UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF CONNECTICUT

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BOEHRINGER INGELHEIM PHARMACEUTICALS, INC.,

Plaintiff,

vs.

UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, ET AL.,

Defendants.

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3:23-CV-1103 (MPS)

JUNE 20, 2024

10:00 A.M.

MOTIONS HEARING

450 Main Street
Hartford, Connecticut

BEFORE: THE HONORABLE MICHAEL P. SHEA, U.S.D.J.

COURT REPORTER: Julie L. Monette, RDR, CRR, CRC
(860) 212-6937

Proceedings recorded by mechanical stenography, transcript produced by computer.

APPEARANCES:

FOR THE PLAINTIFF:

PULLMAN & COMLEY
850 Main Street, Post Office Box 7006
Bridgeport, Connecticut 06601-7006
BY: JAMES T. SHEARIN, ESQ.

COVINGTON & BURLING LLP
One CityCenter
850 Tenth Street NW
Washington, D.C. 20001
BY: KEVIN KING, ESQ.
BY: ROBERT ALLEN LONG, JR., ESQ.

KING & SPALDING LLP
1700 Pennsylvania Ave., NW, Suite 200
Washington, D.C. 20006
BY: ASHLEY C. PARRISH, ESQ.

FOR THE DEFENDANTS:

UNITED STATES DEPARTMENT OF JUSTICE, CIVIL DIVISION
1100 L St., NW
Washington, D.C. 20005
BY: ALEXANDER V. SVERDLOV, ESQ.
BY: MICHAEL J. GAFFNEY, ESQ.

(Call to order, 10:00 a.m.)

THE COURT: All right. We're here for argument on motions for summary judgment in Boehringer versus HHS. Let's -- the case is 23-CV-1103. Let's begin with appearances of counsel, please.

MR. SHEARIN: Morning, Your Honor. Timothy Shearin on behalf of Pullman & Comley on behalf of Boehringer. And for Your Honor, from left to right is Kevin King from the Covington firm, Ashley Parrish from King & Spalding, and Mr. Long from the Covington firm as well, Your Honor. Messrs. King and Parrish will be talking.

THE COURT: All right. Good morning, Gentlemen.

MR. SVERDLOV: Good morning, Your Honor. For the defendants, Alexander Sverdlov from the U.S. Department of Justice, Federal Programs Branch. And I will let my colleague introduce himself.

MR. GAFFNEY: Mike Gaffney with the Department of Justice on behalf of the defendants. We also have Michelle McConaghy from the U.S. Attorney's Office.

THE COURT: All right. Good morning everybody. So a couple things before we start. First, just for everyone's information and as a reminder, we don't allow broadcasting or recordings of federal court proceedings. Under our local rules, that's not allowed. If you want a transcript of the proceeding, you can order one from the court reporter, whose

telephone number is available on our website.

The other thing just for the lawyers, please know that I have read the briefs and that I have read many of the cases, as well as other cases, so I think I'm prepared. So there's no point in summarizing your briefs for me. I'm aware of your positions.

I think what would probably make the most sense since there's cross-motions here is for me simply to begin asking some questions, actually quite a few questions that I have for both sides. And I can switch back and forth as to the issues as different things come up. And then if at the end you think that I've missed something or you want to emphasize a point, I can give you some time to do that, to sum up and the like. Okay?

So why don't we begin -- Mr. King, are you going to be speaking today largely?

MR. KING: Yes, Your Honor.

THE COURT: So why don't we begin with you.

And with regard -- I think this will -- first part of my questions will focus on the Fifth Amendment claims that you're making.

Just so I understand how the statute works, is it true that -- is it Boehringer? Is that how I pronounce it?

MR. KING: Yes, Your Honor, Boehringer.

THE COURT: Is it true that Boehringer could avoid

incurring the excise tax or the civil penalty if Boehringer, at this point in the game, if Boehringer signed the maximum fair price addendum by August 1st and then gave notice of withdrawal from Medicare sometime before January 30th, 2025, and still would not have to actually sell at the maximum fair price; is that correct?

MR. KING: I think, Your Honor, yes, that's correct, that we would not be required to sell Jardiance at the maximum fair price if we did all the things you said.

THE COURT: Nor would you be subject to the civil penalty or the excise tax.

MR. KING: As far as I'm aware, that's correct, Your Honor. But I do want to point out there's another side to this. The Government makes the point that you just made, Your Honor, but one thing that the Government crosses over in making that point is that there was no away for Boehringer to have withdraw from the program before October 2023 when it was required by law to sign the Manufacturer Agreement.

THE COURT: Well, let's talk about that. So the Government came out with its guidance on -- revised guidance -- on June 30th, 2023; is that right?

MR. KING: Yes.

THE COURT: And so I guess the point you're making is, well, if under the withdrawal statute we would need -- the earliest we could have withdrawn at that point to make it

effective would be if we withdrew on July 1st, 2023, it wouldn't be effective till January 1, 2025; is that right?

MR. KING: I think that's right, Your Honor. You've got these 11- and 23-month provisions.

THE COURT: Now, of course, the Government responds that they've got in the guidance this 30-day option, this good cause option. And let's talk about that a little bit.

First of all, I get that you don't agree that it's a -- it's a correct reading of the statute, that is to say, of the Government's good cause authority. But how are you prejudiced by it, that is to say, by the fact that they've said in the guidance actually you have this option to withdraw within 30 days, in effect?

MR. KING: Your Honor, I'm not -- well, I'm thinking about prejudice here. I think what we would say is, yes, they've said those words in their revised guidance, but they can say any kind of words in their revised guidance. The revised guidance just gives the views of CMS. It's not binding law on CMS or on anybody.

THE COURT: Right. But as a practical matter, though, suppose you took advantage of that option, perhaps tongue in cheek or sort of skeptically, and said, "Well, we'll give it a try. We'll use this good cause option that the Government has allowed." And, in fact, the Government terminated you from -- terminated your agreements under Medicare and Medicaid within

the 30 days. How's that going to come back and bite you?

MR. KING: Your Honor, it could come back and bite us for any number of reasons. One of the reasons is that the statute, of course, controls here, not the revised guidance. And the statute says that a withdrawal by the manufacturer -- and you can see the statute on page 8 of our reply -- takes effect 11 or 23 months later. So even if CMS writes down on a piece of paper, "We hereby declare you are withdrawn by statute," that withdrawal by the manufacturer does not take effect until at least 11 months later.

THE COURT: Just thinking about -- I get that that's your position. But just thinking about the possible bad things that could happen to you, you've pointed out many of them: you could be subject to the excise tax; you could be subject to the civil penalty; and from your standpoint, you could have to sell at a price that you believe is well below the market price. That's basically the three bad things from this statute as a practical matter; is that right?

MR. KING: Well, I think, yes, all three of those are bad things. I would add at least a fourth bad thing here, which is that on the Government's view we could avoid all of this by just opting out of Medicare and Medicaid entirely, which would mean that we would have to withdraw not just Jardiance --

THE COURT: I get that. We're going to talk about

that.

MR. KING: Sure.

THE COURT: Just coming back to this good cause sort of piece --

MR. KING: Yeah.

THE COURT: -- I'm trying to understand how any of those bad things would happen to you in the real world if you took advantage of the 30-day option. Because the Government is taking the position before this Court, and in its guidance, that, no, in fact, you can withdraw within 30 days.

You think that's a misreading of the statute. I get that. But as a practical matter, are you concerned that -- I don't know -- the Secretary of the Treasury won't respect that or something like that, that, Hey, HHS doesn't speak for the Secretary of the Treasury, and the Secretary of the Treasury is the one who enforces the revenue laws. Is that what you're concerned about?

MR. KING: That's one of our concerns. Another concern, Your Honor, we're about to have a presidential election. We're going to have potentially different people in charge or not. We don't know. But even if we don't have different people in charge, different people who could come to different conclusions, the same people now in Government could come to different conclusions themselves.

THE COURT: Would there be any estoppel under those

circumstances? I mean, there are, admittedly, narrow circumstances when the Government can be estopped. I don't -- I haven't studied that here.

The Government here put out guidance that they claim is the way they're supposed to implement this statute that says, "No, trust us. 30 days, you're out, if that's what you want." You rely on that in my scenario. And then a new administration comes in and says, "Sorry, that's not what this statute says. We're imposing this excise tax." That's a serious concern to you.

MR. KING: Yes, it is, Your Honor.

THE COURT: All right. Fair enough.

MR. KING: And not just that. But again -- forget the presidential election. This guidance does not purport to be binding on CMS or on anybody. They could change it tomorrow. In fact, they could just put out --

THE COURT: Well, wait a minute. Let's talk about that.

When you say the guidance doesn't purport to be binding, CMS has taken the position that, in fact, the way that they are supposed to implement this statute, and I think the statute supports this, says "shall implement the program for '26, '27, 2028 by program instruction or other program guidance." So how is it -- how is what they issue not binding?

MR. KING: It could be binding. My point is that it

can change -- right? -- in the sense that they put out a proposed guidance and then a revised guidance. Now they've put out yet another different guidance, a new guidance for 2027, and there's nothing anywhere in the statute or in the guidance or anywhere else that says that they couldn't -- you gave the date on which the revised guidance was published. Suppose that one week later they said, "You know what? Actually, we want to amend Section 16." I'm not aware of anything, Your Honor, that would stop them from doing that.

THE COURT: Okay. You mentioned new guidance for 2027. Does that -- when did that come out, and is that any import in this case other than the fact that your point is, well, they can amend the guidance at any time?

MR. KING: It's the latter, right, Your Honor. It does not purport to speak to 2026 as far as I'm aware, but the Government is more apt to speak to that.

If I could, Your Honor, I do have a division of issues between myself and Mr. Parrish, and I'm glad to advise you of that division if that would be helpful.

THE COURT: I was hoping you could address the Fifth Amendment.

MR. KING: Yes, I could address anything on Fifth Amendment, on First Amendment, unconstitutional conditions, and especially voluntariness.

THE COURT: But he's the admin guy.

MR. KING: He's APA, due process, and excessive fines.

THE COURT: Well, due process is part of the Fifth Amendment. So how are you going to separate -- I mean, they're very closely related, those two claims.

MR. KING: If you would like to hear them together, I'm happy to speak to part of that. But Mr. Parrish is the one who we've been thinking of on the lead on that.

THE COURT: On the takings and due process?

MR. KING: Just on due process.

THE COURT: I have to be honest with you. That's an odd separation here, to separate the due process. Let's get to that. I'm struggling -- well, all right. Let me ask this question, and if you think this is going in a way he should get up, then he can kind of jump in. All right? So let's get there.

Why isn't this case closer to the Second Circuit's decision in *Garelick* and other similar cases involving federal health insurance programs than *Horne*, which is a case involving, you know, raisins? I mean, I don't just mean because the industries are -- obviously, you know, the way I phrased it, certainly this case looks closer. But here we've got a Government-created market -- right? -- for Medicare and Medicaid. There, before the Government was around and doing anything, people were selling raisins. So it's not a Government-created market.

Here, the Government's -- I know you say it's acting as a regulator too, but I don't think you're disputing that it's also acting as a buyer. Not so in the raisin example. Why isn't this case closer, therefore, to *Garelick* and those cases instead of *Horne*?

MR. KING: A few responses, Your Honor. First, I accept that there are factual differences between what's going on here and what was going on in *Horne*. We do have raisins and prescription drugs, and those things are different and the frameworks behind them also are different. I acknowledge all of that.

I will say that the market here preexisted Government action the same way it did for raisins. I will dispute that premise you had here. People were buying and taking prescription drugs before Medicare --

THE COURT: That's true, but there was no Medicare and Medicaid market before. And that's the market you're concerned about here. You're saying one of those -- that fourth bad thing you cited is the possibility of having to withdraw from selling to the Government, or through the Government, if you like, not selling in the private market.

MR. KING: Your Honor, I would -- I think it is through the Government. We're not selling to the Government. We're selling to people, and the Government has inserted itself as an intermediary here. And I would say there is at least

some similarity between that and the role where the Government had inserted itself as an intermediary for a large segment of the raisin market in *Horne*.

But forgetting for a moment the factual differences -- again, I accept there are factual differences -- I think the key point from *Horne* from our perspective, Your Honor, is the legal analysis, is the principle that drove the decision there; right? In that case what you had is you had essentially a mandate: Give us our raisins. Or else do what? Pay a large penalty. What we have here is the very same thing in substance, a mandate: Give us your drugs. Provide access to your drugs, or else pay these massive excise tax penalties.

THE COURT: I get it. Let me stop you there for a sec. One difference, though, in the two situations, in *Horne*, that "give us your raisins," the physical appropriation, takes place before the point of sale for the Hornes; right? The Hornes are -- in fact, Chief Justice Roberts emphasized that the Hornes were unlike other handlers, both because they were growers and handlers and because, unlike other handlers, they actually paid for all of the raisins, including the reserve raisins that they purchased from growers.

So the Hornes now have these raisins which include -- which are all their raisins because they bought them and they've grown them. And the Government comes in and takes some. They drive the truck up, and they take some, all before

the Hornes sell any raisins. Not true in this case, is it?

MR. KING: I think the appropriation here, it again, you know, it's 13-20, I think it's f-2(a)(1), says "provide access."

THE COURT: To the price.

MR. KING: Right, to the price.

THE COURT: Of the drug.

MR. KING: Right. You can't have access to a price without the underlying product.

THE COURT: That's true, but you also can't have access to a price until there's a sale. How are you going to have access to a price without a sale?

MR. KING: Well, I guess I would say, Your Honor, I'm not sure we see it that way. If I'm a car dealer and I advertise, I'm advertising a $10,000 price for luxury sedans and someone shows up to my lot and says, "Okay, I want to take that deal," you say, "I'm giving you access to the price, but guess what, you don't get a sedan," I think I would have an angry mob on my hands, not to mention an enforcement action from the Federal Trade Commission for unfair and deceptive trade practices.

THE COURT: I don't see how that rebuts my point. Doesn't that just prove my point? In other words, you get the price when you get the sale. You pay the price when you get the product. I mean, okay, there are situations where you can

talk about installment plans and the like, but that's not what we're talking about in either of these situations, either in *Horne* or in this case.

MR. KING: Yeah.

THE COURT: There's a sale, and that's when -- I mean, when, in your view, does the physical taking occur here?

MR. KING: The physical taking here occurs by a statute when the Government says, "You shall give access." And when you're required to give that access, that's when our right to exclude, our right to possess, is appropriated for the benefit of third parties.

THE COURT: But you don't have to give access until you sell the product; right? Nobody's actually going to pay that price -- even if you've negotiated it already, nobody's actually going to pay that price. That price is going to have zero economic impact on you until there's a sale; true?

MR. KING: I'm not sure that's right, Your Honor, because if we don't make the sales, if we don't provide access to that price, we're not discharging our statutory obligation, and we're going to be subject either to the civil mandatory penalties or to the excise tax.

THE COURT: When you fail to make the sale at that price.

MR. KING: Your Honor, that's -- I don't think that's what the statute says. The Government has made that argument.

They make an argument that's much like that at page 20 of their reply brief. They say, "You don't have to sell this to anybody." But that's not in the statute anywhere. The statute says, "You shall provide access, and these drugs shall be on the" --

THE COURT: But let's talk about, as a practical matter, okay, when you -- the first time someone actually pays the price that you have to give access to is going to be the first time you have to sell at the maximum fair price; isn't that true?

MR. KING: The first time that we sell, I think that's true, yes, Your Honor.

THE COURT: Right. So you're not giving access to the price until there's a sale. When are you giving -- let's say I'm a Medicare beneficiary, okay, and I'm really excited to purchase Jardiance at the maximum fair price and I'm really following this case closely and I'm looking at the negotiations. And let's say you sign your agreement on August 1st and, you know, I know what the price is and I'm just thrilled because I'm going to save money or whatever it is, okay. And I'm getting my dollars ready to pay that price, but there's something blocking me, which is it's not January 1, 2026, yet. I can't pay that price yet. Isn't that true, or am I missing something?

MR. KING: Yes, that's right, you cannot pay that

price till January 1, 2026.

THE COURT: So I don't have access to the price till January 1, 2026; isn't that true?

MR. KING: Yes, that's correct, you don't have access to the price till January 1, 2026.

THE COURT: Right, when the first purchase occurs.

MR. KING: Yeah, when the drug is on the market. So I guess, Your Honor, if your point is that, to avoid this program, Boehringer would have to take Jardiance completely off the market, then that would just be an even worse form of economic coercion than the ones we've described in our brief. We're talking here about all the patient harms that are in the March declaration.

THE COURT: No, no, my point is not that, although we can talk about that. My point is simply, I'm trying to understand -- you rely heavily on the *Horne* case in your takings claim; is that true?

MR. KING: We do, but we rely on it in two different ways. We rely on the substantive takings analysis there but also the voluntariness piece.

THE COURT: We'll get to the economic coercion piece in a moment. I'm talking about just the physical taking part.

MR. KING: Sure.

THE COURT: There, there's no doubt there's a physical

taking. The Government shows up before the point of sale, takes the Hornes' property; right? That's very clear.

What I'm trying to struggle -- what I'm struggling with here is it doesn't seem to me to be as clear here because it all happens at the point of sale. It seems to me that you give access to the price, which you call a taking. And I think we've just kind of established, through my sequence of my hypothetical Medicare beneficiary, that I'm not going to be able to have access to that price until I purchase the product.

MR. KING: Yes, and I guess the dichotomy is if we could just fast-forward to January 1, 2026, it's basically one thing or the other. It's either provide access to that product -- that price, right, or pay the excise tax.

THE COURT: That's true.

MR. KING: So the combined effect of those two things, Your Honor, the combined effect, which is what *Cedar Point* says is what matters, the combined effect is the same as backing up the trucks. It's the same as a direct seizure. Your Honor's questions focus on the form by which the Government takes the property. It is true, nobody from CMS is backing up trucks. But the effect of these provisions, when you put them together, is the same as if they brought trucks to our property.

