that to be accorded the kind of respect under the Supremacy Clause that is required where a state law has a conflict, imposes a conflict with a provision of a federal statute entrusting a federal agency with making the access and safety determinations necessary for the provision of that medication?

And that, to me, is a fairly straightforward question that has not really been joined by the other side in this case. Because if you look at all the different things that Congress told the FDA to do, to come up with rules for mitigating strategies, and if in a certain limited class there needed to be additional elements for safe use, to enact those as well, there are a very small number of drugs for which that is true. Mifepristone happens to be one of them.

Now, my colleague argues that somehow because there are additional elements, that that somehow adds to the availability of the states to jump in and offer additional restrictions. To the contrary, I think it argues the opposite.

Because if you look through 355-1 where it has

monitoring, evaluation, periodic updating, there is no indication in the statute that Congress intended for 50 states to come up with their own rules regarding FDA-approved medications and force the FDA to somehow keep track of them.

My friend says there's no effect on the system, but in the very first paragraph of 355-1, there is the admonition by Congress to ensure access without undue burdens to the system. The system here is the healthcare delivery system.

And it has both preemption consequences and overlapping Commerce Clause consequences because medications made out of state is affecting interstate commerce. Health insurance is part of the system. It is generally driven by national carriers. Regional and national medical providers, part of the healthcare system. And so all of these elements are affected, and the question is whether the functional ban that is conceded today of this drug is interfering with that healthcare system.

We submitted and we alleged in the complaint, in paragraph 16 and 17 -- they've ignored 16 as alleging that the system is affected adversely by what the State is seeking to do here, and I would note that there is not really any limiting principle to their argument. So under their position, all 50 states can override an FDA expert judgment about the additional elements for safe use that would ensure access, and that would be okay under their scenario simply

because Congress didn't use the words "pregnancy termination" in the 2007 act. Well, Congress didn't use the words "polio" or "small pox" or "acne" in the 2007 act either. But under the logic of their position, if the states wanted to take extraordinary actions to address those conditions, it has the lawful authority under the Supremacy Clause to do so.

FDA rules have never operated in a situation where anybody can come in and countermand the expert judgment in that way. To be sure, there are labeling requirements, and my colleague spends a lot of time talking about *Wyeth versus Levine*, which I'm very happy to talk about, but I don't think that case is really on point here because we're not talking about a labeling challenge.

We're talking about a specialized set of rules under 355-1 that are intended to ensure access while not burdening -- creating such burdensome safety rules that that avoids access that Congress thought was important for this particular class of drugs.

THE COURT: As I recall, I think it was a year or two after this act, that Congress passed the medical device act, and they had explicit, express preemption language. Is that not of some significance here where you're saying that they intended this comprehensive REMS process for deciding safety, efficacy, and availability basically?

MR. FREDERICK: If I could offer this correction to

the chronology suggested by the Court.

The medical device amendments was enacted in the 1970s, and there was an express preemption provision as to certain aspects of the approval of the device. It didn't cover all devices. It depended on when they were in the various stream and whether or not devices that had been grandfathered in also would be subject to the express preemption provision.

And that's why in *Medtronic versus Lohr* -- I don't think that's a case cited by any of the parties, but there the Court did not find preemption regarding a certain class of drugs. Now it is true in *Riegel versus Medtronic*, and that's another case that I don't think has been cited here, the Court did find the application of express preemption to nullify the state lawsuit.

But I think this -- your question, Your Honor, points exactly to the right problem, which is, what are the words of Congress, and how do they apply in light of what a state is seeking to do? And our point here is that you cannot have ensuring access and not creating an undue burden on the healthcare system and a state's functional ban that today counsel has functionally conceded that's exactly what the State seeks to do. And those are not compatible, and that is why the preemption clause and the preemption provisions of the Constitution under the Supremacy Clause, we submit, governs

here.

THE COURT: Well, just while we're on the subject, just so I can keep things clear as I sit down and review all this to try to decide it, do you still maintain that field preemption applies?

MR. FREDERICK: Yes.

THE COURT: Tell me briefly how you get there.

MR. FREDERICK: Yes, let me explain the field preemption argument. And first let me help by explaining how the system is designed to work.

So there are a certain class of drugs that have these risk mitigation strategies, REMS. Only for a particular subset of those REMS-approved drugs are there special elements to assure safe use.

So you start with 20,000 drugs --

THE COURT: Uh-huh.

