UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

JANSSEN PHARMACEUTICALS, INC.,	**CIVIL ACTION NUMBER:**
Plaintiff,	**3:23-cv-03818-ZNQ-JBD** **3:23-cv-03335-ZNQ-JBD** **3:23-cv-14221-ZNQ-JBD**
v.	**3:23-cv-20814-ZNQ-JBD**
XAVIER BECERRA, in his official capacity as Secretary of Health and Human Services, et al,	**ORAL ARGUMENT**
Defendants.	

Clarkson S. Fisher Building & U.S. Courthouse
402 East State Street
Trenton, New Jersey 08608
March 7, 2024
Commencing at 11:20 a.m.

B E F O R E: **THE HONORABLE ZAHID N. QURAISHI, UNITED STATES DISTRICT JUDGE**

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(PROCEEDINGS held in open court before The Honorable ZAHID N. QURAISHI, United States District Judge, on March 7, 2024, at 11:20 a.m.)

THE DEPUTY COURT CLERK: All rise.

THE COURT: All right, folks. You may be seated. Thank you.

All right, everybody. We are on the record actually in four matters, so let me just put that on the record: Bristol Myers Squibb v. Becerra et al., Docket Number 23-335; Janssen Pharmaceuticals v. Becerra et al., Docket Number 23-3818; Novartis Pharmaceuticals v. Becerra et al., Docket Number 23-14221; and Novo Nordisk v. Becerra et al., Docket Number 23-20814 for oral argument.

Folks, before I take appearances, let me just briefly address the gallery this morning.

I understand that there was a delay this morning, and I do want to apologize to members of the public, other folks that are here, including counsel, for the delay.

But I also want to make clear to everybody here that we do not apologize for ensuring the safety of the folks that work in this courthouse, the attorneys and the parties that appear before this courthouse, and the members of the public that have a right to be here.

And I hope this serves as a reminder to all of you about where you are today, the matters of importance that this

Court has to address on a daily basis, and the real dangers and risks that come with serving on this court.

And with that, I'm not going to say much more.

Let me have appearances from counsel, beginning with the plaintiffs.

MR. GREENBAUM: Good morning, Your Honor.

In the Bristol Myers Squibb case, Jeffrey J. Greenbaum, Sills Cummins & Gross. I'm here with my partner, Victor Herlinsky.

I'd like to introduce to the Court two lawyers from Jones Day who have been admitted pro hac vice, Mr. Yaakov Roth and Toni-Ann Citera.

Mr. Roth will be arguing for us today.

THE COURT: All right. Good to see you, Mr. Greenbaum and counsel.

Additional appearances?

MR. CHIESA: Good morning, Your Honor. Jeffrey Chiesa, Chiesa, Shahinian & Giantomasi, on behalf of Janssen.

I'm joined by my colleagues from Covington & Burling, Kevin King and Robert Long. My colleague Patty Bergamasco is also here in the courtroom.

THE COURT: Good to see you, Mr. Chiesa, and counsel as well.

MR. DEGER-SEN: Thank you, Your Honor.

Samir Deger-Sen from Latham Watkins. I'm joined by Daniel Meron and Christina Gay.

THE COURT: Good morning to you as well.

MR. DAHAN: Israel Dahan from King & Spalding here with my colleagues, Ashley Parrish and John Shakow, on behalf of Novo Nordisk.

THE COURT: Good morning to you as well.

I think that's everybody on the plaintiff's side, right? It's a little crowded over there.

Government?

MR. NETTER: Good morning, Your Honor. Brian Netter from the Department of Justice for the defendants in all the case. I'm joined here at counsel table by Alexander Sverdlov and Michael Gaffney.

THE COURT: Good morning to the three of you as well.

So, look, it's my understanding that the parties have already submitted a proposal of how you want to proceed today in oral argument. I appreciate you all doing so.

Do we have any housekeeping that we need to address before -- I believe we're going to deal with opening remarks, right, Mr. Chiesa?

MR. CHIESA: Yes, Your Honor.

THE COURT: All right. So do we have any housekeeping from either the plaintiffs or the defense before we proceed?

MR. NETTER: None from the defense, Your Honor.

THE COURT: Plaintiffs, none?

MR. CHIESA: None.

THE COURT: All right. Mr. Chiesa, you may proceed.

Actually, I have a question already, but I'm going to wait. I'm going to hold my tongue. I'm going to hold my tongue.

Go ahead, Mr. Chiesa.

MR. CHIESA: Good morning, Your Honor. May it please the Court.

Your Honor, on behalf of the four plaintiffs, we are grateful for your time and attention to the important issues presented by these cases.

It is my role this morning to provide a brief roadmap of how plaintiffs intend to present their arguments and to identify the lawyers and the specific arguments that they will be making.

As Your Honor is aware, these cases challenge the drug price control provisions of the Inflation Reduction Act. Different plaintiffs challenged different aspects of the law, but we anticipate Your Honor will note some consistent themes. I'll discuss three of them.

First, the cases before you raise issues that go beyond drug prices and this particular statute. The government has advanced the extreme position that there can be no

constitutional violation whenever a party has elected to participate in a federal benefit program. That principle, if accepted, without that long-settled principle of constitutional law and have extraordinary ramifications.

Second, the statute at issue is unprecedented because it strips away many constitutional safeguards that are essential to protecting private rights, ensuring accountability, and safeguarding the public interest.

Third, the constitutional problems are reinforced by the lengths to which the government has gone to obscure the statutes requirements.

As just one example, the government repeatedly refers to a negotiation process, but, in fact, the government is unilaterally dictating the price at which it is forcing certain manufacturers to sell their drugs.

Consistent with our submission, plaintiffs have split their arguments into two sessions: one this morning, one this afternoon.

Plaintiffs will focus first on the statutes' constitutional failures. Plaintiffs will then address the way in which CMS has exceeded its statutory authority.

We plan on starting this morning with the issues raised by Bristol Myers, Janssen, and Novartis, that the statute violates the takings clause because it forces certain manufacturers to sell their property on terms dictated by the

government.

Yaakov Roth, counsel for Bristol Myers, will address these arguments.

Next, we will address the defendants' primary defense to the takings claim, which is based on their assertion that participation is voluntary. Plaintiffs have two responses.

First, plaintiffs will explain why the Voluntariness Doctrine does not apply. Samir Deger-Sen, counsel for Novartis, will argue that issue.

Second, plaintiffs will explain why the statute's forced sale regime is not voluntary and why it violates the Unconstitutional Conditions Doctrine. Kevin King, counsel for Janssen, will address these arguments.

After the government addresses these issues, plaintiffs respectfully request to reserve ten minutes for rebuttal, with that rebuttal time deducted from the 60 minutes allocated to plaintiffs for the morning session.

In the afternoon, we plan to address the other constitutional claims and then turn to the statutory violations.

For each argument, we expect counsel for one of the plaintiffs to present the argument, for the government to respond, and for plaintiffs' counsel to present rebuttal.

First, plaintiffs will explain why the statute forces manufacturers to speak the government's preferred message in

violation of the First Amendment. Mr. Roth will address these issues.

Second, Novartis will argue that the fines the statute imposes to prevent manufacturers from escaping price controls are constitutionally excessive. Mr. Deger-Sen will address this claim.

Third, Novo Nordisk will argue that the statute violates separation of powers and due process because it includes no standards to constrain CMS's price setting decisions and no procedures to protect against confiscatory prices. Ashley Parrish, counsel for Novo Nordisk, will address these claims.

And finally, Novo Nordisk will argue that CMS's actions violates express statutory mandates. Mr. Parrish will address these arguments as well.

Your Honor, thank you again for your careful consideration of these important issues.

THE COURT: Thank you, Mr. Chiesa.

Now can I ask my one question?

MR. CHIESA: Of course, Your Honor.

THE COURT: Only because I want to make sure my record is clear.

So, Mr. Chiesa, there's been decisions in this arena already, and I'm thinking of -- let me just make sure I have the cases right. You have the *National Infusion Center*

Association v. Becerra. That's a case out of the Western District of Texas.

You have *Dayton Area Chamber of Commerce v. Becerra* in the Southern District of Ohio.

You have *AstraZeneca v. Becerra*, which is a decision from our sister court in the District of Delaware that came out recently.

In light of any of these decisions, are plaintiffs withdrawing or waiving any arguments in this matter?

MR. CHIESA: We are not, Your Honor.

THE COURT: All right. It's as simple as that. So no less homework for me. All right.

MR. CHIESA: Sorry about that.

THE COURT: I appreciate that.

MR. CHIESA: Thank you, Judge.

MR. ROTH: May it please the Court, Yaakov Roth on behalf of Bristol Myers Squibb.

THE COURT: Good morning.

MR. ROTH: And I'll be addressing why the program affects a physical taking of property, and I'm hoping to keep this part to about 15 minutes.

Your Honor, the point of the takings clause is that if the government wants to take private property for public use, even for the most noble reasons, it has to pay for it. The reason is we want to make sure the costs of those social

welfare programs are borne by the people as a whole and not by a select few.

What's going on here is that the government has, through the Medicare program, chosen to and promised to cover the costs of prescription drugs for millions of citizens, and that is very expensive to do.

This program is designed to get those medications to the Medicare beneficiaries without the government having to pay their market price; instead shifting the costs of that program and that promise to what is for now ten manufacturers who have been selected to bear the brunt --

THE COURT: By the way, Mr. Roth, when you say "market price," is it a market price if by definition you're the only seller? Isn't that a monopoly price?

MR. ROTH: It's both a monopoly and a market price, Your Honor. If the market is a monopoly, then that is the market price.

I'm going to speak about specific pricing and how that plays into this later, but there is a market for these products and there's a price that is paid in the market. And the purpose of this program is for the government not to have to pay that price, and that is the taking clause.

Now, the government says in one of its briefs essentially, Come on, look, it's not like CMS is sending trucks to your factories and hauling off the drugs. And that

is true. But I'd actually like to start there because it seems that the government concedes that that would be a physical taking.

THE COURT: Well, is this a voluntary program, Mr. Roth? I know you argue that it isn't, but let me just say -- I'll be more specific, right, because we're in a courtroom now.

Have you found any case law in this circuit or any other that holds that the participation in the Medicare system is not voluntary? That's my question.

MR. ROTH: No, Your Honor, but this program operates differently --

THE COURT: Well, that's my next question. You're reading the tea leaves here because why is this case different, then?

MR. ROTH: Right.

So what I'd like to do is explain the way the program operates and then explain how Medicare and the sort of participation in Medicare fits into that.

The way I'd like to do it is -- if Your Honor is amenable -- I'd like to suggest that there are four distinctions between the hypothetical I just gave, the truck showing up, hauling off drugs from the factory, and this program.

Now, I'm going to address three of them. The fourth is

actually the one that Your Honor's question goes to, which is this idea that, look, this is part of participating in Medicare. You don't have to participate in Medicare; therefore, we don't have to worry about this.

So it's as if in the hypothetical, trucks are going to show up at your factory and haul off drugs, but only if you participate in Medicare or Medicaid. If you drop out, the trucks won't show up.

Okay. That distinction, which, to be very candid, is really the thrust of the government's defense on these claims. That's actually going to be the distinction that is going to be addressed directly by counsel for Novartis and for Janssen.

I'd like to focus on the three other distinctions between the hypothetical and the program, sort of bracket off the Medicare participation issue for now, not because I want to hide from it. It is a very important issue in the case, but I think, analytically, it's a two-step analysis.

So can the government do this directly as a mandate? If not, is it okay because of this sort of back-end link to Medicare where you can opt out --

THE COURT: No. I hear you, Mr. Roth, but I am a little confused, then, because, look, the voluntariness issue, to me it appears to be a threshold issue, right?

If I were to find that the program is voluntary and that you and your clients and the plaintiffs can withdraw,

then what claims are left?

MR. ROTH: Your Honor, I don't think that makes it a threshold issue. It's an important issue. It's an issue Your Honor absolutely has to address.

But I think analytically, the way to approach this -- and this is the way the Supreme Court approaches other sort of conditions arguments, which is what -- essentially what the government is arguing here -- is to ask first the question of -- put aside the condition and opt out: Is this something the government can do constitutionally?

If the answer is no, you can't force somebody, then the question becomes, All right, well, can't force them, but I'm not forcing you, you have this choice available. Does that change the analysis?

That goes to the issue of unconstitutional conditions. What are the restrictions on the government's ability to condition benefits on the waiver of constitutional rights? So I think it's two separate analytical steps.

I'd like to start with the first, which is put aside the opt out -- and I'll get to exactly how this works in a minute. Put aside the opt out. Can the government say, You've got to sell at this price or we're going to impose a penalty on you, which is directly in the Texas statute how this operates.

And then we'll get to the question of, All right, it

doesn't matter that you can get on Medicare as a whole and then make this go away.

So, Your Honor, I think the first distinction between the hypothetical of the trucks and this program is, here, the government would say -- I think the manufacturers are agreeing to provide the medications at the price. It's an agreement. The reason that distinction doesn't work, respectfully, is the IRA imposes penalties if the manufacturer does not agree to turn over the product.

So it's like the government saying, We didn't take your house. We just said we would put you in jail if you didn't hand over the keys and you handed over the keys. So there's no taking. Obviously, that would not be right.

If the government is using civil or criminal penalties to induce, coerce, transfer property, that's a taking, and the Supreme Court decision in *Horne* is a perfect example. That's the raisin case that we rely on quite a lot.

The farmers had to turn over a share of the raisins. If they didn't, they have to pay a fine. The Supreme Court said that's a taking.

The D.C. Circuit decision in *Valancourt* last year, which is another important case we rely on for physical takings, same thing. If you publish a book, you need to send two copies to the Library of Congress or else you pay a fine. D.C. Circuit said, Sure, you can pay the fine instead of

giving the property. It's still a taking because that's how you're enforcing the obligation to turn over the property.

This program operates the same way, Your Honor. Statute says the Secretary and the manufacturer shall enter an agreement under which they agree to provide access to the maximum fair price for eligible individuals. It's in 1320f-2(a)(1) and (a)(3).

And then the second piece of the statute is, well, what happens if you don't agree to provide access to the drugs? Well, then you incur a tax penalty every day going forward. They call that the noncompliance periods, and they're huge, huge penalties. There's some dispute about how much --

THE COURT: The parties -- the math, someone is going to have to walk me through the math because when you read these briefs, your folks are claiming that the penalties are astronomical, that it would be a deterrence to ever being able to actually withdraw from the program.

I feel like I'm watching a Godfather scene. You've got Luca Brasi trying to get Johnny Fontane out of a -- you know, a deal with the band leader. You've got a gun to the head, and the Godfather says, Either your brain or your signature is going on the contract.

That's what you guys are claiming. The government has a completely different argument here. I mean, they're saying that the penalties are not remotely what you guys are

alleging, so somebody's going to have to walk me through the fuzzy math because only one of you can be right, or it's possible both of you are wrong.

MR. ROTH: Your Honor, I think it actually doesn't really -- I think the difference on that point actually is not legally material. It goes to how you calculate the percentage of the price that is the tax.

So it's like if you charge a hundred dollars for the pill, the question is: Is the tax $95? In other words, you take the 95 of the hundred, or do you gross up, in which case it's sort of a -- it's a much higher number.

But either way, we're talking about tens or hundreds of millions of dollars a day. I don't think the government is going to dispute that.

So it is a huge penalty and, frankly, the amount of penalty doesn't -- for this purpose doesn't actually matter. I mean, in *Valancourt*, it was something like $250, you know, if you don't pay, if you don't turn over the property.

The point is still you're using that threat and that penalty tax to coerce the transfer of property. That makes it a taking.

If you put these two things together in the statute, the obligation to agree, the penalty if you don't agree to provide the access, then I think this is just like *Horne* and *Valancourt*.

Manufacturers have to either hand over the medicines, or they have to pay large penalties. That is a compelled transfer of the product that legally is no different from a direct seizure.

Now, before moving on to the second distinction, I want to address the government's argument that when the statute says we have to provide access, they say that doesn't mean you actually have to sell the drug to Medicare at all.

They sort of hinted this in the first brief, but they really double down on it in their -- in their reply. They say you have to provide access to the maximum fair price. That just means if you sell it, you can't charge more, but you don't have to sell it in the first place.

Respectfully, the government's just wrong in its premise about what the statute says and means. I think they can't -- they can't defend what the statute -- the statute that Congress actually wrote, and so I'm trying to change it.

It's an economically significant distinction, though, because if the manufacturer didn't have to provide the drug at the government-dictated price, that would provide the manufacturer with some leverage in the negotiations, say, Look, we don't like your price. We're just not going to sell it to Medicare. Right?

But Congress didn't want to take the risk that Medicare beneficiaries would lose access to their medications, and so

Congress provided that manufacturers have to agree to just that "access." That's the word that the statute uses. Access means we need to allow the Medicare beneficiaries to get the drugs on these terms.

Now, it's true, as the government says, the statutory phrase is "access to the maximum fair price." You can't have access to a price without access to a product, and it just really -- to me, it doesn't make any sense. If you refuse to sell the product to a person, you're not giving access to the price.

And I sort of imagined a hypothetical. The statute said, Store is required to provide access to a senior's discount of 25 percent off. And the store said, Okay. We're going to check IDs at the door. If you're 65 and older, you can't come in. Sorry.

Nobody would say they're complying with the duty to provide access to a senior's discount on those facts.

And the structure of the statute, I think, powerfully confirms that our reading is correct. And that's because, as Your Honor alluded to earlier, Congress did provide that you can suspend the tax penalty if you withdraw all of your products from both Medicare and Medicaid. That's the way to suspend the penalty all together.

So it just makes no sense to say, Well, Congress demanded wholesale withdrawal all products from both of these

programs in order to suspend the penalty, but Congress was perfectly okay with the manufacturer just withholding the one drug, the selected drug from Medicare on the government's terms while continuing to receive comprehension reimbursement for all of its other products.

THE COURT: Has anybody withdrawn?

MR. ROTH: No, Your Honor.

THE COURT: Has there been a single pharmaceutical company that has withdrawn from Medicare based on the issues that you've raised under the IRA? I'm just curious. I mean, has anybody said, I'm out, we'll find another way to do deal with this?

MR. ROTH: To my knowledge, nobody has withdrawn.

THE COURT: And by the way, government, that question is coming to you as well, so I'm not going to hold Mr. Roth to anything more than his knowledge on the case.

But you're not aware of a single company saying, We're going to withdraw. We can't -- we can't manage this.

MR. ROTH: No. I'm not aware of that, and I think that actually goes to what we'll talk about next, which is the Unconstitutional Conditions Doctrine.

THE COURT: Well, I don't know. It can count both ways. But I understand that you're going to argue that it counts one.

MR. ROTH: I think that's right.

Just on that structural point, the government really never grapples with that problem with its interpretation of the statute.

So the bottom line, Your Honor, on this is the statute, on its face, clearly does require the manufacturer to hand over the product on the government-dictated terms or else pay a penalty, and that is a physical taking of property, just like in *Horne* and in *Valancourt*.

Two other distinctions between this program and the truck hypothetical. Second distinction: Instead of a CMS truck picking up drugs in bulk for the government, this is actually third parties. They're Medicare beneficiaries who are coming, and they are getting their individual pills. That doesn't matter to the analysis either.

For one thing, it's the government who is the payor. The government is the insurer for these products. That's why they're doing this. So the government is actually the one reaping the benefits of the compelled discounts designed to save money for Medicare.

Second point: Putting that aside, it actually doesn't matter for takings purposes whether the statute requires access for the government or access for third parties. It's still a taking.

The best example of that is the Supreme Court's *Cedar Point* decision. That's the one involving the California

law that required agricultural facilities to provide access -- same word -- to union organizers to come onto their property, and the Court said, Yeah, that is a physical taking of the property because the government is forcing you to provide access to your property to these third parties.

The third distinction is there is some payment made.

THE COURT: I just want to go back, Mr. Roth.

MR. ROTH: Sure.

THE COURT: I thought you said earlier -- and correct me if I'm wrong. You're saying the government benefits from this. Is that what your point is?

What about Americans? They don't benefit from this?

MR. ROTH: They're not the principal beneficiary directly.

THE COURT: That wasn't my question, though.

Do they benefit from the price reduction?

MR. ROTH: They may. Some Medicare beneficiaries may see lower co-pays. It depends on how the Part D plan works because they work in different ways. So they may; they may not. But the government, as you can see, a very large benefit in the form of paying less money to buy these products.

Just to go back to where I started, the problem is that benefit or that the cost of that is not being spread among the people as a whole. It's being taken out of these ten manufacturers.

So, Your Honor, unlike the truck hypothetical, this is the third distinction I wanted to draw. The program does provide some payment. It's not taking it and giving you nothing. Right? It's as if the trucks show up, they haul off some drugs, they leave you a check for half. Okay?

That matters. It matters for damages purposes. Certainly, when we got to that point, you would deduct the maximum fair price from the market, fair market value, which is the standard under the takings clause for just compensation.

And it would -- it would go to the amount after that manufacturers are entitled to recover after the taking occurs, but it doesn't mean there isn't a taking in the first place.

And the Supreme Court decision in *Horne* controls on this point, too. The raisin farmers there retained a right to be reimbursed after the government resold the raisins, you know, less certain expenses.

And the Supreme Court said, Yeah, that goes to the amount of just compensation you might be owed on the back end, after the fact. It doesn't change the existence of the taking in the first place.

Now, if the program guaranteed fair market value, that would be a different story, of course, but it doesn't. The whole point is for Medicare to get a discount.

And, in fact, the statute caps the maximum fair price

at a fraction of at least one benchmark market value that's out there, the non-federal average manufacturer price.

Now, look, drug pricing is very complicated. There's a lot of numbers. There's a lot of different prices.

But our point is simple for now, which is the program takes them. The program doesn't guarantee just compensation. That's the declaration judgment we want.

The actual amounts of how -- you know, what is the real value of the drug, how much should we be entitled to get, that's not before the Court right now. That would be a later-stage issue for damages, if and when the government actually proceeds with the taking.

For now, all we are trying to say -- and this is sort of a sum-up for this part -- is requiring a manufacturer to sell its products to certain buyers at a government-dictated discount, no different from a takings clause perspective than sending government trucks to seize the property from the factory.

With that predicate, the only remaining question, I think, becomes does this become constitutional because the manufacturers can withdraw entirely from Medicare and Medicaid?

And that's the question to which my co-counsel will turn next, with Your Honor's permission.

THE COURT: All right. Thank you, Mr. Roth.

MR. ROTH: Thank you.

MR. DEGER-SEN: Thank you, Your Honor.

I'm Samir Deger-Sen for Novartis. I'm going to speak for about ten minutes.

THE COURT: Good morning.

MS. DEGEN-SEN: Good morning, Your Honor.

The government's primary defense is that there's no taking here because manufacturers agreed to terminate all of their contracts for all of their drugs under the Medicare and Medicaid programs.

In making that argument, the government has sort of tried to cause that as a condition on participation.

My colleague, Mr. King, is going to address why -- even if that characterization is correct -- the program is still an unconstitutional condition and unduly coercive.

But I want to make two important threshold arguments that challenge that premise. First, the program shouldn't be understood as a condition at all. Rather, it is a requirement to hand over property backed by a penalty, and that needs to be analyzed differently.

And, second, when you have a physical taking backed by a penalty like this, it doesn't matter that a party can avoid the taking by exiting the relevant market.

This case is, therefore, very different from the cases Your Honor was describing, which are regulatory takings cases

or due process challenges to the rate itself. Those are all cases saying that the rate is too high.

This is a case saying that there was a physical taking and it's not a condition. And that makes the analysis more akin to the *Horne* and *Valancourt* cases --

THE COURT: So just so I'm clear, is it your position that whether the program is voluntary or not is irrelevant? Basically, the circumstances of this case.

MR. DEGER-SEN: It's not irrelevant, but the -- when you have a physical taking there is special sort of doctrinal considerations that apply, and that -- that's really governed by *Horne*. And those doctrinal considerations say that there's a distinction between voluntariness and avoidance. And avoidance, which is what this is, is not a sufficient basis to say the government gets to do the taking.

So on this first point it would be clear, because I think it's easy to miss, this regime is not actually a condition on participation. The clearest way to see that is to think about what happens if we -- if the manufacturer rejects the MFP.

The result isn't that we don't sell that drug. The result isn't even that we don't get to be part of the Medicare/Medicaid program.

The result is we stay in the program. So we sell the drugs at the market base prices we were previously paying,

that everyone is reimbursed at the rates they were previously paying. Everything stays the same except we're subject to a massive penalty.

That is a not condition on coverage like the other programs the government analogizes it to, and it's not a price tag. It's not the government saying, We're just going to pay a specific price. If you don't like it, you can go.

The crux of the program is a physical taking requirement, as Mr. Roth described it, backed by a penalty. It's sort of nested within Medicare and Medicaid.

And that brings me to the second point, which is when it comes to a physical taking, no court has ever said that the fact you can leave the relevant market place excuses the physical taking.

And the reason, I think, is pretty clear, because it would give the government carte blanche to say, Well, you're in a government program, a federally regulated program, so now we can violate your constitutional rights.

THE COURT: Let me ask you this. I don't mean to interrupt, but let me just step back.

Is the format for today that you're all going to address all your arguments on all the claims and then I'm going to hear from the government? Because that's not as helpful to me.

My understanding is that you guys were going to address

an issue on the plaintiffs' side, and then I get to hear what the government's response is.

It's not going to be helpful if I have two hours or two and a half hours of plaintiff argument, and then I have to go back in time to remember all the things you've said to hear what the content is going to be from the government.

So how do we do that, Mr. Chiesa? Is that what you all agreed to, that you would raise all the arguments from the plaintiffs first, and then I would then hear from the government? Because I would prefer to hear from them on the takings issue first and then hear from Mr. Deger-Sen and then go back and forth.