THE COURT: Well, you're still getting something for it. I mean, it's really more like price regulation, isn't it?

MR. KING: Well, Your Honor, Congress has enacted

scores and scores of price regulations, but none of them work the way this one does; right? None of them put words in our mouth. That's the First Amendment issue. None of them require us to call the drugs fair. None of them, you know, have this scenario where there's no way to get away from it without massive penalties. So I think that's the difference. That's not price regulation.

And, by the way, our claim here is really about the tablets themselves, the drug itself. It's not about the price. So to the extent that the Government is relying on regulatory takings cases, like you mentioned *Garelick*, what the Supreme Court told us in *Tahoe-Sierra* -- you've read the briefs, you know this -- those regulatory cases have no bearing here.

THE COURT: Let's talk about that, though. *Garelick*, in its discussion of voluntariness, doesn't suggest that there'd be a different conclusion on voluntariness when it's discussing that it's voluntary if you participate in a Government price-regulated program or choose not to. It doesn't suggest that that depends on the type of taking involved, does it? I mean, it's hard to see how the logic of *Garelick* in similar cases would change in any way depending on the nature of the taking.

MR. KING: That -- that might be true, Your Honor. I don't know. What I do know is, again, that *Tahoe-Sierra* says, Take those -- right when you're dealing with a physical takings

claim, take those regulatory takings cases, put them to the side. They're not relevant.

But I guess to just -- to take the issue head on, Your Honor, *Garelick* predates *Horne*, and it relies on a voluntariness rationale that was rejected directly in *Horne*.

THE COURT: Well, now let's talk about that. So one difference -- I mean, it's hard for me to get around this difference -- is that in *Horne* the option was, that the Supreme Court rejected as a basis for the defense to a takings claim, was: Stop selling raisins entirely to anyone. The entire market of raisins is foreclosed to you.

Not true here; right? You still have the private market. If you choose to exit Medicare/Medicaid, you still have the private market.

Now, you may say, "Judge, that's cold comfort" because I think you said in your brief at one point last, 2022, 55 percent of your sales were in it. So I get it. It's a large -- it's more than half. But it's not the entire market. You still have the private market.

MR. KING: Your Honor, respectfully, I understand everything you said, and a lot of what you said we agree with. But there is one part that we disagree with, which is somehow in *Horne* they have to leave the whole market and we don't have to leave the whole market here; right?

In *Horne* they didn't have to leave the whole market.

As the Government argued in that case, they could plant different crops, they could take those very same grapes that they were growing, and they could sell them for table grapes, they could sell them for wine making. So, no, they didn't have to stop selling.

THE COURT: You know, from an antitrust standpoint, for example, table grapes and raisins are different markets. They're different markets. There's no question about that.

MR. KING: But, Your Honor --

THE COURT: A raisin is not a substitute in economic terms for a grape.

MR. KING: I mean, it literally is the very same grape that --

THE COURT: I realize that, but that's like saying that oil is a substitute for -- or gas at the pump is a substitute for heating oil. It's just not a substitute. They both come from the same source, but they're not substitutes for each other, not the same product.

MR. KING: Understood, Your Honor. But I guess if you're going to look at it from that perspective, what you're saying is, Well, there's a raisins market and there's a grapes market. What the Government is saying here, Well, there's a Medicare market and a non-Medicare market. And so it's the same.

THE COURT: Well, I don't know. I mean, there's a

pharmaceutical market; right? There's a market for Jardiance. There's a market for -- probably your market is -- I think Jardiance is for diabetic and pulmonary and some other.

MR. KING: Heart disease, chronic kidney disease.

THE COURT: So there's a market for drugs that treat those conditions; right? That's the market that Jardiance participates in. Yeah, so I don't really buy the notion that the product market is different because one is -- because the buyers are different.

MR. KING: Well, I mean, it --

THE COURT: I don't think any antitrust lawyer would buy that notion. You probably do practice antitrust.

MR. KING: I do not practice antitrust, Your Honor.

THE COURT: I figured at Covington everybody does, so ...

MR. KING: There are certainly. And Mr. Long, my colleague, is one of those antitrust experts.

THE COURT: Okay.

MR. KING: But I would say, you know, you don't have to look just at *Horne*. You can look beyond *Horne* to cases like *Butler* where there the regulated party, the cotton growers, they could keep selling their cotton. They have to pay the tax. That's what they'd have to do, but they could keep selling their cotton.

So this idea that *Horne* and the other cases we rely on

are categorically distinct because in those cases you would have to quit the market entirely, it's just not true. *Butler* is one example of that. Some of the other cases we cite are of the same kind.

THE COURT: Okay. Let me ask you a couple other questions. Let's turn to your argument about the sort of information portion of the claim, that is to say, that there's a taking because the Government requires that you submit what you believe are trade secrets to HHS as part of the so-called negotiation process.

So here's my question on that: How does a requirement that you submit trade secrets to the Government, where the Government agrees, as I understand -- in fact, it doesn't just agree. The statute requires that it won't disclose them. How does that amount to a taking, or a deprivation of property for that matter?

MR. KING: Your Honor, this is one where hopefully I can save you a little bit of work. We do not assert any takings claim based on the deprivation of trade secrets. We assert the trade secrets as one of the property interests that is affected here for due process purposes. We have a due process claim, and the Government comes back and says, "No, no, we haven't violated your due process rights, not because we comply with the Fifth Amendment, but because there's no property right at stake." And our retort to that is, yes,

actually there is.

THE COURT: I thought their argument was because there's no deprivation.

MR. KING: They say there's no property interest, and the Government can speak for itself.

THE COURT: Well, let me ask you this: How is there a deprivation? You want your colleague to handle this? I'm happy to have you handle this, but if you think he's the due process guy.

That was next in my notes, so I'm sorry to drag you up here. How is there a deprivation of property under that scenario?

MR. PARRISH: So, Your Honor, the way I would look at it is sort of two things. And I hope this is responsive, but if I could just get there a little circuitously.

THE COURT: Okay.

MR. PARRISH: As you said, the argument here is just that there's no due process entitled at all because there's no property interest at stake. And, Your Honor, our response to that is to point out two property interests, the one you've identified and then also the fact that these are our drugs.

What's telling, Your Honor, is that the Government's response on this is: Trust us. There's no property interest because we are exercising regulatory authority; and using that regulatory authority, we will not disclose your information to

other people. And, therefore, you have no due process rights related to that.

Of course, Your Honor, you will notice that is directly self-contradictory to their position that they are only acting as a market participant in procuring and not exercising --

THE COURT: You're going a little fast for me.

MR. PARRISH: Yeah.

THE COURT: I guess -- so if you have a trade secret, your point is, you have a property interest, period.

MR. PARRISH: Correct.

THE COURT: But to show a Fifth Amendment violation, you also have to show a deprivation of property; correct?

MR. PARRISH: Well, Your Honor, I think what we would say --

THE COURT: Am I correct about that?

MR. PARRISH: I don't think so, Your Honor, because you're thinking of this in takings terms. What we're saying is there is a property interest. That means there have to be --

THE COURT: Not if there's no deprivation.

MR. PARRISH: But to protect against a deprivation, yes, Your Honor.

THE COURT: How so? If there's no deprivation or danger of a deprivation, then why does there need to be any procedure?

MR. PARRISH: So, Your Honor, those two things are linked together -- right? -- which is, on one hand, we don't want -- we're negotiating a price that we don't want them to impose, and they're asking for confidential information as a counterparty that we would never disclose to a regular counterparty that they're demanding as the Government. They're disclosing it to themselves for purposes that we do not want them to have --

THE COURT: The same was true in *Monsanto*; right? In order to get a permit to pollute, you had to produce trade secrets to the Government. And there, of course, there were situations where the trade secrets would be disclosed. And under one of those scenarios, the Supreme Court said, Well, that would be a taking when there were investment-backed reliance, that kind of thing. But here the Government's not going to disclose it.

MR. PARRISH: So, Your Honor, with respect, this is why we're distinguishing between due process and a taking, which is -- in the due process context, our point is that there are all these procedures that since the 1940s, if not earlier, that the Government has always been required before it regulates. So you have to have -- if you're imposed on a regulation, if you have a price at all or there's a risk of a taking, you're entitled to things like a neutral --

THE COURT: Where's the risk?

MR. PARRISH: Your Honor, the risk is that we want to sell our property.

THE COURT: We're talking about the information; right?

MR. PARRISH: I know, Your Honor, but in order for them to figure out what price to impose, they are taking and using our confidential information for their benefit. They're either doing that --

THE COURT: That was true -- I mean, that was true in *Monsanto* as well.

MR. PARRISH: But, Your Honor, *Monsanto* was a takings case; right?

THE COURT: Yeah, it was, but this is where -- candidly, I think this is where your argument falls apart on this point. Okay, let me explain why: Because there was no taking in *Monsanto* as long as the Government didn't disclose the information or use it to benefit a subsequent pesticide permit applicant. Here, they're not going to do those things. They're not going to disclose it or use it to benefit anybody else.

MR. PARRISH: Your Honor, I'm sorry, with respect, that second part of your statement is wrong. They're using it to benefit themselves.

THE COURT: Yeah, but the same could have been said of the Government in *Monsanto*.

MR. PARRISH: No, Your Honor. In that -- in the cases where disclosure -- and we see this in the FDA all the time, that there is a division between those who are taking the information for regulatory purposes and those who are using it as a market participant.

THE COURT: So your point is: Look, they're a proprietor. They're in competition with us; and, therefore, the fact it was a disclosure to them is, in fact, a taking.

MR. PARRISH: And, Your Honor, this is a fundamental point we would like to make which I think goes to the heart of this case, which is the Government says, on one hand: We are exercising spending powers only of proprietary interest. And because of that, we're exempt from the constitutional constraints, which are minimal constraints, but we're exempt from them.

On the other hand, and this claim shows it very clearly, they are actually exercising very strong regulatory powers. And what we would say is any time you regulate private conduct, including taking information, the minimal constitutional requirements of due process apply. Now, we should talk about what those are because they're very -- it's a low burden. But what's unprecedented about the statute is that all of those due process protections have been stripped out, which is why we separated this claim as being more akin to the APA notice in common than the takings because it isn't just

about a situation where the Government takes property, although that's the concern here. It's also in a situation that whenever the Government regulates in a way that impinges on your private rights and private interests, as long as there's a property interest at stake, which there clearly is here, there has to be some minimal due process protections.

And I can walk you through those, Your Honor, but that's where the Government's argument really falls down. And your question goes right to the heart of the problem, which is, if they were a proprietary interest, they don't get the confidential data and they can't use that for their advantage.

THE COURT: Let me ask you a question then: Suppose that this statute had been done -- put together differently. Suppose that the statute simply said, This is the price the Government's going to pay for Jardiance going forward. Any due process problem? Any taking?

MR. PARRISH: Your Honor, if the -- I want to be careful with the taking. But on the statute, if the statute just said that, "This is the price we're going to pay," and there were no penalties for being able to say, "We don't want to sell it to you at that price," no penalties meaning we could -- we could still sell our other products or we wouldn't be subject to the excise tax --

THE COURT: What if it also said you either sell to this price or you don't participate in Medicare or Medicaid

anymore?

MR. PARRISH: So, Your Honor, that would be better than where we are in the sense that we're far beyond that. But the thing to realize, Your Honor, is that -- and I just use the simple analogy is that -- I assume you might, but I own a home. I think the home might be worth $500,000. If the Government set itself up as an intermediary because it felt housing prices were too high and it took 15 million people around me and said, "Look, you can sell your house to billionaires and to really poor people, but for the people you really want to sell in your neighborhood to, you come through us and you can sell your house at $5, not the $500,000 it might be worth but $5, take it or leave it," there would at least have to be some judicial check and due process to make sure that, A, it wasn't a taking --

THE COURT: So this is -- I think you're kind of suggesting my hypothetical is, in fact, a regulatory hypothetical, when my view is it's a proprietary hypothetical. In other words, the Government says: Look, we're buying Medicare. We're praying too much. We don't want to pay that anymore. Here by law, by statute, we're enacting a statute that says we're not going to do that anymore. You sell to this price or you don't sell to Medicare and Medicaid.

MR. PARRISH: So, Your Honor, what I want to make clear is first this point, the way you've changed the

hypothetical, would help a whole lot. So I just want to emphasize there's a whole lot of other problems with the statute.

THE COURT: Would help with what?

MR. PARRISH: With the constitutionality of it in the sense that if the Government were to just say, "This is what we're prepared to pay for the drugs," that would be much different. But your question goes to an important --

THE COURT: But if it would help, would there be a due process violation under those circumstances?

MR. PARRISH: Your Honor, if -- what I'm pushing back against is the idea that they can take over a market, put themselves up in an intermediary -- if they're buying --

THE COURT: But in my hypothetical they're not taking over anything. They are the buyer, in effect, payor, for Medicare and Medicaid.

MR. PARRISH: But, Your Honor, with respect, what they are is they are a regulator of the price of the drugs. If they're saying, "We're buying this" -- in their brief they talk about buying planes for the military. That's a procurement process. But what they're trying to do here is they're trying to subsidize a large swath of the economy.

And one of our positions -- we don't need to win on this to win the case, but one of our positions is that you still have to have due process protections because there the

Government is not only just buying it, it's not just a prior interest, it is also regulating the price. And instead of taking a subsidy from general tax revenues and proceeding by general law, it is targeting particular parties --

THE COURT: That would mean that *Garelick* was wrongly decided and that all those other cases that have for years said, Look, it's not a problem when the Government for Medicare and Medicaid purposes establishes a reimbursement rate that everybody has to pay or you don't sell to Medicare.

Under your argument, there suddenly would have to be due process protections there.

MR. PARRISH: So, Your Honor, two points. One is we do think, and Mr. King can talk more about this, but the voluntariness analysis that's relied on by *Garelick* in those other cases have been cast in doubt significantly by controlling Supreme Court precedent and the analysis of Coragen. So those cases are -- the reasoning of those cases is no longer good.

But, Your Honor --

THE COURT: So you're suggesting that, yes, in fact, because of *Horne* --

MR. PARRISH: And *NFIB*.

THE COURT: -- and *NFIB*, I'm sorry, but there's due process and takings concerns any time, you know, the anesthesiologists don't have to be subject to the same

reimbursement rates. Or if they are, they get some compensation for it for, you know, when they sell to Medicare.

MR. PARRISH: That takes me to my second point on --

THE COURT: But that's your argument; right?

MR. PARRISH: Yes, Your Honor, but let me just say this: In the Medicare context, the due process issue is very different. In there, there's an entire channeling process between an administrative proceeding with neutral arbitrators, a chance of judicial review, a chance to challenge evidence.

So the thing is, those cases, even if they were still good law, would be something we would want to address on the taking side. On the due process --

THE COURT: For reimbursement rate?

MR. PARRISH: Yeah, Your Honor, that's right. If you're a hospital today -- like your clerks can look at the DDC litigation. Every week there's a new case. And what you have to do is you have to channel it in. And the whole fight is over what the channeling process looks like, but it's through the administration process that allows for judicial review. If you go through hearing officers, there are three layers of review.

THE COURT: I'm familiar with that, not on the rate side, but I'm familiar with it in other contexts.

MR. PARRISH: The thing that's really extraordinary

about this case and what's so unprecedented in many different ways but on the due process side is that even those Medicare cases, which we think the voluntariness part has been called into doubt, those have lots of procedures that get applied.

Here, Your Honor, if I could just walk through it really quickly --

THE COURT: Sure.

MR. PARRISH: -- because it really is unprecedented since, like, we talk about this in the case that, even during emergency wartime periods, those cases had procedures of neutral arbitrators and so forth. Here, there's no neutral arbitrator, no tribunal, nothing like that. There's no right to a hearing, certainly not before a neutral --

THE COURT: I know all this.

MR. PARRISH: You know all this, okay. But, Your Honor, it's -- I guess I just emphasize because, maybe you get this as well, but they have never cited any other statute that we know of or any other case that has ever said that you can go through all those process -- with no process at all, no procedures in place. And the Government's only argument on that, as you noted, is not that those procedures are adequate or that there's alternative procedures or you have to channel like in the Medicare context. Their only argument, Your Honor, is what your question got to, which is there are property interests.

And on that basic simple question, there is a property interest. And, again, it just goes to your question, which is: Is the information that they say they're protecting, are they exercising a procurement power there, or is it a regulatory power? It's clearly a regulatory power, which means there has to be some procedures. And the Government has no argument of that point to defend the statute.

THE COURT: So let me -- you're the APA guy. Actually, you know what? Let me ask some questions of the Government, and I'll let you regroup.

MR. PARRISH: Thank you, sir.

THE COURT: Let me ask some questions of you, sir. Mr. Sverdlov, is that right?

MR. SVERDLOV: It is.

THE COURT: All right. So on the Fifth Amendment issue -- well, let me actually start with the information thing that we talked about.

So the response to my argument about *Monsanto* was: Judge, in *Monsanto* the Government was just a regulator. Here they're trying to have their cake and eat it too. They're using their regulatory power to require us to submit information, to then turn around and use it against us as a proprietary. You don't see that anywhere else.

That's the argument. What's your response?

MR. SVERDLOV: So we disagree with that, Your Honor,

and we disagree with that for several reasons. The only -- as a starting point, I think it's not accurate to say that the Government is acting as a regulator here. There are circumstances in which the Government collects information as a regulator. But the only way in which the Government collects information here is when the manufacturers agree to enter negotiations. Their first point at which they have to decide whether they're going to negotiate the price of drugs was October 1st, 2023. And as we can talk about, at the Court's convenience, there were options to not participate in the process at all.

THE COURT: Well --

MR. SVERDLOV: They were never --

THE COURT: We can talk about that, and I do have some questions. But why don't you keep going.

MR. SVERDLOV: Absolutely. So the point is, there is a layer, unlike in *Monsanto*, where in order to be in the market of selling pesticides, you had to submit information to the EPA for regulatory purposes, and the Court made clear that, in *Monsanto*, that the petitioners there weren't challenging that overall regulatory scheme.

