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UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

JANSSEN PHARMACEUTICALS,
INC.,

Plaintiff,

v.

CIVIL ACTION NUMBER:

3:23-cv-03818-ZNQ-JBD

3:23-cv-03335-ZNQ-JBD

3:23-cv-14221-ZNQ-JBD

3:23-cv-20814-ZNQ-JBD

XAVIER BECERRA, in his
official capacity as
Secretary of Health and
Human Services, et al,
Defendants.

ORAL ARGUMENT

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

B E F O R E:

THE HONORABLE ZAHID N. QURAIISHI,
UNITED STATES DISTRICT JUDGE

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

4 THE DEPUTY COURT CLERK: All rise.

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

7 All right, everybody. We are on the record actually in
8 four matters, so let me just put that on the record: Bristol
9 Myers Squibb v. Becerra et al., Docket Number 23-335; Janssen
10 Pharmaceuticals v. Becerra et al., Docket Number 23-3818;
11 Novartis Pharmaceuticals v. Becerra et al., Docket Number
12 23-14221; and Novo Nordisk v. Becerra et al., Docket Number
13 23-20814 for oral argument.

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

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

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

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

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

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

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

6 MR. GREENBAUM: Good morning, Your Honor.

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

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

13 Mr. Roth will be arguing for us today.

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

16 Additional appearances?

17 MR. CHIESA: Good morning, Your Honor.

18 Jeffrey Chiesa, Chiesa, Shahinian & Giantomasi, on behalf of
19 Janssen.

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

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

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

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

3 THE COURT: Good morning to you as well.

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

7 THE COURT: Good morning to you as well.

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

10 Government?

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

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

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

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

22 MR. CHIESA: Yes, Your Honor.

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

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

2 THE COURT: Plaintiffs, none?

3 MR. CHIESA: None.

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

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

8 Go ahead, Mr. Chiesa.

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

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

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

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

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

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

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

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

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

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

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

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

1 government.

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

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

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

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

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

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

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

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

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

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

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

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

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

18 THE COURT: Thank you, Mr. Chiesa.

19 Now can I ask my one question?

20 MR. CHIESA: Of course, Your Honor.

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

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

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

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

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

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

10 MR. CHIESA: We are not, Your Honor.

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

13 MR. CHIESA: Sorry about that.

14 THE COURT: I appreciate that.

15 MR. CHIESA: Thank you, Judge.

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

18 THE COURT: Good morning.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

16 MR. ROTH: Right.

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

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

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

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

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

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

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

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

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

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

1 then what claims are left?

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

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

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

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

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

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

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

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

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

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

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

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

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

3 This program operates the same way, Your Honor.
4 Statute says the Secretary and the manufacturer shall enter an
5 agreement under which they agree to provide access to the
6 maximum fair price for eligible individuals. It's in
7 1320f-2(a)(1) and (a)(3).

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

6 THE COURT: Has anybody withdrawn?

7 MR. ROTH: No, Your Honor.

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

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

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

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

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

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

25 MR. ROTH: I think that's right.

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

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

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

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

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

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

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

6 The third distinction is there is some payment made.

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

8 MR. ROTH: Sure.

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

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

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

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

16 Do they benefit from the price reduction?

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

1 MR. ROTH: Thank you.

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

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

5 THE COURT: Good morning.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

25 My understanding is that you guys were going to address

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

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

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

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

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

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

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

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

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

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

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

11 MR. NETTER: Yes.

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

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

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

20 Did you want to say something?

21 MR. NETTER: No.

22 MR. DEGER-SEN: Great.

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

1 way.

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

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

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

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

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

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

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

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

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

25 That is exactly what the Supreme Court rejected in

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

4 THE COURT: Involuntary.

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

7 THE COURT: All right. Thank you.

8 MR. KING: Good morning, Your Honor.

9 THE COURT: Good morning.

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

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

18 THE COURT: All right.

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

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

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

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

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

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

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

19 Now, the government asserts that this program is
20 voluntary because plaintiffs could theoretically withdraw all
21 their drugs, not just the four selected drugs we're talking
22 about here today, but all of their drugs for Medicare and
23 Medicaid, which, by the way, for the four plaintiffs that are
24 before you today, Your Honor, that's 120 drugs -- more than
25 120 drugs that cover serious medical conditions like cancer,

1 HIV, heart disease, and more.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

25 MR. KING: Those programs are -- and those

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

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

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

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

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

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

1 takings claim under the Unconstitutional Conditions Doctrine.

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

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

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

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

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

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

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

23 MR. KING: Yes.

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

1 to be voluntary.

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

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

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

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

19 MR. KING: Yeah, that's right.

20 THE COURT: The due process claims, mostly.

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

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

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

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

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

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

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

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

1 THE COURT: All right.

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

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

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

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

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

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

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

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

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

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

17 So the statute has a very complex formula. This is
18 26 U.S.C. 5000D. It calls for a tax that's a ratio of one
19 figure to another.

20 And when you do the math, as the Congressional Research
21 Service did, what you get is an excise tax of starting at
22 186%, going all the way up to 1,900%. There's a debate in
23 this case about, well, what is the percentage? Is it actually
24 95%?

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

1 correct?

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

4 The 95% figure is not accurate because the government
5 uses an analogy. They say suppose there's a bill for a
6 hundred dollars, a \$5 sale and \$95 tax on top of that \$5 sale.
7 \$95 is 1,900% of 5, so even if you do it their way, it's
8 1,900%. It's 19 times.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

25 But there is a broader coercion principle that cuts

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

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

8 Coercion by economic pressure makes the asserted power
9 of choice illusory. Illusory. That's what we have here. You
10 don't need to take it from me as far as *NFIB* working this way.
11 This is a new case, and so I want to call this to your
12 attention. It's not in the briefing, as far as I'm aware, but
13 I point you to *American Health Care Association v. Burwell*,
14 217 F.Supp.3rd, 921 from 2016.

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

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

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

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

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

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

1 respect.

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

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

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

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

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

1 do that here through their revised guidance.

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

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

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

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

20 THE COURT: Thank you. I appreciate it.

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

24 MR. NETTER: A few responses.

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

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

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

8 Go ahead.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

1 its drugs to Medicare beneficiaries.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

1 can terminate its Medicare subscription agreement.

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

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

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

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

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

24 MR. NETTER: Right.

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

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

3 THE COURT: Right.

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

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

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

23 So that covers exiting entirely.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

6 Likewise, *Valancourt* created an --

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

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

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

15 Is that accurate? Is that the dispute here?

16 MR. NETTER: That is, Your Honor.

17 THE COURT: All right. Why are you right?

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

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

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

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

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

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

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

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

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

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

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

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

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

21 MR. NETTER: Well --

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

1 Isn't that the argument by opposing counsel?

2 MR. NETTER: I think that --

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

1 the attorneys on the other side.

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

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

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

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

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

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

1 medication and pharmaceuticals through the government.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

25 THE COURT: Thank you, Mr. Netter.

1 Mr. Roth, you're coming back?

2 MR. ROTH: If I may.

3 THE COURT: Is it rebuttal?

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

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

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

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

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

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

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

1 they want to pay. They set the coverage terms.

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

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

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

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

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

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

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

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

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

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

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

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

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

1 your contract.

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

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

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

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

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

23 THE COURT: I agree.

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

1 of -- an early takings case.

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

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

12 Thank you, Your Honor.

13 THE COURT: Thank you, Mr. Roth.

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

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

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

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

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

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

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

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

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

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

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

23 That's point number 1. May I continue?

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

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

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

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

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

13 THE COURT: Right.

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

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

22 THE COURT: All right.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

15 MR. KING: Thank you, Your Honor.

16 THE COURT: Anybody else coming up?

17 MR. KING: Nope.

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

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

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

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

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

6 Anything further from plaintiffs before we take a
7 break?

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

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

11 MR. NETTER: No, Your Honor.

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

14 MR. CHIESA: Your call.

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

18 Thank you. We are adjourned for this morning.

19 THE DEPUTY COURT CLERK: All rise.

20 (Luncheon recess was taken from 12:37 p.m. until
21 1:17 p.m.)

22 THE COURT: Thank you. You may be seated.

23 Folks, we're back on the record.

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

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

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

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

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

16 MR. SVERDLOV: Good afternoon, Your Honor.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

25 MR. SVERDLOV: It was, in fact --

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

3 MR. SVERDLOV: Correct. Correct.

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

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

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

17 Is this in response?

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

20 THE COURT: However you want to proceed.

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

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

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

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

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

13 THE COURT: Right.

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

16 So unless Your Honor has further questions on
17 jurisdiction --

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

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

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

1 THE COURT: First Amendment.

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

6 THE COURT: Go ahead. I'm listening.

7 MR. ROTH: Okay. Great.

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

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

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

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

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

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

1 do something? They mandate or prohibit that thing.

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

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

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

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

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

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

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

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

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

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

1 government to then go out and say we've reached an agreement.

2 This is fair.

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

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

10 MR. ROTH: Correct.

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

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

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

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

7 THE COURT: Do this.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

1 case.

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

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

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

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

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

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

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

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

7 MR. ROTH: Right.

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

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

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

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

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

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

7 THE COURT: All right.

8 MR. ROTH: Thank you.

9 THE COURT: Thank you, Mr. Roth.

10 Who's coming up for the government?

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

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

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

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

25 MR. SVERDLOV: Correct, Your Honor.

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

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

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

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

17 That was how they sought to establish --

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

20 MR. SVERDLOV: Correct.

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

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

25 THE COURT: I appreciate that. That clarifies at

1 least our prior discussion.

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

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

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

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

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

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

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

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

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

5 And so why is that language even in there?

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

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

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

19 THE COURT: Yeah.

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

25 They are in the template agreement to make clear that

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

9 THE COURT: Is there a disclaimer?

10 MR. SVERDLOV: There is.

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

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

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

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

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

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

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

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

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

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

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

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

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

1 there's no political propaganda language in the agreement.

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

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

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

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

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

1 The disclaimer, Your Honor, specifically asked
2 whether --

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

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

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

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

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

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

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

1 developing the revised guidance to promulgated initial
2 guidance.