MR. FREDERICK: -- okay, that have been approved by the FDA and are on the market, a certain subclass have what are called REMS, and it is only within that subset of the REMS-approved drugs where the FDA has enacted these elements to assure safe use. They're sometimes called ETASU in the briefs, but that's what these are.

At the time of the enactment of the 2007 act, there were only 16 that had these elements to assure safe use. Mifepristone was one of them.

Now, if you track through the language of 355-1, what it says is that if the Secretary, here the FDA, determines that a REMS drug needs to have these elements to assure safe use, the Secretary shall impose these additional rules.

Why is that important? We cite the *Locke* case in our brief, and in the *Locke* case the Secretary of Transportation was charged under certain ports and waterways acts to deal with regulations concerning oil tankers. For some of them, Congress said it's permissive regulatory authority, the Secretary may issue certain regulations. As to those, the Supreme Court held, if the Secretary issues those rules and the State conflicts with them, conflict preemption applies.

But there was Title II of the port and waterways act, and in that title what Congress had said was that the Secretary shall issue regulations concerning certain topics, and they had to do with equipment design features of oil tankers and the like. And the rationale the Court explained was that when Congress mandates that the federal agency deal with certain specific rules, there is not room for states to come in and offer contrary rules. The field is preempted because Congress entrusted that particular field to the federal agency.

Our field preemption argument, Your Honor, is relatively modest. At present, there are only about 58 drugs that have both the REMS and these special elements to assure

safe use. And as to that specific category, what Congress said was that FDA shall do a whole range of balancing and determine whether or not its rules would provide safe access and not create undue burdens for the system.

So our argument on field preemption flows directly out of the words of the statute, Congress's intent to mandate that the FDA, with this very small category of drugs, have very specialized rules that were designed to balance access with safety. Now, why is that important? Because every year Congress provided in 355-1, FDA is supposed to update its rules.

Now, field preemption operates by saying states should not have a role in that field because it's too important to entrust for national uniformity purposes. It would be impossible for the FDA to update its rules periodically given how fast states are enacting various issues and laws with respect to various topics concerning the termination of pregnancy. And so it's logical to suppose that Congress intended for that field to be completely entrusted to the FDA in that very narrow category where there is both a REMS drug and drugs that are needed to assure safe use.

So our field preemption argument, Your Honor, is very narrow, it's highly specialized, but I think it applies when you track through the monitoring, the evaluation, the periodic updating, and all of the different things that Congress

required the FDA to do with respect to those elements to assure safe use.

If, however, you were not to agree with me about that field preemption theory, our conflict preemption theory I think is rock solid, and it is completely impossible to imagine Congress's words saying ensure access to this medication and a state saying not ensure access to the medication, and that's what is conceded today to be what the State is seeking to do.

THE COURT: I know we've bandied these terms about, functional bans and so forth, but it is a fact that even under the West Virginia statute, mifepristone can be sold and used in West Virginia for its intended purpose.

MR. FREDERICK: Well, only under highly specialized circumstances that go well beyond restrictions that are imposed by the FDA.

THE COURT: Well --

MR. FREDERICK: And so it is impossible to comply with the permissive regime authorized by the FDA for the safe use of the drug and those circumstances where they allege that mifepristone would be available to deal with certain exceptions under the state statute.

THE COURT: Yeah, honestly I have some difficulty agreeing that that's an impossibility factor. You're able to sell it to a point, just not as much as you would like or as

much as the label would allow, and that that constitutes impossibility.

And I admit, these are cases that I haven't finished reviewing and thinking about, but I don't know that I've seen a case where it seems to me there is a similar sort of foundation.

MR. FREDERICK: Let's take the average person who does not have a medical emergency or otherwise fit within the exception. Under federal law, that woman is able to take mifepristone under the FDA rules.

Under the State of Virginia's rules --

THE COURT: West Virginia.

MR. FREDERICK: I'm sorry. West Virginia, excuse me. I'm thinking about Virginia mining, which I do want to talk about in a minute.

Under West Virginia's rules, that person is not able to take the drug in that circumstance. It is impossible for her to comply in both the West Virginia scheme and what permissions are afforded to her under federal law. That is preemption. That is the classic form of preemption. You can call it impossibility, you can call it inconsistency, you can call it irreconcilable conflict. There are many words that the Supreme Court has used to describe preemption principles over the years, but I think that the bottom line is the same.

THE COURT: Okay.