Our point here is that there is not an overarching regulatory scheme. The obligation to submit information only attaches when these companies come in and decide that they are going to go through the negotiation process. That's point

number one.

Point number two --

THE COURT: I do have to stop you on point number one because I think they would say a lot of things, I think one of which would be they resist the whole notion that it's an agreement. But it is regulatory because, in effect, the excise tax forces them to enter into the agreement. If they don't enter into the agreement by October 1st, on October 2nd they get hit by the excise tax. It's not voluntary. Their entering into the agreement wasn't voluntary at all because they have to pay the excise tax if they don't enter into it.

MR. SVERDLOV: Your Honor, we disagree with that for several reasons as well because fundamentally that is not an argument that this is a regulatory regime. That's an argument this is a regulatory coercive regime. And we have drawn a very clear line, which I think is supported by the cases, about the differences between a spending clause program and a regulatory program which regulates the whole market.

THE COURT: But this -- the tax isn't just a spending clause. It wasn't enacted under the Spending Clause, was it?

MR. SVERDLOV: No. It was enacted under the taxing power.

THE COURT: That's a regulatory power, is it not?

MR. SVERDLOV: But, Your Honor, it only attaches -- it only attaches in specific contexts. And those contexts are

triggered by --

THE COURT: Contracts?

MR. SVERDLOV: They're triggered by the decision to engage or not engage with the Government in the process. In other words, if you want to be part of Medicare, you have several choices, one of which is, hanging out in the background, is the excise tax.

THE COURT: But their position is they couldn't have withdrawn before October 2nd even if they felt the whole thing was unfair. They had to sign this agreement because they were going to be hit with this monstrous excise tax.

MR. SVERDLOV: Right. So, again, several points on that. One --

THE COURT: Which takes us to the good cause issue.

MR. SVERDLOV: It takes us to the good cause as one issue among several.

THE COURT: Okay.

MR. SVERDLOV: The other -- just -- and just to be clear, under the provisions established in the revised guidance, they could have withdrawn -- and the revised guidance is crystal clear on this, that the timelines are established such that manufacturers can exercise their withdrawal options to avoid any penalty or tax. So under the administrative procedures that are set up under the good cause authority, and we can talk about the case laws interpreting what good cause

means, they had the option to avoid the excise tax. That's point number one.

Point number two, the excise tax, just like the maximum fair price, again, attaches only to sales that manufacturers choose to make. So if a manufacturer decides that it does not want to sign a price agreement, it doesn't want to sign a negotiation agreement, and it doesn't want to divest the drug, it wants to hold onto the drug, it's still not required to sell the drug to Medicare beneficiaries.

THE COURT: Right.

MR. SVERDLOV: It could set up a pipeline.

THE COURT: The way the excise tax is written -- and it's not a frivolous argument on its face. The way the excise tax is written, it says, "any sale of a designated drug." So it doesn't say "any sale of a designated drug to Medicare."

Now, I know that the IRS has come out with this statement, as I understand it, that says, yeah, what it really means or what we're going to interpret it as meaning is sales to Medicare. But, you know, I got into this colloquy, and it's the same as the good cause discussion in this sense, that their view is: What happens if another administration comes along and says, Sorry, that's not the way we read the statute? There's no good cause and there's no -- we're not going to limit it -- we need the revenue. We're not going to limit it to Medicare. Nothing in the statute requires us to do that.

That's just another administration. Here's a new notice.

What do they do then?

MR. SVERDLOV: So several points, Your Honor, and, one, I would respectfully exercise my prerogative on the issue splitting. My colleague, Michael Gaffney, will speak to all the issues, the jurisdictional and the merits, related to the tax.

THE COURT: Okay.

MR. SVERDLOV: But I think I can address the Court's question for these purposes, which is to say that the IRS notice itself states that taxpayers can rely upon this in the absence of subsequent promulgation.

THE COURT: Yeah, but I couldn't find any case law -- and I did look. Maybe I just didn't find it -- attributing any great significance to that. I know what it says, but I haven't found a case that says: Therefore, the IRS is estopped from changing its mind.

In fact, the estoppel cases are pretty good for the Government. In fact, the Government often takes the position that it can never be estopped when it's acting in a sovereign capacity.

So even though it says you can rely on it -- which presumably is true of any guidance in some ways. When an agency says something, you should be able to rely on it to some degree. Then how does that stop a new administration from

changing things?

MR. SVERDLOV: So, Your Honor, I obviously don't want to paint -- you know, create a paint-by-numbers sort of pathway for potential future lawsuits, but I think what I would say is that estoppel may be the first thing that comes to mind, but it's obviously not the only route by which manufacturers who have the rug pulled out from under them in the way that my friends on the other side fear would be able to come to court. I mean, there's obviously a whole slew of doctrines --

THE COURT: Including some they're raising in this case perhaps.

MR. SVERDLOV: Perhaps. There is a whole slew of doctrines, both constitutional and as a matter of administrative law, that could be brought to bear if a government suddenly changes its position, especially with retroactive effect essentially. That's what they're afraid of; right?

THE COURT: That's right.

MR. SVERDLOV: And I think it's just worth noting and worth emphasizing that, in the guidance that CMS put out and the notice that IRS put out, it meant what it said and said what it meant. The Government looked at the statute. It thought about the appropriate way to implement it, and it intended parties to rely on the interpretations that have been announced. I think the speculative fear about potential

rescission, potential rug pulling, and potential harmful effects that could come down the pike certainly would be far short of establishing standing to raise those kind of challenges.

THE COURT: You're talking about the good cause now; right?

MR. SVERDLOV: I'm talking about good cause, and I'm really talking about --

THE COURT: But don't they have standing -- they have standing to bring the case. So once they're in the case, can't they make any argument?

MR. SVERDLOV: They can make any argument they want. My point is we shouldn't get too far down the line of worrying about -- of sort of rushing to address constitutional issues with the current statute on the fear that the statute may be interpreted differently.

I mean, I think in some sense this points to kind of the nature of -- the nature of these lawsuits; right? These lawsuits -- all of these lawsuits by the manufacturers and by the trade associations were brought before negotiations even opened; right? They were facial in the sense that nobody knew what the actual price that the companies would agree to would be, and we still don't know because they don't have a deadline to sign any agreement until August of this year.

So traditionally in a facial challenge, one just has

to show that the statute is capable of being administered in one constitutional way.

THE COURT: Right.

MR. SVERDLOV: And I think it's a little bit -- it's -- it shows us the risks of sort of trying to imagine abstract, hypothetical ways in which the statute could be applied unconstitutionally when my friends on the other side have to speculate about different political winds and different legal actions by an agency in order to make out a case.

THE COURT: Why don't we move to the broader response to my opening question about proprietary versus regulatory and the Government having its cake and eating it too.

MR. SVERDLOV: Sure. So, Your Honor, I -- just as a framing device, I mean, I think in my mind all of these issues that we have just been discussing speak to the way in which we conceptualize all of this, including the exchange of data as still a spending clause power; right? So our arguments I think pretty clearly rely on the idea that these entities don't have to participate in this process at all, just as they don't have to sell the drugs -- just as they don't have to agree to a price and just as they don't have to sell drugs at this price.

But putting that aside, the second prong here, which is, in order to have a deprivation, you need to have a cognizable property interest, I view my friends' attempts to

point to the data provision -- point to the data as the relevant property interest as essentially an effort to kind of mix and match the property interest with the thing that they claim needs to have procedures to protect it.

No aspect of this case that they have brought -- at no phase of this case, or frankly the other cases that they have brought, have they said that the problem here is that we don't have a notice and a hearing about the requirement to submit data; right? They are arguing that the lack of procedures for purposes of the Due Process Clause is related to the price that's eventually imposed.

And we point out, consistent with decades of case law, that the price that the Government pays, the reimbursement rate, is not a proprietary interest. The price that the Government pays on the selected drug is not a proprietary interest for the manufacturers. The price that the Government pays on the manufacturers' other drugs for Medicare is not a proprietary interest.

THE COURT: Well, just because the information is a means to that end doesn't mean they don't have a distinct property interest in the information itself if, in fact, it comprises a trade secret; right?

MR. SVERDLOV: I don't think we ever disputed that they have a proprietary interest in the information. I think our point is that: one, there's no deprivation of that

property interest.

THE COURT: Because?

MR. SVERDLOV: One, because the whole thing is voluntary. They don't have to participate in negotiations at all; and therefore, they don't have to submit the data. Two, for the reasons that are essentially laid out in *Monsanto*, which is that the Government is not taking this information and disclosing it to third parties or using it in evaluating, like, other applications for the benefit of other manufacturers.

THE COURT: Of course, their point is, yeah, the Government is using it to benefit itself in negotiations.

MR. SVERDLOV: I understand. And I think that gets to -- I think that gets to our first point, which is that fundamentally they -- if they really value their trade secrets and don't want to go through this process, then they need not participate in the negotiations at all.

And I think the third point, Your Honor, is that, once again, we sort of mean what we say here. If the manufacturers were really concerned about the lack of procedures surrounding their submission of data, they would have presumably identified the lack of procedures surrounding the data as a point of concern. Instead, all the lack of procedures that they're talking about is the establishment of the final rate.

Well, the Government -- the data provision procedures there in the statute function to essentially make sure that the

Government is, in Congress's views, looking at the relevant information when it's -- when it decides to set a price.

If the Government didn't have that information, if manufacturers did not submit that information, the other provisions of the statute would still work to allow the Government to set the price. And this is why I say that what they're trying to do is they're trying to sort of have a -- have a pick-and-choose, kind of a la carte approach to what they're actually challenging versus what they're claiming is the underlying interest.

THE COURT: Let me ask you a different question, still on the Fifth Amendment issues. What if we had -- this is a hypothetical. Suppose we had Medicare for all so that, when it came to buying prescription drugs, in effect, the Government was the only game in town. It represented a hundred percent of the sales of Boehringer and all other manufacturers of selected drugs. Would your answer on the voluntariness issue be the same?

MR. SVERDLOV: I think it would depend on the way in which that statute is implemented, and here's what I mean: If the Government takes over a hundred percent of the market using its regulatory powers, then that umbrella, like in *Monsanto*, that -- or like in *Horne*, that umbrella creates involuntariness in the sense that now the market is controlled by involuntary forces. That is essentially what sort of happens in the

defense sphere; right? There are restrictions on Boeing or Lockheed's ability to sell missiles to people on the street.

Within the umbrella of that regime, individual dealings with the Government can still be voluntary. Boeing doesn't have to sign a contract with the Pentagon for a missile that it -- one, it thinks the price the Government is offering is too low.

THE COURT: But then it's just not going to sell the missile.

MR. SVERDLOV: Right. So they may have claims challenging the regulatory regime that restricts their ability to sell to others. That doesn't mean they get to dictate the Government's price.

By contrast, I think it's possible to imagine that the Government could come in and create a statute like Medicare for all using its spending powers and take over the market on, not through an exercise of its regulatory powers but through an exercise of the fact that it just offers the best deal in town. There are still private insurers out there. They just don't get any crumbs left over because the Government's deal is so good.

I think to suggest that that somehow constitutes a regulatory regime would blow a massive hole in how we understand this spending clause. And, similarly, I mean, this really gets to kind of the economic coercion theory that

plaintiffs are offering. Um, I think it's hard to see the limiting point, the limiting principle in a situation where they say, you know: The Government's deal is just too good. It's too good to give up. Therefore, all of these constitutional protections dictate that the Government basically offers us an even better deal.

THE COURT: All right. Let me ask you a different question.

So in your brief you list these alternatives to subjecting themselves to the price, one of which is -- and this doesn't seem to be all that developed in the briefs -- that they could simply stop selling Jardiance to Medicare and Medicaid. And, I guess, two questions about that: first, what is -- how do you get that from the statutes? What's the source for that argument? And, second, would the Government regard it as a breach of the Manufacturer Agreement if, in fact, that's what Jardiance did?

MR. SVERDLOV: So I'll take those questions in turn, Your Honor. The source of that interpretation essentially derives from the interpretation of the 5000D provision which sets out the scope of the tax. And because the IRS has interpreted the scope of the tax to be related to Medicare sales, it follows that, if you don't have any Medicare sales, then whatever tax -- like, in theory, essentially the tax might accrue, but it would be a tax of zero dollars if there's no

sale.

THE COURT: Right.

MR. SVERDLOV: So that's to the first, to the first point.

I think the second point, whether the Government would regard that as a breach of the manufacturers' various agreements, is essentially a question about whether manufacturers are required to make sales. And the short answer is they're not. There's no -- there's no provision, either in the IRA or elsewhere in the Social Security acts, that require manufacturers to make sales.

THE COURT: Why would Congress draft a statute that says on its face: Look, to avoid the excise tax, you need to withdraw all your products from Medicare and Medicaid if, in fact, there was a way to avoid the excise tax that was much simpler, which is to simply stop selling one product to Medicare and Medicaid? Is it just a loophole?

MR. SVERDLOV: I don't think it is a loophole, Your Honor. I think it reflects -- I'm not going to speculate about Congress's motivations. I don't think that's at issue in this kind of constitutional challenge, nor should it be.

THE COURT: Right. But, of course, it's a question about intent; right? It's a question of: Is that a reasonable reading of the statute if, in fact, it seems like it would undermine the goals or, let's put it this way, the measures

Congress put in place to encourage people to -- or manufacturers to enter into the program?

MR. SVERDLOV: So, Your Honor, I take that point. And I think the answer really is that Congress is drafting the statute against the background of sort of how the pharmaceutical works. And the pharmaceutical market has sort of established patterns of operations. And I'm sure if the Court were to ask my friends on the other side how easy it is for manufacturers to set up systems of control to make sure that no Medicare beneficiaries get these drugs, they would say, Well, it's actually very difficult because of the ways in which we produce our drugs and sell them to intermediaries.

THE COURT: Hospitals and the like.

MR. SVERDLOV: There's a whole pipeline; right? So they would -- I think they haven't made too much of this in the brief either. But I think it is safe to assume that it might be logistically difficult for companies to start parsing out where the sale is going and try to restrict Medicare beneficiaries from receiving a drug. And I think Congress likely assumed that that would be a hard thing to do, and that's just not how the market operates. And so they drafted the statute, like, with that understanding.

Now, does that mean, though, the fact that something is difficult to do, because that's how these business models have been established, does that mean that there is a legal

requirement --

THE COURT: I get it.

MR. SVERDLOV: -- a legal regulatory requirement or contractual requirement to sell the drugs? No, it doesn't.

THE COURT: Right. Okay. Let me move on.

Right, so they -- let's talk about the good cause issue for a minute. And, of course, that language appears in the, as I understand it, the Medicare coverage gap and manufacturer discount statutes. And it says that the Secretary may provide for termination within 30 days if there are knowing willful violations of the agreement or for other good cause shown. I think that's more or less what it says.

And, you know, they make an argument that, well, you know, sort of like, I guess -- I don't know if I'm pronouncing this right but ejusdem generis type argument that, Well, it says "knowing and willful violations or other good cause shown." So really the good cause that Congress had in mind was something like a knowing and willful violation. It was some kind of malfeasance.

And I guess -- so I'll ask you to respond to that. But I guess, more broadly, is that provision a good fit for allowing manufacturers to withdraw from Medicare on an expedited basis to avoid the excise tax?

MR. SVERDLOV: I think it is, Your Honor. And if I may just as I -- for my own purposes, if nothing else, I would

like to roadmap my answer a little bit.

THE COURT: Okay, sure.

MR. SVERDLOV: I want to talk about how courts have interpreted the good cause.

THE COURT: Yeah, I did want to hear from you on that because you mentioned case law.

MR. SVERDLOV: Yes. And then I also want to make a broader point about the statutory timelines absent the good cause provision because I also have case law on that.

THE COURT: Okay.

MR. SVERDLOV: So on the good cause point, we cite in our brief the *United States ex rel. Polansky* case, in which the Supreme Court -- I'm happy to provide the citation. That's 143 S. Ct. 1720. And it's Footnote 2 where the Supreme Court talks about the good cause being a uniquely flexible and capacious concept.

THE COURT: Good cause in this statute?

MR. SVERDLOV: No, not in this statute. No, not in this statute. It's a statute that deals with the United States' authority to intervene in a relator suit, specifically to dismiss a relator suit.

So the Supreme Court says as a general matter that good cause is a capacious concept, and I think it is fair to assume that it is meant to expand the categories that are provided in the statute, categories of types of actions that

could trigger it and not contract it. And so the idea that good cause is just another way of specifying malfeasance would sort of read good cause out of that statutory language entirely. I mean all the work I think in the eyes of the competition.

THE COURT: Give me another example of what it might be besides, of course, the circumstance here and besides a knowing and willful violation. Can you think of one?

MR. SVERDLOV: I'm not sure I fully track.

THE COURT: Would the bankruptcy of the manufacturer be a good cause?

MR. SVERDLOV: Potentially.

THE COURT: Do you know if it's ever been invoked in those circumstances?

MR. SVERDLOV: I don't know. I don't know, Your Honor.

THE COURT: That's what I thought you meant when you said you were going to give me case law.

MR. SVERDLOV: Well, I'm happy to do so, Your Honor.

THE COURT: Okay.

MR. SVERDLOV: Because the Supreme Court's language I think is fairly general.

THE COURT: Yeah, I'm aware of that.

MR. SVERDLOV: And could be sufficient.

But the cases underlying, the case from the Third

Circuit that went up to the Supreme Court in which the court discusses in good cause.

THE COURT: The one you just said, *Molansky*?

MR. SVERDLOV: *Polansky*.

So the Third Circuit decision that the Supreme Court's reviewing has an even broader discussion of good cause. And that's -- the citation for that is 17 F.4th 376. And it specifically -- within that decision, it also cites cases from other circuits that discuss the ways in which good cause is particularly appropriate to avoid constitutional questions. So we've -- we've --

THE COURT: So an *Ashwander* theory kind of thing? *Ashwander* is the constitutional avoidance case.