Otherwise, I'm getting all the arguments at one time from one side. I'm not sure how helpful that is to me.

MR. CHIESA: I won't speak for everybody, Your Honor, but whatever is best for you to understand what is going on here.

THE COURT: Mr. Chiesa, I'm not trying to interrupt you, and I want to hear from you, but I don't want to wait two and a half hours to hear what the government has to say about the case --

MR. DEGER-SEN: And to be clear, that's not what this -- this is all part of the takings --

THE COURT: So you're still addressing the second part of the takings?

MR. DEGER-SEN: We're still addressing the takings. This is part of our takings -- I mean, it's broken up into three sections.

And the reason we did that is because I think we wanted to get -- make it analytically clear that this doesn't look like the kinds of other cases, the regulatory takings cases, because physical takings have a different analysis.

THE COURT: And the government, you're going to address all of these particular pieces in one shot when they're done breaking it up?

MR. NETTER: Yes.

MR. DEGER-SEN: Exactly, Your Honor. And then with respect to our other claims -- I'm sorry. I was going to say with respect to our other claims in the afternoon, we'll be discussing them --

THE COURT: Fair enough. All right. That makes sense to me --

MR. DEGER-SEN: Sorry if that was confusing, Your Honor.

Did you want to say something?

MR. NETTER: No.

MR. DEGER-SEN: Great.

So this is all sort of part of the takings doctrine -- this is sort of part of the takings doctrine -- is when it comes to physical taking -- that's why we broke it up this

way.

You have to first establish it's a physical taking. That puts you into the special doctrinal bucket governed by *Horne* where voluntariness looks a little bit different, and, you know, that -- that sort of -- the hypothetical that -- that Mr. Roth stressed, the question becomes, Is it okay to come to our plants, to our facilities, take all of our stuff? And say, Well, you can avoid that, you don't have to be in Medicare and Medicaid. You can -- you can just leave, but, you know, we're here and we're going to take this, and if you don't want us to grab the stuff, you have to pay us an enterprise destroying penalty. Is that fine?

And the Supreme Court said -- and no Court has ever said that is fine. All the cases they rely on are regulatory takings cases or due process cases.

And the Supreme Court in *Horne* made clear that's not the case. And this is very similar structurally to the argument that was made in *Horne*. In *Horne* the government said a very similar thing. They said, Look, we stabilized the price in the raisins market. It's because of this program that the price in the raisins market is what you get.

This is a federally regulated and subsidized market. You're people who grow grapes. You don't have to be part of the raisins market. You can go sell your grapes directly. You can go sell them to a winemaker or you can go make wine.

These are all things you can do, but if you want to be part of the federally regulated raisins market, then you have to agree to a taking.

And the Supreme Court said, No, that's not appropriate, that -- when it comes to physical takings, the government doesn't just get to say, You can just leave the entirety of the federally regulated market.

And I would just like to read from Justice Sotomayor's dissent because it perfectly characterizes the government's argument in that case, the dissent argument. The argument was rejected.

This is what she said: "Insofar as the *Horne's* wish to sell some raisins in a market regulated by the government at a price supported by governmental intervention, the order requires that they give up that right to sell some portion of those raisins at that price and, instead, accept disposal of them at a lower price."

That is word for word what the government is saying in this case. If you want to be part of the Medicare and Medicaid markets, you have to subject yourself to this, and we're going to give you the difference between the price you want and the other price. And if you don't want to be part of the federally regulated market, we're not taking anything from you. You can go somewhere else. There is no taking.

That is exactly what the Supreme Court rejected in

Horne, and it's also -- the only other case that's even remotely close to this is the *Valancourt* case and the analysis goes exactly the same way.

Again, if you look at the government's brief, they look exactly like this. They said that the physical taking there was depositing books at the Library of Congress. It was voluntary because you could just abandon the government's protected market by giving up your copyright.

You know, you don't have an entitlement to a copyright. The government is the only reason you have the copyright, give up your copyright.

And the D.C. Circuit said, First of all, the conditions framework isn't the right way to even think about this because this isn't an actual condition.

You get copyright protection, in any event. This wasn't, you know -- there is no incremental benefit for the book deposit requirement.

So we're not going to analyze this as a condition, and that way of thinking about it is wrong. And then it said, you know, ultimately, that is a physical taking, and it's not acceptable to say you can just abandon your copyright.

In addition it said, Maybe if there was a costless and seamless way of abandoning your copyright, the analysis might be different. But as I said, it's not costless here because of the $125 penalty. We're not sure that that cost seamless

exception applies. But even if it does, Mr. King is going to explain this is clearly not costless.

THE COURT: The government's position is this is how much we're willing to pay. Take it or leave it.

You're saying that's a problem for them?

MR. DEGER-SEN: No. They're saying when it comes to that -- that would not be a problem, Your Honor.

THE COURT: You're saying that's not what --

MR. CHIESA: That's not what they're doing, exactly. If the government had a price cap and it said, We just -- this is how much you want to pay. If you don't like it, don't sell us this drug, or even -- you know, it might -- even if they said, You don't like it, don't sell us any drugs. Maybe they can do that.

I'm not sure -- Mr. King will give you reasons why probably that doesn't work either, but that -- you don't even have to go there because that's sort of a more classic price cap system.

This is a physical taking backed by a penalty at its crux. None of the programs -- this is what makes this unprecedented and novel. There is no other program that looks like this where it says you have to put the drugs in the formulary. You have to physically hand them over at the government-dictated price, and if you don't, we're going to tax you billions and billions and billions of dollars.

That is at its crux physical taking backed by -- and, you know, it's wrong for the government to just keep calling this a spending clause case or a spending clause legislation. It's not. This is not a question of what the government wants to spend or doesn't want to spend.

It's using its sovereign power to coerce someone to hand over something, and then backs it with an enterprise destroying tax. That is all regulatory. That is the government acting in a sovereign capacity, not at all acting like a market participant.

That's why you think it's so important, to see that that is the crux of the program. At -- at bottom, this is just -- it isn't -- they tried to sort of mask it, and they've done a great job in sort of making it sound like this is all voluntary. But at its absolute core, it is exactly like the trucks at the factory hypothetical, and they have not responded in any of the briefs to that hypothetical.

If you find that hypothetical to be, you know, unacceptable, and I think it's imputed unacceptable and *Horne* makes it clear it's unacceptable, that is what this program is. The fact that the person at the factory door could just leave Medicare, Medicaid does not mean the government gets to go and seize their property.

THE COURT: Even if I find the program is voluntary, that's not the end of -- your claims survive?

MR. DEGER-SEN: I think the way to think about it is when it comes to physical takings, the fact that you can avoid something doesn't make it involuntary.

THE COURT: Involuntary.

MR. DEGER-SEN: Exactly. Avoidance is not voluntary. Thank you, Your Honor.

THE COURT: All right. Thank you.

MR. KING: Good morning, Your Honor.

THE COURT: Good morning.

MR. KING: Kevin King, counsel for Janssen Pharmaceuticals. I'll be addressing the remainder of the government's voluntariness defense and then the unconstitutional conditions framework that plaintiffs have put forward as an alternative basis for their claims.

I'm the last plaintiffs' side lawyer you're going to hear on these takings issues before we hand it over to the government.

THE COURT: All right.

MR. KING: And I'd be glad to answer any of your questions about those issues.

But just to pick up where Mr. Deger-Sen left off, voluntariness is not a defense. He gave the reasons for that.

My role here is to show you that even if voluntariness were theoretically available as a defense, the government's argument would fail here. The statute gives plaintiffs no

choice but to acquiesce in the program's requirements, both as a matter of law and as a matter of fact.

The Supreme Court has said that a program is not voluntary if it relies on coercion to secure participation, and that is exactly what the program does here. Indeed, Congress designed this program to be voluntary in theory but mandatory in fact.

As Mr. Roth said, it subjects plaintiffs to an excise tax penalty that is so crippling that Congress knew in advance and recognized that no company ever could incur it.

Just to give you one concrete example of what that tax would look like -- you asked earlier about what it would look like -- our declaration -- this is ECF 30 10 in the Janssen case -- shows that this tax, if it were to be applied to Janssen Pharmaceuticals, would be three times as much as Janssen's parent company across all its products. Not just pharmaceuticals, but everything. So that's the size of what we're dealing with here.

Now, the government asserts that this program is voluntary because plaintiffs could theoretically withdraw all their drugs, not just the four selected drugs we're talking about here today, but all of their drugs for Medicare and Medicaid, which, by the way, for the four plaintiffs that are before you today, Your Honor, that's 120 drugs -- more than 120 drugs that cover serious medical conditions like cancer,

HIV, heart disease, and more.

The government's argument is essentially that the program is optional because the plaintiffs could either give an arm if they complied with the program's requirements or an arm and a leg if they did not, and that is no choice at all.

Let me just tick quickly through a few of the reasons. One of the reasons there is that Medicare and Medicaid have this dominant role.

THE COURT: Look, I don't want to beat up your analogy, but there's a lot of folks that would say pharmaceutical companies can give up an arm. They've got plenty of appendages.

So, I mean, what's the real bottom line here as to how this impacts -- I mean, there's a threat that the plaintiffs are saying that, you know, we wouldn't be able to fund R&D, and this is going to prevent us curing diseases and developing new drugs.

And I don't have -- I've got to be honest, Mr. King, I don't have much before this Court, because if you're going to make that argument before the Court and say the effect of the IRA and this reduction program that is coercive in nature would destroy the pharmaceutical companies' efforts to develop new drugs, to help assist Americans in curing new disease, then I would probably want to know a whole bunch of more things, like what else are you spending the money on? What

are you spending on advertising? What are you spending on executive compensation? What are you spending on all these other areas, stock buybacks and all the rest of it?

I don't have any of that before me, so if you are taking the argument that this would destroy the pharmaceutical business and we wouldn't be able to develop drugs for Americans to survive or cure new diseases, you have to give me more than just I said it, so, therefore, it is so.

I mean, do you have more before the Court? Is there a declaration before me, ECF Number 1056, or whatever number of documents you guys have filed in this case that I should be looking at to say this is the real deal?

If we are bound by this program, if we stay in this program, it will effectively hurt Americans as opposed to helping them.

MR. KING: Your Honor, thank you for the opportunity to address that.

You asked earlier during Mr. Roth's presentation, Do Americans benefit from this program? And the answer is no, they do not benefit because -- because of the reason you were just alluding to, and the best place to look to find those facts -- which, by the way, are uncontested, the government has had ample opportunity. Its filed hundreds of pages of briefs in these cases. It has not contested anything that we say in ECF 30 10, the Penkowski declaration, which shows that

this program would have a debilitating effect on plaintiffs' ability to compete and to innovate by developing the new drugs that Americans depend on to treat those kinds of conditions that I was talking about: cancer, HIV, heart disease. And a lot more. Right?

And so it's a sworn declaration and it's uncontested and what it says is there's a cycle of innovation here and that this program would have debilitating effects on the ability of that cycle of innovation to continue. A cycle, which, by the way, just to fill in some of the blanks, Your Honor, new drugs cost on average more than $2.6 billion each to develop. 99.98 percent of those drugs never get to market. There needs to be a way to cover that R&D, and the revenues for these programs, Medicare and Medicaid, are an essential part of that.

THE COURT: But there are some of those mechanisms in place already? I mean, we have a patent system, right? We have market exclusivity. That's conferred by the FDA.

Do we need to have other protections for pharmaceutical companies that we haven't already put in place to protect -- with respect to development and the amount of cost it takes to develop, you know, drugs and all the rest?

I mean, don't we have programs in place to already protect that interest?

MR. KING: Those programs are -- and those

protections that you refer to are undermined by this program because what the IRA does, in effect, is it devalues and undermines the patents and the exclusivity rights that plaintiffs have.

That's not the core of what we're talking about when we talk about takings. Physical takings here is the takings of the pills themselves, but as a policy matter, it's true that those patents aren't worth much if you can't enforce them, if you don't have the benefits of exclusivity.

So that's the policy side of it, but I really don't want to lose track of the patient side of it.

The government's voluntariness arguments is essentially that plaintiffs can withdraw all 120 plus of their drugs from Medicare and Medicaid, leaving millions and millions of Americans without coverage for the drugs they depend on in their daily lives. That's not voluntary given the core mission of these companies.

Now, this goes to some questions you asked to Mr. Deger-Sen. You said, Does voluntariness matter? Is it relevant? The answer is, yes, it's relevant to some of the arguments, but at the end of the day, it's not relevant to this.

Either the program is not voluntary, in which case you need to address our takings claim head-on, or if it is voluntary, then you still need to address and resolve our

takings claim under the Unconstitutional Conditions Doctrine.

Indeed, the entire point of that doctrine is that something is not immunized from constitutional scrutiny merely because it's labeled as a condition on participation in a voluntary program.

So one way or the other, Your Honor, you're going to need to confront and resolve the merits of our takings claim.

THE COURT: Are any of you going to give me a break today, or is it just going to be -- is there one claim that I can maybe not address if I address another claim?

We have, what, over 400 cases a judge in this district, and there's not one you're going to -- you're going relieve me from?

All right. That's fair, Mr. King.

MR. KING: Your Honor, I sympathize. I know you've got a busy docket. You've got four big cases before you today. We appreciate the opportunity to come in and to talk about these cases together. We have done our best --

THE COURT: But your point, just so I'm clear, is regardless of whether I find that the program may be voluntary, that does not address the -- I would still have to do the analysis of the takings claim?

MR. KING: Yes.

THE COURT: It doesn't fail on its face simply because you may have an opt-out in the program, and I find it

to be voluntary.

I know you're arguing that it's not. I'm not saying we're going to make that finding, but if I were to make that finding in that hypothetical universe, my work is still ahead of me. It is not -- at least your position is it would not eliminate the other constitutional claims.

MR. KING: Yes. That's correct, Your Honor. That's right.

And just -- you asked earlier about the *Dayton* case, the *Nico* case from Texas, and the *AstraZeneca* case from Delaware. Those cases did not involve what I'm here to talk about, which is unconstitutional conditions. And by the way, when the government points -- hits voluntariness cases from the 1980s before *Horne* was decided, those didn't involve unconstitutional conditions.

THE COURT: Those are due process -- there are some overlapping claims from those cases, right? It's just not the one you're handling.

MR. KING: Yeah, that's right.

THE COURT: The due process claims, mostly.

MR. KING: Yeah. And we are trying to do this one at a time.

THE COURT: Yep. I'm not going to put you on the hot seat for something your colleague or one of your co-counsel is going to address.

MR. KING: Sure. So that's the big picture. I guess if it would help the Court, I would like to just walk through the reasons one at a time why we think this program is not voluntary and then, on the back end of that, talk with you, if it's all right, about, okay, even if it is voluntary, here's how the Unconstitutional Conditions Doctrine analysis would work.

So starting with involuntariness, the first component of that is legal -- legal compulsion. Once CMS selected plaintiffs' drugs last summer in August, plaintiffs had a statutory obligation to participate in the program for a minimum period of time, either 11 or 23 months, depending on exactly the timing. That's right there in the statute.

There was no way to get out without paying that monstrously large excised tax.

THE COURT: Mr. King, I want to make clear because the papers are -- there's no consistency with your adversary on this position.

I'm going to ask this from the government counsel as well. You said 11 to 23 months, and they say 30 days. So which one is it? Those are extremely different timelines for withdrawal, no?

MR. KING: They are incompatible, mutually exclusive. One of us is right; one of us is wrong. Let me tell you why I think we're right.

THE COURT: All right.

MR. KING: The statute refers to withdrawal by the Secretary, and that's 42 U.S.C. 1395W-114(a)(b) -- 4(b)(i) for those of you -- withdrawal by the Secretary.

Then separately, in a different provision with a different heading, it refers to withdrawal by whom? By a manufacturer. The withdrawal that we're talking about here today is by a manufacturer.

The government's defense is that a manufacturer can avoid the program and its mandates by withdrawing from the program. So we're under withdrawal by a manufacturer. And the by a manufacturer says unequivocally it's a minimum of 11 or 23 months. That's legal compulsion. That means that there's no way for us to get out of the program immediately, certainly not the 30 days, as they say.

The practical reality, Your Honor, just to bring it all the way to the ground, is that plaintiffs would have to have withdrawn from this program in January 2022, months before the statute was enacted, in order to avoid things like the duty of last October to sign the manufacturer agreements.

So that's really all I have to say about legal compulsion, which is that there's a statutory requirement that we be in this program for a time.

The big-ticket item, though, Your Honor, is economic compulsion, so let me shift gears and talk about that.

The government insists that plaintiffs have options because they could withdraw, for example, all their drugs from Medicare and Medicaid. They have options to get out of this program. But those options exist on paper and not in the real world. Let me just explain one piece at a time why that's the case, starting with the excise tax.

You asked earlier about the excise tax. I'm the person up here to try and explain how that incredibly complex mechanism works.

THE COURT: And why are those numbers so different between what you're claiming and what the government's claiming?

MR. KING: Well, I think the government is -- the government is going to get up and advocate on their view on this, but they're putting a lot of spin on the ball and they're stepping away from what the statute actually says.

So the statute has a very complex formula. This is 26 U.S.C. 5000D. It calls for a tax that's a ratio of one figure to another.

And when you do the math, as the Congressional Research Service did, what you get is an excise tax of starting at 186%, going all the way up to 1,900%. There's a debate in this case about, well, what is the percentage? Is it actually 95%?

THE COURT: I mean, that's the government's position,

correct?

MR. KING: So, yeah. Let me tell you why that's not right, Your Honor.

The 95% figure is not accurate because the government uses an analogy. They say suppose there's a bill for a hundred dollars, a $5 sale and $95 tax on top of that $5 sale. $95 is 1,900% of 5, so even if you do it their way, it's 1,900%. It's 19 times.

And just to -- again, to give you a concrete example, this is at ECF 30-10 in our case, and in the Vineis declaration in the Novartis case -- I hope I'm saying that right -- we're talking about more than $90 billion per year is what this would say. Again, sworn declarations haven't been challenged.

So that's what the excise tax would look like. The government also says that the excise tax would apply only to sales to Medicare beneficiaries, only sales in Medicare.

But, again, if you look at the statute, it refers to sales by the manufacturer, full stock, no exceptions.

The by -- you know, to the Medicare part of it, the government has just blue penciled in there through their litigation counsel. That's not how statutory interpretation works.

In the end, though, I guess I'd agree with Mr. Roth that the debate about these points, the finer points of how

the excise tax works, it's academic. As the Congressional Budget Office said -- and this is Exhibit F to the Chiesa declaration -- the manufacturers are going to comply with this program because the cost of not doing so far outstrip the cost of participation.

And so that's the Congressional Budget Office. Don't take it from us. So no matter how you slice it, the taxes are going to be astronomical. That's the tax.

Now, as far as the ability to withdraw all of a company's drugs, all of them, not just the selected drugs, but all of those 120 plus drugs I was talking about earlier for Medicare and Medicaid, that is not an option for too many reasons. The first is what I was referring to earlier: the effect on patients. Millions and millions of Americans who would lose their Medicare coverage for these drugs they depend on in their daily lives. The government really doesn't account for that. They talk about cost savings, but they never really deal with that real human impact.

And by the way, you mentioned drug companies. These plaintiffs do a lot of things. They research. They have, you know, large revenues.

Well, let's talk about what they do with those revenues. The mission of these companies is to research and develop innovative products that improve people's lives. That is woven into the fabric of what they do, and they go out and

they research and develop countless molecules and things that -- 99.98 percent of which do not work out, do not make it to market.

THE COURT: Well, Mr. King, I appreciate the noble mission of the pharmaceutical companies, but they're also businesses that their goal is profit, no?

I don't want to talk about like your clients -- I mean, Mother Theresa is here just developing drugs for free to sell to the American people. I mean, let's explain it for what it is.

These are businesses that not only have a mission of developing these drugs that help Americans, but there's a significant amount of profit that is part of the margin there for doing so. No? And the government is coming in and saying, You can still profit, but less. Do you not agree with that? I presume you don't.

MR. KING: Well, I think we disagree with a lot of what the government says, but I take your point, Your Honor. I absolutely own it. These companies are not Mother Theresa. They are not non-profits. They're for-profit companies, and they're for-profit companies that need to cover their R&D expense for these 99.98 percent of drugs that never make it to market.

THE COURT: That goes back to my question: Where is the rest of the money going?

You're saying that based on what happens with the IRA that you wouldn't be able to do an R&D, but we don't have other information before the Court that says what are your clients and the pharmaceutical companies spending the rest of their money on? How much goes to excess compensation? How much goes to advertisements? How much goes to stock buyback and all these other things that we don't know about?

What you're trying to tell me is that if this money is taken away from the pharmaceutical companies, we will not be able to do research and development to develop new drugs to help Americans and save lives. That's an important fact.

My problem with that is I don't have enough information before me to say if I agree with you or not.

MR. KING: Well, you've got a sworn declaration saying exactly that.

THE COURT: But how much other money do the pharmaceutical companies have, and where are they going? Why can't they take money from excess compensation and put it into R&D?

MR. KING: You know, Your Honor, the government hasn't raised that point. We've not had an opportunity to brief it, so I don't know, standing here, the answer to those questions.

What I do know is, you know, within the four corners of the doctrine -- and maybe this is a good place to shift gears

and talk about the doctrine -- is that the Supreme Court has told us, for example, in *NFIB* and in other cases that a program is voluntary only when the party that's subject to it has the ability in fact -- not just in theory -- but the ability in fact to say no. And given the significant role, the market dominating force that Medicare and Medicaid play -- that's the Third Circuit in the *Sanofi* decision just a few years ago -- the answer to that is no, it can't happen here.

THE COURT: I presume your answer is the same as Mr. Roth's, which is you are not aware of anybody withdrawing?

MR. KING: No, I'm not. And counsel for another company in the District of Connecticut, they have not withdrawn. I'm not aware of any company that has withdrawn. And, in fact, my understanding is that every company that's subject to that program, the first ten drugs, all of them are in court uniformly raising constitutional challenges to it, either directly or through an association. That tells you something about the size and nature of the problem here.

Just to bring it back, if I could, to *NFIB*. The government says *NFIB* and its coercion principle is limited to the federalism context, and I want to address that.

The answer is, no, it is not limited to that context. Federalism was the reason Congress and the Affordable Care Act could not directly impose its Medicaid on the states.

But there is a broader coercion principle that cuts

across cases, cuts across contexts. It's the reason why Congress could not do it indirectly through a condition.

And you see the very same coercion principle in cases like *Union Pacific*, *Thompson*, *Carter and Butler*, all of which involve regulation not of states, but of private parties. All of those cases said -- and I'll just quote quickly from the Supreme Court's decision in *Butler*:

Coercion by economic pressure makes the asserted power of choice illusory. Illusory. That's what we have here. You don't need to take it from me as far as *NFIB* working this way. This is a new case, and so I want to call this to your attention. It's not in the briefing, as far as I'm aware, but I point you to *American Health Care Association v. Burwell*, 217 F.Supp.3rd, 921 from 2016.

That federal district court held that *NFIB* works in exactly the way that I'm talking about here, that it applies to private parties.

The Court acknowledges, yes, there are some differences, but nevertheless, the basic question is still the same.

And so, I guess, that brings me to unconstitutional conditions. The idea of the Unconstitutional Conditions Doctrine classifying as a condition on voluntary participation is not a blank check. There are limits on what the government can do in a condition.

And the question here before the Court is whether or not this program transgresses those limits, and the reasons Mr. Roth gave, the answer is, yes, it transgresses those limits under the Unconstitutional Conditions Doctrine. There what you would look at is, is this program -- is there a nexus and is there proportionality between this program and the government's interest? The answer to that question is no, there is not proportionality here. The government is ransoming the revenues from all of those 120 other drugs that I was talking about to secure compliance as to the selected drugs -- the four selected drugs that are before you today. So there is not proportionality in that regard.

The program, too, is a massive, massive change to the way Medicaid worked from when the plaintiffs signed up for it. There was a noninterference provision that said CMS is not going to interfere with the dealings of the private market, and yet now we have a fundamentally different kind of program, the same kind of fundamental difference that you had in *NFIB*.

I guess I tied into the Third Circuit -- you asked about circuit precedent, the Third Circuit's decision in *Koslow*. This is 302 F.3d at 174, where the Third Circuit said that private entities lack the formidable institutional resources of the states and are more easily coerced by the federal government. So the case for applying the coercion analysis here is even stronger than it was in *NFIB* in that

respect.

I could go on, but, you know, just to deal with a few of the government's other defenses, because that's really what I'm here to deal with, the government says, Well, these cases don't matter because they involve regulation of the market generally. You couldn't sell to anybody, period, under those programs, and that's not true either.

For example, in *Horne*, the plaintiff there -- you know, it was said you could sell juice or wine. You could use your grapes for other purposes. You could sell your farm. None of those things were a defense in *Horne*, and so none of them are a defense here.

Finally, just to wrap up with this idea of the government as a market participant, the government is not acting here as a market participant, as Mr. Roth alluded to.

The government is exercising sovereign power by doing things that no market participant ever could do. A market participant doesn't impose crippling excise taxes on its counterparty. A market participant does not issue regulations that are backed by a requirement to comply, and if you don't comply it's a million dollars a day in civil monetary penalties.

A market participant cannot unilaterally amend the parties' agreement after the fact without the other parties' consent or even notice, and yet CMS has claimed the power to

do that here through their revised guidance.

Finally, Your Honor, just to wrap it up, a market participant under the antitrust laws could never do what the government is doing here. The government exercises significant market power.

Again, that's the Third Circuit in *Sanofi*, and yet the antitrust law says that you can't impose time arrangements when you have that kind of market power, that those are per se illegal under the antitrust laws. That's *U.S. v. Fortner Enterprises* from the Supreme Court.

So at the end of the day, you know, our position is that the government's voluntariness defenses fail, but even if you disagree with us on that, Your Honor, the Unconstitutional Conditions Doctrine and you'd have to answer all the same questions.