MR. FREDERICK: Now, with respect to obstacle preemption, which is the concept my colleague spends most of her time arguing, there is no question that when Congress is providing FDA authority to regulate these drugs under particularized systems and rules do not apply to 99.9 percent of all the drugs, that they're seeking to interfere and create an obstacle with that system.

And so under obstacle preemption cases, and *Geier* is one that is, I think, pretty directly on point -- that has not been discussed today, but there the question is if the federal agency provides for an option, it can't be for the state to come in and interfere with that selection of what option the federal government made available. That was a case involving airbags and seatbelts, so I appreciate that its subject matter is different.

The point I want to stress, though, is that whether you look at this problem under any of these three theories of preemption, the bulk of the situations in which the West Virginia ban applies run afoul of the federal permission to allow usage of mifepristone.

Now, *Virginia Mining* was mentioned. I want to point out just one fact, that in that case there was no federal rule concerning mining, uranium mining on private land, and so the argument for preemption would have meant that there was no law available by any sovereign to address uranium mining. And

what Virginia had sought to do was to say, because there is no federal law here, the State can take action with respect to uranium mining on private land, and a majority of the Court said that is not preempted, that is afar afield from what we're talking about here.

Similarly, my colleague invokes the *Harris* case. That involved actually a holding by the Supreme Court of preemption. The Court there held that the Federal Meat Inspection Act preempted California law regarding slaughterhouses, so I'm not sure how that helps the State here in this case.

And then with respect to the *PG&E* case, the Court held that there were state statutes regulating economic aspects --

THE COURT: I have a note, though, on the slaughterhouse case, that the Court ultimately did say, though, the State could ban horse meat, it just couldn't regulate it in a way inconsistent with the federal regulation.

MR. FREDERICK: Well, it was dicta, and that was not -- there was no ban at issue in that particular case. I'm not sure how far the dicta gets you in a situation like what we're talking about here, where the express words of the statute are to ensure access. I would submit that that just doesn't help the State here.

And then with respect to *PG&E*, the states here obviously retain their traditional authority over economic

electric utilities, but that doesn't go to the question we have here, which is that there is no state role for FDA-approved drugs in these particular circumstances.

To be sure, as all members of the public can offer comments when the FDA is reconsidering its rules and periodically updating them, but the State can't override the FDA's determination what is necessary for an element to assure a safe use.

On the major questions doctrine, Congress gave FDA authority to regulate access to these REMS drugs so that it can review the scientific and underlying aspects of the restrictions, and it endorsed with its approval when it did that in 2007. That's in Section 909 of the act itself, the statutes at large version of the act.

And so I think that it's important to say that, unlike the *West Virginia versus EPA* case -- what the EPA was seeking to do was to create a nationwide rule regarding electric power generation and its climate consequences. What the FDA did here was exactly what Congress told it to do, take these drugs that are subject to the REMS that you have approved under Subpart H, continue to refine those rules; if they need to be periodically updated, do that, and make those rules uniform and applicable nationally. And to be told otherwise would be really to create enormous chaos.

And it's not just in the drug industry and the

distribution of drugs, but it's in health insurance, retraining for providers, the effects on interstate commerce regarding when particular drugs are available and when they are not.

And the State just simply refuses to acknowledge that in 355-1 itself, Congress said to do these rules in a way that do not unduly burden the system, the healthcare system, and that's exactly what this functional ban is trying to do.

Now, flipping over to the Commerce Clause, let me address the Pike balancing because that is what we are seeking to do here.

There are interstate effects for the reasons that I've just outlined, and the court -- the cases properly understood it's an effort by the State that will have burdensome effects on interstate commerce, not just in drug delivery, not just pharmacies, but in all manner of education for providers, for healthcare delivery, for insurance provision, and all of these aspects of the healthcare system are interstate in their dimensions.

And if you were to accept the State's argument here, you would be opening up exactly the kind of problem that Chief Justice Roberts noted in his separate opinion in *National Pork*, which is to take what should be a national common market and fragment it so that states are each issuing their own rules in a way that would alter the balances that are intended

to be struck by having national arguments.

Now, ultimately the State's argument boils down to the idea that 355-1 applies to most everything except for pregnancy termination, and that means that there is actually no limiting principle to what the State is arguing. Because if you create judicially an exception to the words of 351 to apply -- 355-1 to apply to all the drugs that have been approved by the FDA subject to this limited subset, you're inviting states to say, well, we think small pox is different, we think vaccines are different, we think that acne is different, we think that polio is different.