MR. SVERDLOV: Yes, I think in a sense.

So the issue raised in those cases is -- the issue that *Polansky* is addressing is good -- interpreting good cause in a particular way to avoid potential separation of powers and Take Care Clause obligations because it deals with the Government's authority to intervene in a relator suit and so questions about whether relator suits are sort of properly justified under Article II provisions.

THE COURT: Where would I find cases, if there are any, on how good cause has been interpreted in this statute? Is there some administrative place where those -- that HHS keeps those decisions or --

MR. SVERDLOV: Your Honor, I'm not -- I'm not aware of any.

THE COURT: Okay.

MR. SVERDLOV: I think that, given that we are dealing with a broader -- these broader constitutional questions, the *Polansky* decision and, in fact, the underlying, as I said, the underlying authority in *Polansky* provide a pretty good roadmap.

What the Third Circuit said, citing *Black's Law Dictionary*, among other things, it said that, "Showing good cause is neither a burdensome nor unfamiliar obligation. It means simply a legally sufficient reason."

So I think here where manufacturers are really emphatically making the point -- and they made this point to CMS even before CMS was -- had finalized its guidance, when they're emphatically saying that not being able to withdraw prior to the imposition of the requirement to either sign an agreement or pay a tax creates constitutional problems, I think it's entirely appropriate for the agency to --

THE COURT: In other words, I didn't read the draft guidance. I just read large parts of the revised guidance. Was the good cause also in the draft guidance, or was that added in the revised guidance after the agency received these arguments?

MR. SVERDLOV: I don't have that off the top of my

head, Your Honor.

THE COURT: That's fine. All right.

MR. SVERDLOV: If I -- if I may, just one point --

THE COURT: Yes.

MR. SVERDLOV: -- because I did -- this is the benefit of roadmapping it for myself at the outset. I did say --

THE COURT: Yes, you did. Go ahead.

MR. SVERDLOV: -- that even if we weren't dealing with a 30-day timeline, our arguments would still stand.

THE COURT: Correct, correct.

MR. SVERDLOV: And I think that flows directly from the Supreme Court case we cited, *Yee vs. City of Escondido*. So essentially, as I think --

THE COURT: That's the 6-month, 12-month thing?

MR. SVERDLOV: Correct, correct. And the issue there is essentially --

THE COURT: Although the financial penalties are much bigger here, aren't they?

MR. SVERDLOV: There are different financial penalties, correct, but the Supreme Court doesn't look at the amount of the penalty or the financial loss. The issue in that case is renters of mobile home lots are saying: Well, we're trapped in this market. So restrictions that limit our ability to sell -- basically restrictions on our ability to make profits from our rentals would constitute a taking.

And the Supreme Court says -- this is at 503 U.S. 519, 527 to 28, it says, Yes, there's a delay in the ability to withdraw 6 to 12 months, but that doesn't render -- this sort of incidental burdens during that time period don't render participation in the market involuntary.

THE COURT: I'm going to switch in a second, but let me just go back to a question I asked you because I'm not sure if I really got your answer on it.

So coming back to where I started on the information -- I know we're switching back here but -- so, again, Boehringer takes the position that: Look, in fact, no other counterparty to a transaction, which is what the Government is here when they're negotiating with us, could demand that we give up our trade secrets as part of the negotiations. And, therefore, the Government's improperly leveraging its regulatory power together with its status as a proprietor here. And that -- their view -- turns it into at least a due process -- a deprivation of property.

What's your response to that?

MR. SVERDLOV: So several points, Your Honor. I think, putting aside potential, like, antitrust concerns or something like that, which are obviously creatures of Congress and meant to regulate the market, I don't think anything prohibits Walmart from saying: You know, as a condition of us negotiating some kind of deal with you, we want to see your

books. We want to see an audit. You know, we want to see how much money you're making.

THE COURT: And your point is, the negotiation with the Government here is every bit as voluntary as the supplier's negotiation with Walmart.

MR. SVERDLOV: Correct. The supplier may think: No way are we giving over that information to Walmart when we're negotiating with Walmart for the price. Like, no way.

And, again, absent some sort of, like, statutory restrictions that legislators can create on that kind of conduct --

THE COURT: You said you had multiple points on this. You said you had other points on this?

MR. SVERDLOV: Yes, I do, Your Honor. Just a minute. I have to orient myself.

THE COURT: That's all right. I know I interrupted you. That's all right.

MR. SVERDLOV: I'm trying to orient myself on the second point. It is this: We have cited cases in the -- in the process of rebutting their *NFIB* arguments --

THE COURT: Yup.

MR. SVERDLOV: -- standing for the proposition, very clearly holding in fact, the Government's regulation of a particular market doesn't make the Government's activities in that market less of a commercial transaction. There's a case I

believe from the Fourth Circuit. If the Court gives me a minute --

THE COURT: Sure.

MR. SVERDLOV: -- I can point to it. But the basic point that I want to make is that there are different constitutional strictures and levels of review that apply when the Government acts in its proprietary capacity. And courts have affirmed that doesn't go away. That proprietary activity doesn't go away even if the Government is regulating the market in which it is acting.

So I think even absent --

THE COURT: When you get back, why don't you write down that Fourth Circuit case and give it back to me.

I'm going to switch gears. I'm going to switch to these guys now for a minute.

MR. SVERDLOV: Thank you, Your Honor.

THE COURT: Thank you.

I do have a Fifth Amendment question for somebody, and then we can turn to the other issues. So, yup, Mr. King.

So hypothetical for you: Suppose that 1965, when Congress enacts Medicare for the first time, that it actually includes Medicare Part D and the drug Negotiation Program that we're now discussing. And suppose Boehringer was around there and selling Jardiance when the legislation passed and Jardiance was included on the list of selected drugs.

So at that point we know that, under my hypothetical, no manufacturer would have signed up to sell drugs to Medicare. This is all brand new. There's no market share that the Government has of your dollars at that point. Would you be making the same Fifth Amendment arguments?

MR. KING: No, Your Honor, we wouldn't be making the same Fifth Amendment arguments. I think, depending on the particulars of how that statute is set up, we might still be making some Fifth Amendment arguments, but that sounds very different than what we have here where the program's been around for a very long time, where it worked in a fundamentally different way, where CMS was statutorily precluded from interfering in market negotiations, for example.

THE COURT: But that didn't come in until 2003. So let's talk about 1965. Suppose it's exactly the same way, except, of course, that we add to the 1965 program Medicare Part D and the Negotiation Program. Would you be making any Fifth Amendment claim?

MR. KING: Yeah, Your Honor, if I could just seek clarification, so is this covering -- is this Medicare for all? In other words, is this everything or --

THE COURT: No, no. It's a new program. It's just what happened in 1965. There's a private market. Medicare's coming in and saying, "Hey, we want to play too."

MR. KING: Sure. So in that circumstance, if we have

exactly the program that we have today but we just have it, you know -- what is it? -- 60 years earlier in 1965, then, yes, I think we'd be making a number of the same arguments we're making now.

THE COURT: How would you have an economic coercion argument under those circumstances?

MR. KING: Well, I think the coercion would be proved up differently. We would have to show that this program by its nature is going to, does, occupy a very large segment of the market. And for that reason --

THE COURT: But at the time you're making that argument, it occupies zero percent of the market. So how -- it's a new program. We don't know how, you know, much people are going to -- you know, what the Government's market share is going to be.

MR. KING: Yeah.

THE COURT: I don't see -- this is why I asked the hypothetical. It sort of depends -- I mean, what I'm getting at, as you can see, it seems your economic coercion argument depends on basically the Government -- the size of the Government's share.

MR. KING: It does. Yes, Your Honor, it does. And so I guess we'd have a problem of proof in that circumstance.

THE COURT: So you argue -- so what is the -- what is the threshold at which the Government's share is so big that

economic coercions kicks in?

MR. KING: Yeah, I'm glad you asked about that. I've been thinking a lot about that, and I think there are two cases that can help you with that one is the *Dole* case that had to do with highway funds. That was -- I think it was something in the order of 5 percent of a state's highway funds would be lost if the state did not adopt the kind of underage drinking laws that Congress preferred; right? And so that translated into about one half of 1 percent of a state's overall budget.

THE COURT: And the other is a *NFIB* at 10 percent.

MR. KING: 10 percent of the state's budget.

THE COURT: Now we get into the issue of, should I really treat those as appropriate analogies given the federalism concerns in those cases?

MR. KING: And fair enough. Those were federalism cases, but I would say federalism was the claim in those cases. It was the specific context of the parties. But the court in those cases is applying a broader coercion principle that you see in *Carter* and *Butler* and *Thompson* in the cases that we cite that don't involve states, that involve private parties.

So I think you get the very same analysis from those and you can take the same -- essentially it's "extent" is one factor that helps you determine whether there is coercion, in fact. That's the word that the Supreme Court used in *NFIB*. And so "extent" matters. "Extent" mattered in *Butler*, which

was the cotton case, but it's not just extent. It's also proportionality in a way.

These are not expressly unconstitutional conditions cases, but they have, I think, some unconstitutional conditions type reason here, which is: How great is the Government's interest? Is what the Government doing here proportional to its interest, or is it just going way beyond?

THE COURT: Okay. Let's switch -- you're doing the First Amendment?

MR. KING: Yes, I am.

THE COURT: Let's switch to that.

So the first question on that is, you know, you cite *Texas vs. Johnson*, the flag burning case, in your brief, and that has the language in it that, "When we're trying to decide whether conduct is expressive enough to bring the First Amendment into play, we've asked whether an intent to convey a particularized message was present and whether the likelihood was great that the message would be understood by those who viewed it."

So here's my question: How great is the likelihood that someone reading the manufacturing -- or Manufacturer Agreement would conclude that your signing, Boehringer's signing that agreement, meant that you believed that there was a real negotiation and that the price was actually fair given that the recitals in the agreement seem to associate the terms

"negotiation" and "maximum fair price" with the statute and the statements in the disclaimer that the use of those terms does not reflect your views? How would a reasonable observer come to the conclusion that Boehringer actually thinks the price was fair after reading the Manufacturer Agreement?

MR. KING: Well, Your Honor, several responses. Maybe I'll do a little roadmapping of my own to follow Mr. Sverdlov.

THE COURT: Sure.

MR. KING: First sticking with the idea a disclaimer can work, we cite the *Pappert* case on page 34 of our brief.

THE COURT: Is that the schools case?

MR. KING: That's right.

THE COURT: Pretty different situation; right? I mean, this is -- this is -- these were the mandatory -- was it mandatory pledge or was it mandatory teaching of something? I can't remember.

MR. KING: It was a mandatory statement. I too don't recall the particular circumstances. But what the Circuit said there, Third Circuit I should say, "The fact that you could later disavow what you were required to say isn't good enough." Or to put it in Supreme Court's terms, I want to quote, "Congress can't force you to affirm in one breath what you take away in the next."

THE COURT: Yeah, that's like *Pacific Gas*. But the problem it seemed to me with that analogy, that here the

message is contained in the Manufacturer Agreement. It's one text. It's not a response like *Tornillo* or another piece of literature like *Pacific Gas* or a later statement like your schools case.

It's all the same text. It's all. It's a short text. And it's got this disclaimer in it, not only the disclaimer, but it's got, I think, language that clearly shows that those terms "negotiation," "maximum fair price," that you don't agree with, are terms of art. No? This is why I'm wondering, you know, somebody who doesn't know anything about this, reads it for the first time, would they really come away -- is there really a risk they come away with the impression: Wow, they signed this agreement, so they think it's a fair price?

MR. KING: Your Honor, these terms are not just in the Manufacturer Agreement. They're in the statute. And more than that, I guess --

THE COURT: But how does that help you? How is that -- the fact that they're in the statute, how does that -- how is that compelled speech?

MR. KING: Well, the statute tells us what we have to do, and the statute does not define two of these three words; right? It does not define "negotiate." It does not define "agree."

And people will encounter -- you went to *Texas v. Johnson*, Your Honor. People will encounter these concepts,

fair price, maximum fair price, negotiate, all the time without ever seeing the Manufacturer Agreement. The President of the United States said, and we quote -- I'm on page 30 of our reply -- that "We're bringing the manufacturers to the negotiating table" and has said since then --

THE COURT: But he can say that without the text of the Manufacturer Agreement. I mean, he could say -- just because the Manufacturer Agreement includes those words, that's not what sort of is -- I mean, my guess is he hasn't read the Manufacturer Agreement, no disrespect intended, but, I mean, he's got a lot to do.

MR. KING: He does have a lot to do. But I guess the difference is we've had to put these words in our mouth. We had to sign a document attesting that there has been a negotiation and that these prices are not just fair, when we don't agree that they're fair, but that they are the maximum fair prices. The agreement requires us to indict our own conduct in our own pricing.

THE COURT: So let me give you another sort of hypothetical, and this one I have to thank one of the amici for doing that. I think this is the hypothetical.

So the Uniform Commercial Code, right, it requires sellers to include specific words in some circumstances in a contract. For example, you have to include -- in Connecticut you have to include specific words to disclaim the warranty of

merchantability, things like "as is," or I think there's another option you can use too.

But suppose you're a seller and you have strong views that your car, which is used, and, you know, you don't want to make merchant -- you know, a specific warranty of merchantability about that, but you have strong views that you're not selling it as is. It's a good car. And "as is" is pejorative, and you don't agree with it.

Is the Uniform Commercial Code compelling your speech in those circumstances?

MR. KING: It sounds like it is compelling your speech if I -- there's sort of two responses here. One is that you're not required to engage in that sale, that transaction that's governed by the UCC. You can walk away scot-free, no problem.

Here we can't walk away. It's compelled in the sense we pay an excise tax if we want to walk away; right? So fundamentally different in the sense --

THE COURT: But if you want to sell used cars, you have to use that language in every contract; right?

MR. KING: Yeah. So in that circumstance I guess I'd come to my second response, Your Honor, which is, okay, suppose you have no choice. You need to engage in these transactions. Then the only conclusion here is that, yes, okay, that is compelled speech, and now we're going to apply the First Amendment.

What the Government wants to do here is to make this a Constitution-free zone. They want to say there's not even speech here. We don't even need to analyze under the First Amendment whether or not these provisions are valid under the Constitution. They want to say there's no speech at all; right?

THE COURT: Along those lines, have you found a case for the proposition that signing an agreement amounts to speech as opposed to conduct?

MR. KING: Yes, Your Honor, *USAID* from the Supreme Court of the United States. It states that was a contract that grant participants were required to sign. And in that contract they were required to say: We have a policy against prostitution. That's not for us. We disagree with that.

That was a contract. That was a First Amendment violation.

THE COURT: I thought -- I thought it also said -- I have to go back and look -- but they have to tell people that too; right? Like *Rust*. I thought that they had to go out and tell people. They had to make that clear: We have a policy against prostitution. We disagree with prostitution. We don't support it. We're against it.

MR. KING: The place they had to tell them was in the contract.

THE COURT: In the contract that they entered into

with providers?

MR. KING: In the contract they entered into with United States Agency for International Development.

THE COURT: I have to read the case again because I thought it was more than simply signing a contract in that case, but I could be wrong.

MR. KING: It involved signing a contract that committed the agency to a particular policy, yes. And you mentioned *Rust vs. Sullivan*. *Rust* was about what you can do when you're spending the Government's money. *Rust* didn't involve compelled speech. There was nobody that had to say anything in that program. It was, okay, when you accept those Title X funds, what can you do with them?

THE COURT: Well, the analogy seems kind of obvious. No? This is Government money we're talking about.

MR. KING: It's Government money. And the difference is the Government isn't saying, "Okay, Boehringer, you can't go out and do certain things that are inconsistent with the program." They are putting words in our mouth. And they are putting words in our mouth in a way that didn't happen at all in *Rust*.

THE COURT: *Rust* was not a compelled speech case. It was a prohibition case. But do you think it would have been decided differently if, for example, instead of saying you can't advocate abortion as a means of family planning, in fact,

instead it said, You have to advocate that -- I don't know -- the rhythm method is the only safe and legitimate method of family planning? Do you think *Rust* would have been decided differently under those circumstances?

MR. KING: Yes, and I don't have to speculate it because that case you just spelled out, that's *USAID*. So, yes, absolutely yes. It's fundamentally different when you put words in someone's mouth. And these words, "maximum fair price," they're not just any words. They're words that have value judgments, words that are involved in major issues of public debate.

THE COURT: *USAID* is an unconstitutional conditions case; right? I mean, the constitutional right involved was speech, but it's an unconstitutional conditions case; right?

MR. KING: Yes, absolutely.

THE COURT: We can turn to that. Are you going to do the unconstitutional conditions case?

MR. KING: I am, and I'm glad to speak to it if I could just close with a few points on First Amendment.

THE COURT: Sure.

MR. KING: The Government has one defense and one defense only here. That's there's no speech at all, and yet these words have significant communicative value just the way they did in *Expressions Hair Design*. This is not a regulation of what price the Government will pay. Your Honor has

speculated about a number of statutes that Congress could have pointed to that say, "We will pay X"; right? Congress could have done that here. They could have enacted a much simpler statute that said, "We will pay X" or "CMS will determine X."

But the provisions we're challenging, they don't do that. They require us to say, We negotiated for X, and we agreed that it's fair, and not only that it's fair, that it's the maximum fair price.

And there's a debate about this with the President and in Congress, and there's a public debate about drug affordability. And now we're having to indict our own practices and say implicitly they're unfair and that these low-ball prices are fair. They didn't need to do any of that to regulate prices.

THE COURT: So, I mean, if I'm understanding your argument given your answers to my hypothetical about the car seller, I take it that it's the case that any Government contractor who really needs the business to survive and is presented by the Government with a take-it-or-leave-it contract can make the same argument, that the Government's compelling it to endorse whatever the content of the agreement is.

MR. KING: Yes, Your Honor. And then that requirement, like the UCC requirement, you'd run it through a standard First Amendment analysis. You would say, Okay, is this commercial speech? Is it purely factual and

noncontroversial?