So I think at the end of the day, I'm sorry that I can't save you any homework, but the honest reality is that I can't. The Court must resolve the takings claim one way or the other.

THE COURT: Thank you. I appreciate it.

Let me -- it's been a one-sided discussion this morning. Let me at least hear from the other folks and hear if you have any response.

MR. NETTER: A few responses.

THE COURT: By the way, I just want to make this

clear: Counsel, if for any reason anybody needs to take a personal break at any point in time, even before we break for lunch, all you need to do is ask.

I won't need a break, but I'm happy to accommodate. If counsel for any reason needs a five-minute recess or anything like that, just make sure that you're getting my attention to let me know. Fair enough?

Go ahead.

MR. NETTER: Thank you, Your Honor. Good morning. Brian Netter from the Department of Justice for the defendants.

More than 49 million people are eligible to receive prescription drug benefits under Medicare and Medicaid. Large sums of federal money totaling somewhere in the nine figures are dedicated to providing those beneficiaries with prescription drugs.

So it would make sense that drug manufacturers would want to sell their drugs to the federal government, and it would make sense that they would want to maximize the revenues that they obtain in doing so. But the Constitution does not entitle drug manufacturers to dictate the terms on which the government will purchase their product. If manufacturers do not wish to sell their product on the terms that the government is making available, then the manufacturer's recourse is to stop selling their products to the government.

As the Court is aware, every manufacturer of a drug that was selected for the Medicare Drug Price Negotiation Program is involved in litigation in some manner or fashion. None of those manufacturers has signaled an intent to withdraw from Medicare.

Over the course of today, the federal government will be offering its responses to the various objections that are raised by the four manufacturers.

THE COURT: Since you say -- well, you've answered my question. I've asked it twice on the other side: Has anyone withdrawn?

And you're saying not only has no one withdrawn, but no one has even expressed an intent to withdraw. Doesn't that cut against you, too? That maybe the program is so coercive in nature that they're simply signaling what the plaintiffs' counsel is arguing, which is we can't withdraw. We are forced at gunpoint to execute these agreements with the government.

MR. NETTER: I don't think so, Your Honor. And this is all ultimately a question of leverage, and we'll get into this over the course of the government's presentation.

But there surely would exist a set of conditions under which the pharmaceutical manufacturers would say, This program isn't worth it to us. We aren't making money on this. We'd rather dedicate our resources toward something else.

We're not at that point. Each of the manufacturers

is -- signed an agreement to participate in the negotiation program, has made a counteroffer as part of that program.

There hasn't been any withdrawals, and I think that that just signals that the negotiation program is functioning the way that Congress intended and in the way that, you know, appropriately determines whether there's a price that the government is willing to pay, that the manufacturers are willing to accept for these products.

So I will be handling this morning all of the presentations that the various plaintiffs' counsel presented. My colleagues will be splitting the afternoon discussions.

But for purposes of this morning, I want to emphasize four points. First, the premise of plaintiffs' takings challenge is that the government is forcibly appropriating their property to serve a public function, but there is no physical taking.

Medicare is a voluntary program. It's a voluntary spending program, and there is no applicable takings standard for voluntary commercial transactions entered into between the government and a willing commercial counterpart.

Second, even if the negotiation program were somehow evaluated as a regulatory program, as -- instead of a way in which the government is the proprietor of its own funds, it still wouldn't run afoul of the Fifth Amendment because of the opt-out mechanism.

Third, the Unconstitutional Conditions Doctrine has no application here because, again, there's no constitutional right in danger of being trampled.

And fourth, drug manufacturers are not subject to some form of unconstitutional coercion.

Mr. Roth presented on behalf of the plaintiffs the question of whether there is a physical appropriation, and the premise of that argument is that the IRA creates some sort of statutory obligation, not just to agree to a price, but to physically make pills or syringes or whatever the drug product is, to physically transmit or transport drug products at that price.

And he said that that was a matter of statute, and I thought that we were going to have a chance to talk about what statutory provision actually imposes that requirement. It turns outs, however, that there is no statutory provision that imposes such a requirement because the program as a whole and individual sales of prescription medications under that program is voluntary.

Now, as the Court is aware, both of the courts that have considered constitutional challenges to the IRA so far, the AstraZeneca Court and the Dayton Area Chamber Court, have found that there is no compulsion.

Chief Judge Conley down the street found that neither of the IRA nor any federal law requires AstraZeneca to sell

its drugs to Medicare beneficiaries.

Judge Newman in the Southern District of Ohio wrote as a more general matter that the law established in the Sixth Circuit and beyond is clear. The participation in Medicare, no matter how vital it may be to a business model, is a completely voluntary choice.

So the plaintiffs' theory seems to turn on the use of the word "access." Now, the statute says that the manufacturers have to provide access to a price as part of the Drug Price Negotiation Program.

Now, that's a fairly thin read on which to infer that actual commercial transactions need to take place at that price. So I think it's useful, first of all, to highlight the statutory text.

I would refer the Court to the provision on civil monetary penalties. This is 42 U.S.C. Section 1320f-6 or Section 1197 of the Inflation Reduction Act.

So what that provision says -- and I'll try to read this verbatim. It says, "Violations Relating to Offering of a Maximum Fair Price." That's the subheading.

"Any manufacturer of a selected drug that has entered into an agreement under Section 1320f-2 of this title with respect to a year during the price applicability period with respect to such drug that does not provide access to a price that is equal to or less than the maximum fair price for such

drug for such year ... to a maximum fair price ... eligible individual who is dispensed such drug during such year shall be liable for the civil monetary penalties that the statute identifies."

So what does that mean? If you only pay a penalty to the individual who is dispensed the drug and there is no separate obligation to dispense the drug, then all the statute is doing is creating an if-then relationship; if you sell the drugs, then you can charge only prices at or below the maximum fair price that has been determined through the negotiation program.

Nothing in the statute or in its program guidance requires manufacturers to manufacture any particular quantity of the drugs or to distribute them in any particular manner.

One can imagine that if this were an actual requirement of the program, how much statutory and agency implementation would be required to create the standards for understanding whether the manufacturer's making the appropriate amount of the drug available, et cetera.

This would be a fairly serious undertaking, but none of that is in the statute. None of that is in the program guidance that has been issued by CMS in this case simply because these requirements don't exist, and that's an important distinction here because none of the cases that have been cited by the plaintiffs involve a program that is truly a

voluntary undertaking that does not exist in the context of an obligatory legal framework.

Now, here, the drug manufacturers can sell their drugs outside of Medicare at whatever prices they choose to charge, and they don't need to sell to the government at all.

So this negotiation program has set up an operation where the government is going to determine through the receipt of information and through a back-and-forth with the drug manufacturers the price that it's willing to pay.

And hopefully, at the end of the day, the parties can reach a price that the government is willing to pay and the manufacturers are willing to accept. If that is not the case, then the manufacturers have a number of different options.

THE COURT: What are those? Walk me through the options for withdrawal and the difference between the time period of 11 and 23 months, which is what the plaintiffs are claiming, and I believe you guys are claiming 30 days, right?

So there's a discrepancy there on how you can withdraw, the time period to withdraw. Can you walk me through that process?

MR. NETTER: Yes, Your Honor. So the distinction is there are two statutory provisions for withdraw from medication. Now, I think that our friends on the other side accurately described the key distinction, which is that the 11 to 23 month period is a period where under the manufacturer

can terminate its Medicare subscription agreement.

So for purposes of this taking claim, a company would have to file its notice no later than January 30th, 2025 to be out of Medicare in time for the first sales that are actually subject to the maximum fair price.

So it's not entirely clear how -- even if that were the only way to get out of Medicare -- that helps the plaintiffs, because if their position is that this program can't result, that they have to at least give up an arm under this program, then one would expect that they would have initiated this process. They still have time to initiate this process before they sell a single drug, subject to the maximum fair price.

The 30-day period on which the government is relying is the provision that entitles the Secretary to remove a manufacturer from Medicare for good cause. So as we explained in our brief, good cause is a capacious concept that takes on a meaning that makes sense in its context.

And in the revised guidance that CMS issued as to the implementation of the negotiation program for this first price possibility here, the agency determined it would constitute good cause if a manufacturer said, I don't want to participate in this program.

THE COURT: We want out. That would be sufficient.

MR. NETTER: Right.

THE COURT: Or we can't agree on a price.

MR. NETTER: Right. They want -- well, if they can't agree on the price and as a result want to get out --

THE COURT: Right.

MR. NETTER: -- that would constitute good cause for them to get out.

It is rather curious for the plaintiffs to be challenging what is, in effect, a favorable interpretation of the statutes. If they were trying to challenge that directly, we would say that they don't have standing, right? Because you don't ordinarily have standing to say that an interpretation is to your benefit. Here they want the interpretation to be contrary to their benefit so they can say that it is more onerous and creates a constitutional barrier.

But, you know, especially in a circumstance in which there are principles of constitutional avoidance that can dictate how an agency is going to implement and interpret its statutes. That doesn't seem to be an appropriate question that really ought to be before the Court here, both because the agency has made the determination that it has made and because even under the 11 to 23 month standard, there still is ample time for these manufacturers to exit Medicare, should they wish, prior to the maximum fair prices going into effect.

So that covers exiting entirely.

The second opportunity or option for the manufacturers is that they can divest of an individual drug product that is

subject to negotiation such that they no longer would be the manufacturer for that drug product and wouldn't have any requirements under the program.

Now, the plaintiffs' response to that is to say that it would be a fire sale, right? If they went on to the market and tried to divest the various drugs, subject to negotiation, well, they would only get the value of the drug based on what the maximum fair price is, and they say that that's unfair.

Now, that seems, to us, to be a pretty telling concession in that the government is determining how much it's willing to pay, and the pharmaceutical companies are entitled to market their drugs and to monetize them, subject to what willing buyers they have.

But if their position is that they should be entitled to divest their drugs under the old pricing system, prices that the government is no longer willing to pay, then all that's saying is they think they have some sort of vested constitutional right to prices that the government isn't willing --

THE COURT: No one's going to buy their drugs if they're -- I mean, if you're asking to divest themselves of one of their products, who is going to buy that product knowing full well they'll be in the exact same boat that these folks are all sitting in today?

I mean, I understand that argument. There's no

argument simply saying we have to sell for this price because who else is going to buy for a higher price when they've got the federal government that is going to be staring right at them on day 2.

So isn't that the argument they're making? Of course we have to sell it for this lower price. No one will buy it at a higher price because your folks will have the IRA and they're going to be subject to the same conditions or requirements, however you want to voice it today, that they're under right now.

MR. NETTER: I think that fundamentally we agree with that, Your Honor. The point is that Chief Judge Conley wrote in his opinion that what the government is providing here is access to an enormous market, and some companies would view that as an opportunity.

So the plaintiffs have complained through these proceedings that any drug that's subject to negotiation is included on all of the formularies. That doesn't impose a requirement on the drug manufacturers again. All that says is that the -- the pharmaceutical benefit management companies that are creating these formularies, they all have to include the drugs, subject to negotiation. So there's a bigger market for these drugs.

Now, the price that the government is willing to pay is -- that's the price the government is willing to pay, and

whether or not there are companies willing to manufacture the drug at those prices, if -- that's a question for the market to bear.

But as to the question of whether the plaintiffs should somehow be entitled to divest these drug products at a rate that presumes that the government is going to keep paying the rates that it historically paid, there's simply no constitutional warrant for such a claim.

One can imagine outside the drug context that there are all sorts of companies -- defense contractors come to mind -- that would love to say that there's a specific rate that they had anticipated that the government would be paying for a new set of fighter jets and that the government is the only client of these defense contractors.

So what else are they to do? But any company that is in pursuit of process necessarily takes risks and has to make decisions under the guise of uncertainty in pursuit of those profits. And there is no constitutional right to contract with the government in order to make those bets turn out for the companies that have made them.

Now, the cases that the plaintiffs have cited in opposition to our theory of voluntariness all suffer from the defect that they involve some sort of obligatory legal framework, and they don't arise in the context in which the government is the purchaser or the government is using its

spending clause authority as the proprietor of its own assets as opposed to regulating how a market is going to operate.

So the *Horne* case regulated all sales of raisins on the open market. These aren't sales of raisins to the government. They're sales to other purchasers on the open market.

Likewise, *Valancourt* created an --

THE COURT: I want to make sure I'm clear on this issue. That's one of the issues in dispute, right?

So when you analogize the program in the context of, like, a regulatory program, right? And it's the plaintiffs -- or I'm sorry. The plaintiffs are returning in the context of a regulatory program.

Your folks are saying no, that's not what we're looking at. We look at it as a product of Congress's spending powers.

Is that accurate? Is that the dispute here?

MR. NETTER: That is, Your Honor.

THE COURT: All right. Why are you right?

MR. NETTER: Well, we're right because this is plainly an exercise of Congress's spending clause authority, and the case is -- over many decades and in many contexts that have discussed Medicare spending have acknowledged that this is a voluntary program because it arises in the spending clause content.

Now, in many of those cases the issues that are before the courts involve economically significant disputes for the

industries. For example, there have been hospice providers and nursing homes that have come in to court to say, Well, Medicare is not truly voluntary for us because one can imagine that a hospice provider or a nursing home is getting the vast sum of its monies from Medicare and Medicaid.

But the courts have, nonetheless, said in those contexts that Medicare is still -- it's a spending clause program in which the government is procuring services on its own account, and the government gets to decide how it's going to spend its money.

So that's fundamentally why this is a spending program of -- an exercise of the government's proprietary function and not a regulatory program.

Now, the response to the plaintiffs' offer is, well, you know, the government is the sovereign, so, you know, it does things that one would not expect to see in a transaction just between two people on the street.

And it is surely true that the government, as a proprietor of its own funds, has to operate in a different manner than would two individuals interacting through some arm's-length transaction on the street. There are pros to that, and there are cons to that. There aren't constitutional claims that can be brought into court when there's a transaction on the street.

But at the end of the day, the government is still

spending its money, and parties cannot bind -- cannot obligate the United States to spend money with their company to buy their products at rates that they would like the government to pay.

The other case on which plaintiffs spent a lot of time is the *Valancourt* case. This is the copyright case that was decided by the D.C. Circuit last year.

That was another circumstance in which there was a obligatory legal framework that couldn't be escaped, so the Court suggested that perhaps the analysis in that case would have been different if there were some straightforward process for renouncing copyright protections such that the publisher or the owner of the creative work could understand this as a transaction; that in exchange for the copyright protection, that you have to provide these copies of the work.

Instead, the Court found that there was no way to get out of this system without paying a fee such that this was an obligatory legal framework, which is, again, not the situation here.

THE COURT: Well, the plaintiffs are arguing it is.

MR. NETTER: Well --

THE COURT: They are arguing that these are not conditions, these are mandates, that they are compelled to agree with the government on these terms. They don't really have a choice in the matter.

Isn't that the argument by opposing counsel?

MR. NETTER: I think that --

THE COURT: I'm paraphrasing. I'm simplifying for purposes of having a discussion. But, in essence, isn't that what they're saying?

MR. NETTER: Sorry. I think that that's what they're arguing, but they're hard-pressed to identify what the legal compulsion is.

The thrust of their argument is that there is a practical compulsion. That's once we set aside the fact that the statute doesn't actually obligate the manufacturer to introduce doses of the medications into commerce.

So once you resolve that issue, then what's left of the plaintiffs' arguments is, Well, we make a lot of money off of Medicare beneficiaries, and we don't really want to get out of Medicare with respect to an individual drug or with respect to all of our drugs.

So even though it's not legal compulsion, there's some sort of practical pressure that is exacted by the government, but for purposes of the Fifth Amendment and for takings analysis, there isn't a constitutionalization of commercial transactions between the government and government contractors.

And there have been many decades and entries, transactions in which the question is, is there a price that

the government is willing to pay, and is there somebody willing to provide the services at that price?

And if the answer to those questions is yes, then that's the end of the story. The Constitution doesn't get involved in determining whether the price that -- whether the price that reflects the meeting of the minds is the best price or a price that can be validated through some sort of economic means.

Now, I should note also that even in circumstances where there is some mandate for a company to provide some service -- and usually this is in the context of public utilities -- the Supreme Court has held -- this is the *Verizon v. FTC* case. That one doesn't apply this typical takings analysis to say you're taking the electricity, therefore the government or the courts have to step in at the outset and figure out what the price should be for that electricity.

So the Court in *Verizon* says that when you're in this utilities context, that the constitutional questions are answered on the basis of the rates, not the methods for determining the rates.

And, of course, at this juncture, we don't know what the rates are because we're only at the threshold with this sort of facial challenge.

Now, I promised at the outset that in addition to covering the fact that there's no forced appropriation here,

it's also our position that you can opt out. We covered in -- most of the aspects of this.

You can opt out by exiting Medicare entirely, you can divest or you can stay in the program and you can just not make any sales into the program. These are three ways in which one is not forced to make sales at a price that the manufacturer deems to be undesirable.

I think we have, in fact, covered that point. We can move on to unconstitutional conditions.

So the Unconstitutional Conditions Doctrine provides that, at a high level, the government can't coerce people into giving up their constitutional rights.

Now, here the implication of that doctrine doesn't help the plaintiffs because, as we've been discussing, they don't have a constitutional right to continue selling their drugs as part of a government program.

So the plaintiffs' theory is they try to analogize to the land use context. So there are cases typically known as the Nollan-Dolan Doctrine that refer to how the Unconstitutional Conditions Doctrine is going to be applied when the government tries to take property in the context of granting zoning approval or some land use authority.

Now, the Supreme Court in *Koontz* explained why it's necessary to have a special test in that context, and that's the nexus proportionality test that was referenced by one of

the attorneys on the other side.

But the Court in *Koontz* explained why it's essential to have a different standard in the land use context because the government has so much discretion in deciding whether or not to approve a particular use of land and that it would be easy to abuse that power by saying, okay, well, you can use this plot of land for the purpose you want to use it.

THE COURT: I presume your position is that's not analogous here. The government is not stepping in to tell them how to use their profit at all. It's simply a pricing issue, correct?

MR. NETTER: Right. It's a particular context that really arises in the land use context. It has not been applied outside of that context. It shouldn't be expanded here, I think, for all the obvious reasons, that this isn't zoning. This isn't land use. This isn't a place where in order to sell to the government, the plaintiffs have to give up their rights.

The government will offer a price, and the plaintiffs can accept that price or it can reject that price.

THE COURT: But then how do you also reconcile that with your prior analogy where you're talking about government contracts and fighter jets?

That's not analogous to the Medicare program where you have millions and millions of Americans who are getting their

medication and pharmaceuticals through the government.

So isn't that also separate and apart from some typical government contract where some company is manufacturing fighter jets with the United States? I mean, isn't that separate and apart, similar to this land use analogy that fails?

MR. NETTER: I don't think so, Your Honor. I mean, that's also a circumstance in which there are companies that have developed expertise to manufacture certain products, and they will make bids to the government to manufacture things that serve the government's needs at particular prices.

But, again, there's no role for the courts to intervene in the defense contractor cases to say, well, this company really needed that contract because they were banking on the fact that there was going to be some war that was going to require some new form of stealth jet.

This isn't the role of the courts, and the companies get to decide where to develop their expertise and which sorts of engineers to hire, how they're going to be able to come up for their bids for these individual contracts, and either there's a meeting of the minds or there isn't.

The Federal Circuit in the context of government contracts has held that there isn't really a takings overlay that the courts should be looking at. Once there is a contract, the question is what are the terms of the contract?

We've had a meeting of the minds, and that's the end of the story.

So I do think that the defense contractor and the negotiation program analogies are fairly similar here.

On the coercion point, at the end of Mr. King's presentation, he referenced the *NFIB* cases, *NFIB v. Sebelius*. And as he foreshadowed, it is fundamentally the view of the federal government that *NFIB* is about to take sovereignty.

And the Supreme Court has said in many times -- in many different contexts that its holdings have to be understood in the context in which they arise. *NFIB* was a case in which the federal government was using its spending authority to try to convince the states to expand the availability of Medicaid within those states.

The Court was trying to enforce the limitations on the government's regulatory authorities. So the concern that motivates *NFIB* is that the government has limitations on its ability to regulate and can't make an end run upon those regulatory limitations by altering the fundamental characteristics of the relationships between the federal and state governments.

Here the fact that this arises in a proprietary content where it is not the government trying to overstep in the way in which it can regulate is, again, a critical point.

The plaintiffs' approach to *NFIB* we think approves far

too much because, again, it would just constitutionalize the law of government contracting in the way where there is no precedents. We don't have cases suggesting that *NFIB* is of the breadth that the plaintiffs would have suggested.

They cited a new case we hadn't seen, which we just tried to pull up during their argument. That case doesn't seem to turn on constitutional grounds at all. It seems to be about the statutory scope of the Federal Arbitration Act.

Even if there were -- and that case was in the Northern District of Mississippi. There certainly isn't any applicable precedent here in the Third Circuit that would suggest that *NFIB* has the effect the plaintiffs are trying to attribute.

Now, in describing what form of coercion exists, the plaintiffs tried to suggest that there would be effects on patients, on patient outcomes, and that despite their corporate structure and their obligations to their shareholders, that they can't be coerced to do things that are bad for patients.

We'll certainly discuss this some more this afternoon in the context of the statutory claims, but I do think it's important to mention now that the prerogative to set the national policy here belongs to Congress.

But it is certainly a matter of judicial notice that the pharmaceutical industry spent a lot of money trying to lobby Congress against the policy determination that Congress

ultimately made. But their concerns about patient outcomes are certainly undercut by some of the problems that the IRA was designed to defeat.

For example, the phenomenon of product hopping, in which innovation is stifled with respect to new pharmaceutical products by companies extending their periods of exclusivity so that they don't need to innovate and develop new products that will actually result in better health outcomes.

So I think with that, Your Honor, we've covered all of the main points that the plaintiffs have addressed this morning. Fundamentally, this is a voluntary program. It's voluntary at a high level because no company is obligated to participate in Medicare that does not wish to participate in Medicare.

It's also voluntary with respect to individual sales because there's no statutory or regulatory provision that obligates a manufacturer to introduce into the stream of commerce the individual pills that are going to result in a transaction at or below the maximum fair price.

So there is no taking because this is a voluntary commercial transaction. The other theories that the plaintiffs have creatively tried to apply to this circumstance are inapposite. And as a result, we would ask the Court to rule for the government on the voluntariness issues.

THE COURT: Thank you, Mr. Netter.

Mr. Roth, you're coming back?

MR. ROTH: If I may.

THE COURT: Is it rebuttal?

MR. ROTH: That's what I was hoping, Your Honor.

THE COURT: You may have that opportunity. I think Mr. Chiesa requested it. I didn't grant it, but I think he presumed that I would, so it's granted.

MR. ROTH: I don't want to take anything for granted, but, thank you, Your Honor, for that.

Your Honor, at a high level, I understand the government -- trust the government's argument on takings to be -- look, we run Medicare. We get to decide how much we want to pay for products, and you, manufacturers, can't dictate to us that you want a higher price. That's our prerogative.

And you know what? I completely agree with that. They can decide how much they want to spend, how much they want to subsidize because they're the insurer to cover the drug.

And if they say from now on -- just to use the EMS example, Eliquis, they say, Look, we're not going to pay for more than $10 a pill, a bottle, whatever, for Eliquis.

We wouldn't be here with the takings clause challenge to that. They can do that. In fact, that would have been a much simpler thing to do if that's really what they wanted to do. They don't need us for that. They can decide how much

they want to pay. They set the coverage terms.

The point of the statute is to obligate us to sell it to them at the price they want. That's why the statute regulates us and forces us to agree to provide access to the price.

So just to flip it around, sure, they don't have to buy at a high price, but we can't be forced to sell at a low price. That's the thrust of our position and about what the statute does.

Let's look at and take the fighter jet hypothetical. The Pentagon doesn't want to pay more than a hundred million dollars for a fighter jet. Nobody can force them to pay more than that.

But they can't turn around to the defense contractor and say, you know, you've got to provide us access to that jet for 50 million or else we're going to impose taxes on even a billion dollars a day until you fold and turn it over.

That would be a taking, and that is what this statute does by requiring the manufacturers under threat of penalty to promise access to the price. That's the obligatory --

THE COURT: Even with the opt out -- even with the withdrawal provision that you're --

MR. ROTH: No. The opt-out provision is a separate thing because -- yes. We can say, look, we can't handle those penalties. We're completely pulling all the products from

Medicare and Medicaid all together so that we don't have to deal with you ever again.

That gets into conditions and the restrictions on what they can do with the conditions. Again, I'm focused on the first part of it, which is you promise to provide access or you pay this huge amount every day until you fold. That is the taking.

Now, they say the statute doesn't require that, but I didn't hear any response to the hypothetical about the senior's discount. I don't think the word "access" in the statute is an accident.

Again, they didn't need to regulate us at all if all they wanted to do was restrict the amount they were willing to pay. Counsel pointed to the provision that's a simple monetary penalty for charging more than the maximum fair price, and that is true.

There is a penalty provision in the statute that says, in addition to agreeing to provide access at the fair price, if you charge more, we're going to penalize you ten times the delta, but that's the penalty after the fact.

At the front end, you have to agree to provide access to the price, and if you don't provide access to the price, you're not complying with your contract. If you're not complying with your contract, you're in trouble, and there's also a million dollars a day penalty for not complying with

your contract.

Then I heard the government say, well, this is -- there's nothing in the guidance about how you have to provide -- how you have to sell, but actually what's telling about the guidance, the guidance goes to lengths to say, oh, manufacturers have lots of options.

We had already sued before the guidance came out. So they took their time to say, CMS, look, this is voluntary. You have got options. You can divest the drug. You can pull out of Medicare entirely. You can pay the penalty.