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

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

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

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

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

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

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

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

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

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

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

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

22 MR. SVERDLOV: Right.

23 THE COURT: I do.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

7 MR. SVERDLOV: Absolutely, Your Honor.

8 THE COURT: It was best for the mission.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

25 I would like to maybe address three additional points

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

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

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

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

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

25 An ordinary price regulation, as this Court noted, has

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

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

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

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

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

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

15 THE COURT: Thank you, Mr. Sverdlov.

16 Mr. Roth, do you have rebuttal?

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

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

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

10 MR. ROTH: I agree, Your Honor.

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

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

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

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

23 MR. ROTH: Your Honor, first, I think what takes out
24 99 percent of that is, most of the time, you are penalized if
25 you don't sign the agreement. This is very unusual because,

1 unlike the defense contractor who reaches a deal --

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

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

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

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

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

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

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

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

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

1 THE COURT: Thank you, Mr. Roth.

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

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

6 THE COURT: Good afternoon.

7 MR. DEGER-SEN: The program here states that a
8 failure to reach agreement with the government as to the
9 maximum fair price leads to a fine that is 19 times the
10 national sales revenue of the drug, which Novartis is
11 \$93.1 billion a year, which is so ludicrously high that even
12 the government has not tried to defend it. Instead, the
13 government, through this IRS guidance, has tried to lower that
14 to a number that seems somewhat more reasonable. That
15 rewrite, we don't really think it makes any sense, but we
16 address in our briefs why it doesn't make sense. I don't want
17 to get bogged down in that because I don't think anything
18 turns on it.

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

1 conduct.

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

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

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

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

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

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

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

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

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

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

16 THE COURT: Yes. So say I'm following you. Say I'm
17 following you that -- let me make sure I paraphrase. If I'm
18 inaccurate, then correct me on the record. The program poses
19 an excise tax -- I don't know if this is right, but I have
20 notes here -- beginning 186%, and after 276 days reaches
21 1,900%. Is that the position, 1,900%?

22 MR. DEGER-SEN: That's correct.

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

1 Would 95% excise tax cause you irreparable harm?

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

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

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

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

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

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

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

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

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

11 MR. DEGER-SEN: That's great. That's the first part.

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

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

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

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

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

11 Even if you don't agree with us on that, I think this
12 goes to the next question, which is the *Williams Packing*
13 exception. You only get to the *Williams Packing* exception if
14 you think that this is a suit for the purpose of restraining
15 the assessment and collection of tax. We don't think you need
16 to get to the exception, but if you get to the exception, then
17 it's irreparable injury on the merits, and that irreparable
18 injury is not just the financial injury. And it's irreparable
19 at least in the sense that there is no way we would be able
20 to --

21 THE COURT: What about the agreements for their -- to
22 exercise forbearance?

23 MR. DEGER-SEN: What they say there is -- you can
24 apply the statute once, and we'll exercise forbearance on that
25 collection challenge. They change the fact that the statute

1 -- because it applies through all of noncompliance periods --
2 means that you're going to be racking up the excise tax the
3 whole time. So you have that lawsuit and that refund action.
4 You challenge it and, after two years, you lose, you pay 93
5 million or 200 billion; these figures that obviously no
6 company could ever pay.

7 So it's a completely unrealistic option to think we
8 could ever have a challenge, just wait for these penalties to
9 accrue in the background, and down roll the entire company on
10 winning one single lawsuit. And the government knows that.

11 Just stepping back, that is what -- the position that
12 they have in this case, Your Honor, means that you have --
13 that they are going to be able to say any time they want to
14 compel compliance like this, we can take this out of the
15 constitutional challenge by calling it a tax and making it
16 unchallengeable. That is the sort of extreme nature of the
17 challenge they have in front of you in this court. I don't
18 think you can accept that premise to say this tax.

19 The final thing they say is that we sued the wrong
20 party. The most straightforward thing to say about that is
21 under Rule 21, at any time you can add or drop a party. So if
22 you think there's any concern with that, would serve the
23 government. The government is obviously aware of this case.
24 It's a completely technical, formalistic thing.

25 THE COURT: You mean like the IRS or the Treasury

1 Department? I'm going to ask that question to your friends on
2 the other side. I like Mr. Sverdlov's use of the word
3 "friends." That's something they do before the Supreme Court.
4 We should probably implement that more in district court, but
5 I have heard that before in the Supreme Court, and I do
6 appreciate that. I'm going to ask your friends on the other
7 side of the aisle about why we need those, folks, especially
8 -- you make a point in your paper. HHS isn't joined. Would
9 that keep a tax from being collected? Right? Let me see what
10 they have to say about that.

11 MR. DEGER-SEN: Your Honor, it would stop the tax
12 from being collected, but more fundamentally what we're asking
13 for here it sort of syncs well with our AIA argument. What
14 we're asking for is a declaration of the tax is unlawful. And
15 the injury that's happening here is the use of that tax to
16 compel our behavior. And with that declaration -- and it's
17 HHS and CMS that are doing that -- with that declaration they
18 can't do that anymore, and the game changes, and that's what
19 we're saying. It's the use of this tax -- I think the last
20 thing I'll say about this is it is sort of telling the way
21 they described the program throughout the day. They tried to
22 avoid the tax and say it's just the government, you know, the
23 government is just, you know, setting the price it wants. If
24 you don't like it, walk away. All of that stuff.

25 Why do they want this tax? Why is the tax here? Why

1 do you need to have this enterprise-destroying penalty backing
2 everything? If it's so unnecessary, maybe they should just
3 give it up. I think that's an important question to ask the
4 government.

5 Thank you, Your Honor.

6 THE COURT: I will. Thank you, Mr. Deger-Sen.

7 Who is coming on from the United States?

8 MR. GAFFNEY: Good afternoon.

9 THE COURT: Good afternoon. Before we do anything,
10 why don't you answer Mr. Deger-Sen's question? I mean, now,
11 presume I asked it. Why do you need this excise tax?

12 MR. GAFFNEY: I think the question is not why do we
13 need the tax. The question is whether the tax is
14 constitutional, and there's even a threshold question before
15 that, which is whether the Court can get to it. You asked
16 this morning are there going to be any claims where I don't
17 need to run the analysis all the way to ground in order to
18 dispose of that claim? This is one.

19 THE COURT: This is one.

20 MR. GAFFNEY: This is one.

21 THE COURT: All right.

22 MR. GAFFNEY: It's no surprise. I think that counsel
23 for Novartis starts with -- to jump to the merits instead of
24 talking about the Anti-Injunction Act. The defendants aren't
25 the ones that contrived this judicial review scheme. Congress

1 did. And under the Anti-Injunction Act, the question is not
2 -- this is from *Florida Bankers*, a D.C. Circuit case, 977 F.3d
3 1065 at 1067. The issue here is when, not if, plaintiff may
4 challenge this tax. Under the Anti-Injunction Act, Congress
5 chose to have refund suits be the mechanism by which taxpayers
6 challenge taxes. The Court in *NFIB* at 567 U.S. at 544
7 explains this. AIA is like -- taxes that Congress creates,
8 quote, "Creatures of Congress's own creation and how they
9 relate to each other is up to Congress, and the best evidence
10 of Congress's intent on that question is the statutory text."

11 So this is one of those issues where the label itself
12 matters. And you don't hear any dispute that the 5000D tax is
13 labeled a tax. So the first of the two questions that must be
14 asked under the Anti-Injunction Act, the first one is
15 satisfied. The 5000D tax is a tax.

16 So the second question is -- and that's true. It's not
17 disputed, but it's true, even when there's this
18 characterization of the tax as a regulatory tax, as opposed --

19 THE COURT: The bottom line, Mr. Gaffney, just so I
20 am clear as day, if Congress calls it a tax, it's a tax. Is
21 that the point that you're trying to make there?

22 MR. GAFFNEY: That's what the Court said in *NFIB*.
23 That's what the Court said in *CIC Services*. And that's true
24 even when a challenger to a tax says, yeah, but this tax isn't
25 even really revenue raising. The Court said -- this is in *CIC*

1 Services 593 U.S. at 225 -- the AIA, quote, "Draws no
2 distinction between regulatory and revenue-raising tax rules."
3 Congress says it's a tax, it's a tax for AIA purposes.

4 That leaves the second question. What is the purpose
5 of suit? Now, Novartis does not cite a single case -- and
6 defendants aren't aware of one -- where the legal claim is
7 about the legality or constitutionality of a tax, and
8 Anti-Injunction Act did not apply to require that taxpayer to
9 challenge that tax in the course of a refund suit. That's
10 what we have here. They're saying the tax violates the
11 Eighth Amendment. The claim squarely challenges the
12 constitutionality of the tax, and I'm not aware of any case
13 where that has been the legal claim. And the purpose of the
14 suit has been not to restrain or enjoin the collection or
15 assessment of that tax. And the AIA --

16 THE COURT: This is probably the question I was going
17 to ask you. Novartis makes an interesting point. They
18 basically say that if HHS is enjoined, then that will keep the
19 tax from being collected. That would be a complete relief,
20 right? That's the argument that you're saying that's unique.
21 There's nothing out there that would support that, in every
22 situation where we have an issue of an actual tax, the IRS and
23 Treasury department are in.

24 MR. GAFFNEY: Sorry. I keep cutting you off. I
25 think your summary of their redressability argument is exactly

1 right. And I pulled a couple of the quotes from their
2 redressability argument. Their redressability argument is we
3 don't have to sue the IRS and Treasury because even though we
4 know those are the agencies that are going to collect the tax,
5 that are going to enforce the tax provision, they know that.
6 Even though that's true, they say in their brief, yeah, but
7 CMS performs this statutory trigger for enforcement of tax.
8 In other words, CMS is involved in the enforcement.

9 I want to point a couple of spots where they say this
10 in their briefing. This is at ECF Number 57. So -- I've got
11 eight examples, I think, but I'll just give you three. At
12 page 52, CMS is, thus, plainly necessary to the enforcement of
13 the excise tax. Also at page 52, there's simply no realistic
14 basis to think that the IRS or Treasury would or could impose
15 the excise tax if CMS was enjoined. The last one they say,
16 quote, "It's inapplicable here because CMS has an integral
17 role in the causal change of enforcing the excise tax."

18 In other words, there's no question. Their answer on
19 redressability as to why it's fine that they just got CMS and
20 HHS in the case. Why? They're involved in enforcing the tax.
21 What are they trying to stop? Enforcement of the tax. That
22 is exactly what the AIA precludes.

23 As I mentioned, they don't cite a single case where the
24 legal claim directly challenges the constitutionality of a
25 tax, and yet the AIA was held not to apply.