THE COURT: So the courts would have to scrutinize every single Government transaction, at least where the Government contractor really needs the business to survive, for First Amendment issues whenever somebody sued.

MR. KING: Yes.

THE COURT: All right.

MR. KING: Yes.

THE COURT: Let's turn to the unconstitutional conditions claim. And there, of course, in *AID*, which you cited, or which you mentioned a moment ago, the court used the following language: The relevant distinction that has emerged from our cases is between conditions that define the limits of the Government's spending program, those that specify the activity Congress wants to subsidize, and conditions that seek to leverage funding to regulate speech outside the contours of the program itself.

Doesn't that language hurt you here?

MR. KING: No, it does not because, again, I'm going to come back to *USAID*, and I'm going to quote from page 18 of the court's opinion there. What the court said is, When a program requires manufacturers -- or here it's manufacturers -- now I'm quoting, "to adopt -- as their own -- the Government's view on an issue of public concern," that by its very nature affects protected conduct.

THE COURT: Yeah, but it can do that if it's a condition that defines the limits of Government spending.

MR. KING: Right. And what *USAID* said is, by definition, when you're putting the Government's words in someone's mouth, that is by definition outside the scope of the program when you're requiring --

THE COURT: I don't read this quote that I just read to you that way. In other words, it seems to be saying that it matters whether the condition is intrinsically related to the activity Congress wants to subsidize. Otherwise, *Rust* is wrongly decided.

MR. KING: No, I don't think *Rust* is wrongly decided. I think *Rust* was very different. It's about what you do with the Government's dollars and whether you're free to use those dollars in a way that --

THE COURT: Yeah, it's a limit of the Government's spending program that specifies the activity Congress wants to subsidize. Congress did not want to subsidize speech advocating abortion, so they said you can't do that.

MR. KING: Right.

THE COURT: So how is that any different?

MR. KING: It's different because here what they're telling us what we have to do, they're saying we have to say, "We agree, these are negotiations," rather than cover for Government price setting. "We agree that these prices are

fair."

And so just to come back to what I was saying, the Government is requiring us to adopt as our own the Government's view on an issue of public concern, and that by definition means this is outside the scope of the program. But even --

THE COURT: Even if the program is about an issue of public concern?

MR. KING: The program is about prices; right? And as I said a moment ago, the Government could be --

THE COURT: It's about fair prices. It's about prices that are reasonable. It's about prices being too high. That's what the Government would say.

MR. KING: Right. And I guess what *USAID* is coming in and saying is, No, there are limits on that; right? Or, you know --

THE COURT: There are limits on that when it's outside the contours of the program itself but not otherwise. That's what *USAID* is saying, as I understand it.

MR. KING: Right. *USAID* is saying that, and *USAID* is telling you something very specific about what is and is not within the contours of the program.

THE COURT: So if the -- if the spending limit there, if the restriction there, the court had concluded that, in fact, it looks like it's inside the contours of the program, but because it involves a public issue, it's outside the

contours of the program?

MR. KING: Yes, that's right.

THE COURT: So if it had been just, like, commercial speech, it wouldn't have been?

MR. KING: I don't know how that would have worked, Your Honor.

THE COURT: That's not the way I read the decision. I mean, otherwise, otherwise, this language is meaningless. I mean, it doesn't say "outside the contours of the program depends on the nature of the speech." It doesn't say, public -- "speech on publicly important issues is outside the contours of the program always." It says that, if it's within the contours of the program, it's something Congress -- certainly abortion-related speech was a publicly important issue, probably one of the most hot-button issues of the day and of today.

MR. KING: Right.

THE COURT: So I'm not following that --

MR. KING: Well, let me see if I can come at it then, Your Honor, from a different angle. The program in *USAID* was about preventing prostitution. It was about providing these services. And yet, even though preventing prostitution was a key part of the program requiring the grantees there to go and to make as their own an anti-prostitution message, that invaded their First Amendment rights. That went outside the program,

because the Government could combat prostitution without requiring the grantees to go and make that their message. It defined the grantees rather than the program.

THE COURT: Okay. All right.

MR. KING: So that's the argument there from *USAID*.

I do want to clarify something. You asked about the Uniform Commercial Code. And I said yes to your question there. I just want to make sure I'm very clear. That's yes if there's a penalty for not engaging in the sales; right? Which here there is.

THE COURT: Well, I gave the example of -- I didn't say there was a penalty for not engaging in sales. I said -- well, actually, I didn't even put that condition on it. I said -- I talked about the Government contractor who really needed the business to survive.

MR. KING: Right.

THE COURT: I mean, that doesn't depend on a penalty, does it?

MR. KING: Really needing it to survive in economic coercion, that doesn't depend on the penalty. I guess what I'm saying, we have something in addition here beyond --

THE COURT: Although in my example -- I mean, there is economic coercion. This is where I think we ended it. Correct me if I'm wrong. I said, Well, but, you know, they can't sell used cars otherwise. And you said, That is economic coercion.

That's their business.

MR. KING: Yeah, that's their business. So that is economic coercion. I guess what I'm saying is we have something here in addition to economic coercion. We have this "and you're subject to a penalty." We have a more formal, legal kind of coercion as well.

THE COURT: The tax.

MR. KING: The tax as well.

And, Your Honor, that gets to a point you were making earlier about, Well, is the Government acting here as a regulator or market participant? And if I could jump in on that. I don't want to interrupt your flow.

THE COURT: No, that's good.

MR. KING: You mentioned the tax is one way in which Government is acting as a regulator. But it's not the only way. I want to point out a few other ways and make sure you take into account one of them is that CMS has claimed the ability to unilaterally amend the Manufacturer Agreement without notice to Boehringer, without Boehringer's consent, at any time in perpetuity.

THE COURT: I read that. All that says -- unless I'm missing something, all that says is, We'll do that if the law requires it. In other words, if there's a new statute, a new regulation, we'll amend it, which they have to do anyway; right?

MR. KING: We understand it differently.

THE COURT: If there was a new regulation or new statute that said, "You've got to amend this agreement," it doesn't really matter what the agreement says. They've got to amend it; right?

MR. KING: I would agree with that readily, Your Honor. We don't understand it to be that limited. We understand it to be saying, If we think that we need to do this in the future, not just because there's been a change of law but because we think it's wise and just -- the Government will be up here. Maybe you can ask them.

THE COURT: I'm going to look at the agreement. Let me pull it up.

MR. KING: We're talking about Sections II(e) and IV(b), Declaration, Exhibit C.

THE COURT: Maybe I missed it.

MR. KING: I don't think it's quite that limited. If it were that limited, my point wouldn't work. I concede that.

THE COURT: II(b) I think says -- sorry. It's IV(b).

MR. KING: Yeah, IV(b) and II(e).

THE COURT: "CMS retains authority to amend this Agreement to reflect changes in law, regulation, or guidance. When possible, CMS shall give the Manufacturer at least 60-day notice of any change to the Agreement."

Your point is the guidance is basically the whim of CMS?

MR. KING: Correct.

THE COURT: Okay, and what was the other provision?

MR. KING: Provision II(e).

THE COURT: Yeah, but that's right out of the statute, isn't it? In other words, they have these administrative duties in the statute and they have to -- you know, this is just saying, When we exercise our statutory authority, you're going to have to comply with it; right?

MR. KING: Right. That's exactly my point is they have this power, and this is in the statute, Section 13-20f-2(a)(5) it says, CMS has the statutory power to order manufacturers to comply with any requirements determined by the Secretary to be necessary to administer the program.

Well, guess what. Market participants, they don't have --

THE COURT: I get it. Your point is as a regulator. That makes them a regulator.

MR. KING: That makes them a regulator. It's a limited point, but it's an important one. The Government here is not Walmart. Look at all these things the Government can do that are just fundamentally different, categorically different than what Walmart can do in its negotiations.

THE COURT: Let's turn to the APA argument, or the

notice and comments argument.

Okay. So a couple questions on this. The statute says that CMS shall implement the Negotiation Program for '26, '27, '28 through program instruction and other forms of program guidance.

MR. PARRISH: Yes.

THE COURT: Why isn't the "shall" language as opposed to saying "may," for example, exclusive?

MR. PARRISH: Oh, it is, Your Honor. It is exclusive, you're right.

THE COURT: They can't engage in legislative rulemaking. They can't do notice and comment.

MR. PARRISH: For the first three years. But, Your Honor, what's key there is what it doesn't say, and this is the debate between the two parties.

THE COURT: But just so I'm clear, you agree that the statute excludes the ability of CMS to engage in notice and comment for those first three years.

MR. PARRISH: Correct. But, Your Honor, what's the implication of that? And if I could just step back for just a second, because your questions are showing how all of this fits together and how ultimately the Government's position depends on two points, which is that there are no constitutional restraints at all and that they can make up laws as much as they want. And we've known since 1946, Your Honor, under the

Administrative Procedure Act, the Government, by guidance, can do lots of things. But if it wants to impose any binding obligations, any regulatory authority that binds us or goes beyond what the statute requires, they have to follow the procedures of the APA.

THE COURT: Well, but let's talk about that. So you cite the *NRDC* for that, the D.C. Circuit case.

MR. PARRISH: There's lots, yes.

THE COURT: Is there a Supreme Court or Second Circuit case that says that?

MR. PARRISH: The *Mach Mining* case I think is the Supreme Court case, but I'm happy --

THE COURT: *Mach Mining*?

MR. PARRISH: M-A-C-H M-I-N-I-N-G. We're happy --

THE COURT: I mean, here, this statute, it's kind of interesting, I looked at the IRA through some detail, and there's a host of provisions, as you know, that cover things that have nothing to do with this program. There's the tax. There's other things as well.

MR. PARRISH: Right.

THE COURT: And the statute has different provisions, using different language, regarding implementing different aspects of the IRA. Some of them say -- and I haven't tallied it, but when I was going through it, it seemed like the majority said the Secretary, whether it was the Secretary of

HHS or Treasury or somebody else, the Secretary shall implement this section through regulations and program guidance.

On the other hand, some of -- there are a few, including this one, that say -- and I think it was pretty much always when it was limited to a couple of years, usually at the start-up time -- that they shall implement through program guidance.

Doesn't that suggest that Congress was expressly exempting them from the APA?

MR. PARRISH: So, Your Honor, this goes back to our due process. I don't think Congress can do that in the sense of we don't have to win on that because the law is very clear that if Congress wants to exempt from the APA, it has to be clear and it has to provide constitutionally adequate alternative procedures, which every case they cite there's constitutionally adequate alternative procedures where the court says, Well, they don't have to go through the APA because Congress told them to do A, B, and C.

What's fundamental about that, Your Honor, in no case that we are aware of, and this would be a revolution in administrative law, can an agency that's been delegated authority make up law, impose binding requirements just on its own whim.

And, Your Honor, you -- Mr. King was highlighting this about the Manufacturer Agreement.

THE COURT: Yeah.

MR. PARRISH: There's several provisions in there that seek to bind us in ways that go beyond the statute.

THE COURT: Let's talk about that.

MR. PARRISH: Can I say just one other thing? But, Your Honor, also just notice what we've been doing for the last hour when you asked the Government, my friend, the questions. They also are rewriting the statute all over the place to try to avoid the constitutional problems. And Mr. King's objection, which is that we can't rely on that, is the whole point, that if you're going to rewrite a statute, you have to do it through particular procedures under the APA because you're changing the law.

And one of the fundamental objections here, Your Honor, is the Government's view -- and when you read the brief, you'll see this -- is that their position is that both on the front end that Congress has provided no procedures to protect either the broader public interest to ensure accountability through the political process but also that our private interests get wiped out. There's nothing there. But then on the back end, there's also no procedures in place that the Government has because it says it can do all of this by guidance, which essentially means it can make up law.

And, Your Honor, let's go to your question, which is, What are the things in the contract? But one of the

interesting things before I get to that, Your Honor, is that the provision that you talked about with Mr. King where you said, "Well, wait a second. I didn't realize it had the word 'guidance' in there," the contract says that they can bind us by contract to future guidance. Future guidance can be implemented with no procedures at all. On whim, they can just point it out, and there's nothing in their theory that they couldn't do.

So right now we're talking about the information they might provide. But they could do anything else they might want by that guidance. And in theory they would say that we are bound by that contract. That's a problem on the face, not something you have to wait to see what would happen. It's a problem right now.

Your Honor --

THE COURT: Let's go through the agreement.

MR. PARRISH: Yeah. So there's the authority to amend the contract at any time, which you've talked about. That's Section II(e) and Section IV(b). There's the civil monetary penalties for violating the agreement, which is Section IV(j).

THE COURT: Which is required by statute; right?

MR. PARRISH: Well, yes, Your Honor. But usually when you're exercising negotiating with a counterparty like a Walmart, you don't make it a contractual, binding requirement.

THE COURT: But what's the substantive effect of that?

MR. PARRISH: Well, because it's -- what the substantive effect is is that they're essentially using the contract to make binding what Congress would not allow them to make binding, which is that if we violate any of the provisions of the contract, including whatever they incorporate by whim, by guidance, we are now subject to civil monetary penalties.

THE COURT: But you're suggesting that that provision -- which, by the way, is where? Remind me.

MR. PARRISH: That's IV(j).

THE COURT: Let me pull it up here. I'm sorry. I don't see -- I was looking at (i). I'm sorry.

So what it says: "CMS ... acknowledge and agree that in accordance with section 1197 of the Act" and the tax statute, "the Manufacturer may be subject to civil ... penalties and an excise tax, as applicable, for failure to meet the requirements of the Negotiation Program, including violations of this Agreement."

MR. PARRISH: So whether the violations of this agreement -- they've already told you the violations of the agreement in perpetuity is anything they might change by guidance not complying with the requirements of law.

THE COURT: But you're being now presented with a particular agreement, which I have in front of me.

MR. PARRISH: Right.

THE COURT: So for things they might do in the future,

you know, if they, for example, were to try to impose civil penalties against you for things that go beyond what civil penalties can be imposed for in the statute, at that time you would be able to bring a challenge, I think.

MR. PARRISH: We would, Your Honor. But I also think --

THE COURT: But why is it right now?

MR. PARRISH: Because, Your Honor, for the Government to impose by agreement a substantive obligation that we agree in this contract to any changes they might make by guidance is itself a new substantive obligation that Congress did not impose that they are making up through this agreement.

THE COURT: Although, although Congress did say they're supposed to implement the program through guidance.

MR. PARRISH: But, Your Honor, what that means is Congress clipped their wings. It would be remarkable -- and, Your Honor, this goes back to the broader due process. Just thinking about your statute and your questioning Mr. King about what happened if nineteen sixty --

THE COURT: I'm going to interrupt you. I think, if it's true that Congress clipped their wings, that, in fact, the guidance isn't supposed to include any substantive rules that affect substantive rights and the like in the first three years until they start doing things by regulation, then how does that help you make the argument that this agreement, when it refers

to guidance, is making substantive changes to what is already the law in the statute?

MR. PARRISH: Well, Your Honor, the agreement itself has obligations in there that are not required by the statute, including that we are bound by the guidance. And, again, the idea here is that we've -- it says we must disclose the information provided by guidance. That's in Section II(d). And that --

THE COURT: But the statute requires you to disclose information.

MR. PARRISH: But the guidance requires more information than what the statute requires. Now, this agreement did not go through notice and comment rulemaking.

THE COURT: I know that, although you did have a chance to comment on the guidance; true?

MR. PARRISH: Right. But they're now --

THE COURT: The substance of the agreement was pretty much discussed in the guidance. No?

MR. PARRISH: No, Your Honor. I think it's really extraordinary when you think about it. I realize it's easy to sort of say, Look, Congress said they could proceed by guidance. They proceeded by guidance. Who knows what that means. And now they're making into a statute -- I'm sorry -- an agreement that makes it binding. But I think if you step back and look at it, what we would say is the proper way --

THE COURT: I'm sorry to interrupt, but where does it say that -- your point is it makes it binding because CMS retains the authority to amend this agreement to reflect changes in the guidance. That's what makes it binding.

MR. PARRISH: And we're now being asked to agree to that. And, Your Honor, the key is is that if Congress told them to proceed by guidance against a backdrop that they cannot, with guidance, impose additional binding obligations, they can apply the statute, but they can only -- they can only do policies that affect themselves. They can't do extra things on us. And now what they're doing is they first issue a guidance that goes beyond that and says, "We can impose substantive requirements." In another litigation they've admitted those are substantive requirements. It's very hard not to see that.

THE COURT: Which are substantive requirements?

MR. PARRISH: The changes in --

THE COURT: A particular change, for example?

MR. PARRISH: There's lots of things in the guidance, like they've added additional requirements on information disclosure. They've changed the definition of who a primary -- of what a manufacturer is. They've changed the definition of how you decide what products are subject to price controls. Those are all things that would have to be notice and comment rulemaking. They're now baking that into an agreement they say

is binding with no opportunity for the public notice and comment process that is essential for an agency to engage in anything that binds. And, Your Honor, the key here is to just think about what that means.

THE COURT: Sorry. Sorry.

MR. PARRISH: Yeah.

THE COURT: What if you took out all the provisions of the agreement that you say reflect substantive changes to the provisions of the statute. Would you still have the key terms of the agreement that you have to sell the drug at a particular price or whatever the maximum fair price that's negotiated is? Would you still have those terms?

MR. PARRISH: You could have a skinnied-down contract for sure. Of course, Your Honor, what the problem with that is, that a lot of the things that they're trying to do to save the contract would just underscore the problem.

So in the First Amendment issue, you asked questions about -- to Mr. King -- about the fact that, Well, you're not really being required. That's put in the agreement. But in the statute it's different.

You asked about the IRS guidance which is nonbinding and said, "Well, that must change the terms of what the excise tax is." That's not in the statute.