You know what they never say anywhere in the guidance? You can withhold the one drug if you don't like the price and continue to receive reimbursement for everything else, no problem. There's not a word of that in 186 pages of guidance. I think that's very telling.

Just to close, Your Honor, we had some discussion about policy-related issues. Is this good, is it bad for Americans, for innovation? And so on.

Obviously, we think it's bad policy. I'm not going to try to convince the Court. I don't think it's appropriate for me to try to convince the Court that it's bad policy. That is a congressional judgment.

THE COURT: I agree.

MR. ROTH: But what I would like to do is read a quote form Justice Holmes from *Pinnacle v. Mahon*, which is one

of -- an early takings case.

He said the following: We're in danger of forgetting that a strong public desire to improve the public condition is not enough to warrant achieving the desire by a shorter cut than the constitutional way of paying for the change.

That's our point. Yes, Congress can be able to drop high drug prices. Yes, Congress can limit how much they're willing to pay in Medicare, but they can't take constitutional shortcuts of saying we're going to force you to turn over the property, but we don't want to pay you the market value for it.

Thank you, Your Honor.

THE COURT: Thank you, Mr. Roth.

MR. KING: Your Honor, I'm the last stop between you and all of us and the break, and so with your permission --

THE COURT: I don't take breaks. I'm a machine. I will get you all your break shortly, but let me hear what you have to say in rebuttal. I'm still listening.

MR. KING: A break for all of us mere mortals.

Just five points, Your Honor, on rebuttal. Number 1, legal compulsion. Mr. Netter, when he stood up here, conceded that the 11 and 23 month manufacturer withdraw delay applies, and given that, there was no way for plaintiffs to get out of this program immediately, as CMS said.

THE COURT: Well, no, but didn't he also say

something about the fact that good cause would allow you out in 30 days, and there's been guidance that says that if you guys want out, that's good cause.

So I think he was agreeing with you about your initial position, but he was saying that 30 days is right, too, because all you have to say is I want out, and that would be enough for you to go.

MR. KING: It's true. He did allude to that. He alluded to the guidance, but -- and he focused in particular on good cause, so let me just to try to persuade you that good cause doesn't matter here.

Good cause is only in the withdrawal by the Secretary provision. It does not appear in the withdrawal of the manufacturer provision, so you never get to the concept of good cause.

Mr. Netter is right. Good cause is a capacious concept. It applies broadly, but you don't even get to the question of good cause unless you're talking about withdrawal by the Secretary.

What we're referring to here and what the guidance makes clear is that this is a withdrawal that would be initiated not by the Secretary, but by the manufacturers.

That's point number 1. May I continue?

THE COURT: My more intelligent law clerk may have a question.

January 2022 or January 2025? Different numbers keep being said here. What is the cutoff or what's the deadline?

MR. KING: Thank you for that opportunity. There are different cutoffs.

If the manufacturers wanted to avoid any part of the program at all, they would have needed to have withdrawn by January 2022 to avoid, for example, the requirement backed by the excise tax to sign the manufacturer agreement last October.

So -- and January 2022 is before the statute even was enacted, so that's -- if you wanted not to have to do anything in the program --

THE COURT: Right.

MR. KING: If you want to be part of it, it's 2022. If -- Mr. Netter referred to 2025, and his point there, which is accurate, is that if you don't want to have the maximum fair price, the MFP ever come into effect, it comes into effect January 1, 2026.

If you never want to be subject to that MFP, then I think you'd have to withdraw by -- it's January of either this year or next. I don't recall. But it's not 2022.

THE COURT: All right.

MR. KING: It's either 2024 or 2025. But this matters here, right? It matters, for example, for the First Amendment argument Mr. Roth is going to give this afternoon.

There is a period of time that, no matter how you slice it, these manufacturers are required by statute, backed by excise taxes to be in this program, and that's legal compulsion.

Mr. Netter says we don't have legal compulsion. We do. That's legal compulsion right there.

As to economic compulsion, my second point, Mr. Netter talked about divestiture, the ability to divest these drugs, and we agree, Your Honor, with everything you said about that, but I just add on top, divestiture just passes the takings problem to someone else.

And by the way, divestiture was not a defense in *Horne*, in *Loretto*, or in other physical takings cases, so for that reason, it's not a defense here either.

Number 3, Mr. Netter talked a lot about the government acting as a market participant, relying on its spending clause authority.

It is true the government is spending money when it operates Medicare, but here at this program, that's not the only thing or even the main thing the government is doing. As Mr. Roth pointed out, the government is regulating its sovereign capacity.

It is requiring the plaintiffs here to do things. It is imposing on them excise taxes and requiring handing over information and other things. It's imposing regulations.

So this is not only a spending clause. It's a spending clause augmented with very significant sovereign power, and that fundamentally changes the analysis.

Mr. Netter said, well, the government acts differently than people on the street. Maybe that's true, but there's nothing that says the government has to operate in the way it has here, and, in fact, there are many, many government programs that look at work differently, that don't have the coercive overlay.

Two points remaining. Again, there was a reference to a need for legal compulsion. That's -- actually, we have that here, but even if we didn't, there's economic compulsion.

The court in *Valancourt* talked about the inability to withdraw on a costless basis. There is no costless withdrawal option here.

And then finally, on Unconstitutional Conditions Doctrine, the proportionality test. Mr. Netter said it doesn't apply here. He said it's limited to the land use context. Not true.

If you look at the *Dolan* case, it drew on *Perry v. Sindermann*, which was not a land use case. It's a public employment case.

If you look at *Cedar Point*, it refers to *Monsanto*, also not a land use case. So we think that the special conditions that triggered proportionality apply here and that this

program is not proportional for all the reasons we've given in our briefing, but especially the fact that participation is conditioned not just on withdraw from Medicare, but also Medicaid, an entirely separate program, which just goes further to show that the government's condition here is not proportional.

But even if you disagree with us on nexus proportionality, even if you take out of Nollan and Dolan, it's still clear that the baseline unconstitutional conditions test would apply.

In other words, you take the thing that's a condition, you make it mandatory, and you decide whether it's constitutional.

THE COURT: All right. I have no further questions.

MR. KING: Thank you, Your Honor.

THE COURT: Anybody else coming up?

MR. KING: Nope.

THE COURT: Everybody is ready for a break? All right. Why don't we do this. Why don't we recess for lunch.

I know we started a little bit late, but, Counsel, just do me a favor. I know we spoke briefly off the record, but I at least would like to put something on the record before we get into the next claims in the afternoon about subject matter jurisdiction.

I do think it's important to have something on the

record even if this case is distinguishable from some of the other related or unrelated cases, as you want to call them, in other districts.

So just be mindful that I would like to at least have a discussion about that before we go into the counts.

Anything further from plaintiffs before we take a break?

MR. CHIESA: No, Your Honor. Thank you.

THE COURT: What about Mr. Netter, anything from the government before we recess?

MR. NETTER: No, Your Honor.

THE COURT: Thirty minutes, is that sufficient? Do you want to do 45? 30 minutes.

MR. CHIESA: Your call.

THE COURT: I'm going to say 30 minutes. If you guys reach back out and tell us you need a little more time, I'll accommodate.

Thank you. We are adjourned for this morning.

THE DEPUTY COURT CLERK: All rise.

(Luncheon recess was taken from 12:37 p.m. until 1:17 p.m.)

THE COURT: Thank you. You may be seated.

Folks, we're back on the record.

I know there's an agenda or an itinerary for this afternoon, but just briefly, I know we spoke about this

earlier off the record, but I think it's worth noting because there was no briefing on subject matter jurisdiction.

And I just want to be clear that that's not an issue that's either being raised by the Court or there's an issue before me. As you guys know, I need to make sure that the Court has jurisdiction whether you raise it or not.

I do know that there was at least one decision out of Texas where there was a finding that the claim does arise under the Medicare Act, and because of that, plaintiffs would not have standing or a substantive basis for a claim for reimbursement.

It was not a federal question before this Court. I don't know who wants to address that first, but I want to hear at least something on the record that says why is that issue not before me in this particular case, if you don't mind?

MR. SVERDLOV: Good afternoon, Your Honor.

I think it makes the most sense for the government to address that. Plaintiffs will surely say that the Court has jurisdiction.

THE COURT: I agree. So, yeah, let's hear why you're not -- you're not raising the issue as to whether there's --

MR. SVERDLOV: Your Honor, in the interest of clarity, I want to maybe separate the question out claim by claim because, of course, we do have some jurisdictional objections.

We have constitutional and jurisdictional objections on the Eighth Amendment jurisdiction. We have statutory jurisdictional objections on the statutory claims.

We have not raised the type of channeling arguments that were at issue in the Texas litigation, among other reasons, because that litigation involved providers. And under the case law, provider's claims of the type that they were bringing are channeled.

Now, manufacturers are differently situated in a number of respects that, from our standpoint, means that we think that argument is not one that was worth raising here.

We have also, as a general matter, again, aside from the Eighth Amendment claim, we have not challenged the subject matter jurisdiction with respect to the constitutional claims.

I'm happy to sort of explain why, if that's of interest to the Court. The bottom line is that on the First Amendment claims, the Fifth Amendment claims, we have not made a jurisdictional objection once the companies named the primary manufacturer, who are, in fact, being affected by the program.

They have the -- the companies do have some compliance costs if they choose to participate in the program, and we think, under those circumstances, an Article III objection doesn't really fit within the contours of this case.

I will say, obviously, the Court in Delaware in the *AstraZeneca* decision raised a question about whether pleading

a property interest that's affected goes to the merits or goes to jurisdiction.

And in the interest of clarity, I just want to say that we agree with the Court down the line on the *AstraZeneca* decision. We think certainly the case law is mixed on that question. We think the Court got it right. We also agree for reasons that are not relevant here on the jurisdictional ruling on the statutory claims.

Here we don't have the same defect -- the same Article III defects on the statutory claims, among other reasons, because as alleged, Novo Nordisk has, in fact, been affected by the interpretation they're challenging. That was not the case for AstraZeneca.

So I think with that, there's -- from my standpoint, I think there's not much more that we have to say. I would love to relieve the Court of some amount of work, but I think -- I think --

THE COURT: Yet, I'm asking for it anyway, right? I'm asking you to argue something that was not briefed, but I appreciate it.

So you're saying this is even different than the Delaware decision even more recently that dealt with a pharmaceutical -- that was AstraZeneca, so that was a pharmaceutical company --

MR. SVERDLOV: It was, in fact --

THE COURT: It was a due process claim in that one as well.

MR. SVERDLOV: Correct. Correct.

So I think that case is a little bit different in the sense that that manufacturer really emphasized the statutory claims much more than the constitutional claims. They were present in that case, and the Court gave them very thorough consideration.

But the thrust of certainly the briefing and the discussion was on the statutory elements. And the fact of the matter was in that case, as we think the Court correctly identified, the plaintiffs were challenging a statutory construction that didn't matter.

THE COURT: All right. I appreciate it. I presume is there -- Mr. Roth, are we going to the next issue, the next claim?

Is this in response?

MR. ROTH: No. I'm happy to respond and then move to the next claim, if that works for Your Honor.

THE COURT: However you want to proceed.

MR. ROTH: I agree with the government on subject matter jurisdictional.

What I understand them to be saying is for purposes of the takings claims and the First Amendment claims, the challenges to the statute, the plaintiffs here have standing

because their drugs are subject to programs, so we can challenge the statute on constitutional grounds. And there's no special provision that would, for some reason, deprive the Court of ordinary jurisdiction to hear and resolve those claims. So we agree with that.

Part of the confusion with the Delaware case on the due process claim was that there was some uncertainty, I think, about what is the property interest that is being impaired for purposes of a due process analysis?

And that's a little tricky. I hope what I've explained -- addressed this morning is for takings purposes it's not really that fuzzy. It's the product. It's the drugs.

THE COURT: Right.

MR. ROTH: That's sort of the end of it from a property standpoint.

So unless Your Honor has further questions on jurisdiction --

THE COURT: I don't. But I appreciate both parties at least putting something on the record. I felt like the absence of it, especially when it's been addressed in at least one or two other cases in different contexts I thought was important, at least for the record for oral argument.

MR. ROTH: Absolutely, Your Honor. Thank you.

And good afternoon. Then I'm going to address the First Amendment --

THE COURT: First Amendment.

MR. ROTH: -- challenge now, and before I do so, I'll just say this one actually does have the capacity to save work because if we were running on the First Amendment, that actually does moot everything else in the case.

THE COURT: Go ahead. I'm listening.

MR. ROTH: Okay. Great.

THE COURT: I can read and listen at the same time, Mr. Roth.

MR. ROTH: I wasn't sure if it was a question.

THE COURT: I chew gum, too, but I prohibit it in the courtroom, so I can't do all three.

MR. ROTH: Okay. Your Honor, I think the best way to appreciate the compelled speech problem with the program is to focus on the very unusual way in which this program is structured.

If I were Congress and I wanted to require manufacturers to provide their drugs to Medicare beneficiaries at a discount, the easiest, most obvious, most direct way to do that would be to say exactly that.

Manufacturers, you have to provide eligible individuals with access to the maximum fair price the CMS will decide or else you will incur penalties. Economically, that is exactly the same thing as the program. It's also generally how Congress regulates. Does Congress want someone to do or not

do something? They mandate or prohibit that thing.

That is not how the IRA is structured. It's unusual. It creates an extra step -- actually two extra steps in the process. Instead of mandating access to the maximum fair price, the statute mandates that the manufacturers negotiate and then agree to provide access to the maximum fair price.

Everything substantive is funneled through this negotiation and agreement framework. So I think the obvious question to ask is why do it in that very circuitous way? Instead of ordering you to do something, I'm going to order you to agree to do the thing, and then it's the agreement that actually controls. It's strange.

I think there's an equally obvious answer to the why, and the reason is this: Although those are economically identical, they're politically very different because there is broad, public support for negotiating prices with drug companies, but there is not broad public support for talk-down mandates and price controls. So by structuring this program through this framework of negotiation and agreement, Congress has dressed up one as the other to make it look like everyone is on board, this was all a big voluntary negotiation and agreement. The manufacturers are ordered to negotiate, they're ordered to agree to the price, and they're ordered to agree that it's the maximum fair price for their product, and they have to do all of that in public written documents.

This is something the government, both at the legislative and executive branch levels, has seized on for political purposes.

Tonight is the State of the Union Address, and the White House put out a fact sheet yesterday in advance of those State of the Union. The first bullet in the fact sheet: Announcing that manufacturers of ten drugs were made at the negotiating table. This is because the deadline was recently to provide a counteroffer.

They said, look at this. The manufacturers are at the negotiating table. We're all here hammering out a fair price that we're all going to agree on.

And this is in the context, importantly, of a lot of political messaging about price gouging, corporate greed, all of that, and by forcing -- by mandating the manufacturers to agree these are the maximum fair prices for our product.

Program effectively is requiring the manufacturers to indict themselves on these charges of price gouging. You got us. We've been charging unfair prices for the last however many decades.

THE COURT: They're not asking you to say that.

MR. ROTH: Well, they are because the statute requires the manufacturers to agree in a written contract. We've got to sign on the dotted line. These are the maximum fair prices for the product, and that's what allows the

government to then go out and say we've reached an agreement. This is fair.

THE COURT: Mr. Roth, not all agreements are expressive, right? So what makes this particular agreement so unique?

I mean, you could say this in any contract or any agreement, and I know that wouldn't hold up, and I don't believe that's the argument you're making before the Court or the ones that you had in your written submissions.

MR. ROTH: Correct.

THE COURT: So just, I guess, in simple terms, how is this so different than other agreements?

MR. ROTH: I think there are three things that make it critically different. Number 1, if you don't agree to it, you have a penalty. You are taxed. That's when the excise tax kicks in. So you are compelled by the tax to sign. That's number one.

Number two, the agreement itself embeds an implicit political value judgment by using this phrase "maximum fair price." It means when you sign, you express ascent to that, you are agreeing this is the maximum price that is fair for this product, and when I've previously charged more -- but when I now charge more to every other buyer outside Medicare, it's unfair. Most contracts don't have that type of value judgment embedded in it.

And number three, I think that's the only reason to do it this way. It goes back to where I started. There is no other plausible government interest -- legitimate government interest in funneling everything through an agreement when it would have been ten times easier to just say here's the mandate.

THE COURT: Do this.

MR. ROTH: Do it. Instead, you've got to agree to it, and that is the compelled speech problem because that is what lets the government walk around and waive around this paper that you signed and say this is a great thing, everyone agrees, this is fair, and we all -- we all worked it out at implicit value, but, of course, the manufacturers don't agree to it. They don't believe this is the maximum fair price, but they have to say it or else they're going to be hit with hundreds of millions of dollars in penalties every day.

Now, the Supreme Court has not been shy about applying Compelled Speech Doctrine. Just in the last decade or so, we have cases holding that compelled union dues --

THE COURT: I know, but I'm not here to predict what the Supreme Court may or may not do to expand the First Amendment one day. I mean, you're in the trial court today. And if the Supreme Court decides to extend that, that's not for me to speculate now and try to get ahead of the highest court.

MR. ROTH: I agree, Your Honor, but I do think we have to look at what the case law says and the precedent that we look at. I think this fits really neatly into this pattern of cases that we've seen where they say if you're going to force somebody to adopt -- to express something that they do not agree with, that is a problem for the First Amendment standpoint.

You need a really good reason to do it, and the government hasn't even tried to offer a reason. They haven't tried to satisfy any form of heightened scrutiny for this.

THE COURT: Well, when you talk about scrutiny, though, isn't any effect on speech by the agreement merely incidental here? Because you're going to have to get to that. Because you've already taken me to strict scrutiny. I mean, that's another issue that you're all debating, I think, before the Court.

MR. ROTH: I agree, Your Honor. The -- we don't get to -- they're going to try to argue that they set -- they say scrutiny doesn't apply at all, this isn't really a speech compulsion.

So let's go through the reasons they give for why that is, and their first one and their main one is, oh, this is just incidental.

Respectfully, Your Honor, I think they have it exactly backwards. Incidental means the consequence of something

else. It's not what you intend. It's how you get there.

And so that applies when the government says here's a restriction on conduct or a requirement on conduct. In order to effectuate that in practice, maybe that I can't say something or I have to say something to make it happen, but the actual statutory directive is the conduct.

There the speech is just incidental. This is exactly the opposite. The only thing the statute mandates is the agreement, the speech, and then that is what gives rise to the obligation relating to pricing and conduct.

So it's exactly the same error that the Supreme Court corrected in the *Expressions Hair* case from 2017 where this isn't a restriction on pricing. This is a restriction on how you communicate your pricing, and, therefore, it does implicate the First Amendment. I think we had exactly the same dynamic the way this program was structured.

Okay. So then they say, Okay, even if we're compelling speech, it's not expressive speech. We touched on that a little bit earlier. I don't think it's credible to say that when the manufacturers are being obligated to sign their name and thus express their consent to something, that is a contested political narrative that the CMS price is the maximum fair price for the product.

Importantly, it doesn't matter that it's in a contract. The *USAID* case, which is a recent Supreme Court -- compelled

speech case was also a contractual -- it was an amendment in the contract.

That was the requirement, that if you want subsidy -- if you want grants under this program, you have to adopt a policy opposing prostitution and sex trafficking.

The way that was effectuated was through a provision in a contract by which you would get the grant. It was in there. I agree that I oppose sex -- prostitution and sex trafficking, so the fact that it's in a contract doesn't make any difference.

Then they say, well, okay, but we put a disclaimer in, so if you go further down in the contract, there's this thing saying, I don't really mean it. But every court that has looked at the disclaimer question, including the Third Circuit, has said disclaimers don't cure compelled speech. They actually make it worse.

Now, you have to speak out of both sides of your mouth. You say this, but actually I don't really mean this. There's no case, and the government has not cited a single case that has upheld compelled speech based on a disclaimer.

Then they say, well, even still, there's no real First Amendment harm here because you can just go out in public and make your case. You can speak. You can write it off as the paper. You can issue a press release. That is true -- that is true, Your Honor, in every compelled speech

case.

And nonetheless, what the Supreme Court has said for decades is, again, Congress can't force you to affirm in one breath what you take away in the next. They can't put you to the requirement of responding to your own statements in public. That itself manipulates the marketplace of ideas in a way that offends the First Amendment.

And then the final argument on First Amendment is, again, to go back to this conditions idea that we spent a lot of time on this morning, and they say, all right, even if it's compelled speech, it's part of Medicare, and so it's a condition on the government benefit, and that's okay.

I'm not going to retread the ground we covered this morning on unconstitutional conditions, although all of it applies here, too.

What I will say, though, is it's actually much easier for us in the First Amendment content because the Unconstitutional Conditions Doctrine is especially robust when it comes to compelled speech.

And the best case on that is the *USAID* case from the Supreme Court where they said, essentially, you can't condition public benefits on the recipient's agreement to convey the government's preferred message. We don't let you do that.

THE COURT: And just so I'm clear, Mr. Roth, the

conveyance of that message is based on the language that's already built into the agreement. By your signature alone, your argument is that the government is compelling you to convey that message because you executed the agreements.

So whatever language is in there, this is fair. We negotiated. All the things that you disagree with --

MR. ROTH: Right.

THE COURT: -- you would be bound by that statement because you signed it.

MR. ROTH: Right. And it is all in there. It says in the negotiation agreement and it's there dozens and dozens of times across about a five-page template agreement. And, again, all of that is by design because, again, no reason to do it that way unless you wanted to then issue a fact sheet like this one and a State of the Union address that I suspect we'll hear tonight that makes the same points.

This is great. We're all getting together in a room, and we're working out fair prices for the American people. That is not the truth of what is going on here.

And, look, for better or worse, the First Amendment doesn't require government officials to be honest, but the reason they can make these statements and what enables them to make those arguments in public is the statutory obligation to speak by signing these contracts.

So just to conclude, Your Honor, on this point, even

assuming Congress is allowed to coerce manufacturers to provide their drugs at a discount -- this is what we talked about this morning -- it at least needs to do that in an honest and accountable way and not by co-opting the regulated parties to manipulate the marketplace of ideas, and that's how this program operates.

THE COURT: All right.

MR. ROTH: Thank you.

THE COURT: Thank you, Mr. Roth.

Who's coming up for the government?

By the way, just make sure because -- I know Mr. Netter because he identified himself at the podium, but I have both your names and I don't have a face to a name, so you're going to have to let me know who's who.

MR. SVERDLOV: I apologize, Your Honor. My name is Alexander Sverdlov.

THE COURT: All right. Mr. Sverdlov, before you begin this issue, though, I'm going to have to do what I don't like to do. I have to go back in time.

So when we talked about subject matter jurisdiction, since I have you up at the podium, in the Texas litigation, the reason why judicial review was barred was because the Court found that the claims were all matters that arise under Medicare.

MR. SVERDLOV: Correct, Your Honor.

THE COURT: I just want to be clear about that for this record. Why are these claims not also arising under Medicare? Why is that distinguishable? Why are these claims distinguishable from that case?

I mean, everything about this case is the impact of the Medicare program, so and the -- I don't know. I would like to have some idea of why that doesn't pertain to this particular case. I don't know if that was answered. If it was, it wasn't clear to me.

MR. SVERDLOV: I apologize if I didn't make it clear when I was here earlier.

I think the short answer is that is a rule that applies to the reimbursement for providers. So in that case, the -- the Pharma trade group -- association found local -- an association of local providers to be one of the named plaintiffs.

That was how they sought to establish --

THE COURT: Because the providers are not in this case, that's not the analysis here.

MR. SVERDLOV: Correct.

THE COURT: All right. Now you've hit it.

MR. SVERDLOV: -- a different statutory framework by which compensation happens, and that rule applies differently. It applies to providers in a way that does not apply here.

THE COURT: I appreciate that. That clarifies at

least our prior discussion.

All right. Well, do you want to talk about the First Amendment?

MR. SVERDLOV: I do, Your Honor, very much.

THE COURT: All right. Let's hear it.

MR. SVERDLOV: Your Honor, this morning my colleague, Brian Netter, explained that the IRA negotiation program is fundamentally a form of government procurement in the commercial market and that for that reason it triggers no Fifth Amendment concerns.

But the same insight, this understanding that the program creates a framework for commercial agreements, for contracts, also defeats plaintiffs' First Amendment claims and the specific objections they make.

So Supreme Court decisions like *Expressions Hair Design,* that my friend on the other side mentioned, like *Rumsfield v. Forum For Academic Institutional Rights* and others make clear that regulation of commercial conduct, including ordinary price regulation, does not implicate constitutional --

THE COURT: But that's not what they're saying. Mr. Roth is saying there's more in this agreement than in these typical agreements.

You're telling them that they have to sign off saying this is fair. We negotiated this, this is the right price, or

words to that effect. I'm paraphrasing now, but there's additional language in this agreement that doesn't necessarily -- isn't necessarily contained in a typical contract.

And so why is that language even in there?

MR. SVERDLOV: So, Your Honor, I have --

THE COURT: If they agree to the price, why do they have to agree it's fair or any of these things? Why wouldn't they just say -- or why wouldn't the government just say, look, if we're going to negotiate the price, and if you agree, great; if not, you're going to have to opt out, but you don't have to actually sign off on this type of language that says it's fair, that we fairly negotiated. The government is right on it, on this, and almost concede that we were not being fair to the public before because we had a different price prior to signing this agreement.

MR. SVERDLOV: So, Your Honor, I have three responses to that, if I may.

THE COURT: Yeah.

MR. SVERDLOV: The first line -- response is that they named category error. And the category error is that these terms that they're objecting to, terms like "agreement," terms like "maximum fair price," these are statutory terms of art. Right?

They are in the template agreement to make clear that

when the parties actually affix their signatures -- and I have several points I'd like to make about the expressive content of the signatures or lack thereof -- but those terms are ported over from the statute, they are defined by the statute, and they are there to make clear that manufacturers are agreeing to abide -- they are contracting to abide by the same technical understanding of these terms. And I would like to direct --

THE COURT: Is there a disclaimer?