1 In *CIC Services*, that's not what's happening. There's
2 a question about the legality of an IRS notice. There are a
3 lot of upstream things in this case that they complain about
4 that they say lead them -- could lead them down this path to
5 paying a tax. We haven't raised the Anti-Injunction Act to
6 preclude these things that if they do or don't do it might
7 trigger a tax. We raise the Anti-Injunction Act where it
8 applies where there is a tax that they're challenging and
9 where the purpose of their Eighth Amendment claim is to say,
10 Court, declare this thing excessive under the excessive fines
11 clause and prevent them from enforcing it. The AIA applies
12 there squarely.

13 On the Declaratory Judgment Act, I just want to loop
14 back. This is the last comment that we heard is on the
15 redressability point. Well, you know, we're still seeking a
16 declaratory judgment even if an injunction here wouldn't do
17 the trick with CMS and HHS defendants. What about the
18 declaratory relief that we're seeking? That's an even easier
19 case. Their argument on the Anti-Injunction Act -- again,
20 this isn't a tax -- is that the purpose of their suit isn't to
21 restrain the assessment or collection of taxes. The
22 Declaratory Judgment Act tax exception is even easier. It
23 just says no declaratory judgments for declaratory judgments
24 that are, quote, "with respect to federal taxes."

25 THE COURT: Federal taxes.

1 MR. GAFFNEY: That's that. There's no declaratory
2 judgment available here. So the redressability argument can't
3 be cured by pointing to that.

4 On their reliance on the Congressional Research
5 Service, they point to this over and over as if Congress
6 itself announced that the tax would never generate revenue as
7 if HHS and CMS said that. That's not true. We cite ECF
8 Number 24 at page 56, note 13 there. This case is 56
9 F.Supp.3d 280, 296. But basically, long story short, courts
10 don't take what CDO or CRS says as evidence of congressional
11 intent. We cite a couple cases there, but there are a host of
12 others that do the same thing.

13 I will note I looked closely at that Congressional
14 Research Service report. At page 30, it says to challenge
15 this thing, you've got to pay the tax in full and bring a
16 refund suit. They don't agree with that part of the CRS
17 piece. So everybody had some disputes about what exactly is
18 going on here, and nobody thinks that the CRS research report
19 is the definitive answer here on congressional intent.

20 So AIA applies. So the question is, is there an
21 exception that applies? There are two judicially recognized
22 ones. They don't try to fit within one of them. That is
23 *Williams Packing*. The point of *Williams Packing* -- and it's a
24 very narrow exception -- the Third Circuit has said these
25 exceptions apply, quote, "only in extraordinary

1 circumstances." That's *Thornton*, 493rd F.2d at 166. Third
2 Circuit also said that the taxpayer bears a, quote, "very
3 substantial," end quote, burden. That's *Flynn*, 786 F.2d 591.

4 The thing you have to show as a taxpayer is two things:
5 irreparable harm between now and when you could bring your
6 refund suit', and, two, that you will definitely certainly
7 succeed at that suit.

8 So what's the point of that? The point is if you
9 definitely got a winner of a claim, but in between now and
10 when you could bring that refund suit you're going to suffer
11 irreparable harm to the point that, let's say, you're not even
12 going to be around to actually win, well, then you put in the
13 claim now and win now. But that's not what we have here.

14 So the thing that they ignore -- and I think Your Honor
15 picked up on it earlier -- is the point that this tax is a
16 divisible tax. So what is it Novartis needs to do between now
17 and the refund suit? Here is what they have to do. They have
18 to file -- this is assuming -- put aside all the voluntariness
19 stuff. Like, that they choose to remain in Medicare, they
20 choose to make Medicare sales, all of these other things.
21 Okay? They have to, one, file a return and pay tax on a
22 single sale. One. That's all they have to do. They have to
23 file a refund claim. As we discussed earlier, IRS policy
24 statement 516 says IRS won't collect the balance in the
25 interim. And then step 3, if and when there's a denial, they

1 file a refund suit. So what irreparable harm will they suffer
2 between now and the filing of that refund suit, which is the
3 irreparable harm that's required under *Williams Packing*,
4 paying tax on one sale? That is not going to put Novartis
5 under.

6 You asked earlier about the math, so let's get right to
7 that, because that's pretty important here. Everybody keeps
8 throwing out different numbers. Let's clarify this. You sell
9 -- during World War II --

10 THE COURT: Oh, my goodness. I mean, I'm asking you
11 to clarify the math in oral argument, and you're going back to
12 World War II.

13 MR. GAFFNEY: In World War II, in 1944, the top
14 marginal tax bracket -- thank goodness it's not the case today
15 -- 94%. Okay. So how did that work? You get paid a hundred
16 bucks. You fork over 94 of it to the government. You retain
17 the other 6. If we're in the world of 271 days, so let's skip
18 the 65, 75, 85%. So let's just jump to the 95%. If you sell
19 a drug for a hundred dollars, the customer pays a hundred
20 dollars. You, the manufacturer, retain your -- you retain the
21 \$5, and \$95 goes towards the tax. We don't dispute that 95
22 times 5 is 19. What we dispute is this looks anything like
23 these other cases, like in *Kurth Ranch* and *Dye* where they say,
24 Well, look, that was only four or five times. Here's the
25 difference. In *Kurth Ranch*, you sell your marijuana for a

1 hundred bucks. You owed in tax \$400. You're out \$300. In
2 Dye, it was five times. You sell your drugs for a hundred
3 bucks, you're out 500. You're down 400 bucks. Here this is
4 like a high income tax. You sell your drug, and you will pay
5 a portion of that in tax. It is not four or five times the
6 sale price. It's not what the customer pays times four or
7 five times. You retain less, a fraction of what you sold it
8 for, not that you owe a multiple of it to the government.

9 And that means -- I was looking back at some of the --
10 the declaration at 8, 11 -- paragraphs 8 and 11. I'm doing
11 math here. It's somewhere in the 40 to 50 times what they --
12 their number is 40 to 50 times what the number would actually
13 be. And by the way, that's because the rate is 20 times and
14 their Medicare sales are -- all their sales are not Medicare.
15 Right? This gets to the point of the Anti-Injunction Act, in
16 part. They don't -- they want to, like, point to these
17 massive numbers, but how the IRS is actually going to enforce
18 this thing we'll know in the refund suit. Like, they claim as
19 if the IRS isn't going to do it, even though the IRS notice
20 says taxpayers may rely on this thing now. They couldn't --
21 these interpretations, in any event, are favorable to them.
22 It would be very unlikely, I expect, come that refund suit. I
23 have a strong suspicion that they will not say, actually, you
24 were supposed to tax us on all our sales. Actually, it was
25 supposed to be 1,900%. I bet, in the refund suit, full

1 alignment on the IRS notice interpretation. But let's get to
2 the refund suit and see what the actual amount is so we don't
3 have these numbers that are floating around that are never
4 going to materialize.

5 The other thing that they have to show under *Williams*
6 *Packing* is they have to show a certainty of success on the
7 merits. They have to do both of these things, certainty of
8 success on the merits and irreparable harm between now and
9 that refund suit.

10 THE COURT: Is it certainty or likelihood? I don't
11 have it before me, but is that the language?

12 MR. GAFFNEY: It's certainty.

13 THE COURT: Okay.

14 MR. GAFFNEY: There's like -- the cases pile on. So
15 it's not just certainty. It's not just certainty. It's
16 certainty taking everything in favor of the government,
17 looking at this in the light most favorable, et cetera,
18 et cetera. It's an extremely high bar. Again, the point is
19 supposed to be you say to the taxpayers you're definitely
20 right, but you're telling me you can't possibly even get your
21 day in court. All right. Fine. We'll hear it now. We'll
22 make this one narrow exception to the requirement you got to
23 bring a refund suit.

24 But that's not what we have here. They don't point --
25 this is going to get into merits in a second -- but they don't

1 point to any excessive fines clause case and lacks a
2 connection to criminal conduct and withheld to be a fine. No
3 taxing. No tax ever held to be a fine under the excessive
4 fines clause. The only taxes that they cite that have ever
5 been held to be punishment, *Kurth Ranch* and *Dye*, look
6 completely different. They both involve drug taxes. They
7 both involve criminal convictions. Lots of pieces that look
8 different.

9 On this very thing I'll say, Your Honor, is they don't
10 really make a defense that they could have sued the IRS and
11 Treasury. They know those are the entities that enforce.
12 They say, well, then why doesn't the Court just amend -- why
13 doesn't the Court just say, okay, well, I'm anti-IRS and
14 Treasury here. We do not do that because it would be futile.
15 We just said the anti-injunction applies. It would, however,
16 hammer home that the anti-injunction definitely applies. I
17 don't know why they didn't name the IRS or Treasury, but
18 certainly a complaint that did would have really cast a
19 spotlight on the fact, oh, yeah, this is a case in which the
20 Anti-Injunction Act squarely applies. All these cases that
21 involve challenges to taxes, they involve the IRS and
22 Treasury.

23 Okay. On the merits, so the courts --

24 THE COURT: To save you some time, I want you to
25 build your record on merits, but I have no questions about

1 that section.

2 MR. GAFFNEY: Okay.

3 THE COURT: Just to note that, so you can run through
4 it, but I'm --

5 MR. NETTER: I'll go pretty quickly, then.

6 The one thing I'll say is there is this discussion --
7 there's this back-and-forth about whether this thing is a
8 fine, and that term has been defined. It's punishment for
9 some offense. How do we figure out what that is? We should
10 be guided by the cases. So, yes, where there's criminal
11 forfeiture, that's *Bajakajian*. Yes, where there's civil
12 forfeiture, that's tied to criminal conduct. But, no, where
13 there's merely a high tax rate. That's *Kurth Ranch*. No,
14 where the tax has a deterrent purpose. That's both *Kurth*
15 *Ranch* and *NFIB*. They haven't pointed to any case where a tax
16 was held to be a fine under the excessive fines clause -- and
17 there are lots of taxes. Sometimes when there's no case, it's
18 because the thing is so anomalous.

19 There are just only seven taxes in the world, and so
20 how could one tax percolate up and have a ruling be challenged
21 under the excessive fines clause? We have plenty of taxes, we
22 have plenty of excise taxes. We've got plenty of excise taxes
23 that are at a rate of a hundred percent. And I am happy to
24 rattle them off to you. But there's never been a tax held --
25 at least that I'm aware of, the defendants are aware of, and

1 that Novartis identified -- that was held to be a fine under
2 the excessive fines clause. And the only taxes that have ever
3 been held to be punishment for some -- the same standard under
4 the excessive fines clause to be a fine, they involve, like I
5 said, in *Kurth Ranch* and *Dye*, characteristics, anomalies that
6 are totally absent here, innocent owners defenses, a criminal
7 conviction being required, et cetera.