These are all drugs on the list of 16 that, when Congress enacted the 2007 act, it expressly incorporated and deemed them to have in effect REMS subject to the FDA's considered judgment.

And I would submit that I'm not aware of any case -- and I've argued many cases involving preemption -- that has been decided solely on the basis of a presumption against preemption. And the reason why is because the whole concept behind the presumption is to try to understand what did Congress mean in particular circumstances, what was the scope of its intent and effect on state law. But here, where the other side doesn't even talk about the statute that Congress enacted with any kind of detail, you can't simply, I would submit respectfully, decide, well, the presumption applies and

so, therefore, the State can do what it wants notwithstanding the enactment that Congress made.

Let me address the telemedicine question that you posed. We do think --

THE COURT: Before you do, let me ask you another question about *National Pork*. And I admit I've struggled with trying to figure out -- I appreciate the thoughtfulness with which each side briefed the issues, as it does seem clear to me from reading Judge Gorsuch's opinion that the Court agreed that Pike should still be applied.

But I'm troubled that throughout that part of his decision, which was joined by the other judges, it's clearly part of the majority, that he often, I think three or four times, made reference to the fact that, in his view, the states still had the authority to enact laws and regulations that pertain to health and welfare, things like that -- and I'm sorry I don't have the language right in front of me.

But, as I read it, he said *Pike* is still good law, but it doesn't go as far as maybe some would argue -- have been arguing. But that in any event, even when we examine *Pike*, we have a setting where states are still traditionally able to set laws and regulations pertaining to healthcare.

MR. FREDERICK: Your Honor, I think that the proper way to understand Justice Gorsuch's opinion is in context where I think six justices disagreed with his way of limiting

Pike balancing. And so there is a certain quality of the Supreme Court's *National Pork* decision which you have to kind of create a chart and then figure out which justice fits into which bucket.

The way we've outlined it in our brief, our supplemental brief is to try to explain that Pike balancing can apply and has applied in situations where you're comparing straight economic considerations with considerations that, on their face, do not appear to be economic.

But where the Chief Justice's opinion is particularly helpful for our side, we believe, is in dealing with what are called derivative harms. And that's where if you were to take the idea of safety as an extant value that you wanted to promote through a state law, there actually is an economic consequence.

And as we pointed out in our supplemental brief, to force a woman to carry to term is 14 times higher mortality rate than to have a safe termination of pregnancy. There are economic consequences to the medical care system, to the drug delivery system by having that forced pregnancy all the way to term, and those economic consequences do have interstate effects.

Now, it is true that in our complaint we didn't plead, you know, fully elaborately. What we said is that we believe that the State through the ban does have these interstate

effects. I think it's sufficient for pleading purposes, especially as amplified by the briefing and argument today. But for purposes of accepting our allegations to be true, I think we're at a stage here where we easily should be surmounting a motion to dismiss where the allegations in the complaint are assumed to be true.

And where you take that kind of derivative harm allegation and you do apply certain economic consequences to that kind of what is called a safety rationale, there are economic forces on both sides to balance. And if you were just talking about safety in one realm, you have to understand what those consequences might be.

THE COURT: All right. I interrupted you when you were talking about --

MR. FREDERICK: I just wanted to say on the telemedicine ban, we agree with Your Honor that that is still in effect, that West Virginia does ban and that this is a direct conflict -- we talk about this in paragraph 73(c) of our complaint, where the FDA specifically considered and rejected an in-person requirement. That we allege at paragraph 88 of our complaint.

And so when you look at the FDA's rejection of an in-person requirement, the State's ban on telemedicine, I think you are drawn to the conclusion that West Virginia says you can only do this in person whereas the federal government

has said that's not necessary, and that is a conflict directly.

THE COURT: All right.

MR. FREDERICK: If the Court has no further questions --

THE COURT: I do have one sort of general question, and that is, as you noted here, we're at a motion to dismiss stage. So in your view, if I deny this motion, what sort of discovery fact development do you believe will ensue?

MR. FREDERICK: Your Honor, the way we would envision the progress of the case is that, upon your denial of the motion to dismiss, the parties would confer. We believe that within 45 days we could offer cross motions for summary judgment that would be based on affidavits. I think the preemption arguments are law-based arguments, they are not fact-based arguments. We could probably do preemption just simply on the basis of what the legal requirements are.