MR. SVERDLOV: There is.

THE COURT: What's the purpose of the disclaimer, though, then?

MR. SVERDLOV: It's belts and suspenders, Your Honor. Your Honor --

THE COURT: I mean -- well, I'm going -- I don't want to interrupt your line. I don't want to interrupt your argument, but you're going to have to explain to me, then, when you get to the right point of this presentation that based upon what you just said to me, why would you need a disclaimer at all?

If what you're saying is the reality of this language in the contract as a term of art, it's coming from the statute, then why the disclaimer at all?

But I'll let you address that when it's the appropriate time, but I do want you to address it.

MR. SVERDLOV: Absolutely, Your Honor. Absolutely happy to address it.

But if I may, I'd like to just set a framework for addressing it, and that framework, among others, is the Supreme Court's decision in *Meese v. Keene* from 1987, and the cite for that is 481 U.S. 465. This was cited by some of the Amici in these cases.

That case is very instructive because in that case plaintiff challenged a statutory requirement that it affixed a term "political propaganda" to certain types of materials that were sponsored by the government of Canada, right?

And the claim was, look, this term has a political valiance. It has an emotional valiance. It has resonance that people will sort of intuitively understand.

The Supreme Court looked at that, and it said no. The term "political propaganda" is defined in the statute. Congress gave that term a definition. It is being used in the technical sense of that legislation.

We're not going to inquire into Congress's motives for defining that term, but the fact that Congress can define terms and they're used in a technical way doesn't then give the Court leeway to consider sort of the --

THE COURT: Just to be clear, Congress is mandating that that language be placed in the agreement?

MR. SVERDLOV: That that was -- no. No. Obviously,

there's no political propaganda language in the agreement.

Also I should note, Your Honor -- and this goes to a point that I wanted to highlight at the end, but my friends on the other side say that the First Amendment claims resolve the entire case.

I think that's not quite true for several reasons. Among them is the fact the language that they're objecting to is in the template agreement that was promulgated by the agency. The statute itself in Section 1193 in the public law -- and I can convert that to the U.S. Code if the Court would like -- it just provides for manufacturers to enter into agreements. Right?

So as far as like -- as far as their challenge to the statute, they seem to be almost contesting the mere fact that Congress has said, hey, manufacturers, we want you to sign an agreement.

Now, I posit for the Court that if Congress had said we want manufacturers to sign a contract, this claim that my friends on the other side are making would feel a lot less weighty, and, in fact, there is no distinction between the two.

Congress is using the term "agreement" in the technical sense, just like it's using the term "maximum fair price" in a technical sense, just like it's using all of these terms in -- in the way that they're intended in the statute.

The disclaimer, Your Honor, specifically asked whether --

THE COURT: I don't have it before me. There's a lot of documents. I'll look at them later. What does the disclaimer say? If you have it, I don't have the -- I have --

MR. SVERDLOV: Your Honor, I do have -- I do have it in one of the numerous PDFs that I have opened, and I'm happy to --

THE COURT: Or generally what does it say, so I have a sense of what we're talking about here?

MR. SVERDLOV: I'm happy to read. This is page 4 of the template agreement that we cited to in our brief.

Subparagraph F, quote: "In signing this agreement, the manufacturer does not make any statement regarding or endorsing of CMS's views and makes no representations or promise beyond its intention to comply with its obligations under the terms of this agreement with respect to the selected drug."

Use of the term, quote, "maximum fair price" and other statutory terms throughout this agreement reflects the parties' intention that such terms be given the meaning specified in the statute and does not reflect any parties' views regarding the colloquial meaning of these terms.

Why did CMS put that in there? Because, Your Honor, CMS promulgated initial guidance for manufacturers when it was

developing the revised guidance to promulgated initial guidance.

It had a lot of provisions, and predictably manufacturers who were gearing up to challenge this law raised a host of objections to various provisions that CMS -- that CMS -- various proposals that CMS made.

CMS saw that manufacturers, among other things, stated that they have First Amendment concerns about these agreements and other elements of the program.

And so to make clear to them what should otherwise be clear, right, when Congress says these are the statutory terms and the contract says --

THE COURT: Well, is the disclaimer to make it clear to them or to make it clear to others?

MR. SVERDLOV: I think it's to make it clear to them. They are the signatories. It says in the contract that we are not -- we are not in any way forcing you to say anything outside the scope, outside the corners of this contract.

We are not in any way trying to put words in your mouth. You're -- by signing this, you're saying that you will give effect to -- you're signing up to give effect to these statutory terms. These are terms of art.

Your Honor, if I may, I think it's instructive to talk about the other Supreme Court cases that I mentioned -- the *Expressions Hair Design* case, the *Rumsfeld v. Forum for*

Academic Institutional Rights case, and the *Agency For International Development* case -- because I think all of them made it clear just how different this is than this program is than the types of regulations or arrangements that raise First Amendment concerns.

So -- as an overarching principle, what *FAIR* -- *Rumsfeld v. FAIR*, what *Expressions Hair* -- *Expressions Hair* decision, even the D.C. Circuit's decision in *Nico* makes clear that when analyzing these things, the Supreme Court looks to what is the thing that's actually being regulated, right?

When it's speech, when it's expressive conduct, that raises First Amendment questions. When it's not expressive conduct, when it's just commercial conduct, when it's not speech, when the underlying thing being regulated is not speech, that doesn't draw First Amendment concerns.

So *Rumsfeld v. FAIR,* the requirements in that case is the -- what's called the solvent amendment, the requirement that institutions that receive federal funds provide access to military recruiters on terms equal with other --

THE COURT: I remember this back in the day, by the way.

MR. SVERDLOV: Right.

THE COURT: I do.

MR. SVERDLOV: So the Court looks at this and it says, What's being regulated here is conduct, right? And it

does so even though -- even though the law schools were actually required to generate speech to facilitate that. They were required to put up bulletins. They were required to send out emails, right?

The Court says, no, no, that's incidental. What is -- the core thing that's being regulated here is conduct, and that does not create a First Amendment problem.

So it says, among other things, compelling a law school to send scheduling emails for a military recruiter is simply not the same as forcing students to pledge allegiance or forcing a Jehovah's Witness to explain motto, and it trickled to --

THE COURT: It allowed more than that. The law schools were allowed to protest even while allowing the military to recruit, because my law school was one of those.

So it's interesting that you raise that issue. I'm not sure -- I know the case law is relevant, but if we're talking about freedom of speech, even though the law schools were required to allow the military recruit, like, private law firms and private employers, the institution should -- or at least were still allowed to publicly protest them being there.

MR. SVERDLOV: I think this actually gets to the other case that was mentioned. This gets to the *Agency For International Development* case, because as my friends on the other side mentioned, the *Agency For International Development*

case looks to a requirement that -- in a constitutional condition context, right? It looks to a spending program where the government says the only people eligible for this program are going to be those that espouse a particular set of beliefs.

Now, here's the interesting thing. What my friends don't mention is that the case actually involved two conditions.

The first condition was that the government funds in that case that were being distributed through that contract not be used to distribute the message, and then the second broader condition was that the organization profess a belief.

And the Supreme Court looks at that and it says the first one is fine. No one takes issue with the first condition. It's the second condition we object to.

And what they say is Congress is free to attach conditions that define the limits of the government's spending programs, those that specify the activities Congress wants to subsidize, but when you start imposing conditions on the entity, on the speaker itself, what it can do or can't do outside the confines of the contract, then you have a First Amendment problem, right?

So if the contract says -- if the agreements here say, hey, manufacturers, you're going to sign this --

THE COURT: You can't speak against it. You can't

say anything contrary to it. You have to go out there and lip service that this is fair, that you negotiated it.

So you're saying the contract doesn't prohibit all these manufacturers going out there and saying, hey, gun to your head, we had to do this. I don't even agree with this. We did it because it was best for the company.

MR. SVERDLOV: Absolutely, Your Honor.

THE COURT: It was best for the mission.

MR. SVERDLOV: Absolutely. That -- and that is, in fact, a reflection -- I think not to take us back to this morning or later this afternoon when we talked about unconstitutional conditions in the due process context.

But the core of the unconstitutional conditions theory is that there has to be a freestanding right that's being impinged. And so when the government says, hey, I'll give you this benefit on the condition that you'll restrict your First Amendment speech outside the confines of the program, you know, beyond the umbrella of the federal dollars that Congress is authorized to spend and to determine what those dollars are spent for, you know, yeah, that infringes on that separate right.

If manufacturers were being required to take out, you know, political advertisements supporting the IRA as a condition of participating in the program, yeah, that's the First Amendment unconstitutional conditions problem.

But we don't have any of that here, right? We don't have any of that here. We have a contract, and what they're basically saying is we don't like the words of the contract and we want to have the ability to criticize the government within the four corners of the paper that we're signing saying that we will provide -- saying that we will participate in this program.

And that, I think, runs straight into both *FAIR* -- both the *FAIR* case. It runs straight into the *Agency For International Development* case. They're basically saying, hey, we want -- a whole line of cases, I should say, the *Rust* case from the Supreme Court.

There's a whole line of cases that says the government gets to define the limits of its spending programming, and it's not required to subsidize your exercise of First Amendment or other rights within the confines of the program itself.

So I think the D.C. Circuit in *Nicopure* follows this same understanding that regulation of conduct is not the same as regulation of speech.

That's really what this is turning on, right? This is turning on the idea that these agreements are there to codify the -- what is essentially a contractual relationship between these manufacturers and the government, and they're welcome to say anything they want outside of it.

They are signing this agreement to demonstrate that, yeah, we -- that there's a meeting of the minds, right?

I think it's actually interesting, too, to note that in our brief we sort of said, look, by this logic, if you apply First Amendment scrutiny to commercial arrangement of this type and to contracts of this type, there really is no end point.

Like, every DOD contract now has to be scrubbed for language that manufacturers -- that defense contractors may find objectionable.

Now, plaintiffs say, well, it's not the same, right? They say it's different -- it's somehow different, but they don't actually provide an analytical framework for explaining why it's different.

And I -- at least standing here today, I thought about these issues as we were briefing them. I can't really identify what the limiting principle would be. It seems to me that if plaintiffs have a First Amendment right in sort of the -- the expressive valiance of technical terms of art, then potentially any type of commercial agreement, any type of contract is vulnerable to interpretation.

That is just -- that has not been the law. We can't predict where the law is going, but certainly on the established precedent, that is not where the law is.

I would like to maybe address three additional points

really quickly, because my friends on the other side have highlighted them, and I think it's worth -- I think it's worth explaining exactly why we think they don't work.

The contested political narrative point that they kept bringing up, the notion that these words have this understanding, as I've said, is answered by *Meese v. Keene*. It's answered by the overarching idea that courts don't just take the plaintiffs' word for what is being regulated. They actually look -- cases like *FAIR* look to what is being regulated, words or conduct.

The *Expressions Hair Design* case that I flagged at the top and didn't circle back to until now is instructive because in that case the Court specifically said what is being regulated here by the New York ordinance is not the price. It's how the price may be communicated.

The Court went through and explained, look, nothing in this ordinance actually restricts what manufacturers can charge. What it does restrict is what they can call a discount and what they can call a surcharge, right?

And so looking at that, when the Court sees a regime in which plaintiffs are free to charge whatever they want but there's limits on how they communicate that charge, yeah, that looks like a regulation of expression as opposed to ordinary price regulation.

An ordinary price regulation, as this Court noted, has

long been subject to the standard that -- that it is -- it is not subject to First Amendment protection, cases like *Sorrell* from the Supreme Court that say the First Amendment does not prevent restrictions directed at commerce or conduct from imposing incidental burdens of speech. And there's a whole line of cases.

Second point. Plaintiffs have tried to distinguish these contracts, these agreements from contracts by saying three things. That, one, there's penalties involved. Two, that the implicit message and value judgment, which I have just addressed, and the only reason to do it this way -- I'm paraphrasing -- is because of that message, right?

That basically asks the Court to step in and try to guess what Congress had in its mind when it promulgated this program as a policy matter, when as a policy matter it decided that it wants to model these agreements on other types of fundamentally contractual procurement relationships.

The fact that Congress could have imposed a price -- a regulatory price cap, and we'd be analyzing that under different constitutional standards. That was a policy call for Congress to make. Congress decided it wanted to conduct these -- to -- in establishing these prices it wanted CMS to hear from the manufacturers. It provided a whole host of statutory criteria so that manufacturers who chose to participate could come in and lay out what they think their

drugs should be worth. Here are the factors that CMS needs to consider. This is -- this is structured as a give-and-take. Right? It was structured to bring manufacturers into the room and have this be a back-and-forth.

The fact that, at the end of the day, Congress also said, well, we're not going to pay more than a certain amount even at the end of this process, doesn't change the fundamental fact that the same is true for other types of government procurements. The Pentagon negotiates contracts under a given budgetary constraint. That doesn't make -- back to what we were saying this morning -- that doesn't make that any less voluntary, and it doesn't make it any less an exercise of the government's procurement power than what we're facing here.

THE COURT: Thank you, Mr. Sverdlov.

Mr. Roth, do you have rebuttal?

MR. ROTH: Thank you, Your Honor. I started by asking what's the reason for Congress to do it this way instead of that way when the simpler thing is to mandate what you want the manufacturer to do? I don't think I really heard an answer to that offered. What I heard was, well, the agreements are there to codify it. It's very strange. The agreements are there to codify it? Not the U.S. Code? I mean, the U.S. Code is what we codify obligations. Here, U.S. Code says you've got to agree to do these things. I'm not

aware of any other situation like that, and I haven't heard any reason why Congress would do it that way other than --

THE COURT: Does it matter? Do I have to figure out why Congress decided to do it this way versus what you would think is the more streamlined preferable way? Is that an analysis I need to have in this First Amendment issue? I don't see why I need to speculate as to why they did it this way. I think the issue is whether because they did this way, is there a violation of the First Amendment?

MR. ROTH: I agree, Your Honor.

THE COURT: I know you're going to say something on rebuttal, but since I have you up here, I might as well ask you. What's your response to the fact they said you can say whatever you want? Nobody is compelling you to make any statement that this is fair or that you agree with it or that you even like it. And you're free to go out there, just like the analogy with the sovereign amendment, to say, I absolutely oppose all of this. We're here to do it, but we're verbalizing that we disagree. And the government is saying you're more than free to do that. How are your clients' First Amendment rights being impeded there?

MR. ROTH: I'm going to address *FAIR* separately because it's a different issue. To take that one on, absolutely true. We can go in public and say whatever we want. You know what? That is true in every single compelled

speech case the Supreme Court has ever decided. *PSG&E*, for example, which is one that we cite in the brief where the utility had to leave space in its envelope for another party to include material. And the argument was you don't have to say anything about it. You can say you disagree with it. You can put another insert in saying we don't believe what those people are saying. That doesn't matter. If you are forced to carry someone else's message, yes, you may be able to go out and say we disagree with the message. But the First Amendment is offended because that is forcing you to go out and make that rebuttal that you wouldn't otherwise have to make, and that itself impairs your First Amendment rights.

THE COURT: First of all, I don't know if that's analogous, the *PSE&G*, but then how does this stuff get in every other contract? I mean, this is an issue where every time somebody signs an agreement, there's going to be language in there that says, well, if I sign this agreement, you're forcing me to agree with the paragraph number eight or paragraph number 365 and, therefore, my First Amendment rights are impeded because, by executing this agreement, you're forcing me to adopt all the language and all the words of the agreement. I mean, where does that stop?

MR. ROTH: Your Honor, first, I think what takes out 99 percent of that is, most of the time, you are penalized if you don't sign the agreement. This is very unusual because,

unlike the defense contractor who reaches a deal --

THE COURT: Absent any penalty provision as part of this would you have a claim?

MR. ROTH: No. Of course not. I mean, if you enter the agreement voluntarily, you enter it voluntarily. The problem is there is an excise tax of hundreds of millions dollars a day if you don't sign. That's what creates the First Amendment problem. In fact, the remedy is to strike that because then we don't have the problem.

So, Your Honor, I don't think the fact that we can speak outside addresses the compelled speech objection. *FAIR* is a little different. That's the conduct versus speech issue. In *FAIR* the Supreme Court said the statute requires you to let them in. Letting them in isn't speech. Everything else is incidental. That isn't how the statute works. If it said you've got to sell us a fair price, then they would have an argument that it's conduct, and we could say we don't think it's fair. Too bad. You're not being forced to say it's fair. No First Amendment problem. It's, at most, incidental. That's not how this works. Again, here it's funneled through the agreement in order to require the manufacturers to subscribe to this judgment that is being embedded in the contractual agreement. That distinguishes it from *FAIR* and from any other ordinary contract.

Then they said, well, it's not really embedding a

message. It's just a statutory term of art. It doesn't mean fair. It's a statutory definition. There actually is no statutory definition, so it doesn't help. There's no statutory definition that says "maximum fair price" means X. It's the colloquial language. And, again, that is the point, and that's what we see in the press releases and the statements in the congressional record. People say this is fair. We're just getting agreement on what's fair. They are using it in a colloquial way. They're forcing us to use it in a colloquial way and take away that it is filtering through to the public discourse is exactly that.

The disclaimer, we've talked about that. It's a similar problem to the right to respond. When they go out and say, look, we've reached agreement. Manufacturers agree these are fair prices, and they've been gouging you for decades. We're supposed to stand up and say, no, you didn't look at Section 4F. It says you don't really mean it. That is not an answer to the compelled speech problem, Your Honor.

USAID and conditions. The government says we're allowed to decide how we spend the money. We don't have to subsidize other speech. We can determine what the contours are of the spending program. That is true. That means they can decide what to spend the money on and what not to spend the money on. This has nothing to do with money because, again, they can do the exact same thing without the agreement,

and the money would be spent the same way. So this has nothing to do with how the money is being spent. It's being spent on drugs. There's no question about that. They're buying the drugs. That's what they want to buy. Fine. The problem is completely collateral to that -- is they want us to say in the contract, as we discussed, that this is the fair price. That is exactly like *USAID*. Sure, the condition that said you can't spend this money on prostitution or whatever, no problem. They can limit how you spend the money because they don't have to subsidize things they don't want to subsidize. But what they can't say now is say in the agreement, you agree that you oppose prostitution. That was stricken under the First Amendment, and that is the analogy to this case.

And then, Your Honor, finally, there was some suggestion that this is really just a problem with the template agreement and not with the statute itself. We actually filed this claim before there was a template agreement because it's all in the statute. It's the way the statute operates. Again, if you look at the statute, the only obligation on the manufacturer is to agree to the maximum fair price and to agree to provide access at the maximum fair price. So it's embedded in the statute, it can't be fixed by CMS, and it violates the Compelled Speech Doctrine. Thank you.

THE COURT: Thank you, Mr. Roth.

Next. I'm going to try to make sure I get you out of the capital before you lose daylight.

MR. DEGER-SEN: Thank you so much for your patience, Your Honor. Samir Deger-Sen on behalf of Novartis.

THE COURT: Good afternoon.

MR. DEGER-SEN: The program here states that a failure to reach agreement with the government as to the maximum fair price leads to a fine that is 19 times the national sales revenue of the drug, which Novartis is $93.1 billion a year, which is so ludicrously high that even the government has not tried to defend it. Instead, the government, through this IRS guidance, has tried to lower that to a number that seems somewhat more reasonable. That rewrite, we don't really think it makes any sense, but we address in our briefs why it doesn't make sense. I don't want to get bogged down in that because I don't think anything turns on it.

Even if you accept the government's numbers, what you still get is at least a $2 billion a year fine for the simple act of failing to agree with what the government says is the maximum fair price. That is still a fine. Obviously, as we discussed earlier, a fine that is close to a third of Novartis's earnings a year, which is an extraordinary fine for what the government itself concedes is completely innocent

conduct.

And I don't think the government can really dispute that the whole point of this so-called tax is to deter noncompliance. The statute itself at 26 U.S.C. 5000D says that the provision is titled "designated drugs during noncompliance periods." And it's expressly triggered by a failure to comply with requirements of the statute. And it said, at such an absurdly high level, that Congress itself -- the Congressional Budget Office said it's not going to get us any money. It expressly has no revenue raising purpose, no remedial purpose. It's just a deterrent purpose.

So what does that mean for the excessive fines clause? The question for the excessive fines clause is straightforward. Is it a fine and is it disproportionate? A fine is a payment to a sovereign as punishment for some offense. And the Supreme Court said in *Austin*, "A civil sanction that cannot fairly be said solely to serve remedial purpose, but rather can only be explained as also serving either retributive or deterrent purposes." It is a fine. This serves no remedial purpose. The government doesn't expect to get any money from this at all, and it serves, obviously, a deterrent purpose. It's designated towards noncompliance periods, and it's meant to deter you into entering back into compliance. So it's clearly a fine, and it is disproportionate where the government itself, I think,

essentially concedes this. It says, well, you know, there's not even an offense here, so it doesn't really make sense to even talk about the proportionality analysis. And it has no explanation for how the simple act of something that the government concedes is innocent conduct -- just not agreeing -- could somehow warrant a third of your annual earnings as a penalty.

What the government does say is, well, this whole doctrine doesn't really apply because excessive fines are just for criminal offenses. That's something the government has been trying -- an argument that they're pushing in cases for a long time, including the Supreme Court's decision in *Austin*, and the Supreme Court squarely rejected that argument in *Austin*. That's the exact argument. This is a quote from *Austin*. The question is not, as the United States would have it, whether forfeiture under the statute is civil or criminal but, rather, whether it is punishment. And the government -- there are dozens of cases in the courts of appeals, in the district courts that apply these to civil penalties.

The government says there are not any -- there's the False Claims Act. There are four circuits that say the False Claims Act applies to civil penalties. For example, *The City of Los Angeles* case that applies the Eighth Amendment to the municipal parking fines. There's the *Quest Court v. Municipal Public Utilities Commission*. There's a civil penalty for

telephone carriers about interconnection agreements. Nothing. No connection to criminal penalties at all.

I think the Third Circuit in the top case is one of the only circuits that has drawn the government's line, and Justice Gorsuch accented from denial of rehearing en banc saying this is clearly wrong and in conflict with the other circuit.

So this idea the government has that it just applies to criminal penalties just has been rejected across the country.

THE COURT: What about irreparable harm or irreparable injury? Are you going to be talking about that, or should I ask my question now? I don't want to cut you off, Mr. Deger-Sen.

MR. DEGER-SEN: This goes to jurisdictional questions?

THE COURT: Yes. So say I'm following you. Say I'm following you that -- let me make sure I paraphrase. If I'm inaccurate, then correct me on the record. The program poses an excise tax -- I don't know if this is right, but I have notes here -- beginning 186%, and after 276 days reaches 1,900%. Is that the position, 1,900%?

MR. DEGER-SEN: That's correct.

THE COURT: Nineteen times the drug's total national revenue. So if you say 1,900% excise tax would cause you irreparable harm, I presume that's your position, correct?

Would 95% excise tax cause you irreparable harm?

MR. DEGER-SEN: It absolutely would, A, because the financial injury is really high, but the other thing to think about here --

THE COURT: What excise tax would not result in irreparable harm?

MR. DEGER-SEN: I mean, I think usually a financial injury of this kind, anything with that degree with is there's no realistic way in which the company can pay I think would result in irreparable harm.

One point on this -- the fact -- the fact that this fine has already compelled a compliance with entering into the negotiation process, as Mr. --

THE COURT: I don't know if that's true or not. I know that's your position that you've been compelled to be a part of this negotiation because of that.

MR. DEGER-SEN: The government has certainly said unless you engage in this negotiation, we're going -- you're going to have to pay to us $93 billion or maybe $2 billion or whatever it might be, but the result is we have to engage in negotiation. We have to speak and say things that we don't want to be saying.

The Supreme Court has said any kind of, you know, First Amendment injury is irreparable harm. All that, I think, goes to a separate question, which is a jurisdictional

objection. We only have to show irreparable harm if you're thinking about the AIA -- I'm going to get to the AIA in a minute, but I just want to establish the underlying merits of this, very, very clearly this is a fine under the Supreme Court --

THE COURT: I appreciate that. I have no questions about your first part. My questions are more tailored to jurisdiction. I'm not just going to have questions just to have them, but these are helpful to the Court. If you have more on the first part, I want you to build your record.

MR. DEGER-SEN: That's great. That's the first part. I think it's telling the government really ultimately, I think, prefaced on the jurisdictional issue. So just stepping back on what it really means -- what the government's argument really means under that Anti-Injunction Act. Under the government's theory, as long as you label something a tax, and then you have a fine and you make it so high that no one could ever realistically challenge in a refund action, you can never challenge it. It's impossible for us to challenge this. That's basically the government's theory. We think it's wrong for two reasons. First, it's just on the text of the Anti-Injunction Act. The statute says: "No suit for the purpose of restraining the assessment of collection of any tax maintained." Our suit is not for the purpose of restraining or collecting -- restraining the assessment or collection of

any tax because, as the government well knows and as the Congressional Budget Office said, no tax is ever going to be assessed or collected. The whole point of this is if the tax is ever assessed or collected, your company is basically out of business. So no one could ever be in a situation where they're going to be assessed or collected. The point of the tax is to be used as a tool to coerce compliance.

That is something that has already happened, and it is in the background -- all the arguments today it's looming in the background, the fine, the tax, and yet, the government has barely mentioned it. It's the elephant in the room. It's the unique feature of this program that doesn't look like any other program, enterprise-destroying tax that is pushing and pulling manufacturers to do things and say things that they do not want to do, and that's the thing that we're ultimately challenging.