8 They, in their briefing, Novartis has suggested that
9 all the Court needs to find is that there is some deterrent
10 purpose. Fine. That's not true. We know that from the Third
11 Circuit's decision in *Artway*, 81 F.3d at 1258. The Court
12 there said *Kurth Ranch*, quote, "announced that the
13 no-deterrent purpose rule of *Halper and Austin* does not apply
14 in all situations. In *Kurth Ranch* at 780, the Court explained
15 why deterrent purpose and even a high tax rate is not enough."

16 In *NFTB*, the Court explained that you can have a
17 regulatory purpose and still be a tax. That's 567, 568. And
18 the Court also noted there at same pages that in
19 distinguishing -- this is quoting -- in distinguishing
20 penalties from taxes, this Court has explained that if the
21 concept of penalty means anything, it means punishment for an
22 unlawful act or omission. While the individual mandate
23 clearly aims to induce the purchase of health insurance, it
24 has some incentive mechanism. It need not be read to declare
25 that failure to do so is unlawful. Neither the act nor any

1 other law attaches negative legal consequences to not buying
2 health insurance beyond requiring a payment to the IRS.

3 That's the same thing here. If a manufacturer chooses
4 to stay in Medicare but not to enter into a negotiation
5 agreement or not to agree to a maximum fair price, there are
6 no other consequences, just like in *NFIB*, beyond requiring a
7 payment to the IRS.

8 Since the Court said they didn't have any other
9 questions, I'll just quickly touch on excessiveness. It's a
10 high bar. Street proportionality is not required. There's
11 another really important piece here, though, given the posture
12 of this case. There is a strong presumption of
13 constitutionality when the fine -- let's call it a fine --
14 when the fine falls within the range prescribed by Congress.
15 We cite a couple of cases on this, but *Bajakajian* says at 524
16 U.S. at 336, quote, "Judgments about the appropriate
17 punishment for an offense belong in the first instance to the
18 legislature."

19 So is this fine, if it were a fine, would it be within
20 the range that Congress prescribed? Of course. We don't know
21 exactly what the amount would be, but according to Novartis's
22 own reading, the fine is actually going to be way less than
23 the range that Congress prescribed because they say the IRS
24 has gone out of its way to have a smaller assessment and a
25 lesser collection than Congress required. But even if it's

1 exactly the same, the question is are we within the range that
2 Congress prescribed? And these cases remind that there's a
3 strong presumption, if you are in that situation, then you
4 don't have excessiveness.

5 The last thing I'll do is just point to some of those
6 excise tax cases in case the Court wants them on the record
7 where the rates go between 50 and a hundred percent. I'll
8 just say to start at 26 U.S.C. 49- --

9 THE COURT: Go a little bit slower, though, only
10 because --

11 MR. GAFFNEY: Sorry.

12 THE COURT: -- you think we're not going to review
13 this. I will review these citations but not right now. Megan
14 is on my left here, and I need her to be able to type this
15 out.

16 MR. GAFFNEY: For Megan's purposes, 26 U.S.C. 4941 is
17 the beginning of them. There's a whole slew of them, and I'll
18 just say ending at 26 U.S.C. 4975. You'll see a whole host of
19 them.

20 Again, I think it's worth pausing for a moment on how
21 this should actually play out. The Anti-Injunction Act, the
22 challenge should be brought in a refund suit. It's required.
23 That's the path that Congress created, and at that point, we
24 would know the actual amount of the tax.

25 And as we've said, what it would be at that time would

1 be the payment of tax on a single sale. And at that point, we
2 can ask is that excessive in light of that single sale? And
3 they don't want to get there because the Anti-Injunction Act
4 requires them to have to do that.

5 But also, once the actual numbers are there, this thing
6 will not appear as excessive as the miscalculations that have
7 been put before the Court.

8 Unless the Court has any further questions --

9 THE COURT: I don't, but thank you, Mr. Gaffney. I
10 appreciate it.

11 MR. GAFFNEY: Thank you, Your Honor.

12 MR. DEGER-SEN: Thank you, Your Honor. Just a few
13 points.

14 So I think that what we just heard from the government
15 really underscores that, under their logic, the tax could
16 be -- could be \$1 trillion. It could be \$5 trillion. It
17 doesn't matter. And they think that the AIA applies, and you
18 have to go through a refund action.

19 And, obviously, that is complete formalism, because no
20 one in the world would go through a refund action in that
21 situation if they're going to be subject to a penalty that
22 high at the end of it. They would just comply like the
23 statute intends them to comply.

24 And the idea that they could just pay one and then, you
25 know, just have the refund action, and then we'll know what it

1 is, I mean, we know it's going to be at an absolute minimum
2 \$2 billion plus a year, and it could be \$90 billion plus a
3 year. The only thing we have to hold onto is nonbinding IRS
4 guidance.

5 So they clearly don't think that anyone is
6 realistically going to do that. There was no response to the
7 idea that you can't just risk paying this kind of enormous
8 fine through refund action.

9 In their theory, it just doesn't -- this fine is
10 basically immune from challenge. That is the legal principle.
11 You call it a tax, and you make it high enough that someone
12 just can't take the risk of challenging in a refund action.
13 That's the end of it.

14 It can be excessive. You'll just never get to the
15 merits and never be able to challenge it, and that is a very
16 dangerous principle in the hands of any government, any
17 administration. And I don't think that this Court should
18 accept that principle, Your Honor.

19 They said we don't cite a single case where this
20 applies to a tax, but there's a reason for that because other
21 taxes do have revenue-raising purposes. There isn't a tax
22 like this that says 19 times the national sales revenue for
23 drugs, which can be \$90 billion a year.

24 And I think the key thing to just -- stepping back.
25 Congress did not want this tax to raise any revenue, not just

1 they didn't predict it to raise any revenue, they didn't want
2 it to raise any revenue.

3 If this tax raises revenue, it means that manufacturers
4 are noncompliant, and drug prices are not coming down. It
5 means the system is failing. So the tax has to be set at such
6 a high level that, as it's described in the statute, it brings
7 people into compliance.

8 If it's gaining revenue, it's failing. The
9 government's own tax cases all say if you have a tax that is
10 excessive in relation to its revenue-building purpose, of
11 course, that can be a fine.

12 So the reason that this is not -- that we haven't seen
13 taxes like this is because Congress has never tried to do
14 anything like this. This is extraordinary. It is novel.
15 There is no such thing as a tax that is a third of a company's
16 earnings for completely innocent conduct or 10, 15 times the
17 company's earning for completely innocent conduct.

18 It is way beyond the bounds of what governments have
19 done before. They say that a tax is a tax, but you have to
20 analyze it as tax. I just want to be clear, that's only true
21 for the AIA and for statutory claims.

22 For constitutional purposes -- and the Supreme Court
23 made this clear in *NFIB* -- the confusion of when Congress's
24 definition doesn't control. If it's substantively a fine,
25 it's a fine. They mention *NFIB* and say, well, that was a

1 reasonable tax.

2 The Court specifically in *NFIB* said that the individual
3 amount wasn't set at such a high level but no one could pay
4 it. People could pay it and then declined to get insurance.

5 So that was part of the Court's analysis as to why it
6 could be construed as reasonable tax. Here when it's set so
7 high that no one is supposed to pay it, when the regulatory
8 scheme is designed such that people don't pay it and instead
9 go into compliance, it's a fine, just by any commonsense
10 measure.

11 If you talk about this to anyone in the street, is it a
12 tax or is it a fine? It's a fine. Of course it is. It's
13 penalizing someone for noncompliance. It's trying to bring
14 you back into compliance, and it's interesting, the other case
15 they mention a lot is *Kurth Ranch*, which, of course, is not
16 even an excessive fines case, and, you know, that statute
17 there was held to be punishment.

18 So I think it underscores -- they don't really have
19 examples of cases where you have a fine that looks anything
20 like this and, again, all that just goes to the excessive. Is
21 this excessive? What is it excessive to? Completely innocent
22 conduct.

23 They don't dispute that it's innocent conduct. They
24 don't dispute there's nothing with saying you don't want to
25 pay the MFP, but if this is a fine, then a fine that --

1 dramatically lower than this would still be excessive under
2 the excessive fines clause because you have to judge it in
3 relation to the conduct, and the conduct here is completely
4 innocent.

5 The final thing I'll say is about the question of which
6 parties to join. Again, we had a surprising amount about
7 that, but I think it ultimately -- if this Court thinks
8 there's any concern with that, it just can easily add --

9 THE COURT: Why didn't you guys have --

10 MR. DEGER-SEN: Because of the nature of the claim
11 that we're bringing. We don't think that the issue here is
12 that we're going to be levied this fine. We are not going to
13 be levied this fine. No manufacturer is ever going to be
14 levied this fine.

15 It is -- HHS and CMS are using the fine to coerce us,
16 and for purposes of a declaratory judgment -- and, again, the
17 purpose of this claim and our constitutional claim is it's not
18 a tax, it's a fine.

19 So that's why it does fall within -- if we're
20 challenging this on a constitutional basis, we can bring a
21 declaratory judgment action, and the Court can say that
22 substantively this is a constitutional claim, and so you're
23 allowed to challenge this as a fine.

24 And so that's what we're asking for. That's the reason
25 we didn't, you know, join them, but if the Court thinks that

1 was a mistake or we tended to be overinclusive, this is not --
2 they didn't say anything about fair notice.

3 The only thing they said here is it would send some
4 kind of message. I wasn't really clear on the answer, but
5 they didn't say there's any problem, they didn't say there's
6 any substantive problem. Rule 21 is designed precisely to
7 lead -- you know, prevent the kind of formalistic results.
8 The claim is then kicked, we refile or restart the whole
9 process again.

10 There's just no purpose to that when the government is
11 clearly on notice, has vigorously disputed it. It's all in
12 front of Your Honor. There's no reason not to address it.

13 The fact that the government is trying to duck it so
14 hard, the fact that the government has eventually rewritten
15 five, and the fact that ultimately counsel didn't answer the
16 question: Why is this fine here?