So if they don't have the guidance, all of the arguments you've heard this morning where they've been trying

to rely on these notices that they say, "Well, you can sort of rely on these things," but they're not law, Your Honor. I mean, this is what's remarkable about this is we have a statute that contains -- and, Your Honor, I would just --

THE COURT: Well, when you say guidance is a draw, I mean, you would need to tell a lot of federal judges that because they rely on it in the Medicare context all the time.

MR. PARRISH: Well, I hope they only rely on it, Your Honor, for purposes of informing their independent interpretation of the statute. And it can't be binding on the Government. If the Government says in guidance, "We're not going to do this," it's possible in some circumstances it can be binding on them. But the problem here is that they're trying to make it binding on us.

And it's since 1946 --

THE COURT: But aren't you now raising essentially future disputes that aren't ripe at this point?

MR. PARRISH: With respect, no, Your Honor. We don't have to wait. When Congress -- so the way we look at it, Your Honor, is sort of two ways is, on the due process point, Congress has to provide the procedures. One of those many procedures is that if they're going to engage in rulemaking or quasi rulemaking, they have to go through, since 1946, the compromise in the APA which says "notice and comment rulemaking with judicial review."

Your Honor, they are now at this point in time, it is completely right now, they are forcing us to sign an agreement that did not go through notice and comment rulemaking, that includes additional substantive requirements, and is remarkably trying to preserve their ability by contract to keep the guidance binding in perpetuity however they might change it.

And, Your Honor, all of that is ripe for you to be decided right now because it underscores the facial nature of the challenge, which is what they are asking for is a constitutional-free zone with the idea that the agency can do whatever it wants on its whim.

THE COURT: Okay. All right. And so I think those are the questions I had on the APA unless you wanted to say anything else about it.

MR. PARRISH: Your Honor, I just would underscore one thing that I think connects this, although I hope I'm not being too repetitive here. But the case law is very clear on this idea that if they're exercising procurement powers and they put any thumb on the scale that's regulatory, then they have to comply with the minimum constitutional requirements.

THE COURT: And that's in your brief?

MR. PARRISH: That's in our brief. But also, Your Honor, this comes up a lot in the state context where a state is trying to exercise both procurement and regulatory powers. So we can see new cases, but there's a Supreme Court case

called *Boston Harbor*. There's the *Winicki* case. There's also the *NFIB* case that we cited, the *Butler* case that --

THE COURT: *NFIB* was a federalism case. That's not --

MR. PARRISH: That doesn't. But, Your Honor, many of these cases -- the other ones specifically say, if you put a thumb on the scale with regulatory powers -- and, Your Honor, if you just step back for a minute, that makes a whole lot of sense because if the Government is just acting like any other market participant, if it's buying pencils for the military, then there's none of these concerns unless it has --

THE COURT: Although, as Mr. Sverdlov pointed out, there are rules about who Boeing can sell missiles -- I don't even know if Boeing makes missiles -- but let's say Lockheed Martin can make missiles to, which are regulatory rules.

MR. PARRISH: That's right, Your Honor.

THE COURT: They're also buying missiles.

MR. PARRISH: But that would require -- this is why, when I started this, I emphasized the importance of both accountability and making sure the Government doesn't go too far. One of the issues about the military context is those things they are buying by regulation they say, No private party can have a missile.

What's happening here, Your Honor, it's much more --

THE COURT: The Government could also say, No Government but the United States can have one of your missiles,

couldn't it?

MR. PARRISH: Yes, Your Honor. What I'm saying, if the Government wanted to say nobody can have drugs, it would have to take the accountability for that regulatory decision. So in the context of the missiles, the public can change that any time it wants.

The problem here that we have with this statute is what they're trying to do is we want to sell our drugs not to the Government. We want to sell our drugs to the 50 million people who are elderly, disabled, who are forced to be part of the Medicare/Medicaid program. They set themselves up as an intermediary, which is fine, Your Honor. But they are clearly exercising regulatory authority both in terms of regulating how the whole program works and who has to be in part of it and so forth and so on but also on all of these requirements that they're imposing.

And what's really remarkable, Your Honor, is this is not only being imposed by the statute without any of the procedures, but now the agency is saying, We can change the legal requirements any time we want, and we're going to force you to do that now.

THE COURT: I gotcha. I want to hear from the Government on the APA issue and the First Amendment issue now.

MR. PARRISH: Thank you, Your Honor.

THE COURT: You're going to do the First Amendment?

MR. SVERDLOV: Yes, all of those issues.

THE COURT: I thought he was going to do something. Sorry.

MR. SVERDLOV: We have tax. We have a lot of tax.

THE COURT: All right. I don't know how much time we're going to have for the tax. I think I understand the arguments.

But, okay, go ahead. What do you have on the First Amendment for me?

MR. SVERDLOV: Your Honor, if I may just have a moment because I think I left my -- the podium here last time with a promise to return with some cases. And, in fact, those cases are directly on point with what Mr. Parrish was discussing here, namely, this intersection between the regulation of the market and participation of the market.

THE COURT: Okay.

MR. SVERDLOV: I would point the Court to page 14 and 15 of our reply brief where we cite a number of cases. The Fourth Circuit case that I was referencing off the top of my head was *Brooks v. Vassar*.

THE COURT: *Brooks*?

MR. SVERDLOV: *Brooks* v. Vassar.

THE COURT: That's in your brief. I'll get it.

MR. SVERDLOV: Page 13. I just want to, if I may,

quote the language from that. Quote, The Supreme Court has approved applying the market participant exception even when a state's regulations are trained on the specific market in which it participates. And in that case, imposing taxes or restrictions to, quote, regulate the market is not sufficient to preclude the state status as a market participant.

That's the *Brooks* case. We have a Supreme Court case in there. We have an Eighth Circuit case in there. It's actually a pretty well-established proposition.

On the First Amendment piece, Your Honor. I think there's sort of a lot to unpack, and I guess maybe where I would start is just to orient ourselves on *USAID* because I think there was some confusion about the scope of *USAID* and what it actually stands for.

I think it's useful to remember that *USAID* actually involved two conditions. Only one was at issue in the First Amendment analysis, but there were two conditions.

So on page 23, 26 of the Supreme Court Reporter, the Court says, "The funds at issue come with two conditions. First, no funds made available to carry out the Leadership Act may be used to promote or advocate the legalization or practice of prostitution or sex trafficking."

THE COURT: And that wasn't at issue?

MR. SVERDLOV: And that was not at issue.

THE COURT: That wasn't challenged.

MR. SVERDLOV: It wasn't challenged. But one has to presume --

THE COURT: That's like a *Rust*.

MR. SVERDLOV: Exactly. Exactly. But I think that sheds light on this distinction, that Mr. King was discussing about how you determine when something is part of the program or outside of it. This -- the setup, the statutory setup sheds light on the Supreme Court's holding that, when you're imposing a condition on the recipient of the funding, that's different than a condition on what the money is being used for; right? And here the money is being used, the Government money, is the contract; right? It's being used in this contractual sense, in this agreement sense. So in a way --

THE COURT: Just so I follow your argument, the difference between imposing a condition on the recipient is doing that can raise First Amendment or conditions problems, whereas imposing a condition on the use of the money doesn't.

MR. SVERDLOV: That's exactly right, Your Honor. And I think that the court in *BMS* parsed as well. I mean, it pointed out, as we do in our briefs, that there is absolutely nothing in the statute and the guidelines or the contract that prohibits these companies from going out and criticizing CMS, criticizing the IRA, criticizing the administration or the prices that they will be providing.

You know, if there were such restrictions, right, if

the contract said, "You shall have a policy of advertising everywhere that this is the maximal price," well, yeah, I think then we would be in *USAID* world. We are not there.

THE COURT: What if this statute here said, or the contract actually said, By signing this agreement, Boehringer acknowledges that the Drug Negotiation Program is essential to lowering prices at a time of crisis in our health care system for seniors? What if it said that? Would that be -- would that be constitutional if the agreement included that language?

MR. SVERDLOV: So I think there are several ways to parse that, Your Honor. I mean, certainly the hypothetical gets closer to the idea that the condition is being imposed, the way the Court has articulated this.

THE COURT: It's part of the agreement.

MR. SVERDLOV: It's part of the agreement, but it seems to make broader statements, right, like broader statements of policy. I think it's possible that that could start getting closer to the *USAID* world.

Now, I think this actually gets to the other point I was going to make is that courts also don't just look to just the label of what's being regulated in the First Amendment. The key -- and this is clear from cases like *Expressions Hair Design*, *Rumsfeld vs. Forum of Academic Freedom*, the D.C. Circuit case *Nicopure*, even *Sorrell*. The point is the courts look at what's actually being regulated to decide whether this

is expressive conduct or whether this is a form as in, like, *Nicopure*, as in -- as here, a form of price control; right?

So I think what the hypothetical --

THE COURT: Was the cigarettes case in the D.C. Circuit or something?

MR. SVERDLOV: It was. It was. But the restriction was on the ability to not provide free samples --

THE COURT: Right.

MR. SVERDLOV: -- of cigarettes. And the challenger said all this violates their First Amendment rights; right?

But I think the point is actually borne out in broader than. *Nicopure* was decided after *Expressions Hair Salon*. But I think *Expressions Hair Salon* --

THE COURT: The *Nicopure* says there's no speech issue?

MR. SVERDLOV: Correct. Correct.

THE COURT: I just couldn't remember. That's all.

MR. SVERDLOV: Correct. *Expressions Hair Salon* kind of does the analysis of saying, Look, what's actually being regulated; right? Is what's being regulated the price that salons can charge credit card customers, or is what's regulated actually how that price is communicated? And for all the reasons that the Court explained, it said, Well, this is really trained on how the price is communicated, because there's nothing that restricts the actual -- the actual price.

Price regulation has, as the *Nicopure* court

recognized, have repeatedly been sustained against challenges. And incidental burdens on speech, when what's being regulated is not speech or expressive conduct but actual commercial conduct, as what we have here, have repeatedly been sustained.

So I don't think I need to go too far into, like, the *Rumsfeld vs. Forum* case, but I think it's worth pointing out that in that case the court finds that providing access to military recruiters on campus is a form of conduct regulation, even though, even though schools have to put out bulletins, they have to send e-mails, they actually have to generate speech, advertising the availability of these recruiters to -- on equal terms with their advertising of other recruiters on campus.

So this -- I fear this was a little bit of a circuitous response, but it gets to -- it gets to several points that are baked in on the First Amendment that we have: One, of course, that this -- again, this is all voluntary. It's not a regulatory regime. We're not forcing them to say anything. You don't like the agreements, don't sign it. Don't participate.

Two, what's being regulated, this is a commercial price regulation. So the idea that First Amendment extends to this would mean, as we pointed out in the brief, there's really no limiting principle. Every single Pentagon, Defense Department contract now has to be scrubbed for expressive

content.

And, finally, back to the *USAID* case, even if one were to think of this as somehow leveraging speech or involving expressive speech, the Court would still have to parse this distinction between speech that is part of the program.

THE COURT: All right. Let's turn to the APA argument.

MR. SVERDLOV: Certainly.

Your Honor, I don't know that -- I'm obviously happy to answer any question. But I think the statute speaks for itself, and it speaks pretty plainly.

THE COURT: It does. But what do you do about *NRDC* and the Supreme Court case? They mentioned that, as I understand, stand for the proposition that, if the agency's going to change substantive rights, that they're going to create new law, then they have to proceed by rulemaking? Is your point the statute opts them out?

MR. SVERDLOV: That is exactly our point. That is exactly our point. We make that point --

THE COURT: So you can use guidance to create new rules the first three years of the program.

MR. SVERDLOV: Absolutely, Your Honor, that is correct. This is actually an issue in some of the other cases that hasn't been briefed here because here the challengers have focused their attentions on just the agreement itself. But in

the other cases, they've argued that any of these substantive requirements that have been -- substantive requirements that have been imposed through the guidance are invalid because they didn't go through a notice and comment rulemaking.

Now, the cases that we cite --

THE COURT: So which case, the Delaware case or --

MR. SVERDLOV: This is the New Jersey case, Your Honor.

THE COURT: So the *BMS* case?

MR. SVERDLOV: It's not the *BMS* case, Your Honor, in the sense there were four cases that were consolidated. Two of those cases, *Janssen* and *BMS*, have been decided. Those are the constitutional issues we provided supplemental authority on. The two other cases that have been consolidated and were argued together have not yet been decided.

THE COURT: Ah, so we're waiting for an opinion from the same judge.

MR. SVERDLOV: Yes.

THE COURT: I see. I didn't know that.

MR. SVERDLOV: And just for the Court's awareness, those other cases involve all the other issues present here and then some --

THE COURT: I didn't know that.

MR. SVERDLOV: -- because there are statutory challenges. The tax issue comes up there. And then the *Novo*

Nordisk case that's there presents statutory arguments and presents a bigger version of --

THE COURT: Arguments happened and --

MR. SVERDLOV: Arguments has happened. The case has been -- the case has been pending with the court.

THE COURT: I'm glad I'm not the only laggard.

MR. SVERDLOV: Not at all, Your Honor. There's lots of these still out there.

THE COURT: Okay.

MR. SVERDLOV: The point I want to make is this, is that the Supreme Court is clear in the *Dorsey* case that we cited in our briefs, both the Medicare Act and the APA allow Congress to exempt agencies from notice and comment rulemaking requirements --

THE COURT: The APA has -- I mean, obviously, one statute can always supersede another, but the APA rulemaking provision doesn't have the same language as the -- sorry. Sorry. I misspoke. The Medicare Act rulemaking provision doesn't have the same language as the APA about, you know, you have to clearly opt out of this.

Your point is simply, well, one statute supersedes another?

MR. SVERDLOV: Well, I think it's a little more than that, Your Honor. I think that here we have an express -- an express intent by Congress to supersede those authorities.

And, again, the *Dorsey* case says, "The word 'expressly'" -- for purposes of the APA, I admit the two are somewhat different. But in the context of the APA, "The word 'expressly' -- I'm quoting from 567 U.S. 274. Quote, "The word 'expressly' does not require Congress to use any magical passwords to exempt a later enacted statute from the provision." And then as we further detail, "The Court described the necessary indicia of congressional intent by the terms of 'necessary implication,' 'clear implication,' and 'fair implication.'"

But what about counsel's argument that, Judge, you can just as easily construe the statute -- I'm turning his argument a little -- but you can just as easily construe the statute to say Congress clipped its wings in the first three years?

Congress was like, Look, you implement our program through program guidance in the first three years, and then we'll see about, you know, legislative regulation after that, or legislative rules after that.

What's your response to that?

MR. SVERDLOV: I think that's both a deeply atextual and sort of profoundly, not just counterintuitive, but really anomalous argument. I mean, basically what they're saying is not only did -- here's a brand new program. It's massive; right? We see the extent of the number of issues that the agency has to confront in the revised guidance; right?

And they're saying, Well, not only, not only did

Congress not allow you to conduct substantive -- basically conduct substantive rulemaking through guidance, you're not allowed to conduct substantive rulemaking at all. You're not allowed to do any kind of substantive decisions for the first three years. You're just supposed to run this off the statute as written.

I think that's deeply implausible. Congress has included --

THE COURT: Because Congress would want to create more flexibility at the outset? Is that your point?

MR. SVERDLOV: That's our point, and I think it's borne out by the language of the statute. It's not just an inference that the Court has to make.

THE COURT: But why is that though? Because they point out that, usually when we hear about program guidance, we are talking about things that bind the agency, clarifications, things like that, rather than -- rather than rules. And so when I see the word "program instruction" or "program guidance," they would argue the text actually supports their argument, that that has a well-understood meaning as not being a notice and comment rule.

MR. SVERDLOV: Your Honor, if I may.

THE COURT: Yes, please.

MR. SVERDLOV: I would love to point to numerous provisions of the IRA which contemplate the Secretary

exercising his discretion in substantive ways. This argument cannot be reconciled with the structure that CMS has set up. There's, as I said, numerous examples where the Secretary must exercise judgment.

I'll take one. Section 13-20f-3(b)(1) which provides that CMS must, quote, develop and use a consistent methodology and process that accords with the specified negotiation process and that aim to achieve the lowest maximum fair price. So it says "develop a method"; right?

Next, Section 1320f-2(a)(5) which requires manufacturers to enter into negotiation agreements to, quote, comply with requirements determined by the Secretary to be necessary for purposes of administering the program.

Sections 1320f-1(b), Negotiation-eligible drugs are to be arranged by total expenditures, quote, as determined by the Secretary.

Section 1320-f(1)(c), Secretary is to determine when standard for generic competition is met for a selected drug.

Section 1320f-2(a), Manufacturers to submit information that the Secretary requires to carry out the negotiation.

THE COURT: I got it. I got it.

MR. SVERDLOV: I think it's deeply implausible to think that of the two interpretations here, that what Congress really wanted was to limit the agency's authorities to make

these kinds of substantive decisions. It is, I think, much -- a much more reasonable inference and much more consistent with the plain text that Congress is expressly exempting the agency from notice and comments.

THE COURT: And the other point I was discussing with counsel, what's your view on whether the agreement does create new rules? He cited a number of them. Are those -- are those, in your view, new rules that create new rights and obligations?

MR. SVERDLOV: They do not, Your Honor. The agency was clear in its guidance, and it said -- I can -- I can refer the Court to the revised guidance at page 30 where it explains that the agreement merely incorporates the substantive requirements of the guidance. It is not a separately -- it is not something that separately creates substantive legal standards is the operative legal term.

THE COURT: Okay.

MR. SVERDLOV: So it wouldn't be subject to notice and comment in the first instance. Of course, here, as the Court knows, there has been back-and-forth. The agency has endeavored, has gone out -- has gone above and beyond because it has actually endeavored to provide as much opportunity for comment.

THE COURT: Are you aware of any other situations where Congress has permitted an agency to adopt either in the early parts of the program or in other circumstances

substantive rules through program guidance?

MR. SVERDLOV: We haven't identified any for purposes of the Social Security Act here. But what I would say is that this language appears throughout the IRA.

THE COURT: Yes, it does. I'm aware of that.

MR. SVERDLOV: It's not just this.