I appreciate from Your Honor's standing ruling that there are facts that we would submit through affidavit to support our standing, and that by Commerce Clause argumentation, we would likely submit those through affidavits as well.

I don't think there is going to ultimately be questions where there are disputed issues of fact. We are certainly open to working with the State to try to develop an

undisputed statement of facts through affidavits that we would share and exchange in advance. But our hope is that if the motion to dismiss were denied, we could move with alacrity to develop what would be a case that would fully satisfy Your Honor's earlier ruling and the necessities.

We all appreciate this case is going to go up on appeal, and our objective would be to provide an ample record so that a ruling that would invalidate the State's criminal abortion ban would be sustained on appeal.

THE COURT: All right. Thank you.

All right. Ms. Hawley, do you want to reply?

MS. HAWLEY: Thank you, Your Honor. A couple of things here.

First, Your Honor, West Virginia in no way concedes that its state law that protects unborn children is in any way directed at mifepristone or the healthcare system.

West Virginia has been clear in its pleading, in its state law and argument today that what West Virginia law does is seek to protect unborn children, maternal health, things that *Dobbs* expressly said were within the province of states and their elected representatives. So in no way do we concede that West Virginia is trying to interfere with the healthcare system.

With respect to --

THE COURT: But the law is aimed only at doctors. It

doesn't make it a crime or other sanction for a woman who decides to have an abortion, does it?

MS. HAWLEY: Well, Your Honor, I think that's recognizing that the State believes there are two victims of abortion, both the unborn child and often the woman who obtains one. So I think the State is being cognizant that women are sometimes in difficult situations and instead of saying that, in these situations, we're not going to go after the woman who may be suffering or in a strait, but instead we're going to say that providers cannot provide that.

For that reason, Your Honor, I think the impossibility claim absolutely follows. There is no case that I'm aware, my counsel on the other side didn't cite any, in which impossibility preemption is found when it's -- when the parties regulated are different parties.

Counsel on the other side mentioned, you know, a woman might be able to have one federally, have an abortion but not have an abortion in West Virginia, but that is not how impossibility preemption works. It looked at whether in *Wyeth* the drug company's label was acceptable under federal law and under state law. Here, the drug company, GenBioPro, has no impossibility of complying both with federal and state law.

In addition, Your Honor, counsel for the opposing side talked a lot about chaos. But to be clear, were this Court to find that the REMS provision did preempt state law, that would

be a sea change. REMS provisions have been around since 2007. Complimentary to those REMS provisions, states have long required things like in-person visits.

If you're going to prescribe an opioid, it's not unusual for a state to say you need to do that in person so the doctor can explain the severe risks --

THE COURT: Are they covered by the --

MS. HAWLEY: They are, Your Honor. Yes, sir.

THE COURT: -- by the elements intended to ensure safe use as well?

MS. HAWLEY: I believe so, Your Honor. And so we're talking about drugs here that, again, are a particular narrow category of drugs that have a grave risk.

Counsel on the other side talked a lot about this statute, and that's exactly where Your Honor should focus. If we look at Section 355-1, again, we do think the presumption against preemption applies here precisely because it requires in this area that has traditionally been governed by the states for this Court to find a clear indication that Congress intended access. That is nowhere in that statute.

Section 355-1 does talk about access, but it talks about access with respect to what FDA itself may do. FDA may not unnecessarily impede access. It in no way suggests that states will be stripped of their traditional authority to compliment the FDCA and the FDA's authority, Your Honor.

Also, I think that one thing that's sort of striking and missing from our discussion here is the Biden Administration, HHS, the Department of Justice has been forthright in its pursuit of abortion availability to the extent that complies with law. But, Your Honor, the FDA is not here today. And on pages 16 and 17 of our brief, we cite FDA questions and answers that establish that the FDA has long recognized that state law does in fact control some of the things that are regulated by the REMS.

In particular, the FDA concedes that, whereas the REMS allow for nonphysician providers, the FDA tells providers go and check with your state. Your state might have other regulations that compliment these REMS, and you need to abide by them. I think the indication from the FDA here is that states are able to do what they've always been able to do under the FDCA, and that's to compliment.

Just a few words, Your Honor, on field preemption. I think rather than being a narrow argument, it's quite a broad argument to say that anytime Congress says shall to an agency, that means that any complimentary state law is preempted.

With respect -- *Locke* was a ports and waterways case. Here we're talking about health and safety, which is a traditional area of state concern, whereas ports, of course, are a traditional area of federal concern. So I don't think that case helps a lot. Nor does the shall language.