17 If there's no need for it, if this whole policy is just
18 the government --

19 THE COURT: I don't know if -- I mean, I think he
20 made the points of legally not required to, right?

21 MR. DEGER-SEN: Of course not.

22 THE COURT: I don't think he's wrong about that.
23 Whether it's there or not is whether it's constitutional.

24 MR. DEGER-SEN: Absolutely. Absolutely, Your Honor.

25 THE COURT: And I wanted to ask the question because

1 I thought he would take the bait, but he did not.

2 MR. DEGER-SEN: It's not -- we don't have to defend
3 it. I think it is telling that you have -- you know, that you
4 could defend this scheme so much as being so valuable to the
5 American people.

6 They don't defend the fine at all, which is a huge
7 component of the coercive nature of it. They don't say
8 anything about why is this. They just say it's
9 constitutional. For the reasons we've explained, it's not
10 constitutional.

11 And their ultimate argument is, even if it's not
12 constitutional, you are not allowed to even examine its
13 constitutionality because we called it a tax.

14 This Court should not accept that premise. Thank you,
15 Your Honor.

16 THE COURT: All right. I appreciate that.

17 This is not a sting on Mr. Deger-Sen, but absent
18 extraordinary circumstances, I'm cutting the rebuttals for
19 oral argument only because of time constraints.

20 I want to hear from both sides, but I also don't want
21 to be here, so if there's something urgent that you will need
22 to come back after the government's spoken, I'll hear from
23 you, but let's limit the rebuttal to what you need to do.

24 Okay. Everybody okay? Nobody needs an -- anybody want
25 to take a five-minute break or anything?

1 MR. SVERDLOV: Your Honor, can I take the Court up on
2 that?

3 THE COURT: Absolutely. Why don't we recess -- is
4 five minutes, ten minutes? You tell me.

5 MR. SVERDLOV: Five minutes is fine.

6 THE COURT: Why don't we recess for five minutes, and
7 then we'll get back on. If anyone needs to take a break, now
8 is the time to stretch your legs. Thank you.

9 THE DEPUTY COURT CLERK: All rise.

10 (A short recess occurred.)

11 THE DEPUTY COURT CLERK: All rise.

12 THE COURT: Please remain seated.

13 Where are we?

14 MR. PARRISH: Your Honor, Ashley Parrish for Novo
15 Nordisk.

16 THE COURT: Good afternoon, Mr. Parrish.

17 MR. PARRISH: Good afternoon, Your Honor.

18 There's two remaining arguments. The first segment is
19 the last of the constitutional arguments addressing separation
20 of powers and due process.

21 And then, Your Honor, the final argument of the day is
22 something very different. It addresses the statutory claims.
23 With your indulgence, what I'd like to do --

24 THE COURT: Are you doing both?

25 MR. PARRISH: I'm doing both, yes, sir.

1 THE COURT: I will tell you, I have no questions on
2 the statutory claims, so I'm going to allow you to go through
3 your presentation, but that will probably move quicker.

4 Is that also with the PowerPoint?

5 MR. PARRISH: It's with the -- not PowerPoint, but
6 with the handed --

7 THE COURT: The handout, which I have already.

8 MR. PARRISH: Yes.

9 Your Honor, what I was going to say, and perhaps this
10 isn't in the Court's interest, but I can actually move
11 relatively quickly through separation of powers.

12 I'd like to have a little bit of rebuttal time on the
13 statutory claim if the Court would indulge me on that.

14 THE COURT: I will.

15 MR. PARRISH: Thank you, Your Honor. I appreciate
16 that.

17 THE COURT: All right. If you're going to be quick
18 on this, then let me ask you the one question I have for you.

19 Walk me through the property interests that are
20 implicated by the program.

21 MR. PARRISH: Yes, Your Honor.

22 So let me say this on the property interest is that it
23 is clear that we want to be able to sell our drugs to elderly
24 and disabled people, right?

25 It is also clear that we have a property interest

1 that's been built up over the reliance interest on how these
2 federal programs have been run for years.

3 Your Honor, one thing I would say is I don't think for
4 purposes of separation of powers that any question about
5 voluntariness applies because the structural protections apply
6 regardless of whether there's consent or otherwise.

7 And, Your Honor, I'm sure you picked up on this, but if
8 the government's position is correct that this is all just
9 about procurement, which is really an extraordinary claim,
10 Your Honor, because -- the government isn't binding for
11 itself.

12 But if it's correct, then, Your Honor, housing prices,
13 food prices, gas prices, every single one of those markets,
14 the government could simply say, we're going to take over half
15 the market, 50 million people, and we will set up a system
16 where we will pay and then provide benefits.

17 And, Your Honor, the bottom line is that they are
18 allowed to do that but only subject to constitutional
19 constraints. There's no get-out-of-the-constitution free
20 card.

21 And, Your Honor, that's why I started off -- and what
22 I'd like to do with the separation of powers argument is
23 really walk the Court through three things very quickly.

24 First, Your Honor, this statute is quite extraordinary
25 because of how many constitutional protections it strips away,

1 and I'd like to quickly walk through what those are.

2 Second, Your Honor, I would like to highlight that the
3 government identifies no case ever that has ever upheld a
4 statute that has stripped away so many essential protections.

5 And then finally, Your Honor, I'll just respond to
6 their two main arguments. It won't take me long.

7 Your Honor, the thing I want to emphasize under the
8 separation of powers, and we see the Supreme Court has --
9 recognizes in its recent cases, it's designed to do a number
10 of things.

11 But one is to ensure that Congress is accountable for
12 the legislative judgments it has to make and that agencies
13 have accurate fidelity to law and are accountable to the
14 things that they do implementing the decisions that Congress
15 has made.

16 Your Honor, what we have here is we have first no
17 standard at all that governs what price is imposed, and,
18 Your Honor, I thought your questions early this morning where
19 you said, well, what's in the record as to how much money
20 you're making? What are the research and development costs?

21 Your Honor, you can ask your clerk after the hearing
22 today, you know, I want to know what the right price is. What
23 is the right price that the government is going to post? Tell
24 me -- obviously, you can't calculate it, but tell me what's
25 the principle in the statute that will guide CMS so that CMS

1 is just not making it up itself?

2 And, Your Honor, your clerk will look for hours and
3 days, and they will not find anything because what the statute
4 says is there's a ceiling price. It says the agency must
5 consider a bunch of factors, things like research and
6 development costs, patents. And there is no substantive
7 standard that tells them what price to be, whether it's zero
8 or up to the ceiling price. It's entirely left at their
9 discretion.

10 Now, Your Honor, that itself is a nondelegation problem
11 that we're familiar with going back to 1935. But what's
12 layered on top of that is that there are no procedures in
13 place to ensure that what the agency is doing is within
14 constitutional bounds, that it is not arbitrary, capricious,
15 reasonable.

16 Your Honor, we've known since 1946 most of the
17 structural due process issues, not the individual rights that
18 you saw addressed in the *AstraZeneca* case, but the idea of
19 due process and echo a separation of powers and the structural
20 constraint on government. We sold that, Your Honor.

21 You'll know that that's the APA, the Administrative
22 Procedure Act, so it doesn't come up because agencies have to
23 comply, except for Your Honor will note here that the
24 government points to no procedures in the statute, and they
25 even claim that the APA doesn't apply and they're exempt from

1 it.

2 And, third, Your Honor, if all of that were not
3 sufficient, there's no judicial review, particularly of the
4 key decision, which is what is the price that will be imposed?

5 So, Your Honor, even if your diligent clerk could spend
6 those days looking for some principle to tell you what is the
7 right price, at the end of the day, the government would tell
8 you that that choice of price is completely removed from
9 judicial review.

10 So not only has Congress delegated sweeping legislative
11 power to the agency with no principle to guide what the
12 agency's price setting decision is, it's also stripped away
13 any type of check on that that would usually be provided
14 through the courts.

15 Again, Your Honor, all you have to think about is if
16 tomorrow the government said, We're going to make sure that
17 your price of your house that you'd want to sell will be going
18 through a government exchange, or the price of the farmer's
19 food or the price of the gas, at least, at a minimum, you'd
20 want to know that that price was within constitutional bounds,
21 and there was some checks -- some judicial check to make sure
22 that the agency wasn't taking it at -- whatever it wanted, and
23 there's nothing in the statute.

24 Your Honor, that takes me to my second point --

25 THE COURT: Well, one quick question, Mr. Parrish,

1 only because you brought it up, the *AstraZeneca* decision out
2 of Delaware. What, if anything, should I take out of that
3 decision?

4 MR. PARRISH: Your Honor, I don't think too much.

5 THE COURT: I mean, all right. Fine. That was a
6 softball the way I phrased the question. That was a little
7 bit of a softball. I mean, go ahead.

8 MR. PARRISH: I'm trying to cut down the things. I
9 don't think you need to read that decision at all, Your Honor.
10 Obviously, there's two parts to that decision. The government
11 was right. The first part of the decision was all about
12 standing.

13 THE COURT: Right. Which wasn't really fully
14 addressed, but it doesn't seem like there's a big argument
15 here today, but...

16 MR. PARRISH: So it's just the due process point, and
17 what I would say, Your Honor, is this: The due process claim
18 in that case very much resonated and was briefed very shortly
19 as a sort of a standalone independent right and there's
20 definitely the point that due process works like that.

21 But what I'm making, Your Honor, is a broader
22 constitutional challenge about looking at this. It really
23 sort of bleeds into the second point, that when you take a
24 look at the free enterprise and *Seila* law cases and the
25 separation of powers, what the Supreme Court has said is that

1 we have to -- we don't allow for multiple layers of
2 constitutional protections.

3 The way that you keep things in check is that Congress
4 has to make some legislative judgment in the first instance.
5 We all know since 1935 that's very broad, just any
6 intelligible principle, but it must some principle.

7 But then after that, what we've always had since 1946
8 is that the agency goes through procedures to avoid basically,
9 you know, tyranny, no arbitrary and capricious unreasonable
10 agency acts always subject to judicial review.

11 What we have here is that that procedural structural
12 check on what agencies do as an exercise of law making is
13 being stripped away here because what Congress has done is it
14 said no principle. We are not accountable at all for what the
15 prices are.

16 But then when the agency goes ahead and exercises
17 authority, no procedures for anyone to take a look at whether
18 it's reasonable or not, and the ultimate decision, which is so
19 sequential not only for manufacturers but also for patients
20 and the market, it's also exempt from judicial review.

21 So, Your Honor, that's our fundamental point. I would
22 just point out that if you take a look at free enterprise and
23 *Seila* law, those are obviously separation of powers cases that
24 arise in the context of appointments.