So we don't think that is a suit to restrain the collection or assessment of any tax. Justice Cavanaugh concurs and *CIC Services* describes this really well. The AIA is best read as directing courts to look at the state as objective of suits rather than the suits downstream consequences. It's because of that word "purpose." What is the suit's purpose? A suit for the purpose of restraining a tax that's not maintainable, but a suit like this that's basically saying we want a declaratory judgment to tell HHS

and CMS you cannot use this as a tool in a negotiation. You cannot use it as a looming threat to make us do something. That's a fundamentally different suit. And that's obviously clear, I think, because it goes to the purpose of what the AIA is, and the Supreme Court said the purpose of the statute is to protect the government's ability to collect a consistent stream of revenue. The government has already said it has no intention of collecting revenue at all under the statute. The AIA is an activist. They're using the AIA as a tool to shield the tax.

Even if you don't agree with us on that, I think this goes to the next question, which is the *Williams Packing* exception. You only get to the *Williams Packing* exception if you think that this is a suit for the purpose of restraining the assessment and collection of tax. We don't think you need to get to the exception, but if you get to the exception, then it's irreparable injury on the merits, and that irreparable injury is not just the financial injury. And it's irreparable at least in the sense that there is no way we would be able to --

THE COURT: What about the agreements for their -- to exercise forbearance?

MR. DEGER-SEN: What they say there is -- you can apply the statute once, and we'll exercise forbearance on that collection challenge. They change the fact that the statute

-- because it applies through all of noncompliance periods -- means that you're going to be racking up the excise tax the whole time. So you have that lawsuit and that refund action. You challenge it and, after two years, you lose, you pay 93 million or 200 billion; these figures that obviously no company could ever pay.

So it's a completely unrealistic option to think we could ever have a challenge, just wait for these penalties to accrue in the background, and down roll the entire company on winning one single lawsuit. And the government knows that.

Just stepping back, that is what -- the position that they have in this case, Your Honor, means that you have -- that they are going to be able to say any time they want to compel compliance like this, we can take this out of the constitutional challenge by calling it a tax and making it unchallengeable. That is the sort of extreme nature of the challenge they have in front of you in this court. I don't think you can accept that premise to say this tax.

The final thing they say is that we sued the wrong party. The most straightforward thing to say about that is under Rule 21, at any time you can add or drop a party. So if you think there's any concern with that, would serve the government. The government is obviously aware of this case. It's a completely technical, formalistic thing.

THE COURT: You mean like the IRS or the Treasury

Department? I'm going to ask that question to your friends on the other side. I like Mr. Sverdlov's use of the word "friends." That's something they do before the Supreme Court. We should probably implement that more in district court, but I have heard that before in the Supreme Court, and I do appreciate that. I'm going to ask your friends on the other side of the aisle about why we need those, folks, especially -- you make a point in your paper. HHS isn't joined. Would that keep a tax from being collected? Right? Let me see what they have to say about that.

MR. DEGER-SEN: Your Honor, it would stop the tax from being collected, but more fundamentally what we're asking for here it sort of syncs well with our AIA argument. What we're asking for is a declaration of the tax is unlawful. And the injury that's happening here is the use of that tax to compel our behavior. And with that declaration -- and it's HHS and CMS that are doing that -- with that declaration they can't do that anymore, and the game changes, and that's what we're saying. It's the use of this tax -- I think the last thing I'll say about this is it is sort of telling the way they described the program throughout the day. They tried to avoid the tax and say it's just the government, you know, the government is just, you know, setting the price it wants. If you don't like it, walk away. All of that stuff.

Why do they want this tax? Why is the tax here? Why

do you need to have this enterprise-destroying penalty backing everything? If it's so unnecessary, maybe they should just give it up. I think that's an important question to ask the government.

Thank you, Your Honor.

THE COURT: I will. Thank you, Mr. Deger-Sen.

Who is coming on from the United States?

MR. GAFFNEY: Good afternoon.

THE COURT: Good afternoon. Before we do anything, why don't you answer Mr. Deger-Sen's question? I mean, now, presume I asked it. Why do you need this excise tax?

MR. GAFFNEY: I think the question is not why do we need the tax. The question is whether the tax is constitutional, and there's even a threshold question before that, which is whether the Court can get to it. You asked this morning are there going to be any claims where I don't need to run the analysis all the way to ground in order to dispose of that claim? This is one.

THE COURT: This is one.

MR. GAFFNEY: This is one.

THE COURT: All right.

MR. GAFFNEY: It's no surprise. I think that counsel for Novartis starts with -- to jump to the merits instead of talking about the Anti-Injunction Act. The defendants aren't the ones that contrived this judicial review scheme. Congress

did. And under the Anti-Injunction Act, the question is not -- this is from *Florida Bankers*, a D.C. Circuit case, 977 F.3d 1065 at 1067. The issue here is when, not if, plaintiff may challenge this tax. Under the Anti-Injunction Act, Congress chose to have refund suits be the mechanism by which taxpayers challenge taxes. The Court in *NFIB* at 567 U.S. at 544 explains this. AIA is like -- taxes that Congress creates, quote, "Creatures of Congress's own creation and how they relate to each other is up to Congress, and the best evidence of Congress's intent on that question is the statutory text."

So this is one of those issues where the label itself matters. And you don't hear any dispute that the 5000D tax is labeled a tax. So the first of the two questions that must be asked under the Anti-Injunction Act, the first one is satisfied. The 5000D tax is a tax.

So the second question is -- and that's true. It's not disputed, but it's true, even when there's this characterization of the tax as a regulatory tax, as opposed --

THE COURT: The bottom line, Mr. Gaffney, just so I am clear as day, if Congress calls it a tax, it's a tax. Is that the point that you're trying to make there?

MR. GAFFNEY: That's what the Court said in *NFIB*. That's what the Court said in *CIC Services*. And that's true even when a challenger to a tax says, yeah, but this tax isn't even really revenue raising. The Court said -- this is in *CIC*

Services 593 U.S. at 225 -- the AIA, quote, "Draws no distinction between regulatory and revenue-raising tax rules." Congress says it's a tax, it's a tax for AIA purposes.

That leaves the second question. What is the purpose of suit? Now, Novartis does not cite a single case -- and defendants aren't aware of one -- where the legal claim is about the legality or constitutionality of a tax, and Anti-Injunction Act did not apply to require that taxpayer to challenge that tax in the course of a refund suit. That's what we have here. They're saying the tax violates the Eighth Amendment. The claim squarely challenges the constitutionality of the tax, and I'm not aware of any case where that has been the legal claim. And the purpose of the suit has been not to restrain or enjoin the collection or assessment of that tax. And the AIA --

THE COURT: This is probably the question I was going to ask you. Novartis makes an interesting point. They basically say that if HHS is enjoined, then that will keep the tax from being collected. That would be a complete relief, right? That's the argument that you're saying that's unique. There's nothing out there that would support that, in every situation where we have an issue of an actual tax, the IRS and Treasury department are in.

MR. GAFFNEY: Sorry. I keep cutting you off. I think your summary of their redressability argument is exactly

right. And I pulled a couple of the quotes from their redressability argument. Their redressability argument is we don't have to sue the IRS and Treasury because even though we know those are the agencies that are going to collect the tax, that are going to enforce the tax provision, they know that. Even though that's true, they say in their brief, yeah, but CMS performs this statutory trigger for enforcement of tax. In other words, CMS is involved in the enforcement.

I want to point a couple of spots where they say this in their briefing. This is at ECF Number 57. So -- I've got eight examples, I think, but I'll just give you three. At page 52, CMS is, thus, plainly necessary to the enforcement of the excise tax. Also at page 52, there's simply no realistic basis to think that the IRS or Treasury would or could impose the excise tax if CMS was enjoined. The last one they say, quote, "It's inapplicable here because CMS has an integral role in the causal change of enforcing the excise tax."

In other words, there's no question. Their answer on redressability as to why it's fine that they just got CMS and HHS in the case. Why? They're involved in enforcing the tax. What are they trying to stop? Enforcement of the tax. That is exactly what the AIA precludes.

As I mentioned, they don't cite a single case where the legal claim directly challenges the constitutionality of a tax, and yet the AIA was held not to apply.

In *CIC Services*, that's not what's happening. There's a question about the legality of an IRS notice. There are a lot of upstream things in this case that they complain about that they say lead them -- could lead them down this path to paying a tax. We haven't raised the Anti-Injunction Act to preclude these things that if they do or don't do it might trigger a tax. We raise the Anti-Injunction Act where it applies where there is a tax that they're challenging and where the purpose of their Eighth Amendment claim is to say, Court, declare this thing excessive under the excessive fines clause and prevent them from enforcing it. The AIA applies there squarely.

On the Declaratory Judgment Act, I just want to loop back. This is the last comment that we heard is on the redressability point. Well, you know, we're still seeking a declaratory judgment even if an injunction here wouldn't do the trick with CMS and HHS defendants. What about the declaratory relief that we're seeking? That's an even easier case. Their argument on the Anti-Injunction Act -- again, this isn't a tax -- is that the purpose of their suit isn't to restrain the assessment or collection of taxes. The Declaratory Judgment Act tax exception is even easier. It just says no declaratory judgments for declaratory judgments that are, quote, "with respect to federal taxes."

THE COURT: Federal taxes.

MR. GAFFNEY: That's that. There's no declaratory judgment available here. So the redressability argument can't be cured by pointing to that.

On their reliance on the Congressional Research Service, they point to this over and over as if Congress itself announced that the tax would never generate revenue as if HHS and CMS said that. That's not true. We cite ECF Number 24 at page 56, note 13 there. This case is 56 F.Supp.3d 280, 296. But basically, long story short, courts don't take what CDO or CRS says as evidence of congressional intent. We cite a couple cases there, but there are a host of others that do the same thing.

I will note I looked closely at that Congressional Research Service report. At page 30, it says to challenge this thing, you've got to pay the tax in full and bring a refund suit. They don't agree with that part of the CRS piece. So everybody had some disputes about what exactly is going on here, and nobody thinks that the CRS research report is the definitive answer here on congressional intent.

So AIA applies. So the question is, is there an exception that applies? There are two judicially recognized ones. They don't try to fit within one of them. That is *Williams Packing*. The point of *Williams Packing* -- and it's a very narrow exception -- the Third Circuit has said these exceptions apply, quote, "only in extraordinary

circumstances." That's *Thornton*, 493rd F.2d at 166. Third Circuit also said that the taxpayer bears a, quote, "very substantial," end quote, burden. That's *Flynn*, 786 F.2d 591.

The thing you have to show as a taxpayer is two things: irreparable harm between now and when you could bring your refund suit', and, two, that you will definitely certainly succeed at that suit.

So what's the point of that? The point is if you definitely got a winner of a claim, but in between now and when you could bring that refund suit you're going to suffer irreparable harm to the point that, let's say, you're not even going to be around to actually win, well, then you put in the claim now and win now. But that's not what we have here.

So the thing that they ignore -- and I think Your Honor picked up on it earlier -- is the point that this tax is a divisible tax. So what is it Novartis needs to do between now and the refund suit? Here is what they have to do. They have to file -- this is assuming -- put aside all the voluntariness stuff. Like, that they choose to remain in Medicare, they choose to make Medicare sales, all of these other things. Okay? They have to, one, file a return and pay tax on a single sale. One. That's all they have to do. They have to file a refund claim. As we discussed earlier, IRS policy statement 516 says IRS won't collect the balance in the interim. And then step 3, if and when there's a denial, they

file a refund suit. So what irreparable harm will they suffer between now and the filing of that refund suit, which is the irreparable harm that's required under *Williams Packing*, paying tax on one sale? That is not going to put Novartis under.

You asked earlier about the math, so let's get right to that, because that's pretty important here. Everybody keeps throwing out different numbers. Let's clarify this. You sell -- during World War II --

THE COURT: Oh, my goodness. I mean, I'm asking you to clarify the math in oral argument, and you're going back to World War II.

MR. GAFFNEY: In World War II, in 1944, the top marginal tax bracket -- thank goodness it's not the case today -- 94%. Okay. So how did that work? You get paid a hundred bucks. You fork over 94 of it to the government. You retain the other 6. If we're in the world of 271 days, so let's skip the 65, 75, 85%. So let's just jump to the 95%. If you sell a drug for a hundred dollars, the customer pays a hundred dollars. You, the manufacturer, retain your -- you retain the $5, and $95 goes towards the tax. We don't dispute that 95 times 5 is 19. What we dispute is this looks anything like these other cases, like in *Kurth Ranch* and *Dye* where they say, Well, look, that was only four or five times. Here's the difference. In *Kurth Ranch*, you sell your marijuana for a

hundred bucks. You owed in tax $400. You're out $300. In *Dye*, it was five times. You sell your drugs for a hundred bucks, you're out 500. You're down 400 bucks. Here this is like a high income tax. You sell your drug, and you will pay a portion of that in tax. It is not four or five times the sale price. It's not what the customer pays times four or five times. You retain less, a fraction of what you sold it for, not that you owe a multiple of it to the government.

And that means -- I was looking back at some of the -- the declaration at 8, 11 -- paragraphs 8 and 11. I'm doing math here. It's somewhere in the 40 to 50 times what they -- their number is 40 to 50 times what the number would actually be. And by the way, that's because the rate is 20 times and their Medicare sales are -- all their sales are not Medicare. Right? This gets to the point of the Anti-Injunction Act, in part. They don't -- they want to, like, point to these massive numbers, but how the IRS is actually going to enforce this thing we'll know in the refund suit. Like, they claim as if the IRS isn't going to do it, even though the IRS notice says taxpayers may rely on this thing now. They couldn't -- these interpretations, in any event, are favorable to them. It would be very unlikely, I expect, come that refund suit. I have a strong suspicion that they will not say, actually, you were supposed to tax us on all our sales. Actually, it was supposed to be 1,900%. I bet, in the refund suit, full

alignment on the IRS notice interpretation. But let's get to the refund suit and see what the actual amount is so we don't have these numbers that are floating around that are never going to materialize.

The other thing that they have to show under *Williams Packing* is they have to show a certainty of success on the merits. They have to do both of these things, certainty of success on the merits and irreparable harm between now and that refund suit.

THE COURT: Is it certainty or likelihood? I don't have it before me, but is that the language?

MR. GAFFNEY: It's certainty.

THE COURT: Okay.

MR. GAFFNEY: There's like -- the cases pile on. So it's not just certainty. It's not just certainty. It's certainty taking everything in favor of the government, looking at this in the light most favorable, et cetera, et cetera. It's an extremely high bar. Again, the point is supposed to be you say to the taxpayers you're definitely right, but you're telling me you can't possibly even get your day in court. All right. Fine. We'll hear it now. We'll make this one narrow exception to the requirement you got to bring a refund suit.

But that's not what we have here. They don't point -- this is going to get into merits in a second -- but they don't

point to any excessive fines clause case and lacks a connection to criminal conduct and withheld to be a fine. No taxing. No tax ever held to be a fine under the excessive fines clause. The only taxes that they cite that have ever been held to be punishment, *Kurth Ranch* and *Dye*, look completely different. They both involve drug taxes. They both involve criminal convictions. Lots of pieces that look different.

On this very thing I'll say, Your Honor, is they don't really make a defense that they could have sued the IRS and Treasury. They know those are the entities that enforce. They say, well, then why doesn't the Court just amend -- why doesn't the Court just say, okay, well, I'm anti-IRS and Treasury here. We do not do that because it would be futile. We just said the anti-injunction applies. It would, however, hammer home that the anti-injunction definitely applies. I don't know why they didn't name the IRS or Treasury, but certainly a complaint that did would have really cast a spotlight on the fact, oh, yeah, this is a case in which the Anti-Injunction Act squarely applies. All these cases that involve challenges to taxes, they involve the IRS and Treasury.

Okay. On the merits, so the courts --

THE COURT: To save you some time, I want you to build your record on merits, but I have no questions about

that section.

MR. GAFFNEY: Okay.

THE COURT: Just to note that, so you can run through it, but I'm --

MR. NETTER: I'll go pretty quickly, then.

The one thing I'll say is there is this discussion -- there's this back-and-forth about whether this thing is a fine, and that term has been defined. It's punishment for some offense. How do we figure out what that is? We should be guided by the cases. So, yes, where there's criminal forfeiture, that's *Bajakajian*. Yes, where there's civil forfeiture, that's tied to criminal conduct. But, no, where there's merely a high tax rate. That's *Kurth Ranch*. No, where the tax has a deterrent purpose. That's both *Kurth Ranch* and *NFIB*. They haven't pointed to any case where a tax was held to be a fine under the excessive fines clause -- and there are lots of taxes. Sometimes when there's no case, it's because the thing is so anomalous.

There are just only seven taxes in the world, and so how could one tax percolate up and have a ruling be challenged under the excessive fines clause? We have plenty of taxes, we have plenty of excise taxes. We've got plenty of excise taxes that are at a rate of a hundred percent. And I am happy to rattle them off to you. But there's never been a tax held -- at least that I'm aware of, the defendants are aware of, and

that Novartis identified -- that was held to be a fine under the excessive fines clause. And the only taxes that have ever been held to be punishment for some -- the same standard under the excessive fines clause to be a fine, they involve, like I said, in *Kurth Ranch* and *Dye*, characteristics, anomalies that are totally absent here, innocent owners defenses, a criminal conviction being required, et cetera.

They, in their briefing, Novartis has suggested that all the Court needs to find is that there is some deterrent purpose. Fine. That's not true. We know that from the Third Circuit's decision in *Artway*, 81 F.3d at 1258. The Court there said *Kurth Ranch*, quote, "announced that the no-deterrent purpose rule of *Halper and Austin* does not apply in all situations. In *Kurth Ranch* at 780, the Court explained why deterrent purpose and even a high tax rate is not enough."

In *NFIB*, the Court explained that you can have a regulatory purpose and still be a tax. That's 567, 568. And the Court also noted there at same pages that in distinguishing -- this is quoting -- in distinguishing penalties from taxes, this Court has explained that if the concept of penalty means anything, it means punishment for an unlawful act or omission. While the individual mandate clearly aims to induce the purchase of health insurance, it has some incentive mechanism. It need not be read to declare that failure to do so is unlawful. Neither the act nor any

other law attaches negative legal consequences to not buying health insurance beyond requiring a payment to the IRS.

That's the same thing here. If a manufacturer chooses to stay in Medicare but not to enter into a negotiation agreement or not to agree to a maximum fair price, there are no other consequences, just like in *NFIB*, beyond requiring a payment to the IRS.

Since the Court said they didn't have any other questions, I'll just quickly touch on excessiveness. It's a high bar. Street proportionality is not required. There's another really important piece here, though, given the posture of this case. There is a strong presumption of constitutionality when the fine -- let's call it a fine -- when the fine falls within the range prescribed by Congress. We cite a couple of cases on this, but *Bajakajian* says at 524 U.S. at 336, quote, "Judgments about the appropriate punishment for an offense belong in the first instance to the legislature."

So is this fine, if it were a fine, would it be within the range that Congress prescribed? Of course. We don't know exactly what the amount would be, but according to Novartis's own reading, the fine is actually going to be way less than the range that Congress prescribed because they say the IRS has gone out of its way to have a smaller assessment and a lesser collection than Congress required. But even if it's

exactly the same, the question is are we within the range that Congress prescribed? And these cases remind that there's a strong presumption, if you are in that situation, then you don't have excessiveness.

The last thing I'll do is just point to some of those excise tax cases in case the Court wants them on the record where the rates go between 50 and a hundred percent. I'll just say to start at 26 U.S.C. 49- --

THE COURT: Go a little bit slower, though, only because --

MR. GAFFNEY: Sorry.

THE COURT: -- you think we're not going to review this. I will review these citations but not right now. Megan is on my left here, and I need her to be able to type this out.

MR. GAFFNEY: For Megan's purposes, 26 U.S.C. 4941 is the beginning of them. There's a whole slew of them, and I'll just say ending at 26 U.S.C. 4975. You'll see a whole host of them.

Again, I think it's worth pausing for a moment on how this should actually play out. The Anti-Injunction Act, the challenge should be brought in a refund suit. It's required. That's the path that Congress created, and at that point, we would know the actual amount of the tax.

And as we've said, what it would be at that time would

be the payment of tax on a single sale. And at that point, we can ask is that excessive in light of that single sale? And they don't want to get there because the Anti-Injunction Act requires them to have to do that.

But also, once the actual numbers are there, this thing will not appear as excessive as the miscalculations that have been put before the Court.

Unless the Court has any further questions --

THE COURT: I don't, but thank you, Mr. Gaffney. I appreciate it.

MR. GAFFNEY: Thank you, Your Honor.

MR. DEGER-SEN: Thank you, Your Honor. Just a few points.

So I think that what we just heard from the government really underscores that, under their logic, the tax could be -- could be $1 trillion. It could be $5 trillion. It doesn't matter. And they think that the AIA applies, and you have to go through a refund action.

And, obviously, that is complete formalism, because no one in the world would go through a refund action in that situation if they're going to be subject to a penalty that high at the end of it. They would just comply like the statute intends them to comply.

And the idea that they could just pay one and then, you know, just have the refund action, and then we'll know what it

is, I mean, we know it's going to be at an absolute minimum $2 billion plus a year, and it could be $90 billion plus a year. The only thing we have to hold onto is nonbinding IRS guidance.

So they clearly don't think that anyone is realistically going to do that. There was no response to the idea that you can't just risk paying this kind of enormous fine through refund action.

In their theory, it just doesn't -- this fine is basically immune from challenge. That is the legal principle. You call it a tax, and you make it high enough that someone just can't take the risk of challenging in a refund action. That's the end of it.

It can be excessive. You'll just never get to the merits and never be able to challenge it, and that is a very dangerous principle in the hands of any government, any administration. And I don't think that this Court should accept that principle, Your Honor.

They said we don't cite a single case where this applies to a tax, but there's a reason for that because other taxes do have revenue-raising purposes. There isn't a tax like this that says 19 times the national sales revenue for drugs, which can be $90 billion a year.

And I think the key thing to just -- stepping back. Congress did not want this tax to raise any revenue, not just

they didn't predict it to raise any revenue, they didn't want it to raise any revenue.

If this tax raises revenue, it means that manufacturers are noncompliant, and drug prices are not coming down. It means the system is failing. So the tax has to be set at such a high level that, as it's described in the statute, it brings people into compliance.

If it's gaining revenue, it's failing. The government's own tax cases all say if you have a tax that is excessive in relation to its revenue-building purpose, of course, that can be a fine.

So the reason that this is not -- that we haven't seen taxes like this is because Congress has never tried to do anything like this. This is extraordinary. It is novel. There is no such thing as a tax that is a third of a company's earnings for completely innocent conduct or 10, 15 times the company's earning for completely innocent conduct.

It is way beyond the bounds of what governments have done before. They say that a tax is a tax, but you have to analyze it as tax. I just want to be clear, that's only true for the AIA and for statutory claims.

For constitutional purposes -- and the Supreme Court made this clear in *NFIB* -- the confusion of when Congress's definition doesn't control. If it's substantively a fine, it's a fine. They mention *NFIB* and say, well, that was a

reasonable tax.

The Court specifically in *NFIB* said that the individual amount wasn't set at such a high level but no one could pay it. People could pay it and then declined to get insurance.

So that was part of the Court's analysis as to why it could be construed as reasonable tax. Here when it's set so high that no one is supposed to pay it, when the regulatory scheme is designed such that people don't pay it and instead go into compliance, it's a fine, just by any commonsense measure.

If you talk about this to anyone in the street, is it a tax or is it a fine? It's a fine. Of course it is. It's penalizing someone for noncompliance. It's trying to bring you back into compliance, and it's interesting, the other case they mention a lot is *Kurth Ranch*, which, of course, is not even an excessive fines case, and, you know, that statute there was held to be punishment.

So I think it underscores -- they don't really have examples of cases where you have a fine that looks anything like this and, again, all that just goes to the excessive. Is this excessive? What is it excessive to? Completely innocent conduct.

They don't dispute that it's innocent conduct. They don't dispute there's nothing with saying you don't want to pay the MFP, but if this is a fine, then a fine that --

dramatically lower than this would still be excessive under the excessive fines clause because you have to judge it in relation to the conduct, and the conduct here is completely innocent.

The final thing I'll say is about the question of which parties to join. Again, we had a surprising amount about that, but I think it ultimately -- if this Court thinks there's any concern with that, it just can easily add --

THE COURT: Why didn't you guys have --

MR. DEGER-SEN: Because of the nature of the claim that we're bringing. We don't think that the issue here is that we're going to be levied this fine. We are not going to be levied this fine. No manufacturer is ever going to be levied this fine.

It is -- HHS and CMS are using the fine to coerce us, and for purposes of a declaratory judgment -- and, again, the purpose of this claim and our constitutional claim is it's not a tax, it's a fine.

So that's why it does fall within -- if we're challenging this on a constitutional basis, we can bring a declaratory judgment action, and the Court can say that substantively this is a constitutional claim, and so you're allowed to challenge this as a fine.

And so that's what we're asking for. That's the reason we didn't, you know, join them, but if the Court thinks that

was a mistake or we tended to be overinclusive, this is not -- they didn't say anything about fair notice.

The only thing they said here is it would send some kind of message. I wasn't really clear on the answer, but they didn't say there's any problem, they didn't say there's any substantive problem. Rule 21 is designed precisely to lead -- you know, prevent the kind of formalistic results. The claim is then kicked, we refile or restart the whole process again.

There's just no purpose to that when the government is clearly on notice, has vigorously disputed it. It's all in front of Your Honor. There's no reason not to address it.

The fact that the government is trying to duck it so hard, the fact that the government has eventually rewritten five, and the fact that ultimately counsel didn't answer the question: Why is this fine here?

If there's no need for it, if this whole policy is just the government --

THE COURT: I don't know if -- I mean, I think he made the points of legally not required to, right?

MR. DEGER-SEN: Of course not.

THE COURT: I don't think he's wrong about that. Whether it's there or not is whether it's constitutional.

MR. DEGER-SEN: Absolutely. Absolutely, Your Honor.

THE COURT: And I wanted to ask the question because

I thought he would take the bait, but he did not.