THE COURT: Yes, that's true.

MR. SVERDLOV: And so I think this gets back to the point that Congress doesn't have to use any particular magic words.

THE COURT: All right. I think I'm ready to move on to the excessive fines argument. And then we'll, I think, call it a day. Let me hear from the other side on that first.

So let me ask you this: One of the two requirements you have to show for me to have jurisdiction is certainty of success. I mean, *Williams Packing*, among other things, the court said to require more than good faith on the part of the Government would unduly interfere with the collateral objective of the act, protection of the collector from litigation pending a suit for refund.

So, in effect, to agree with you that I had jurisdiction here, I would have to make a finding that the Government's arguments that the excise tax was lawful were made in bad faith; true?

MR. PARRISH: Um, Your Honor, that's not how I was

reading it, but maybe I misunderstand. I thought --

THE COURT: I think -- I'm just quoting from the decision. It follows right after they say that, "By the way, we construe this in the light most favorable to the Government. We" -- that it has -- I can't remember the other language. They're describing the certainty standard. And then they end it with, "To require more than good faith on the part of the Government would unduly interfere with the collateral objective of the act, protection of the collector from litigation pending a suit for refund."

So as I read that, as long as there is good faith on the part of the Government, then you don't meet the standard. Am I misreading that?

MR. PARRISH: I think you are, Your Honor. And I guess what I would say on this is the way I looked at it -- but the Court may be seeing something that I didn't pick up. The way I look at it is what the two tests are clear is that: one, you have to show irreparable harm; and, two, you have to show certain success. And so what I would say is what you then need to look at, Is it an excessive fine or not? And the question there --

THE COURT: So, yeah, you have to make some determination of the merits in order to determine the level of likelihood of success; right?

MR. PARRISH: And, Your Honor, I don't mean to be

flip, but let me just give you an example because it goes to their point about this not being a criminal penalty. But if they said to you or if they said to me, "Mr. Parrish, you parked improperly this morning." It's not a criminal fine. It's a civil fine. Off to the gallows for you. The penalty would be death. We would say that's an excessive. They could be acting in perfectly good faith.

THE COURT: That would probably be analyzed under cruel and unusual punishment.

MR. PARRISH: That may be, but it would also be an excessive penalty, Your Honor. I think here the problem is, if you look at this fine, it's not a tax. It's not surprising that when you have a tax that's mislabeled, it's more likely following the *Williams Packing* exception.

THE COURT: Although, as I understand it, correct me if I'm wrong, you haven't cited any cases in which a court has ever found that something labeled as a tax was an excessive fine.

MR. PARRISH: That may be true. I don't know, Your Honor, of any case like this. This is part of the point about being unprecedented.

THE COURT: But if it's unprecedented, why is there certainty of success?

MR. PARRISH: Well, because, Your Honor, I think at some point, I guess the way I would look at the analysis from

the Court's perspective is there must be a point where the Government goes too far. That's the point of having an excessive fine, where it is not proportional, it doesn't meet the standards for an appropriate penalty.

And so the question then -- and it's very telling that the only case they cite is a case involving fraud where there's very high penalties or they cite -- in other cases, they cited situations where there have been general tax revenues that have been collected with very high taxes. They have never cited a case where the Government has said, If you don't do something we like that's completely lawful, you will be subject to a penalty that, in this record, which is uncontested for Boehringer, would be of the nature of 500 million to 5 billion per week. So we're talking about an enterprise-killing penalty here for engaging in lawful conduct.

And I think the way Your Honor would run through the analysis is not to ask ourselves whether the Government has ever been this extreme before but rather to say -- and, therefore, and that's been struck down, but rather to ask itself, Has it ever been upheld before with something like this?

THE COURT: But I'm having trouble seeing how a decision agreeing with you here outside the context of any criminal charge or criminal offense, without even any relationship to a criminal charge or criminal offense, without

any authority in the tax sphere, how a decision would not be breaking some new ground.

I mean, Judge Shea issues ruling finding tax is a fine. That's a new ruling.

MR. PARRISH: Your Honor, I think what you would say, and if I were to write the opinion for you, I'd say: The Supreme Court in the *Austin* case has rejected the Government's distinction between civil and criminal --

THE COURT: That's true, but *Austin* and every other case I found, and I looked at a lot of them, involved a relationship with the criminal case. *Austin* was a forfeiture after a criminal conviction. That's where -- *Bajakajian*, same thing. That's where these things come up. There's a criminal conviction. Criminal liability has been imposed. And the fact that the Government uses a separate filing to impose part of the pain that it's going to impose for the criminal offense doesn't change its character from being a fine.

MR. PARRISH: So, Your Honor, what I would submit to you is that what you've just said and what the Government's defense is is the reason that it doesn't -- it's not a palliative. It's a poison. I mean, the idea that if this was connected to a criminal offense, that they then said, "We can defend this fine" is one thing. The idea that this is for perfectly lawful conduct and it's not a tax that is designed to raise revenue. It's not a generally applicable tax. It's a

penalty, a punishment, for not doing what they want. Yes, it's unprecedented, but, Your Honor, it cuts entirely the other direction.

It would be very strange, I would submit to the Court, and I think you would be breaking new ground, if you said that there is an enterprise-killing penalty that's not connected with criminal conduct that's higher than even what gets imposed --

THE COURT: Of course I wouldn't actually be saying that. I would be saying, if I agreed with the Government here, I don't know, but there's no -- I can't be certain about this. And if I can't be certain, you lose in this argument.

MR. PARRISH: But if you can't be certain, Your Honor, that is correct. But I think if I were in your shoes, Your Honor -- and I would also connect this to the rest of the statute, is I would first say to myself, Well, what is the purpose of this tax? And I would say, Well, the tax is not doing what taxes are supposed to be doing.

And then I would look at it and say --

THE COURT: The legislative history you pointed to, right.

MR. PARRISH: Correct. And then the next thing I would say is, Can any manufacturer actually afford to go through a process of challenging this tax? Certainly not Boehringer. Certainly not any of the other manufacturers we

know.

THE COURT: That's because -- and I'm going to ask the Government about this. That's because, regardless of whether it's divisible and all that, regardless of their guidance, the fact is you'd be risking --

MR. PARRISH: Yes.

THE COURT: -- enormous tax liability if you just said, Yeah, we'll bring our refund on that first tax, but we need to keep selling our product to survive. And you would be risking billions and billions of dollars.

MR. PARRISH: Correct, Your Honor. And then what you would say, you would say, as I asked counsel, Has there ever been a case -- we know there's no case where Congress has ever said before that agencies can just make up the law. We're now in a different view where, Has there ever been a case before where you can impose enterprise-killing penalties that no one can afford to go through the process? You've tried to avoid judicial review by calling it a tax, but it really isn't on its substance.

Then the question is, Is that clearly a violation of the excessive fines provision? And we think, respectfully, it is, Your Honor. And if they can cite some case other than a fraud case in a civil context, then I'd be happy to come back and talk to you about it.

THE COURT: Thank you. Let me hear from counsel.

All right. Do you want to respond to his last challenge?

MR. GAFFNEY: I will get to that point in a second. Let me just hit on a couple of the other things he said first.

THE COURT: All right.

MR. GAFFNEY: The AIA applies on its face, because of the two preconditions that are met here. The 5000D tax is a tax according to the label that Congress assigned to it. And it's labels that mattered.

And he just mentioned that they're trying to skirt -- the Government's trying to skirt jurisdiction even though the tax isn't really a tax. But for AIA purposes, the court said this in *NFIB* and has said it in *CIC Services*, the only thing that matters --

THE COURT: He's disputing that the AIA applies. I think they're arguing there is an exception, and there is, of course. So let's talk about the exception.

MR. GAFFNEY: Yeah. So on the exception, Your Honor is right, and I was rereading the case as you were reading it in terms of the good faith point, that the bar is as you described it.

And on the certainty of success point, the court elsewhere says that it just needs to be sufficiently debatable, that's it.

And there's -- in this context, where they haven't

pointed to a single tax, as Your Honor said, that has been held to be a fine under the Excessive Fines Clause, haven't pointed to any exaction at all that doesn't relate at all to criminal proceedings -- and I want to be really clear about this point. It's not -- for these purposes. Once we get to the merits, we get past. On the face of the AIA, is it a tax? Yes, of course, because it's labeled that way.

Once we're on the merits department, at that point our argument is not it's labeled "civil"; therefore, it can't be a fine under the Excessive Fines Clause. The parties are talking past each other on the briefing, I think.

Our point is that there is no case that I'm aware of, and that the plaintiff has identified, in which the exaction has nothing to do with criminal proceedings or criminal conduct. They all appear as if they are, as Your Honor said, a further filing, a further arm of the state's criminal enforcement mechanism. In that setting, it is at least debatable whether the tax violates the Excessive Fines Clause --

THE COURT: I gotcha. Now let me hear you respond to his challenge about, as I understood it, an enterprise-killing exaction that is, you know -- isn't it -- they would have to be able to challenge that in some way. No?

MR. GAFFNEY: Yes, Your Honor. But let me -- let me address how they can challenge it, but let me also address the

enterprise-killing piece.

THE COURT: Okay.

MR. GAFFNEY: On the latter -- and the parties again I think are talking past each other on the math. In the cases where a tax has been held to be punishment for some offense, and there's -- all the cases say, in order to be a fine, this tax needs to be a punishment for some offense. In the response brief from BI --

THE COURT: Did you just say there are cases where a tax has been held to be a punishment for an offense?

MR. GAFFNEY: Yeah, In *Kurth Ranch*.

THE COURT: Right. There was a criminal proceeding there.

MR. GAFFNEY: It had a whole host of anomalies, and there's a couple things that are important about *Kurth Ranch*. First of all, it's not an Excessive Fines Clause case. So it wasn't held to be a fine, but the test there is overlapping in terms of a Double Jeopardy Clause, looking to see whether a tax is punishment.

The court in *Kurth Ranch* said it's not enough to have a high-rated taxation. That doesn't convert something to punishment.

THE COURT: Just in terms of facts, though, refresh me, because I looked at it yesterday. There was some kind of a criminal proceeding or conviction, and then they came at him

with a fine stat in Montana or something like that?

MR. GAFFNEY: Correct, Your Honor. So in *Kurth Ranch* it was a drug tax.

THE COURT: That's right. And he was a convicted drug dealer. Am I right about that or am I --

MR. GAFFNEY: That's right, Your Honor. And the anomalies at issue in the case -- so what the court said -- and I'll try to weave in the facts as I'm answering on the law too.

So the court said it's not enough that that tax had a deterrent purpose. All taxes have deterrent purposes in part. They have other purposes, remedial purposes, but there's always some incentive to do or not do something. So it's not enough that it's deterrent. It's not enough that it's a high-rated taxation.

So what the court said is it turned on these three anomalous features, and this answers your questions about the facts. So the tax is conditioned on the commission of a crime, which was dealing drugs; it was exacted after the taxpayer had been arrested; and it was levied on previously confiscated goods. The taxpayer didn't own the goods at the time.

The rate wasn't dispositive in that case. Like I said, the deterrent purpose, the rate wasn't enough. It was those three anomalous features. But the rate there was very different than the rate here.

And this goes to my point about the parties talking

past each other on the math. In *Kurth Ranch*, if the drug dealer sold marijuana worth $100, the drug dealer owed the Government in taxes $400. The net result of the transaction is he's out $300. That's not the case here.

Here, if the plaintiff sells a drug for $100, in the early periods the manufacturer will give, in the form of a tax, $35 to the Government. In the later periods, $5 -- will give $95. So I think I have the numbers wrong. Let me make sure I get it right.

They sell it for a hundred bucks. They will remit as a tax $65. They will retain $35. If in the later periods they sell for $100, they will pay a $95 tax, and they will retain $5.

The difference between that *Kurth Ranch* tax rate, which again is not dispositive of it being held to be punishment, but the difference between that rate is, in the *Kurth Ranch* context, the drug dealer is out $300 at the end of the transaction, brought in 100, shipped off in taxes 400.

In the context of this tax, the plaintiff is still making money. The net result is still positive. It's a lot less. It's a lot less. It's a lot -- you know, World War II in taxes were 94 percent. It's a lot less than you're bringing home. But that's a huge difference in terms of how the actual math here works.

THE COURT: Right. Okay.

MR. GAFFNEY: On the point of, is there -- Your Honor's question was I was, you know, pushing back on the premise that this is enterprise killing. But Your Honor asked, If it is enterprise killing, what is the method they can challenge this tax?

And the way that they can do it is by the following three steps: pay --

THE COURT: Yeah, the refund suit.

MR. GAFFNEY: Yeah.

THE COURT: I mean, I guess, whether it's enterprise killing or not, it's -- I think we all agree it's an unusually high tax. You know, they do cite this legislative history that says basically nobody in their right mind's ever going to pay this tax. So, I guess, is it really the case that there isn't irreparable harm when, in order to test out a litigation, they would have to -- even though it's divisible, they just pay it on one, but they're incurring this liability if they lose. Is that a reasonable decision to make to go through that? I mean, it's hard to see that this is a situation we say, Well, money's adequate. You know, you don't get -- there's no irreparable harm here.

But no business is going to undertake that challenge; right?

MR. GAFFNEY: Sorry, Your Honor.

THE COURT: No, you go ahead.

MR. GAFFNEY: A couple responses. First, when Your Honor mentioned that they cited legislative history, I believe they cite a congressional research service.

THE COURT: Oh, okay, that's right. I thought it was Joint Committee on Taxation, but anyway ...

MR. GAFFNEY: It may be that they cite that as well. But I know that this point about "It doesn't appear as if any manufacturer would ever pay this" appears in a CRS report that I believe is one of the exhibits.

THE COURT: But putting aside whether it's legislative history or not, I mean, is it wrong? I mean, you know --

MR. GAFFNEY: A couple things. First, there are a host of district court cases, one in this circuit, 56 F. Supp. 3d 280 at 296 that say that those kind of cost estimates that predict how an entity is going to react to a certain tax provision, that they are not persuasive evidence of congressional intent, period.

THE COURT: Okay.

MR. GAFFNEY: That's one point.

The second point is at page 30 of that CRS guidance, CRS report, even says there that the way you challenge this, you pay it and you challenge in the course of a refund suit. So it's not as if everybody -- you know, it's not as if plaintiffs are relying on, you know, the CRS report as if it speaks to exactly how this is all supposed to unfold. Of

course, that's the piece that they're challenging.

Now, to the question of irreparable harm specifically, every taxpayer wants that clarity that the plaintiff wants here. They don't want to engage in a corporate inversion and find out after they've done it that they're subject to some big tax. They don't want to find out that, if they move this factory overseas and there's some tax provision that says, "Income earned in this place is taxed at this rate, and income earned in this place is taxed at that rate," that they'll have to foot this huge tax bill. They'd rather have that clarity in advance.

But Congress has decided through the Anti-Injunction Act that they have to go through this path. So what about the circumstances in which there's irreparable harm? *Williams Packing* requires that certainty of success.

Well, the answer is there could be a situation in which a taxpayer can't even get to the period of litigating this claim in the course of a refund suit. So between now and when they can challenge the tax that they've paid and say that it's unconstitutional, will they suffer some irreparable harm that they'll effectively be robbed, as a practical matter, of being able to litigate that challenge?

THE COURT: *Williams Packing*, although it wasn't part of the ruling in that case -- well, it wasn't part of the holding I don't think. I thought it did refer to ruinous harm

as being irreparable harm.

MR. GAFFNEY: It did refer to ruinous harm, but that ruinous harm has to be between now and their ability to get paid the refund suit. What would happen in that span is they would have paid on a single --

THE COURT: In other words, between now and the time of judgment in the refund suit. No?

MR. GAFFNEY: Well, the irreparable -- the point here, *Williams Packing* was saying is, You have to show certainty of success in addition to the regular standard equitable factors of getting an injunction, notwithstanding the text of the Anti-Injunction Act. And the reason for getting an injunction would be to make sure that they don't suffer irreparable harm between now and the chance when they can actually litigate, almost like a PI, between now and when you can get to summary judgment. They're not going to suffer irreparable harm between now and the refund suit. All they'll have to do in that time, the only harm they'll have to do is pay this amount, the assessment --

THE COURT: That's not true; right? In other words, you kind of sort of debated the math and all that. But suppose for a minute that it would be ruinous harm for them to continually incur this task for years; right? Suppose for a minute -- accept that proposition for a second. Who knows how long the refund suit is going to take to go to judgment. It

could take years to go to judgment. So in the meantime, they're incurring this enormous liability.

MR. GAFFNEY: And at that point --

THE COURT: Enormous risk of liability.

MR. GAFFNEY: That's the difference though. That's the difference. The ruinous -- the mention of ruinous is that an entity literally paying -- take *Larson*, the Second Circuit case.

THE COURT: Your point is, Look, it actually has to happen during that time, not that -- not that there's some risk that, if they lose, it will happen.

MR. GAFFNEY: Yeah. Because if they lose, the irreparable harm is that they have to pay a constitutional tax. If they win, they don't have to pay any tax.

THE COURT: Right.

MR. GAFFNEY: In *Larson* -- this was the Second Circuit case that we cited, 888 F.3d. This is at 588, 589. So that case the taxpayer, individual taxpayer, owed $61 million. And the court, the Second Circuit, said, quote, he, quote, has an adequate remedy. He simply doesn't like it. He had to pay the $61 million in full before bringing the refund suit.

THE COURT: Okay.

MR. GAFFNEY: Yes, Your Honor.

THE COURT: Why don't you wrap up on this. I think I'm done on excessive funds.

MR. GAFFNEY: I think that's it, Your Honor. The only other thing I would say is Your Honor referred in the discussion about the revised guidance about whether, you know, certain interpretations inure to the benefit of plaintiff in the good cause discussion.

THE COURT: Yeah.