25 And the question of theirs is a situation where there's

1 insulating agency authority from oversight by the president,
2 but it's not very different from what we're talking about
3 here, which is here what we're doing is we're insulating the
4 decision in two ways: both the decision from Congress from the
5 ballot box, and secondly, the decision by CMS, which is why
6 interestingly, Your Honor, you heard all this morning this
7 debate as to what is really going on.

8 And every time you ask the other side, my friends, they
9 always referred to their guidance documents, the new IRS
10 thing, all this attempt to try to rewrite the statute. The
11 only reason they feel emboldened to do that is because the
12 statute has ripped away --

13 THE COURT: Are you saying I shouldn't consider any
14 of those extraneous guidance or documents outside of the
15 statute?

16 MR. PARRISH: Your Honor, obviously, for the purposes
17 of those individual claims, you should consider them on the
18 merits as they've been argued this morning.

19 For purposes of the separation of powers, it's very
20 telling that what the government is trying to do is rewrite
21 the statute through nonbinding guidance documents, which is a
22 sign of an agency that's gone loose. It's free, and it isn't
23 subject to the usual checks of either a principle that
24 Congress applies or a standard that a Court applies through
25 judicial review.

1 Your Honor, I'm just going to finish up here so we can
2 move on, but the government has a few arguments, and they're
3 very weak, so let me just walk through them quickly. And, of
4 course, you can hear from my friends.

5 The first one they say is, well, there may not be any
6 standard there to determine what the price is, but there's all
7 these factors that we have to consider.

8 But, Your Honor, I mean, if they tell you tomorrow that
9 your house is now on an exchange and instead of a \$250,000
10 house, you can sell it for \$10, you don't really care whether
11 along the way they're also able to consider how many times you
12 painted the house or what the driveway looks like or anything
13 like that.

14 There has to be some principle that tells them how to
15 apply those factors, not just the factors that say consider
16 the information. So that's not an intelligible principle.
17 Factors on their own do not count.

18 Your Honor, the next argument is to say, well, there's
19 never been a statute since 1935 with the *Schechter* case that
20 has ever struck something down on nondelegation grounds.
21 Well, they're right about that, Your Honor.

22 Of course, what they put out as palliative for the
23 Court is really just poison for their position because,
24 Your Honor, the reason why there's been no statute is because
25 there has always been an understanding that there must be an

1 intelligible principle. There's nothing here.

2 There's no statute that they pointed to that looks like
3 this because statutes are almost always subject to judicial
4 review, APA procedures, or something alternative to ensure
5 that the agency acts within its delegated authority.

6 You have nothing like that there, Your Honor. I do
7 encourage you to ask them what is the case that -- hold a
8 statute up that says no judicial review, no procedures, and no
9 standards. They will not be able to cite one for you.

10 And then finally, Your Honor, I would just say that the
11 government says here that the absence of judicial review
12 doesn't matter, right? They basically say there's cases that
13 say we looked at judicial review as a plus, but we don't say
14 it's a negative because Congress has authority over what gets
15 reviewed and what doesn't.

16 But, Your Honor, of course, that just takes them into
17 the teeth of the Constitution. It is true that when an agency
18 is acting in the Medicare context, Your Honor, the cases that
19 you have, they almost always have a standard. There's almost
20 always judicial review.

21 And to the extent there's not, it's because of a
22 calculation, some technical thing later as to calculating how
23 much spend was on the drugs. Those are the types of things
24 you keep away from the courts.

25 But in a price control statute, we have known now --

1 we've had 150 years of experience with these statutes. They
2 always come with a standard that is attune to the
3 constitutional standard to make sure it's not arbitrary and
4 confiscatory or unreasonable, and we've always had judicial
5 review, even during war time, Your Honor, when the delegation
6 is at its best.

7 So, Your Honor, I really appreciate your time. I know
8 that this next argument is really important, so unless you
9 have questions, I'll let my friends speak --

10 THE COURT: I don't. Let me hear the government on
11 the separation of powers issue. Then we'll come back on the
12 statutory claim.

13 Thank you, Mr. Parrish.

14 MR. PARRISH: Thank you, Your Honor. I appreciate
15 it.

16 MR. SVERDLOV: Good afternoon again, Your Honor.

17 THE COURT: Good afternoon.

18 MR. SVERDLOV: I will confess, I guess both from the
19 briefing and just the way the argument was set up, I find
20 myself a little disoriented because we kind of briefed these
21 cases with an understanding that there's a distinct
22 due process clause challenge.

23 Then I take my friends on the other side to sort of be
24 folding that into the separation of powers claim. I think
25 there's several ways to address this.

1 Candidly, I don't really have a whole lot beyond our
2 briefs to say on the separation of powers because what this
3 claim amounts to that Novo has brought is basically kind of a
4 residual vessel in which plaintiffs have placed odds and ends
5 of their theories in the hope that it kind of congeals into
6 something, and it doesn't. It doesn't congeal, and it doesn't
7 congeal because doctrinally that is not what the Supreme Court
8 has told us a nondelegation doctrine is.

9 And their efforts to bring in questions about
10 availability, or lack thereof, of judicial review sort of
11 dovetails and leads into their due process argument. On the
12 due process piece, what I would say is we obviously think the
13 Court should give a lot of attention to the *AstraZeneca*
14 decision.

15 THE COURT: I think you guys submitted a letter, no?

16 MR. SVERDLOV: We did, Your Honor.

17 THE COURT: As if I didn't know about that decision.
18 I'm tracking them.

19 MR. SVERDLOV: We think the Court did a very good job
20 in that case. We think the Court got it right. There is no
21 protected interest that's really at stake.

22 I think, just to step back for a moment and to like
23 give an orienting principle here, because it's also relevant
24 to the separation of powers claims.

25 We've seen manufacturers try to bring various angles of

1 their Fifth Amendment theory, right? And the due process
2 challenges is -- is a theory that some manufacturers have
3 pursued and not others.

4 I think the reason is sort of obvious. The takings
5 theory suffers from all the weaknesses that we've identified
6 this morning and explained at length in all the briefs that we
7 have submitted.

8 Plaintiffs want to be able to bring what would really
9 conventionally be a regulatory takings claim in a facial
10 posture, and so they have to sort of dress it up as physical
11 taking. It doesn't work for all the reasons that we've
12 explained.

13 But one way that they've tried to solve that problem is
14 try to go through the due process clause. Both the *Chamber*
15 decision and the *AstraZeneca* decision correctly rejects that
16 because they have not identified a cognizable property
17 interest.

18 And the Court in *AstraZeneca* in detail explained why
19 the expectation -- the desire or the expectation to sell to
20 the government, even at -- I will, in fact, quote from that
21 decision. This is at page 42 of the decision: "Desire or even
22 expectations to sell drugs to the government at the higher
23 prices it once enjoyed just does not create a protective
24 property right."

25 So back to the separation of powers, right, because

1 that sort of seems to be the angle they're -- they're pursuing
2 to try to solve some of these problems, right?

3 Like, well, if we -- we sort of want to plead the
4 taking, but it's too early to plead a regulatory taking.
5 We'll try the due process, but we can't really identify a
6 protected property interest. Well, what about separation of
7 powers? That seems good.

8 We have -- we can cite to cases dealing with
9 appointments clauses for a principle that courts sort of take
10 structural constitutional claims seriously. They do. But the
11 separation of powers claim is also subject to a pretty clear
12 standard, which has been laid out over and over again, and
13 most recently was detailed by the plurality in *Gundy*.

14 I will not take up the Court's time to list the
15 examples in the *Gundy* decision of the kinds of delegations
16 that the Supreme Court has sustained over the years. We cite
17 them in our brief, and I think it's powerful enough to just
18 read them as they are written.

19 But I will make one observation, Your Honor, and that
20 goes back to the overarching theme of what this case is and
21 really what our dispute with our friends on the other side is
22 about.

23 If the Court accepts, as it should, the understanding
24 that this is basically a form of a procurement program, then
25 the idea that Congress has to delegate in some sort of great

1 detail what is a traditional executive branch function, which
2 is procurement, government contracts, becomes, I think, even
3 more stark and even more clearly wrong.

4 That takes me back around to the lack of judicial
5 review. So my friends say, Well, all of this, let's take it
6 seriously, notwithstanding the intelligible principle test as
7 articulated by the Supreme Court, we have the added problem of
8 a lack of judicial review.

9 Several points on that, Your Honor. One, this is
10 basically a way for them to smuggle in their due process
11 claims without really trying to satisfy the threshold
12 standards of identifying the protected property interest.

13 They want to just say, Oh, the lack of procedures is a
14 problem, even though we haven't met the threshold test that
15 the Supreme Court has laid out for a Fifth Amendment claim.

16 Two, the lack of judicial review -- I'm going to be
17 happy to speak to this when we talk about the statutory
18 issues -- is not uncommon in the Medicare statute, among
19 others. In fact, it is commonly something that courts
20 consider and analyze and uphold.

21 So this is -- in that sense, it is not an unusual
22 feature of a Medicaid program or a Medicaid regime to preclude
23 judicial review over certain types of determinations. That is
24 what we're dealing with here.

25 If the Court has no further questions for me, I am

1 happy to rest on our briefs these issues. I think they've
2 been dealt with at length and adequately.

3 THE COURT: I appreciate that. Thank you,
4 Mr. Sverdlov.

5 MR. SVERDLOV: Thank you, Your Honor.

6 THE COURT: Mr. Parrish, you're back up.

7 MR. PARRISH: Yes, Your Honor. Thank you very much.

8 Can I just say one sentence and I'll move on to the
9 next argument?

10 THE COURT: Yes.

11 MR. PARRISH: Thank you, Your Honor.

12 I'll just say that I mention the point that they can do
13 the same thing with your house and the idea that you could be
14 forced to sell your house for \$5 with no judicial review, no
15 check on the agency, and they would come before the Court and
16 say that there's no property interest, Your Honor, I just
17 don't understand it.

18 These are drugs. We want to sell them to elderly and
19 disabled people. There's a government program that's
20 regulating all of that. That's the whole point.

21 But, Your Honor, I'll take us to the next argument,
22 which goes to the statutory point, and I appreciate
23 Your Honor's indulgence. I know you said you didn't have any
24 questions.

25 THE COURT: Well, I may. You know what? I should

1 withhold that. I may have questions. I mean, you never know
2 what you're going to say that will trigger me.