MR. DEGER-SEN: It's not -- we don't have to defend it. I think it is telling that you have -- you know, that you could defend this scheme so much as being so valuable to the American people.

They don't defend the fine at all, which is a huge component of the coercive nature of it. They don't say anything about why is this. They just say it's constitutional. For the reasons we've explained, it's not constitutional.

And their ultimate argument is, even if it's not constitutional, you are not allowed to even examine its constitutionality because we called it a tax.

This Court should not accept that premise. Thank you, Your Honor.

THE COURT: All right. I appreciate that.

This is not a sting on Mr. Deger-Sen, but absent extraordinary circumstances, I'm cutting the rebuttals for oral argument only because of time constraints.

I want to hear from both sides, but I also don't want to be here, so if there's something urgent that you will need to come back after the government's spoken, I'll hear from you, but let's limit the rebuttal to what you need to do.

Okay. Everybody okay? Nobody needs an -- anybody want to take a five-minute break or anything?

MR. SVERDLOV: Your Honor, can I take the Court up on that?

THE COURT: Absolutely. Why don't we recess -- is five minutes, ten minutes? You tell me.

MR. SVERDLOV: Five minutes is fine.

THE COURT: Why don't we recess for five minutes, and then we'll get back on. If anyone needs to take a break, now is the time to stretch your legs. Thank you.

THE DEPUTY COURT CLERK: All rise.

(A short recess occurred.)

THE DEPUTY COURT CLERK: All rise.

THE COURT: Please remain seated.

Where are we?

MR. PARRISH: Your Honor, Ashley Parrish for Novo Nordisk.

THE COURT: Good afternoon, Mr. Parrish.

MR. PARRISH: Good afternoon, Your Honor.

There's two remaining arguments. The first segment is the last of the constitutional arguments addressing separation of powers and due process.

And then, Your Honor, the final argument of the day is something very different. It addresses the statutory claims. With your indulgence, what I'd like to do --

THE COURT: Are you doing both?

MR. PARRISH: I'm doing both, yes, sir.

THE COURT: I will tell you, I have no questions on the statutory claims, so I'm going to allow you to go through your presentation, but that will probably move quicker.

Is that also with the PowerPoint?

MR. PARRISH: It's with the -- not PowerPoint, but with the handed --

THE COURT: The handout, which I have already.

MR. PARRISH: Yes.

Your Honor, what I was going to say, and perhaps this isn't in the Court's interest, but I can actually move relatively quickly through separation of powers.

I'd like to have a little bit of rebuttal time on the statutory claim if the Court would indulge me on that.

THE COURT: I will.

MR. PARRISH: Thank you, Your Honor. I appreciate that.

THE COURT: All right. If you're going to be quick on this, then let me ask you the one question I have for you.

Walk me through the property interests that are implicated by the program.

MR. PARRISH: Yes, Your Honor.

So let me say this on the property interest is that it is clear that we want to be able to sell our drugs to elderly and disabled people, right?

It is also clear that we have a property interest

that's been built up over the reliance interest on how these federal programs have been run for years.

Your Honor, one thing I would say is I don't think for purposes of separation of powers that any question about voluntariness applies because the structural protections apply regardless of whether there's consent or otherwise.

And, Your Honor, I'm sure you picked up on this, but if the government's position is correct that this is all just about procurement, which is really an extraordinary claim, Your Honor, because -- the government isn't binding for itself.

But if it's correct, then, Your Honor, housing prices, food prices, gas prices, every single one of those markets, the government could simply say, we're going to take over half the market, 50 million people, and we will set up a system where we will pay and then provide benefits.

And, Your Honor, the bottom line is that they are allowed to do that but only subject to constitutional constraints. There's no get-out-of-the-constitution free card.

And, Your Honor, that's why I started off -- and what I'd like to do with the separation of powers argument is really walk the Court through three things very quickly.

First, Your Honor, this statute is quite extraordinary because of how many constitutional protections it strips away,

and I'd like to quickly walk through what those are.

Second, Your Honor, I would like to highlight that the government identifies no case ever that has ever upheld a statute that has stripped away so many essential protections.

And then finally, Your Honor, I'll just respond to their two main arguments. It won't take me long.

Your Honor, the thing I want to emphasize under the separation of powers, and we see the Supreme Court has -- recognizes in its recent cases, it's designed to do a number of things.

But one is to ensure that Congress is accountable for the legislative judgments it has to make and that agencies have accurate fidelity to law and are accountable to the things that they do implementing the decisions that Congress has made.

Your Honor, what we have here is we have first no standard at all that governs what price is imposed, and, Your Honor, I thought your questions early this morning where you said, well, what's in the record as to how much money you're making? What are the research and development costs?

Your Honor, you can ask your clerk after the hearing today, you know, I want to know what the right price is. What is the right price that the government is going to post? Tell me -- obviously, you can't calculate it, but tell me what's the principle in the statute that will guide CMS so that CMS

is just not making it up itself?

And, Your Honor, your clerk will look for hours and days, and they will not find anything because what the statute says is there's a ceiling price. It says the agency must consider a bunch of factors, things like research and development costs, patents. And there is no substantive standard that tells them what price to be, whether it's zero or up to the ceiling price. It's entirely left at their discretion.

Now, Your Honor, that itself is a nondelegation problem that we're familiar with going back to 1935. But what's layered on top of that is that there are no procedures in place to ensure that what the agency is doing is within constitutional bounds, that it is not arbitrary, capricious, reasonable.

Your Honor, we've known since 1946 most of the structural due process issues, not the individual rights that you saw addressed in the *AstraZeneca* case, but the idea of due process and echo a separation of powers and the structural constraint on government. We sold that, Your Honor.

You'll know that that's the APA, the Administrative Procedure Act, so it doesn't come up because agencies have to comply, except for Your Honor will note here that the government points to no procedures in the statute, and they even claim that the APA doesn't apply and they're exempt from

it.

And, third, Your Honor, if all of that were not sufficient, there's no judicial review, particularly of the key decision, which is what is the price that will be imposed?

So, Your Honor, even if your diligent clerk could spend those days looking for some principle to tell you what is the right price, at the end of the day, the government would tell you that that choice of price is completely removed from judicial review.

So not only has Congress delegated sweeping legislative power to the agency with no principle to guide what the agency's price setting decision is, it's also stripped away any type of check on that that would usually be provided through the courts.

Again, Your Honor, all you have to think about is if tomorrow the government said, We're going to make sure that your price of your house that you'd want to sell will be going through a government exchange, or the price of the farmer's food or the price of the gas, at least, at a minimum, you'd want to know that that price was within constitutional bounds, and there was some checks -- some judicial check to make sure that the agency wasn't taking it at -- whatever it wanted, and there's nothing in the statute.

Your Honor, that takes me to my second point --

THE COURT: Well, one quick question, Mr. Parrish,

only because you brought it up, the *AstraZeneca* decision out of Delaware. What, if anything, should I take out of that decision?

MR. PARRISH: Your Honor, I don't think too much.

THE COURT: I mean, all right. Fine. That was a softball the way I phrased the question. That was a little bit of a softball. I mean, go ahead.

MR. PARRISH: I'm trying to cut down the things. I don't think you need to read that decision at all, Your Honor. Obviously, there's two parts to that decision. The government was right. The first part of the decision was all about standing.

THE COURT: Right. Which wasn't really fully addressed, but it doesn't seem like there's a big argument here today, but...

MR. PARRISH: So it's just the due process point, and what I would say, Your Honor, is this: The due process claim in that case very much resonated and was briefed very shortly as a sort of a standalone independent right and there's definitely the point that due process works like that.

But what I'm making, Your Honor, is a broader constitutional challenge about looking at this. It really sort of bleeds into the second point, that when you take a look at the free enterprise and *Seila* law cases and the separation of powers, what the Supreme Court has said is that

we have to -- we don't allow for multiple layers of constitutional protections.

The way that you keep things in check is that Congress has to make some legislative judgment in the first instance. We all know since 1935 that's very broad, just any intelligible principle, but it must some principle.

But then after that, what we've always had since 1946 is that the agency goes through procedures to avoid basically, you know, tyranny, no arbitrary and capricious unreasonable agency acts always subject to judicial review.

What we have here is that that procedural structural check on what agencies do as an exercise of law making is being stripped away here because what Congress has done is it said no principle. We are not accountable at all for what the prices are.

But then when the agency goes ahead and exercises authority, no procedures for anyone to take a look at whether it's reasonable or not, and the ultimate decision, which is so sequential not only for manufacturers but also for patients and the market, it's also exempt from judicial review.

So, Your Honor, that's our fundamental point. I would just point out that if you take a look at free enterprise and *Seila* law, those are obviously separation of powers cases that arise in the context of appointments.

And the question of theirs is a situation where there's

insulating agency authority from oversight by the president, but it's not very different from what we're talking about here, which is here what we're doing is we're insulating the decision in two ways: both the decision from Congress from the ballot box, and secondly, the decision by CMS, which is why interestingly, Your Honor, you heard all this morning this debate as to what is really going on.

And every time you ask the other side, my friends, they always referred to their guidance documents, the new IRS thing, all this attempt to try to rewrite the statute. The only reason they feel emboldened to do that is because the statute has ripped away --

THE COURT: Are you saying I shouldn't consider any of those extraneous guidance or documents outside of the statute?

MR. PARRISH: Your Honor, obviously, for the purposes of those individual claims, you should consider them on the merits as they've been argued this morning.

For purposes of the separation of powers, it's very telling that what the government is trying to do is rewrite the statute through nonbinding guidance documents, which is a sign of an agency that's gone loose. It's free, and it isn't subject to the usual checks of either a principle that Congress applies or a standard that a Court applies through judicial review.

Your Honor, I'm just going to finish up here so we can move on, but the government has a few arguments, and they're very weak, so let me just walk through them quickly. And, of course, you can hear from my friends.

The first one they say is, well, there may not be any standard there to determine what the price is, but there's all these factors that we have to consider.

But, Your Honor, I mean, if they tell you tomorrow that your house is now on an exchange and instead of a $250,000 house, you can sell it for $10, you don't really care whether along the way they're also able to consider how many times you painted the house or what the driveway looks like or anything like that.

There has to be some principle that tells them how to apply those factors, not just the factors that say consider the information. So that's not an intelligible principle. Factors on their own do not count.

Your Honor, the next argument is to say, well, there's never been a statute since 1935 with the *Schechter* case that has ever struck something down on nondelegation grounds. Well, they're right about that, Your Honor.

Of course, what they put out as palliative for the Court is really just poison for their position because, Your Honor, the reason why there's been no statute is because there has always been an understanding that there must be an

intelligible principle. There's nothing here.

There's no statute that they pointed to that looks like this because statutes are almost always subject to judicial review, APA procedures, or something alternative to ensure that the agency acts within its delegated authority.

You have nothing like that there, Your Honor. I do encourage you to ask them what is the case that -- hold a statute up that says no judicial review, no procedures, and no standards. They will not be able to cite one for you.

And then finally, Your Honor, I would just say that the government says here that the absence of judicial review doesn't matter, right? They basically say there's cases that say we looked at judicial review as a plus, but we don't say it's a negative because Congress has authority over what gets reviewed and what doesn't.

But, Your Honor, of course, that just takes them into the teeth of the Constitution. It is true that when an agency is acting in the Medicare context, Your Honor, the cases that you have, they almost always have a standard. There's almost always judicial review.

And to the extent there's not, it's because of a calculation, some technical thing later as to calculating how much spend was on the drugs. Those are the types of things you keep away from the courts.

But in a price control statute, we have known now --

we've had 150 years of experience with these statutes. They always come with a standard that is attune to the constitutional standard to make sure it's not arbitrary and confiscatory or unreasonable, and we've always had judicial review, even during war time, Your Honor, when the delegation is at its best.

So, Your Honor, I really appreciate your time. I know that this next argument is really important, so unless you have questions, I'll let my friends speak --

THE COURT: I don't. Let me hear the government on the separation of powers issue. Then we'll come back on the statutory claim.

Thank you, Mr. Parrish.

MR. PARRISH: Thank you, Your Honor. I appreciate it.

MR. SVERDLOV: Good afternoon again, Your Honor.

THE COURT: Good afternoon.

MR. SVERDLOV: I will confess, I guess both from the briefing and just the way the argument was set up, I find myself a little disoriented because we kind of briefed these cases with an understanding that there's a distinct due process clause challenge.

Then I take my friends on the other side to sort of be folding that into the separation of powers claim. I think there's several ways to address this.

Candidly, I don't really have a whole lot beyond our briefs to say on the separation of powers because what this claim amounts to that Novo has brought is basically kind of a residual vessel in which plaintiffs have placed odds and ends of their theories in the hope that it kind of congeals into something, and it doesn't. It doesn't congeal, and it doesn't congeal because doctrinally that is not what the Supreme Court has told us a nondelegation doctrine is.

And their efforts to bring in questions about availability, or lack thereof, of judicial review sort of dovetails and leads into their due process argument. On the due process piece, what I would say is we obviously think the Court should give a lot of attention to the *AstraZeneca* decision.

THE COURT: I think you guys submitted a letter, no?

MR. SVERDLOV: We did, Your Honor.

THE COURT: As if I didn't know about that decision. I'm tracking them.

MR. SVERDLOV: We think the Court did a very good job in that case. We think the Court got it right. There is no protected interest that's really at stake.

I think, just to step back for a moment and to like give an orienting principle here, because it's also relevant to the separation of powers claims.

We've seen manufacturers try to bring various angles of

their Fifth Amendment theory, right? And the due process challenges is -- is a theory that some manufacturers have pursued and not others.

I think the reason is sort of obvious. The takings theory suffers from all the weaknesses that we've identified this morning and explained at length in all the briefs that we have submitted.

Plaintiffs want to be able to bring what would really conventionally be a regulatory takings claim in a facial posture, and so they have to sort of dress it up as physical taking. It doesn't work for all the reasons that we've explained.

But one way that they've tried to solve that problem is try to go through the due process clause. Both the *Chamber* decision and the *AstraZeneca* decision correctly rejects that because they have not identified a cognizable property interest.

And the Court in *AstraZeneca* in detail explained why the expectation -- the desire or the expectation to sell to the government, even at -- I will, in fact, quote from that decision. This is at page 42 of the decision: "Desire or even expectations to sell drugs to the government at the higher prices it once enjoyed just does not create a protective property right."

So back to the separation of powers, right, because

that sort of seems to be the angle they're -- they're pursuing to try to solve some of these problems, right?

Like, well, if we -- we sort of want to plead the taking, but it's too early to plead a regulatory taking. We'll try the due process, but we can't really identify a protected property interest. Well, what about separation of powers? That seems good.

We have -- we can cite to cases dealing with appointments clauses for a principle that courts sort of take structural constitutional claims seriously. They do. But the separation of powers claim is also subject to a pretty clear standard, which has been laid out over and over again, and most recently was detailed by the plurality in *Gundy*.

I will not take up the Court's time to list the examples in the *Gundy* decision of the kinds of delegations that the Supreme Court has sustained over the years. We cite them in our brief, and I think it's powerful enough to just read them as they are written.

But I will make one observation, Your Honor, and that goes back to the overarching theme of what this case is and really what our dispute with our friends on the other side is about.

If the Court accepts, as it should, the understanding that this is basically a form of a procurement program, then the idea that Congress has to delegate in some sort of great

detail what is a traditional executive branch function, which is procurement, government contracts, becomes, I think, even more stark and even more clearly wrong.

That takes me back around to the lack of judicial review. So my friends say, Well, all of this, let's take it seriously, not withstanding the intelligible principle test as articulated by the Supreme Court, we have the added problem of a lack of judicial review.

Several points on that, Your Honor. One, this is basically a way for them to smuggle in their due process claims without really trying to satisfy the threshold standards of identifying the protected property interest.

They want to just say, Oh, the lack of procedures is a problem, even though we haven't met the threshold test that the Supreme Court has laid out for a Fifth Amendment claim.

Two, the lack of judicial review -- I'm going to be happy to speak to this when we talk about the statutory issues -- is not uncommon in the Medicare statute, among others. In fact, it is commonly something that courts consider and analyze and uphold.

So this is -- in that sense, it is not an unusual feature of a Medicaid program or a Medicaid regime to preclude judicial review over certain types of determinations. That is what we're dealing with here.

If the Court has no further questions for me, I am

happy to rest on our briefs these issues. I think they've been dealt with at length and adequately.

THE COURT: I appreciate that. Thank you, Mr. Sverdlov.

MR. SVERDLOV: Thank you, Your Honor.

THE COURT: Mr. Parrish, you're back up.

MR. PARRISH: Yes, Your Honor. Thank you very much. Can I just say one sentence and I'll move on to the next argument?

THE COURT: Yes.

MR. PARRISH: Thank you, Your Honor.

I'll just say that I mention the point that they can do the same thing with your house and the idea that you could be forced to sell your house for $5 with no judicial review, no check on the agency, and they would come before the Court and say that there's no property interest, Your Honor, I just don't understand it.

These are drugs. We want to sell them to elderly and disabled people. There's a government program that's regulating all of that. That's the whole point.

But, Your Honor, I'll take us to the next argument, which goes to the statutory point, and I appreciate Your Honor's indulgence. I know you said you didn't have any questions.

THE COURT: Well, I may. You know what? I should

withhold that. I may have questions. I mean, you never know what you're going to say that will trigger me.

But for now, I don't have any anticipated questions on the statutory claims prior to you speaking. Is that fair?

MR. PARRISH: That's fair, Your Honor. I've been known for being triggering. So let me, if I could, tell you what I like to do.

First, Your Honor, I do think it's important to emphasize that, you know -- now there's something completely different, right? This is -- even if you rejected the constitutional claims, these statutory claims are separate and must be resolved.

Your Honor, I also emphasize that there is no other court where these claims have been presented and will be considered on the merits. There was a somewhat different type of argument on the *AstraZeneca* case, but that got rejected on standing grounds.

Here Novo Nordisk is directly impacted by these what we think are statutory violations, and it's very important to my clients.

So, Your Honor, we're very grateful for your time in considering these issues.

Your Honor, what I would say is that the question here is has CMS as the agency violated its order under the statute?

This morning, Your Honor, the concerns that we've had

have been focused on one part of the delegation, which is that Congress didn't say anything intelligible about price, but they did say a lot of intelligible and specific things about what would be regulated, who would be subject to regulated -- what sort of things.

And CMS has just blown by that, and most specifically, Congress was very clear for the first year of the program, they could only regulate subject to price controls 10 negotiation-eligible drugs, which translates into 10 products, either drugs or biological products, and they made it 15.

And, Your Honor, you probably noticed from our brief on page 18, there was their list that they published, and it's very telling that the list is one, one, one, one, six for Novo Nordisk, and yet, they wanted to tell the Court that that's just one product, and it really isn't, Your Honor.

So what I'd like to do in this part of the argument, finishing up, is really three things: first, walk the Court very quickly through the statutory materials that I passed up earlier and I've given to the government and to your clerks.

I think those provisions make very clear what CMS is trying to do in terms of rewriting the statute.

Second, Your Honor, I'll respond to the government's two main arguments: Their one main argument is that it's -- this entire choice of what to do is barred by the judicial review bars.

Your Honor, that fails because if it's susceptible to a narrow reading, you have to apply that reading, and I'll explain to you why the government's reading is just far too broad.

The second argument they make is that they can rewrite the statutory definitions because there's a statutory provision called the use of data provision and other provisions that allow aggregation, limited circumstances for specific reasons, but they just don't apply here.

And then, Your Honor, if there's time, I might say a few words about, you know, some common rule making, but if we don't get to that, I can rest on the papers.

Your Honor, if you turn to the statutory appendix that I've given you, it's just to orient you. You will see there's two sort of big tabs.

The first one are the excerpts that are just from my argument. The second one is a complete set of the statutory provisions. If you go to the code or your clerks do, it's very hard to figure out how all this works.

THE COURT: I appreciate it. So this is helpful. Then you can walk me through it, and I'm walking through it with you.

So feel free to direct me where you need to.

MR. PARRISH: Thank you, Your Honor.

So the great thing about this argument, Your Honor, is

I don't need to do too much here. So I'm going to refer you to 1192(a), (d), and (e), which is in 42 U.S.C. 1320f-1.

And Section 1192(a), that's where we start. It's probably where we end, Your Honor. It directs that for 2026, only 10 negotiation-eligible drugs. It's precise. It's specific. It's a numerical threshold. It's 10.

Now, what Congress intended is, over time, it will phase into 15, and ultimately to 20 a year, but just for this year, Your Honor, it's easy to just focus on 10.

Your Honor, if you take a look at Section 1192(d), and if you go to D, that's just on page 5 at the bottom, so it's the second page, I think, of the packet, and you see I've got that highlighted in yellow for you, Your Honor.

What you notice there is that it defines a negotiation-eligible drug, and it says it's two things: It must meet the definition that Congress has set for qualifying single-source drug in Subsection E and also it must meet certain high-standard requirements as determined by the Secretary.

So it's two things: Look at the definition that we, Congress, prescribed, and, second, take a look at the determinations that CMS makes.

And then finally, Your Honor, that takes us to 1192(e), which is on page 7, so you have to jump ahead a couple of pages, and 1192(e) gives you the definition of what is a

qualifying single-source drug and what ultimately is the definition of a negotiation-eligible drug.

And, Your Honor, I'm going to combine these together, but you can see that A relates to drug products and B relates to biological products, but they're parallel. They say that it must be -- the definition, it must be products. It must be a drug product or a biological product.

It must be approved under Section 505(c) by FDA of the Food, Drug, and Cosmetic Act or licensed by FDA under Section 351(a) of the Public Health Service Act.

7 or 11 years must have elapsed since FDA approved or licensed those, and it can be a listed drug or a referenced product for a generic or a biosimilar, so there's nothing else on the market.

Those are key congressional judgments. You know, we heard earlier, I think several times -- it was 12:27 -- my friend on the other side said, The prerogatives of Congress, we must respect the prerogatives of Congress. But we see the prerogative. Those are rights there set forth.

Now, what's really key, Your Honor, is if you take a look at page 21 of the government's brief, the government concedes that when FDA approves or licenses products, it does it on a product-specific basis, product by product.

It doesn't license them based on what the ingredients are or what the molecular structure of those products are. It

looks just at individual products. And that, Your Honor, is the key point because that's the same definition that the Supreme Court applied in its generics case 30 years ago.

Now, the definition of drug more broadly can sometimes mean a product, a drug product. It can sometimes mean something like a drug substance, but that's not what we're talking about here.

We're not talking about how it might be used in different content. We're talking about two different things, the definition that Congress provided in the statute, which is specifically tied to the approval or license or decisions by FDA, and those approval license or decisions are tied to specific products.

Now, Your Honor, as you note from the briefing, the government wants to push all of that aside. What the government says is that, No, we're not going to put price controls on individual products. We're going to put it on active moieties and active ingredients.

And what we'll do is write into the statute that we can pick any active group of products, family of products by any individual manufacturer that contain the same active ingredients --

THE COURT: And they count one.

MR. PARRISH: -- and they will count as one.

So, Your Honor, the reason I want to put this

specifically is consider how this applies to Novo Nordisk. We have six different products that they lump together as one, but they are wholly different -- they're two different families.

One is called NovoLog. That's very different from Fiasp. You have meaningful clinical differences, these products, and they have different device presentations.

So within the Fiasp line of products, you have a vial that you can inject. You have like an Epipen, the pen you can use, or you can have a pump that you put down on your hip.

They're very different. They're all innovations. They've all been separately approved by FDA.

Now, Your Honor, as you also noted from the briefing, what's really key there is the whole Fiasp line of products, none of those have even been on the market for the required 11 years that Congress said is essential before you can put price controls on.

So the putting together is not only violating the idea that FDA approved separate products, it is also getting around the critical decision that Congress made as to how long you get an exclusivity before these price controls take place.

And, Your Honor, just for the record and for your future reference, I urge you to take a look at the declaration of Dr. Nathan Laney. That's at ECF 30. There's also another declaration at ECF 29.

And he goes into depth about how CMS is not only ignoring the clinical differences between these products -- and what I mean clinical differences -- and, Your Honor, I'm an okay lawyer, I'm a terrible doctor.

But, Your Honor, the --

THE COURT: I hope you're not a doctor at all. I don't need you back in my courtroom again for performing unlicensed practice of medicine.

MR. PARRISH: But I told you about the triggering.

But, Your Honor, I'm going to start off with a point about Fiasp is that the key thing there, from a doctor's perspective, and Dr. Laney goes into this, these are not interchangeable products.

If you were on Fiasp, you cannot take NovoLog without transitioning off and with special medical care and so forth. They're not interchangeable. These are different things.

One is ultra fast acting. It affects when you can take the insulin, at mealtimes, as opposed to NovoLog, where it's just fast acting, and you have to take it before mealtimes.

And so they're very different with different profiles, and the idea, Your Honor, that FDA would say, Well, we approved insulin -- the underlying active ingredient. We approved that, and, therefore, you can go ahead and put on the market any one of these other things you want is really, Your Honor, ludicrous.

That would never be allowed to happen, and the reason, Your Honor, that Congress tied this to FDA decisions is that CMS has no expertise. FDA is the expert agency. They know the difference between the new product and an innovation that leads to a new product after that. The CMS does not.

What it's trying to do is wipe out the whole FDA scheme in a way that's contrary to the statute.

Your Honor, I'm going to move quickly here, but I do want to just address the government's two arguments because it will be helpful to the Court.

The first one, Your Honor, is they say it falls within the judicial review bars. If you're still on that same page, on page 7, you will see that I've highlight something in purple. That's -- I'm sorry.

I'm messing myself up here.

If you turn to the second tab, Section 1198, that's where the judicial review is. That's actually page 19 at the bottom.

THE COURT: All right.