MR. GAFFNEY: And there's also this discussion about whether certain aspects of the IRS notice in terms of reading it as Medicare sales and the rate of taxation. The same thing applies there, but -- in other words, that the reading is to the benefit of plaintiff. And, of course, in the course of one of these refund suits, they would be alleging, they would be arguing, that of course it should be that lower rate of taxation. Of course it should be limited on sales. But that dispute shows why the Anti-Injunction Act applies and why it's important to do this in the context of an actual tax that has been assessed.

THE COURT: That goes to the certainty issue, I take it.

MR. GAFFNEY: But in the course of that refund suit, we will know exactly how much the IRS assessed. They say that that the taxpayer can rely on it now. The taxpayer can rely on it now. And we'll know in the context of the refund suit whether the IRS held up its end of the bargain.

THE COURT: I did have one more question. I will let

both sides respond to it.

I did have one more question for you, Mr. Sverdlov, on the administrative law. I didn't get to it. It raised a point that your opposing counsel raised. Come up for a second.

MR. SVERDLOV: Certainly.

THE COURT: I think he raised the argument, as I understood it today, that if, in fact, I were to agree with your reading of the statute, that is to say, that Congress, in fact, meant to opt out of APA rulemaking in adopting this statute and, in fact, allow, through guidance, the agency to adopt substantive rules, his -- I think he argues that's a due process problem. What's your response to that?

MR. SVERDLOV: So several points on that, Your Honor. Again, this is one of those arguments that I think comes out more in some of the other suits and has not been articulated that clearly in the briefs.

But I think I get the move they're making. And the move is that they want to constitutionalize the APA's procedures. They want to say that, since 1946, due process has required the APA.

Well, put aside the lack of proprietary -- the lack of property interest. Put aside the lack of deprivation of a protected property interest. They notably, I think, don't cite a case that the APA is constitutionally required. I think there's pretty good reasons to doubt that it would be

constitutionally required.

I would point the Court to -- if I may have just one moment, I would point the Court to two due process cases from the Supreme Court dealing with the issues of standards that apply to price controls. Now, this is -- we're talking about substantive standards for due process as opposed to procedural.

But in *Pennell vs. City of San Jose* at 485 U.S. 1, the court lays out the standard for substantive due process to decide whether a price control regulation is constitutional. And then there's language in an earlier case which plaintiffs make, I think, reference in passing. But *Bowles v. Willingham*, 31 U.S. 503.

THE COURT: That's the landlord?

MR. SVERDLOV: Dealing with rent controls, correct, during wartime. At 519 to 520, I won't quote the full passage, but I think there's fairly instructive language from the court about what kind of procedures are required before establishing price control.

And, again, let's just be clear. We're talking about in that case a regulatory regime. We're not in a regulatory regime here.

THE COURT: Why don't you wrap up in case there's anything I missed today, and then I'm going to ask the other side to do the same.

MR. SVERDLOV: Your Honor, I believe I've covered all

the substantive grounds. I think I would just like to emphasize that we now have three courts that have rejected constitutional challenges to the IRA, and they have all done so on the recognition that the program is completely voluntary. That is in keeping with decades of case law from this circuit, the seminal *Garelick* case and others. That analysis is directly dispositive of all the Fifth Amendment theories because the due process in the Takings Clause provide different protections for property interests. And the problem for plaintiffs here is that there is no impositions on those interests when they are not legally compelled to participate. And it's informative on the First Amendment claim as well.

THE COURT: Thank you.

MR. SVERDLOV: Thank you, Your Honor.

THE COURT: Mr. King.

MR. KING: Yes, thank you, Your Honor, a few points to wrap up here.

First, Mr. Sverdlov at one point referred to facial challenges. This is not a facial challenge. This is an as-applied challenge. Every one of our claims is on an as-applied. We say that in our Complaint. We say it in our briefs.

THE COURT: Even the tax claim?

MR. KING: We're asserting it as applied to us. I acknowledge that the tax claim could have broader consequences.

THE COURT: But we don't know what the tax is yet. There hasn't been a sale, so it's a little bit difficult to see it as an as-applied challenge. That's the point.

MR. KING: Yeah, I guess I'd accept that maybe that one has to operate that way given the procedural posture. But really I'm thinking about First Amendment, Fifth Amendment, those kinds of things. That's the first point.

Second point on Government as a regulator, Mr. Sverdlov referred to the Fourth Circuit's decision in the *Brooks* case. That's a Dormant Commerce Clause case that had to do with how the states can operate in the market. It had nothing to do with the federal government. It had nothing to do with the Spending Clause or the federal government's taxing power. It's a fundamentally different context. So, yes, it uses the words "market participant," but it uses those words as referring to the Dormant Commerce Clause market participant exception. It has no relevance here whatsoever.

On the point about whether or not the program is voluntary, the linchpin of many of the Government's arguments, to say that the Government -- that the program is not voluntary does not mean that it is not constitutional; right? The Government is trying to use voluntariness here as a shield to immunize this program from constitutional scrutiny. But the conclusion, whether it's under economic coercion, illegal compulsion, or anything else, that the program is not voluntary

doesn't mean it's not constitutional. It just means that you run the ordinary First Amendment or Fifth Amendment or other standard of review.

And so I guess what that means, to go back to your UCC hypo, is that if you've got to run First Amendment scrutiny of UCC, it very well may be constitutional, indeed easily constitutional; right? But you're just not out of the normal test. That's really the only point that voluntariness has here. And you see that analysis in cases like *Carter* and *Butler* where they say it's not voluntary, and so now we're going to scrutinize it.

On good cause, Your Honor asked a lot of questions about good cause and ejusdem generis and those kind of things. I think we stand by our arguments on those points, but there's a threshold point that you don't even get to good cause unless you're under the withdrawal by the Secretary statute. I just point you -- this is 42 U.S.C. 1395w-114a(b)(4)(B).

THE COURT: Yeah.

MR. KING: And you've got romanette i that's "By the Secretary"; romanette ii, "By a manufacturer." Good cause does not appear in withdrawal by a manufacturer; right? And the withdrawal that's at issue here would be by Boehringer Ingelheim, by a manufacturer. So good cause is, from our perspective, irrelevant regardless of how you read it. It doesn't matter how capacious it is. It just never comes into

play.

THE COURT: Fair enough. What else?

MR. KING: In terms of whether or not this program is voluntary, in fact, right, that's the Supreme Court term, we have a detailed declaration.

THE COURT: Court's term in *Horne*?

MR. KING: In *NFIB* in fact, right, not just in theory but in fact. And it's the same concept that is applied in *Butler* and those other case.

We're here on summary judgment. We have a detailed sworn declaration attesting that this program is not voluntary in fact as to Boehringer Ingelheim. The Government doesn't challenge the allegations in that declaration, didn't put in their own competing declaration. They've had ample opportunity. They haven't challenged any of it. So on summary judgment, when you've got something on our side and nothing on their side, I would say that means summary judgment in our favor or at a minimum --

THE COURT: No, I mean, it depends. Voluntariness can be assessed from the statute itself. It's really not a factual question though; right? It's a legal question.

MR. KING: There is a legal question, and I guess I would say, under *Carter* and *Butler* and *NFIB* and those cases, factual voluntariness is legally relevant. And we have said that it's not voluntary factually as to us. So it's not just a

legal question. It's a factual question on that point.

And then last on *USAID*, I want to come back to that passage that I was reading because there's some language there that I left out that goes directly to your question.

THE COURT: Okay.

MR. KING: So, you know, the dissent in *USAID* had thought that compelled speech is a problem only if the condition is not relevant to the objectives of the program, which I take to be very similar to the point you were making. But the majority rejected that, and they said that the case law is not so limited. Instead, the distinction is choosing what activities Congress wants to subsidize. Is it speech outside the contours of the program?

And on that issue, Your Honor, the line, the majority acknowledged, is hardly clear, but here's what they said that's really, really important. The court was confident that the contract violated the First Amendment for two reasons. The second requirement, Mr. Sverdlov quite accurately pointed out that there were two conditions, and we're dealing here -- only the latter was challenged, and we're comparing ourselves --

THE COURT: The first was prohibition. The second one was what you called compulsion.

MR. KING: Yeah, the first was the *Rust v. Sullivan* type prohibition. The second was the compulsion.

The second requirement did something more. So to

analogize to here, it's not just price regulation, but it's a requiring of communication about the prices, saying that the prices are, for example, the maximum fair prices.

The grantee, quote, had to adopt a stance and, quote, a particular belief; and requiring the grantee to do that -- and I'm just going to quote from the decision here -- the court was confident that when the Government compels the recipient of a benefit to adopt the Government's view on an issue of public concern, the condition by its very nature affects protected conduct. And here are the keywords that I left out -- "outside the scope of the federally-funded program."

It's categorical. When the Government requires you to do that, that by definition, or by its very nature, is outside the scope. That's what's going on here. And so that's why, regardless of whether or not this program is voluntary, you get to a *USAID* type unconstitutional conditions analysis, and you get to this conclusion that the speech here about the fairness of these prices is outside the scope.

THE COURT: All right. Thank you.

You want to say a last word then?

MR. PARRISH: If I could, Your Honor. I only have three things. One, Your Honor, you asked about *Williams Packing*. I didn't do a very good job of responding to good faith. If I could just suggest to you, if you look earlier in that paragraph there, what it says is it says, if there's --

"under no circumstances that the Government could ultimately prevail, the central purpose of the Act is inapplicable because, under those circumstances, the exaction is merely in the guise of a tax."

And then it goes on to say, there's a question here about whether the Government could actually establish liability for the tax. And in that context, they talk about the Government having good faith.

So, Your Honor, what we would say to you is that, if you were to find that the tax is permissible but there's a question as to whether they could establish liability, yes, you'd look at good faith. But before you get there, you have to ask yourself whether the tax on it is excessive. And in that sense, Your Honor, I think we fall within *Williams*.

THE COURT: Okay.

MR. PARRISH: Second, Your Honor, you know, you asked -- you got our point -- right? -- which is that if he's right, that Congress has said to the agency, "You can make law with no procedures," then that's a due process point. His only answer to that was to say that the APA is not constitutionally required. Of course, he's right about that. But the cases that he's citing to you all rely on a case where the APA's procedures have been replaced with constitutionally adequate procedures. There has to be some constitutionally adequate procedures, a right to a hearing, a right to challenge

evidence, judicial review, some of those, maybe not all of them, but depending on the circumstances --

THE COURT: Rulemaking context?

MR. PARRISH: I'm sorry.

THE COURT: I mean, in other words, the right to challenge evidence comes up in an adjudication; right? But this isn't what we're talking about here. We're talking about whether the guidance can be binding, and that's the issue of whether really ultimately an agency can adopt a binding rule without notice and comment and still be complying with the Constitution.

MR. PARRISH: So, Your Honor, two points on that. On the point that you just made, I think that's right. And what we would say is that if you can read the IRA consistent with the APA, then we have to prevail on that.

THE COURT: I didn't follow you there.

MR. PARRISH: If you can read the Inflation Reduction Act as not precluding application of the Administrative Procedure Act, if you can read those two statutes in harmony, then under *Mach Mining* and the cases we cite in our brief, the other side loses because the presumption is that those statutes are read in harmony, which means he doesn't get exempted from rulemaking.

THE COURT: Just so I'm clear, the other way to read it is, of course, the Government's reading, which is it's an

express exemption from the APA.

MR. PARRISH: What I would say is two things about that. Under the case law, it has to be clear. We would say it's not clear. And, second, it's a strange way to read the statutes with not reading them complementary. So if you can read it -- if it's in balance, then we have to prevail. He can only prevail if he can show it clearly exempted.

THE COURT: That's the issue.

MR. PARRISH: Right. So then on your broader point, Your Honor, our due process argument is making two points, and they come together. One is that even if this was not rulemaking and it was more sort of an adjudication over what the price would be, it's not really an adjudication. But even if that's what was going on, there would still be due process that would be required before they could set the price, take our --

THE COURT: But it's not an adjudication. And so -- so I guess what I'm wondering is, is there any authority for the proposition that as a constitutional matter -- suppose the APA didn't exist. As a constitutional matter, can an agency issue a pronouncement that affects substantive rights without notice and comment?

MR. PARRISH: Your Honor, it can't.

THE COURT: Is there a case that you're aware of that speaks to that issue?

MR. PARRISH: I might be --

THE COURT: It's a yes-or-no question.

MR. PARRISH: So, Your Honor --

THE COURT: Yes-or-no question. Is there any case?

MR. PARRISH: Yes.

THE COURT: Okay. What's the case?

MR. PARRISH: But I don't know because I don't have them off the top of my head. But let me just answer it that way because I'll supplement the record for Your Honor. The idea that an agency cannot impose binding legal requirements on its own without some source of authority from Congress or going through constitutionally adequate --

THE COURT: Source of authority, I mean, they have the statute. They're just -- and counsel quoted multiple places in the statute where it seems clear Congress has told the Secretary, "You have discretion to do these things. Go ahead and do it." And they've given them one tool, program instruction and program guidance.

MR. PARRISH: So, Your Honor, I'm sorry I can't bring them to articulate them right now, but it is very clear that, when an agency is acting within what Congress has specifically said, where Congress sets the rule -- right? -- this is the whole principle of *Chevron*. It's the whole principle of modern administrative law. The agency can do what Congress said. So if Congress said, "Put a price of $5," yeah, they can do that,

but Congress can't give them open-ended discretion to take the next step.

THE COURT: You haven't made a delegation argument in your brief, have you?

MR. PARRISH: No. We're making a due process argument, Your Honor, which is -- the way the delegation works, is that since 1946 delegations to agencies have been permissible as long as they comply with the APA or constitutionally adequate procedures to protect their property interests at stake, which is why the Government in its brief only argues that there's no property interest. We've already showed why that's wrong. But they don't have any argument on this because ultimately what their position comes down to is that Congress could delegate authority to the agency and say, "Make it up." Now, that would be a delegation problem, but it would also be a massive due process problem because the delegation problem is the separation of powers between the agency and the legislature but for everybody who's caught.

So, Your Honor, I use the example of the house. I could have used the example of consumer goods, electronics. I could have used the example of food stuff. If the Government is right, then Congress can pass a statute tomorrow that says, "We're worried about prices. Agency, please fix. Do it by guidance." And no --

THE COURT: The statute here is more specific than

that, I mean far more specific than that.

MR. PARRISH: Of course, Your Honor. But the question, of course, is the principle, which is not that the statute doesn't contain details. The statute -- the question is: When they get beyond those details, are they -- are they making law? And as soon as the agency gets to the point of making law, then the agency has gone too far unless it follows the procedures by which law can be made, which has always been thought of since 1946. Again --

THE COURT: What's the 1946 case?

MR. PARRISH: 1946 is when they passed the Administrative --

THE COURT: But the APA is not constitutionally required, so ...

MR. PARRISH: No, Your Honor, but in the case of the *Yakus* decision, the *Bowles* decision that we cite, which are the wartime cases where they recognize this is an emergency, so extreme circumstances, both of those preceded the APA. Both of those said there wasn't a delegation problem because of the due process protections, including the right to a neutral arbiter, the fact that you had this hearing. And they went through detail about what you would get there. In 1946 they replaced that with the APA; and ever since, every case that the Supreme Court has decided about administrative law is premised on this idea that the agency doesn't get to make law.

THE COURT: All right. I gotcha.

MR. PARRISH: So, Your Honor, all I'll close with is my last point, which is just to say that the Government's position this morning and in their briefs is that, There's nothing to see here. Let's move along.

And all I would leave with the Court with the impression, and I'd ask the Court to reflect on, is how unprecedented this is. We have never seen a statute that has no standards at all and it can impose any confiscatory price it wants below the ceiling with no judicial review.

There's the fourth speech that Mr. King talked about. There's no procedures, and I've gone through all of those, no hearing, no evidence, and so forth. There's no judicial review. It's an enterprise-killing excise tax that, Your Honor's absolutely right, at 500 million to 5 billion a week, there's no way we could afford to go through all that.

THE COURT: I got that.

MR. PARRISH: All that, Your Honor, is designed to do the two things that you and I talked about, which is to avoid the political accountability when the public is upset that they set the price at the wrong level and to tramp on our protected interest both over the drugs themselves and our information stuff. And, Your Honor, as we said, all of this is based on the idea that they can just make up the laws they want. That can't possibly be consistent.

And the only thing I would say, Your Honor, is you could see this morning, if all of these things fit together in some way, the Government doesn't really have an answer except for jump back. So if you push on one --

THE COURT: Wrap up. I got this.

MR. PARRISH: That's it. So all I was going to say, Your Honor, just to wrap up, is we'd ask that you strike it down. But just to be clear, if you don't strike down the statute, at a minimum the way CMS has implemented, it can't possibly be right. We ask for both forms of relief.

THE COURT: I got it.

Let me leave you with this: Obviously, I know you have done a lot of work on this. And the premise of the letter that counsel sent to court was that you need a ruling before August 1st. I expect to get you a ruling before August 1st. I can't tell you a great deal more than that right now, but I'm going to do my best to get it out as soon as possible. I certainly don't want to get it out July 31st, July 30th, July 29th, anything like that. I want to give you as much time as I can. That's the best I can do right now.

Thank you all for coming up. I think you're all from D.C., if I'm not mistaken. Thank you. The case has been very well, very ably presented. And I will do my best to get a ruling out. Thank you very much. We'll be in recess.

(Proceedings concluded at 12:53 p.m.)

C E R T I F I C A T E

BOEHRINGER INGELHEIM PHARMACEUTICALS, INC.

VS.

UNITED STATES DEPARTMENT OF HEALTH
AND HUMAN SERVICES, ET AL.

NO. 3:23-CV-1103 (MPS)

I, Julie L. Monette, RDR, CRR, CRC, Official Court Reporter for the United States District Court for the District of Connecticut, do hereby certify that the foregoing pages are a true and accurate transcription of my shorthand notes taken in the aforementioned matter to the best of my skill and ability.

/S/ JULIE L. MONETTE

Julie L. Monette, RDR, CRR, CRC
Official Court Reporter
450 Main Street - Clerk's Office
Hartford, Connecticut 06103
(860) 212-6937