3 But for now, I don't have any anticipated questions on
4 the statutory claims prior to you speaking. Is that fair?

5 MR. PARRISH: That's fair, Your Honor. I've been
6 known for being triggering. So let me, if I could, tell you
7 what I like to do.

8 First, Your Honor, I do think it's important to
9 emphasize that, you know -- now there's something completely
10 different, right? This is -- even if you rejected the
11 constitutional claims, these statutory claims are separate and
12 must be resolved.

13 Your Honor, I also emphasize that there is no other
14 court where these claims have been presented and will be
15 considered on the merits. There was a somewhat different type
16 of argument on the *AstraZeneca* case, but that got rejected on
17 standing grounds.

18 Here Novo Nordisk is directly impacted by these what we
19 think are statutory violations, and it's very important to my
20 clients.

21 So, Your Honor, we're very grateful for your time in
22 considering these issues.

23 Your Honor, what I would say is that the question here
24 is has CMS as the agency violated its order under the statute?

25 This morning, Your Honor, the concerns that we've had

1 have been focused on one part of the delegation, which is that
2 Congress didn't say anything intelligible about price, but
3 they did say a lot of intelligible and specific things about
4 what would be regulated, who would be subject to regulated --
5 what sort of things.

6 And CMS has just blown by that, and most specifically,
7 Congress was very clear for the first year of the program,
8 they could only regulate subject to price controls 10
9 negotiation-eligible drugs, which translates into 10 products,
10 either drugs or biological products, and they made it 15.

11 And, Your Honor, you probably noticed from our brief on
12 page 18, there was their list that they published, and it's
13 very telling that the list is one, one, one, one, six for
14 Novo Nordisk, and yet, they wanted to tell the Court that
15 that's just one product, and it really isn't, Your Honor.

16 So what I'd like to do in this part of the argument,
17 finishing up, is really three things: first, walk the Court
18 very quickly through the statutory materials that I passed up
19 earlier and I've given to the government and to your clerks.

20 I think those provisions make very clear what CMS is
21 trying to do in terms of rewriting the statute.

22 Second, Your Honor, I'll respond to the government's
23 two main arguments: Their one main argument is that it's --
24 this entire choice of what to do is barred by the judicial
25 review bars.

1 Your Honor, that fails because if it's susceptible to a
2 narrow reading, you have to apply that reading, and I'll
3 explain to you why the government's reading is just far too
4 broad.

5 The second argument they make is that they can rewrite
6 the statutory definitions because there's a statutory
7 provision called the use of data provision and other
8 provisions that allow aggregation, limited circumstances for
9 specific reasons, but they just don't apply here.

10 And then, Your Honor, if there's time, I might say a
11 few words about, you know, some common rule making, but if we
12 don't get to that, I can rest on the papers.

13 Your Honor, if you turn to the statutory appendix that
14 I've given you, it's just to orient you. You will see there's
15 two sort of big tabs.

16 The first one are the excerpts that are just from my
17 argument. The second one is a complete set of the statutory
18 provisions. If you go to the code or your clerks do, it's
19 very hard to figure out how all this works.

20 THE COURT: I appreciate it. So this is helpful.
21 Then you can walk me through it, and I'm walking through it
22 with you.

23 So feel free to direct me where you need to.

24 MR. PARRISH: Thank you, Your Honor.

25 So the great thing about this argument, Your Honor, is

1 I don't need to do too much here. So I'm going to refer you
2 to 1192(a), (d), and (e), which is in 42 U.S.C. 1320f-1.

3 And Section 1192(a), that's where we start. It's
4 probably where we end, Your Honor. It directs that for 2026,
5 only 10 negotiation-eligible drugs. It's precise. It's
6 specific. It's a numerical threshold. It's 10.

7 Now, what Congress intended is, over time, it will
8 phase into 15, and ultimately to 20 a year, but just for this
9 year, Your Honor, it's easy to just focus on 10.

10 Your Honor, if you take a look at Section 1192(d), and
11 if you go to D, that's just on page 5 at the bottom, so it's
12 the second page, I think, of the packet, and you see I've got
13 that highlighted in yellow for you, Your Honor.

14 What you notice there is that it defines a
15 negotiation-eligible drug, and it says it's two things: It
16 must meet the definition that Congress has set for qualifying
17 single-source drug in Subsection E and also it must meet
18 certain high-standard requirements as determined by the
19 Secretary.

20 So it's two things: Look at the definition that we,
21 Congress, prescribed, and, second, take a look at the
22 determinations that CMS makes.

23 And then finally, Your Honor, that takes us to 1192(e),
24 which is on page 7, so you have to jump ahead a couple of
25 pages, and 1192(e) gives you the definition of what is a

1 qualifying single-source drug and what ultimately is the
2 definition of a negotiation-eligible drug.

3 And, Your Honor, I'm going to combine these together,
4 but you can see that A relates to drug products and B relates
5 to biological products, but they're parallel. They say that
6 it must be -- the definition, it must be products. It must be
7 a drug product or a biological product.

8 It must be approved under Section 505(c) by FDA of the
9 Food, Drug, and Cosmetic Act or licensed by FDA under
10 Section 351(a) of the Public Health Service Act.

11 7 or 11 years must have elapsed since FDA approved or
12 licensed those, and it can be a listed drug or a referenced
13 product for a generic or a biosimilar, so there's nothing else
14 on the market.

15 Those are key congressional judgments. You know, we
16 heard earlier, I think several times -- it was 12:27 -- my
17 friend on the other side said, The prerogatives of Congress,
18 we must respect the prerogatives of Congress. But we see the
19 prerogative. Those are rights there set forth.

20 Now, what's really key, Your Honor, is if you take a
21 look at page 21 of the government's brief, the government
22 concedes that when FDA approves or licenses products, it does
23 it on a product-specific basis, product by product.

24 It doesn't license them based on what the ingredients
25 are or what the molecular structure of those products are. It

1 looks just at individual products. And that, Your Honor, is
2 the key point because that's the same definition that the
3 Supreme Court applied in its generics case 30 years ago.

4 Now, the definition of drug more broadly can sometimes
5 mean a product, a drug product. It can sometimes mean
6 something like a drug substance, but that's not what we're
7 talking about here.

8 We're not talking about how it might be used in
9 different content. We're talking about two different things,
10 the definition that Congress provided in the statute, which is
11 specifically tied to the approval or license or decisions by
12 FDA, and those approval license or decisions are tied to
13 specific products.

14 Now, Your Honor, as you note from the briefing, the
15 government wants to push all of that aside. What the
16 government says is that, No, we're not going to put price
17 controls on individual products. We're going to put it on
18 active moieties and active ingredients.

19 And what we'll do is write into the statute that we can
20 pick any active group of products, family of products by any
21 individual manufacturer that contain the same active
22 ingredients --

23 THE COURT: And they count one.

24 MR. PARRISH: -- and they will count as one.

25 So, Your Honor, the reason I want to put this

1 specifically is consider how this applies to Novo Nordisk. We
2 have six different products that they lump together as one,
3 but they are wholly different -- they're two different
4 families.

5 One is called NovoLog. That's very different from
6 Fiasp. You have meaningful clinical differences, these
7 products, and they have different device presentations.

8 So within the Fiasp line of products, you have a vial
9 that you can inject. You have like an Epipen, the pen you can
10 use, or you can have a pump that you put down on your hip.

11 They're very different. They're all innovations.
12 They've all been separately approved by FDA.

13 Now, Your Honor, as you also noted from the briefing,
14 what's really key there is the whole Fiasp line of products,
15 none of those have even been on the market for the required
16 11 years that Congress said is essential before you can put
17 price controls on.

18 So the putting together is not only violating the idea
19 that FDA approved separate products, it is also getting around
20 the critical decision that Congress made as to how long you
21 get an exclusivity before these price controls take place.

22 And, Your Honor, just for the record and for your
23 future reference, I urge you to take a look at the declaration
24 of Dr. Nathan Laney. That's at ECF 30. There's also another
25 declaration at ECF 29.

1 And he goes into depth about how CMS is not only
2 ignoring the clinical differences between these products --
3 and what I mean clinical differences -- and, Your Honor, I'm
4 an okay lawyer, I'm a terrible doctor.

5 But, Your Honor, the --

6 THE COURT: I hope you're not a doctor at all. I
7 don't need you back in my courtroom again for performing
8 unlicensed practice of medicine.

9 MR. PARRISH: But I told you about the triggering.

10 But, Your Honor, I'm going to start off with a point
11 about Fiasp is that the key thing there, from a doctor's
12 perspective, and Dr. Laney goes into this, these are not
13 interchangeable products.

14 If you were on Fiasp, you cannot take NovoLog without
15 transitioning off and with special medical care and so forth.
16 They're not interchangeable. These are different things.

17 One is ultra fast acting. It affects when you can take
18 the insulin, at mealtimes, as opposed to NovoLog, where it's
19 just fast acting, and you have to take it before mealtimes.

20 And so they're very different with different profiles,
21 and the idea, Your Honor, that FDA would say, Well, we
22 approved insulin -- the underlying active ingredient. We
23 approved that, and, therefore, you can go ahead and put on the
24 market any one of these other things you want is really,
25 Your Honor, ludicrous.

1 That would never be allowed to happen, and the reason,
2 Your Honor, that Congress tied this to FDA decisions is that
3 CMS has no expertise. FDA is the expert agency. They know
4 the difference between the new product and an innovation that
5 leads to a new product after that. The CMS does not.

6 What it's trying to do is wipe out the whole FDA scheme
7 in a way that's contrary to the statute.

8 Your Honor, I'm going to move quickly here, but I do
9 want to just address the government's two arguments because it
10 will be helpful to the Court.

11 The first one, Your Honor, is they say it falls within
12 the judicial review bars. If you're still on that same page,
13 on page 7, you will see that I've highlight something in
14 purple. That's -- I'm sorry.

15 I'm messing myself up here.

16 If you turn to the second tab, Section 1198, that's
17 where the judicial review is. That's actually page 19 at the
18 bottom.

19 THE COURT: All right.

20 MR. PARRISH: And what's interesting there is they're
21 focused on 1192, and if I read the whole section for you, it
22 says what is not subject to review, the selection of drugs
23 under Section 1192(b), the determination of
24 negotiation-eligible drugs under 1192(d), and the
25 determination of a qualifying single-source drug under Section

1 1192(e).

2 And, Your Honor, I want to focus the Court's attention
3 on letters and verbs. When I start with the letter, the first
4 thing that you obviously notice, Your Honor, is that
5 Subsection A appears nowhere there.