MR. PARRISH: And what's interesting there is they're focused on 1192, and if I read the whole section for you, it says what is not subject to review, the selection of drugs under Section 1192(b), the determination of negotiation-eligible drugs under 1192(d), and the determination of a qualifying single-source drug under Section

1192(e).

And, Your Honor, I want to focus the Court's attention on letters and verbs. When I start with the letter, the first thing that you obviously notice, Your Honor, is that Subsection A appears nowhere there.

It would have been easy for Congress to say no judicial review of how many products you are lumping together. But, no, Congress said, We said ten, did not eliminate from judicial review Subsection A.

The second thing is you can see that what Congress wasn't doing with these decisions is it was giving CMS discretion as to choose which products within the parameters it set out but not to change the parameters that Congress had set forth.

And so if you look at those verbs, it select, it's determine, and it's determine.

And if Your Honor goes back to the other parts of it, and you take a look at what I've highlighted in blue in terms of the selection of drugs in the Subsection B, the negotiation-eligible drugs, part -- the high spend in D and so forth, in every one of these provisions, what there is is there's specific directions to the agency to make determinations relating to how much the -- what type of spend it is, whether it's high spend or low spend, and what the total revenues related to that drug is.

So what that provision is saying is very consistent with what you might expect a judicial review provision to say, which is courts -- you know, Your Honor will not get pulled in to the difficult position of second-guessing the question of what is a high spend or a low spend drug.

But nowhere in there, Your Honor, suggests that Congress has spoken clearly with the intent that you would not change the definition that Congress has put in the statute.

They don't have authority to do that. Your Honor, if you have any doubt about that, you have to rule in our favor because the case law is very clear that judicial review bars are interpreted narrowly.

Now, the only way they try to get around that is to say, Well, these decisions are sort of all inexplicably intertwined, but you'll look at those cases, Your Honor, and you realize those are all about calculations. They're not about rewriting statutory definitions.

Your Honor, that takes me to the very last argument that they make, which is they say, Well, it's okay, we can take words that don't appear in the statute, like active ingredients, and we can redefine Congress's definitions because there's provisions in there that talk about aggregation.

Your Honor, I misspoke earlier, but if you now go back to the purple highlighting, which is where I was getting to,

you'll see that that purple highlighting is the use of data provision.

And that use of data provision is something that refers to what it's allowed to do when it's calculating what qualifies as a high-spend drug, and you will notice, Your Honor, when you look at it, what it says is it says, In determining whether any drug has satisfied the statute's high-spend criteria, the Secretary shall use data that is aggregated against dosage forms and the strength of the drug.

Now, Your Honor, what is key there is dosage forms and strength. It's not device presentations, and it's certainly not different entire family of product.

So what they can do is if I have a pill that comes in a 2 milligram form and a 5 milligram, they can only pick one for price controls, but what they can do is through the use of data provision, they can look at both the 2 milligram and the 5 milligram.

And then later when putting the price control, there's another provision later in the statute that says they can come up for procedures to apply across those dosage forms and strength.

But in the case of Novo Nordisk, Your Honor, there's nothing in that provision or any other provision our friends will cite to you today that says anything about a cross device presentation.

So again, needle -- sorry, vial injection, needles or pump, those are device presentations differently. Nothing that authorizes them to go across those. Those are not dosage forms or strength. That's something totally different.

And certainly, Your Honor, there's nothing that says they can take an entire family, Fiasp, which is treated differently by FDA, the NovoLog, and merge those together and take the Fiasp products, which have been on the market for far less than the 11 years, and sweep them all in.

And, Your Honor, obviously, we don't think, as you've heard all this morning, that the statute is constitutional, but if the statute is constitutional, we urge the Court to at least have CMS apply it the way that Congress wanted because Congress certainly wanted to jump the bounds of accountability, which is what it did with the First Amendment prongs and the separation of powers and the taking.

It was trying to get away from accountability, but it wasn't crazy, Your Honor. It said that we have this drug market, we have these patients that rely on those products, and we need to have innovation, so we're going to phase this in slowly, and we're not going to allow the agency to move too quickly.

And the agency is moving very, very quickly, Your Honor.

So with that, I'd love to save a little time for

rebuttal. Unless Your Honor has more questions, I'll sit down.

THE COURT: I don't, but you can reserve your time for rebuttal.

MR. PARRISH: Thank you, Your Honor. I appreciate it.

THE COURT: Who is back up from the government, Mr. Sverdlov?

MR. SVERDLOV: Your Honor, I'd love to keep this short, but I feel like there's a few things to walk through.

THE COURT: I don't want to cut off your time. The reason why I didn't have, you know, I guess, questions intended for this particular area in advance is because I think at lot of this -- at least your positions were fairly clear in the written submissions.

So don't read anything into it that I think these are unimportant claims or less important than the constitutional claim. It's just these I think were a little more clear in the written submissions.

But feel free to make your record, and I'm going to give Mr. Parrish some time on rebuttal anyway.

MR. SVERDLOV: Your Honor, I really appreciate that.

As I said before, we've put a lot of thought into the briefs, and so I do think that our positions are encapsulated better there than I'll be able to sort of speak off of the top

of my head here.

There are a few things to say about the statutory claims, both the preclusion piece and the merits piece. I want to separate them out, and I do want to start with the preclusion piece and then move on to the merits.

The two are obviously intertwined in the sense that determining the determinations that are -- figuring out the scope of the judicial review bar has some overlap with the types of claims that plaintiffs are making by necessity.

But nonetheless, I think it makes sense to start with the preclusion of judicial review, and I will start with the text of the statute, as we have -- hopefully in this packet, we have the text of Section 1198, which is codified at 13 -- 42 U.S.C. 1320f-7(2).

And that provision states that the selection of drugs under Section 1192(b), the determination of negotiation-eligible drugs under Section 1192(d), and the determination of qualifying single-source drugs under Section 1192(e) are precluded in determinations.

Now, what is Novo Nordisk challenging? They say, Well, when the statute says "drugs," it really means FDA drug products. We don't think that's right. I'll get to why.

But they are literally challenging the selection of drugs, and more fundamentally, they are challenging what CMS determined the methodologies that CMS has selected to

determine what is a qualifying single-source drug, right?

They are pointing the Court to the definition of qualifying single-source drug when they say that they weigh on the merits of the statutory claim. Well, the determination of qualifying single-source drug is a precluded determination.

One thing to note, Your Honor, we didn't hear a lot about the notice and common claim. I'm more than happy to rest on the papers on that claim. I think it's just -- it's fully dealt with.

But I do think it's worth noting that the preclusion piece -- the preclusion arguments we make reach both the merits of the statutory interpretation and the APA notice and comment claim.

I don't think our friends on the other side appreciated that. At least I didn't read their reply brief to address the preclusion of judicial review in the context of the APA notice and comment claim, but it does, in fact, apply.

And one of the ways we know that it applies or confirmation of the fact that this is how statutory preclusion provisions works comes from the wealth of cases that we have cited in our brief.

Our friends and counterparts say that those cases are all distinguishable from the circumstances, and that provides us as good of an opening as any to explain why they're not. I think there's a number of cases to walk through.

I would just like to highlight two here at the podium. The first, *Texas Alliance for Homecare Services v. Sebelius* from the D.C. Circuit in 2012. That's at 681 F.3d 402. So what was at issue in that case? The suppliers of medical equipment challenged a regulation addressing the eligibility criteria for a Medicare contractor under the APA substantive and procedural requirements. They have both a statutory construction claim and an APA notice and comment claim.

The statutory provision, the preclusion part in that case, stated that there shall be no administrative or judicial review of awarding of contracts under this section. And the D.C. Circuit finds that this provision covers the challenge. It says, quote, "Under the statute, financial standards are indispensable to the awarding of contracts as such standards determine whether or not a contract may be awarded to the bidder."

I think the Court likely sees the parallel I am trying to draw here. A regulation defining the eligibility for the awarding of contracts is found to be covered by a judicial review bar against the awarding of the contracts. What are they challenging here? They are challenging the methodology by which CMS makes the determinations that are explicitly called out in the judicial review bar.

The second case I'd like to point to, *Yale New Haven Hospital v. Becerra*, from the Second Circuit in 2022. That's

at 56 F4th 9. Once again, we have a provision that says that there shall be no administrative or judicial review of any estimate of the Secretary for purposes of determining three statutory factors. The plaintiffs in there say, Well, you know what? We're not going to challenge the substance of the guidance that the agency issues. We're going to challenge it just on notice and comments grounds. We're going to try to undo this. We're going to undo these estimates by saying that it was procedurally improper -- improperly promulgated.

The Second Circuit walks through why that doesn't work. It says no. It says plaintiffs must explain how we could possibly entertain such a challenge without reviewing the estimate itself, which is a precluded determination. What these cases speak to is this standard that we have articulated in our brief, the indispensable or integral to or inextricably intertwined standard.

Courts have made clear that decisions -- administrative decisions that are, in fact, indispensable, integral, or inextricably intertwined with an unreviewable agency action are covered by the jurisdictional bars. That is the case here, Your Honor. That is true for both the substance and the procedural claim.

If the Court has no questions on that point, I am happy to turn to the merits.

THE COURT: I don't. Feel free.

MR. SVERDLOV: Your Honor, the plaintiffs -- Novo Nordisk's basic thesis here that they sometimes articulate, sometimes don't articulate is this desire to equate the term "drug" in the IRA with the notion of a drug product. They want to say "the drug" means product. Look, we have many different products, therefore, they must be different drugs. Neither the text nor the structure nor the purpose of the IRA supports that interpretation. And there are cases that I will get to in a minute that have rejected the same kind of daisy-chaining efforts that plaintiffs made here to tie FDA's practice to the Medicare context.

So, first, let's just turn to the text and talk about the text. My friends have said that there's only one provision, that this interpretation of the qualifying single-source drug definition that CMS uses is based on one statutory provision. That's not true, Your Honor. It's based on three. We've cited them in our brief, but I think it's worth walking through.

So, first of all, on the selection of negotiation-eligible drugs, 42 U.S.C. 1320f-1(d)(3)(b), the use of data. It says, "In determining whether a qualifying single-source drug satisfies any of the criteria described in the relevant paragraphs, the Secretary shall use data that is aggregated across dosage forms" -- plural -- "strengths" -- plural -- "of the drug" -- singular -- "including new

formulations" -- plural -- "of the drug, such as an extended-release formulation and based on the specific formulation or package size or package type of the drug."

Second place there Congress references the idea of one drug having multiple of these aspects is the negotiation of price. When Congress directs the factors that the Secretary is to consider in formulating its offer -- 42 U.S.C. 1320f-3(e), the factors (1)(D) -- this is the manufacturer-specific data. It says that the Secretary shall consider data on pending and approved patent applications, exclusivity recognized by the Food and Drug Administration, and applications and approvals -- plural -- under Section 355 of the FDCA for the drug -- singular. Again, applications and approvals, multiple; the drug, singular.

Finally, the application of price provision. Once they go through the process, they come up with a number, they come up with the negotiated price, and they sign the agreement. The Secretary then has administrative duties related to compliance monitoring. We touched on some of these things. The administrative duties include -- this is 41 U.S.C. 1320f-5(a)(2). The secretary's administrative duties include the establishment of procedures to compute and apply the maximum fair price across different strengths -- plural -- and dosage forms -- plural -- of a selected drug and not based on the specific formulation or package size or package type of

such drug. Right?

So throughout the statute we have multiple references to dosage forms, different -- different formulations, new formulations, extended-release formulations, all being considered part of one drug.

Now, none of those statutory provisions would make any sense under the interpretations that Novo is positing, and here is how we know. We can look to the declarations that they submitted. So the Hauda declaration, ECF 29 at paragraph 21, they say, "To change a product's dosage form or device presentation, the manufacturer will create a new product that must be evaluated, approved, and licensed by FDA."

So they view each of these different formulations, each of these different presentations as a distinct drug. That's the move they want to make. Product equals drug, drug equals product. I previewed this a few minutes ago, but courts have rejected similar attempts to import the FDCA into the Medicare.

THE COURT: This is the daisy chain analogy.

MR. SVERDLOV: First time --

THE COURT: I'm still listening to you, Mr. Sverdlov. It's late in the afternoon, but I'm still quick up here.

MR. SVERDLOV: Two cases I will cite to the Court this afternoon on that point. The first, *Ipsen Biopharmaceuticals v. Azar*. That's at 2020 Westlaw 3402344.

The Court says, quote, at page 9, star 9 specifically, it says, "The Medicaid Act does not adopt the entire FDCA wholesale." And then it goes on to reject the very type of daisy chain that plaintiffs are positing here.

Another case, *Baker Norton Farms versus FDA*, 132 F. Supp. 2d 30 from CDC in 2001. It does something even more relevant here. It says, even within FDA's practice, the term "drug" doesn't mean one thing. So in that case, the Court is looking at the orphan drug, which establishes certain types of exclusivities, eligibilities. And the plaintiffs in that case come in and they say, no, no, no. The word "drug" for purposes of the Orphan Drug Act means the same thing as what it means for FDA's other practice. And the Court explains why that's not correct. You have to read the statutory provisions within the context in which they are presented, not across broad swaths of agency practice, much less across two completely different agencies, as we have.

The -- I said at the top that neither of the text nor the structure nor the purpose of the IRA supports Novo's position. I think my point on the structure and purpose can be summarized pretty quickly. I can refer the Court to the revised guidance at page 12 where CMS explains why the kind of interpretation that Novo was positing here doesn't work. But the short answer is that if it were the case that CMS went through the process of selecting the drug, negotiated the

price, and then were only applying the established price to one dosage form, one package type, one presentation, it would be trivially easy for a manufacturer to just shift production of the same -- what is essentially the same drug, the same active moiety, the same active ingredient, depending on whether you're dealing with a biologic or the drug product, have doctors prescribe the new drug and the -- or the new product, rather, and the entire regime becomes -- becomes vitiated, becomes a nullity. The maximum fair price that was established, that was just for this pill container. That's clearly not what Congress intended. CMS explained that's not Congress's interpretation. I think our briefs lay out in detail responses on some of the other points that my friend made about the high-spend requirements and such. I wanted to reiterate those.

I think I have been up here long enough. I'm happy to address any questions.

THE COURT: I thank you for your time. I appreciate it, Mr. Sverdlov.

Mr. Parrish, do you want to respond to some of these comments, arguments?

MR. PARRISH: I would, Your Honor. I'm going to be very quick. I've got three points on jurisdiction. I've got one point on notice and comment, and I've got three points on the merits, and they're all very short and to the point.

THE COURT: Build your record.

MR. PARRISH: I hope that you and your clerks picked up on opposing counsel's first argument.

THE COURT: They picked up on it. I don't know if I have. They're much smarter than me. I hire very well.

MR. PARRISH: My ears perked up because he said the merits and the jurisdictional issues are intertwined. He said they overlap. Well, Your Honor, I'm going to refer you to the *AJ* case in the D.C. Circuit from 2020, 964 F.3d 1230, because, Your Honor, I'd like to say we close the day on a very positive note. When things are intertwined and the merits are melded with a jurisdictional question, you skip the jurisdictional bar and you go right to the merits.

So, Your Honor, we've got one step based on his concession today that makes it easy for you to go to the merits. If you don't believe that, though, Your Honor, we still win because it's clear that whatever you think about what he says we're challenging, we are not challenging the selection decision under Subsection B. We are challenging the publication of the list under Subsection A and specifically the idea that there are ten negotiation-eligible drugs, not 15, or whatever number the government wants to make up. Subsection A is not covered by the judicial review bar. If you take a look at the *American Clinical Laboratories Association* case in the D.C. Circuit --

THE COURT: Mr. Parrish, just so I'm not confused, because there's a lot of statutory language, but here in Subsection B, doesn't it begin with him in carrying out Subsection A? Isn't that the first line of Subsection B?

MR. PARRISH: Absolutely, Your Honor. What I say is when you look at judicial review bars, because of the fact that if there's any interpretation that's reasonably susceptible, what they often do is apply these formalisms where they say if it's in one section but not another, that's significant. So all I'm saying, Your Honor, is that the ten negotiation-eligible drugs in A is not covered by the bar. And, Your Honor, you are absolutely right that you look, then, and say, well, what's going on in B?

What is interesting -- this goes to my point -- my two points -- one is look at the letters, and the second one is look at the verbs. If you go into B, the agency has not been given discretion to redefine. It's been given discretion to select based on high spend. And then the other provision is to make determinations based on high spend or low spend.

So what Congress was clearly doing is it was saying -- this is always the case -- it gives the parameters by which the agency gets to act. In this case, ten must be the types of things that FDA has licensed or approved only 7 or 11 years, and then within that, agency has discretion to determine which one of those things are high spend and low

spend to select.

On the question of which drugs, they get the discretion no judicial review, but they can't in the way to do that rewrite the plain statutory mandates.

THE COURT: Mr. Sverdlov is saying, look, this is kind of a toothless tiger, this whole thing, if we have all these different modifications of basically the same drug, and you all want them to be considered separate and independent drugs. So you have one drug, it's within the IRA. You have a very similar drug, some modification, and that one you were selling outside of this program. Is that really the intent of Congress that it would be circumvented that way where you could have different ideations of the same product? I keep using "drug," but I'm going to get corrected by somebody. The same product, and then doesn't that circumvent the whole purpose of what Congress was intending with the IRA here?

MR. PARRISH: No, Your Honor. I'm so glad you asked that because there's three things that really explain what Congress wanted. So, first, what Congress was saying was that we want this to phase in, and this gets to the most common argument, but it didn't give the agency any rulemaking authority for three years. After three years, it has rulemaking authority. Now, if there was a product-hopping problem, the agency could address that through proper rulemaking through notice and comment. So the agency would

have an ability to do that.

Second, Your Honor, remember the deference here is not to the inexperience CMS that has never regulated these things before. It's to FDA's determination of what our individual product to be approved and licensed. Product hopping can't happen that quickly because it has to go through the FDA approval process. Of course, what we're talking about is products that have been on the market for 7 or 11 years.

Remember, Your Honor, when you and I were talking earlier, Congress didn't want to blow up the system. It wanted to move in. So what it does it goes ahead and says, There will be some products that are priced subject to price controls. The idea that several years down the road --

THE COURT: Baby steps.

MR. PARRISH: Baby steps. The idea that there might be product hopping will give the agency rulemaking authority in three years' time.

Finally, Your Honor, whatever I think about probably doesn't matter because I'll just return to my friend, who I agree with. It is Congress's prerogative, and nowhere in the statute does it say product hopping. That, of course, if you looked at the legislative history, too, they talk about it all the time, but they didn't address it here because Congress -- as you said -- baby stepping, not going ahead and sweeping everything in.

Your Honor, I think the judicial review bar, notwithstanding concession, the question is can this Court reasonably read that provision as being related to which products meet the high spend, low spend, and other determinations that were within the agency's discretion but doesn't give the agency the ability to redefine and to change 10 to 15, and the answer is clearly yes there.

So, Your Honor, that takes us to the notice and comment point. I'm just going to highlight this. This is one of the most extraordinary things in this case that really highlights the constitutional problems. I mean, usually everybody knows that a guidance doctrine is supposed to only be nonbinding. It's supposed to be, at most, an expression of the agency's views to be done later. But they've conceded in their brief that this is binding substantive, and yet they also tell you that they didn't have to go through APA notice and common rulemaking proceedings, and there's no judicial review. Your Honor, it's extraordinary revolution since 1946 that they can wipe out the APA like this, and all the cases they talk about where the APA doesn't apply, it's because Congress has imposed similarly constitutionally required procedures to displace the APA, but they're very similar. There's a chance to be heard. There's an opportunity to make sure the agency is just not making it all up. But their position here, Your Honor, is that for purposes of all these things, the amount of data

we've had to turn over, that has nothing to do with the statute itself. All of the things they've done to add to the agreement, their redefinition of what type of manufacturers have to provide materials, all of these things that they say they can make up is completely -- you know, courts -- get away, courts. We get to do this on our own. There's no check from Congress. There's no check from courts. Everybody is just at our mercy. Your Honor, that can't be the law.

That takes me to the merits, Your Honor, which is just a few points. Your Honor, I hope you noticed -- because I did -- the twist that I was trying to warn you about. The word "drug" is not the operative term because the word "drug" means lots of different things in different contexts. He's absolutely right. There's no doubt about it.

He cites cases all day long that talks about drugs and refers to the drug substance. In fact, that's often what you see in the patent context, but we're not talking about drug in the abstract. We're talking about it in two specific places. One is how is it defined by Congress in the statute here? And there it specifically refers to the approval and licensing decisions by FDA.

And we know from the Supreme Court for the last 35 years that in that context, not in the patent context, not in another context, but in the approval and licensing process, it is a product-by-product decision. And, you know, he even

admits that in his brief.

So, Your Honor, the idea that there are distant definitions of drugs makes this statute a little confusing because it does refer to drug, but it isn't confusing what it means when it talks about a negotiation-eligible drug.

And, Your Honor, I've never been accused of daisy-chaining before, but it's not particularly difficult because, remember, he stood up and he said, Your Honor, I don't know -- it's so disoriented, I don't understand where they came up with this idea that it's product.

And, Your Honor, the question is do you believe my friend or do you believe the text of the statute? You take a look at page 7, qualifying single-source drug, and what is the definition? It says drug products, a drug that is approved by FDA for seven years on the market and is not a listed drug.

Every one of those things only applies to products. There is no FDA approval process here that says if you've got an active ingredient, you can just go ahead, put it in any form that you want, and sell it. You have to get it approved and licensed if it's something new.

So, Your Honor, the daisy-chaining, it may take a little while to go through two or three statutory provisions, but all you have to do is look at what the text says, and the idea that we're coming up with something crazy with products is belied by the fact that it says it there in the statute.

Your Honor, also he went on about those provisions. I told you he would, and he's absolutely right. There are aggregation provisions, and remember, he focused on strengths and dosage forms.

But, Your Honor, you remember -- let's take a look at the NovoLog products. We have Fiasp and we have NovoLog. Those are two products, separately approved, different clinical uses. Those are not different strengths and dosage forms. Those are totally different products.

And then, Your Honor, you remember that within those products, we have three of them. Again, we have the injection, we have the Epipen, and we have the pump. Those are not dosage forms and strength.

And all three provisions that he referred you to, the ones that he says, well, that means we must -- "drug" must mean something else than what negotiation-eligible drug is defined. None of them go beyond dosage form and strength, and the problem is that our products, which are differentiating by device presentation, different things all together, innovations that go from putting it in your arm to having a very high-tech pump that has just been recently approved as of 2023. Those are different things.

So, Your Honor, let me just close up because I think I speak on behalf of all the plaintiffs of thanking the Court for taking the exception of having oral argument. We are very

grateful for that.

I would just say, Your Honor, that the government challenge here is that this statute is unprecedented. There has never been a statute like this that combines so many attempts to get around basic constitutional protections, whether it's a forced sale, whether it's a forced compelled speech, whether it's a $2 billion fine or even larger.

There has never been anything like that combined with the idea that there's no principle from Congress, and on top of no principle from Congress, there's no judicial review and no procedures.

But if you disagree with us on that, Your Honor, and I really hope you don't because it's very important that we uphold the Constitution, I, at least, urge you to agree with us on the idea that CMS has gone completely off of what the statute is. It does not have authority to rewrite the statute, and it's trying to do that, and we would urge you, at least, Your Honor, to hold the agency to the language that Congress imposed and the statute Congress chose to write.

And with that, unless you have questions, I'm grateful for the Court's time.

THE COURT: I don't. Thank you, Mr. Parrish.

MR. PARRISH: Thank you, sir.

THE COURT: Is there anything further on behalf of the plaintiffs first? Is there anything further we had to

address today?

It looks like we covered all the issues. I know it's been a long day.

Mr. Chiesa, anything on behalf of this team on my right over here?

MR. CHIESA: No, nothing, Your Honor. Thank you.

THE COURT: All right. Mr. Netter, who's speaking for the government here? Do you have anything further?

MR. NETTER: We have nothing further, Your Honor.

THE COURT: All right. I will be brief because you've been here for a long time, but I think it's worth mentioning this on the record.

I will tell you that today I witnessed absolutely outstanding lawyering from the attorneys here in this courtroom, and I say that from both sides.

I think it's worth mentioning on the record -- I think it's mentioning even for the public who are still here: Mr. Chiesa, Mr. Roth, Mr. Deger-Sen, Mr. King, Mr. Parrish, Mr. Netter, Mr. Gaffney, Mr. Sverdlov, I say this because -- I think I mentioned this off the record before, and I think it's worth mentioning now.

This district is not known to be generous in offering oral argument on particular motions or applications, at least not in civil matters, and I am not one personally who is generous offering oral argument.

I find that many times it's redundant, and it's a waste of time, and I will tell you absolutely that was not the case today.

We've had this discussion with the federal bar, and that's a discussion we'll continue to have with members of our bar about encouraging oral argument when it can be informative to the Court, but here -- two things I think are worth mentioning:

One, I found that the oral argument was absolutely informative to the Court. These are complex issues. Many of these issues, I don't have clear-cut law before me. So I appreciate the written submissions but also the oral argument.

But I also want to say I think you all did a bit more today. You also offered a unique educational opportunity for the newer attorneys that are in my courthouse. We have judicial law clerks. We have judicial interns that have been sitting here observing your advocacy today from this courtroom and in an overflow courtroom across the way in Judge Kirsch's courtroom, and he was gracious to offer that to us. I think that is an important opportunity for them to witness effective advocacy and professionalism.

So I do want to thank the lawyers for your preparation, and with that, this matter is adjourned. Thank you.

THE DEPUTY COURT CLERK: All rise.

(Court concludes at 4:03 p.m.)

FEDERAL OFFICIAL COURT REPORTER'S CERTIFICATE.

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I certify that the foregoing is a correct transcript from the record of proceedings in the above-entitled matter.

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/S/ Megan McKay-Soule, RDR, CRR **March 7, 2024**

Court Reporter Date

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