With respect to impossibility, we've talked about that. We've got different -- different actors here, so impossibility preemption doesn't apply.

And when you get to obstacle preemption, Your Honor, in my colleague on the other side's brief, they note that purpose doesn't matter, but that is not correct under Supreme Court law. If you look at *PG&E*, if you look at *Virginia Uranium* mining, if you look at *Harris*, all of those cases plainly say that when you're looking at the sort of purpose requirement for preemption, you can look at why the state did what it did.

When we look at West Virginia, what West Virginia did here was say we want to protect unborn life. We don't care how. We don't care if it's chemical abortion drugs. We're not messing with the healthcare system. We want to protect unborn life. And that really distinguishes the situation from *Geier*, Your Honor.

I think *Geier* is probably the outer bounds of this sort of purpose preemption doctrine. And what *Geier* specifically found was that the regulation there offered the manufacturers a choice among passive restraints, and state tort law came in and said, no, you have to have seatbelts. In that, there was a conflict that the Court found, almost a direct conflict, but one that certainly doesn't exist here where you had different purposes. You've got the federal

safety purpose, and you've got the state law protection for life purpose.

As Your Honor noted, *Harris* I think is very helpful here. It may be dicta, but in *Virginia*, the uranium mining case, the majority cited *Harris* for the proposition that slaughtering horses -- a ban on slaughtering horses would be permissible notwithstanding the nationwide regulation of slaughterhouses in general.

Similar for *Virginia Mining* and *PG&E*, those cases are really clear that when you have a state directed to a different purpose, as is West Virginia's law, that survives purpose preemption.

And just a few words, Your Honor, on Pike balancing. As you mentioned, it's kind of hard to dissect, you know, what garners a majority for what parts of the opinion, but were -- are clear that five justices found that the allegations in that case were insufficient under the dormant Commerce Clause. I think those allegations vastly outweigh the interstate economic effects that GenBioPro has alleged here.

As we mentioned, Chief Justice Roberts, my colleague on the other side relies a lot on his opinion. I'd encourage you to look at pages 20 through 22 of that opinion. On those pages, he expressly says that the harms must be economic, and they must be interstate. And he in no way carves out healthcare, Your Honor.

That would really flip federalism on its head to say an area, as in *Wyeth*, notes time and again -- or go back to *Jones v. Rath* or *Santa Fe Railroad*, or all of these cases in which the Supreme Court has noted that the state's traditional authority is to protect for health and safety, that would be flipped on its head if we could sort of say, well, this is a healthcare case, and so a dormant Commerce Clause could just run wild and preempt or undo all these sorts of state laws. So that would really be flipping on its head.

In summary, Your Honor, just to quote the Chief Justice, we really sort of need sweeping extraterritorial effects under Pike balancing, and those simply don't exist here.

THE COURT: All right. Thank you.

MS. HAWLEY: Thank you.

THE COURT: All right. Well, I appreciate your arguments. I'm going to take all this under advisement, of course.

I think when you were here arguing standing, I was able to tell you that I thought I would have a decision within a couple of weeks. I can tell you here, without question, it will not be in a couple of weeks, it will be considerably longer.

I'm actually going to be unavailable for a while in the next few weeks, but I'll be working on this periodically,

and I certainly hope to get to it with some dispatch. I appreciate how serious this issue is and how important it is to not just the litigants here, but to others as well, so I will give that considerable weight in trying to make time on my schedule to make sure that I address this as thoroughly as I can and as quickly as I can.

Is there anything else that you folks need to bring to my attention today?

MS. HAWLEY: No, Your Honor.

THE COURT: If not, again, thank you for your excellent briefing and your really high-quality presentations today. It's helpful, and I appreciate it.

If there is nothing else, we'll stand adjourned.

THE COURT SECURITY OFFICER: All rise. Court is now adjourned.

THE COURT: Thank you, folks.

MR. FREDERICK: Thank you, Your Honor.

MS. HAWLEY: Thank you, sir.

(Proceedings were concluded at 2:40 p.m.)

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CERTIFICATION:

I, Kathy L. Swinhart, CSR, certify that the foregoing is a correct transcript from the record of proceedings in the above-entitled matter as reported on May 23, 2023.

May 30, 2023
DATE

/s/ Kathy L. Swinhart
KATHY L. SWINHART, CSR