6 It would have been easy for Congress to say no judicial
7 review of how many products you are lumping together. But,
8 no, Congress said, We said ten, did not eliminate from
9 judicial review Subsection A.

10 The second thing is you can see that what Congress
11 wasn't doing with these decisions is it was giving CMS
12 discretion as to choose which products within the parameters
13 it set out but not to change the parameters that Congress had
14 set forth.

15 And so if you look at those verbs, it select, it's
16 determine, and it's determine.

17 And if Your Honor goes back to the other parts of it,
18 and you take a look at what I've highlighted in blue in terms
19 of the selection of drugs in the Subsection B, the
20 negotiation-eligible drugs, part -- the high spend in D and so
21 forth, in every one of these provisions, what there is is
22 there's specific directions to the agency to make
23 determinations relating to how much the -- what type of spend
24 it is, whether it's high spend or low spend, and what the
25 total revenues related to that drug is.

1 So what that provision is saying is very consistent
2 with what you might expect a judicial review provision to say,
3 which is courts -- you know, Your Honor will not get pulled in
4 to the difficult position of second-guessing the question of
5 what is a high spend or a low spend drug.

6 But nowhere in there, Your Honor, suggests that
7 Congress has spoken clearly with the intent that you would not
8 change the definition that Congress has put in the statute.

9 They don't have authority to do that. Your Honor, if
10 you have any doubt about that, you have to rule in our favor
11 because the case law is very clear that judicial review bars
12 are interpreted narrowly.

13 Now, the only way they try to get around that is to
14 say, Well, these decisions are sort of all inexplicably
15 intertwined, but you'll look at those cases, Your Honor, and
16 you realize those are all about calculations. They're not
17 about rewriting statutory definitions.

18 Your Honor, that takes me to the very last argument
19 that they make, which is they say, Well, it's okay, we can
20 take words that don't appear in the statute, like active
21 ingredients, and we can redefine Congress's definitions
22 because there's provisions in there that talk about
23 aggregation.

24 Your Honor, I misspoke earlier, but if you now go back
25 to the purple highlighting, which is where I was getting to,

1 you'll see that that purple highlighting is the use of data
2 provision.

3 And that use of data provision is something that refers
4 to what it's allowed to do when it's calculating what
5 qualifies as a high-spend drug, and you will notice,
6 Your Honor, when you look at it, what it says is it says, In
7 determining whether any drug has satisfied the statute's
8 high-spend criteria, the Secretary shall use data that is
9 aggregated against dosage forms and the strength of the drug.

10 Now, Your Honor, what is key there is dosage forms and
11 strength. It's not device presentations, and it's certainly
12 not different entire family of product.

13 So what they can do is if I have a pill that comes in a
14 2 milligram form and a 5 milligram, they can only pick one for
15 price controls, but what they can do is through the use of
16 data provision, they can look at both the 2 milligram and the
17 5 milligram.

18 And then later when putting the price control, there's
19 another provision later in the statute that says they can come
20 up for procedures to apply across those dosage forms and
21 strength.

22 But in the case of Novo Nordisk, Your Honor, there's
23 nothing in that provision or any other provision our friends
24 will cite to you today that says anything about a cross device
25 presentation.

1 So again, needle -- sorry, vial injection, needles or
2 pump, those are device presentations differently. Nothing
3 that authorizes them to go across those. Those are not dosage
4 forms or strength. That's something totally different.

5 And certainly, Your Honor, there's nothing that says
6 they can take an entire family, Fiasp, which is treated
7 differently by FDA, the NovoLog, and merge those together and
8 take the Fiasp products, which have been on the market for far
9 less than the 11 years, and sweep them all in.

10 And, Your Honor, obviously, we don't think, as you've
11 heard all this morning, that the statute is constitutional,
12 but if the statute is constitutional, we urge the Court to at
13 least have CMS apply it the way that Congress wanted because
14 Congress certainly wanted to jump the bounds of
15 accountability, which is what it did with the First Amendment
16 prongs and the separation of powers and the taking.

17 It was trying to get away from accountability, but it
18 wasn't crazy, Your Honor. It said that we have this drug
19 market, we have these patients that rely on those products,
20 and we need to have innovation, so we're going to phase this
21 in slowly, and we're not going to allow the agency to move too
22 quickly.

23 And the agency is moving very, very quickly,
24 Your Honor.

25 So with that, I'd love to save a little time for

1 rebuttal. Unless Your Honor has more questions, I'll sit
2 down.

3 THE COURT: I don't, but you can reserve your time
4 for rebuttal.

5 MR. PARRISH: Thank you, Your Honor. I appreciate
6 it.

7 THE COURT: Who is back up from the government,
8 Mr. Sverdlov?

9 MR. SVERDLOV: Your Honor, I'd love to keep this
10 short, but I feel like there's a few things to walk through.

11 THE COURT: I don't want to cut off your time. The
12 reason why I didn't have, you know, I guess, questions
13 intended for this particular area in advance is because I
14 think at lot of this -- at least your positions were fairly
15 clear in the written submissions.

16 So don't read anything into it that I think these are
17 unimportant claims or less important than the constitutional
18 claim. It's just these I think were a little more clear in
19 the written submissions.

20 But feel free to make your record, and I'm going to
21 give Mr. Parrish some time on rebuttal anyway.

22 MR. SVERDLOV: Your Honor, I really appreciate that.

23 As I said before, we've put a lot of thought into the
24 briefs, and so I do think that our positions are encapsulated
25 better there than I'll be able to sort of speak off of the top

1 of my head here.

2 There are a few things to say about the statutory
3 claims, both the preclusion piece and the merits piece. I
4 want to separate them out, and I do want to start with the
5 preclusion piece and then move on to the merits.

6 The two are obviously intertwined in the sense that
7 determining the determinations that are -- figuring out the
8 scope of the judicial review bar has some overlap with the
9 types of claims that plaintiffs are making by necessity.

10 But nonetheless, I think it makes sense to start with
11 the preclusion of judicial review, and I will start with the
12 text of the statute, as we have -- hopefully in this packet,
13 we have the text of Section 1198, which is codified at 13 --
14 42 U.S.C. 1320f-7(2).

15 And that provision states that the selection of drugs
16 under Section 1192(b), the determination of
17 negotiation-eligible drugs under Section 1192(d), and the
18 determination of qualifying single-source drugs under Section
19 1192(e) are precluded in determinations.

20 Now, what is Novo Nordisk challenging? They say, Well,
21 when the statute says "drugs," it really means FDA drug
22 products. We don't think that's right. I'll get to why.

23 But they are literally challenging the selection of
24 drugs, and more fundamentally, they are challenging what CMS
25 determined the methodologies that CMS has selected to

1 determine what is a qualifying single-source drug, right?

2 They are pointing the Court to the definition of
3 qualifying single-source drug when they say that they weigh on
4 the merits of the statutory claim. Well, the determination of
5 qualifying single-source drug is a precluded determination.

6 One thing to note, Your Honor, we didn't hear a lot
7 about the notice and common claim. I'm more than happy to
8 rest on the papers on that claim. I think it's just -- it's
9 fully dealt with.

10 But I do think it's worth noting that the preclusion
11 piece -- the preclusion arguments we make reach both the
12 merits of the statutory interpretation and the APA notice and
13 comment claim.

14 I don't think our friends on the other side appreciated
15 that. At least I didn't read their reply brief to address the
16 preclusion of judicial review in the context of the APA notice
17 and comment claim, but it does, in fact, apply.

18 And one of the ways we know that it applies or
19 confirmation of the fact that this is how statutory preclusion
20 provisions works comes from the wealth of cases that we have
21 cited in our brief.

22 Our friends and counterparts say that those cases are
23 all distinguishable from the circumstances, and that provides
24 us as good of an opening as any to explain why they're not. I
25 think there's a number of cases to walk through.

1 I would just like to highlight two here at the podium.
2 The first, *Texas Alliance for Homecare Services v. Sebelius*
3 from the D.C. Circuit in 2012. That's at 681 F.3d 402. So
4 what was at issue in that case? The suppliers of medical
5 equipment challenged a regulation addressing the eligibility
6 criteria for a Medicare contractor under the APA substantive
7 and procedural requirements. They have both a statutory
8 construction claim and an APA notice and comment claim.

9 The statutory provision, the preclusion part in that
10 case, stated that there shall be no administrative or judicial
11 review of awarding of contracts under this section. And the
12 D.C. Circuit finds that this provision covers the challenge.
13 It says, quote, "Under the statute, financial standards are
14 indispensable to the awarding of contracts as such standards
15 determine whether or not a contract may be awarded to the
16 bidder."

17 I think the Court likely sees the parallel I am trying
18 to draw here. A regulation defining the eligibility for the
19 awarding of contracts is found to be covered by a judicial
20 review bar against the awarding of the contracts. What are
21 they challenging here? They are challenging the methodology
22 by which CMS makes the determinations that are explicitly
23 called out in the judicial review bar.

24 The second case I'd like to point to, *Yale New Haven*
25 *Hospital v. Becerra*, from the Second Circuit in 2022. That's

1 at 56 F4th 9. Once again, we have a provision that says that
2 there shall be no administrative or judicial review of any
3 estimate of the Secretary for purposes of determining three
4 statutory factors. The plaintiffs in there say, Well, you
5 know what? We're not going to challenge the substance of the
6 guidance that the agency issues. We're going to challenge it
7 just on notice and comments grounds. We're going to try to
8 undo this. We're going to undo these estimates by saying that
9 it was procedurally improper -- improperly promulgated.

10 The Second Circuit walks through why that doesn't work.
11 It says no. It says plaintiffs must explain how we could
12 possibly entertain such a challenge without reviewing the
13 estimate itself, which is a precluded determination. What
14 these cases speak to is this standard that we have articulated
15 in our brief, the indispensable or integral to or inextricably
16 intertwined standard.

17 Courts have made clear that decisions -- administrative
18 decisions that are, in fact, indispensable, integral, or
19 inextricably intertwined with an unreviewable agency action
20 are covered by the jurisdictional bars. That is the case
21 here, Your Honor. That is true for both the substance and the
22 procedural claim.

23 If the Court has no questions on that point, I am happy
24 to turn to the merits.

25 THE COURT: I don't. Feel free.

1 MR. SVERDLOV: Your Honor, the plaintiffs --
2 Novo Nordisk's basic thesis here that they sometimes
3 articulate, sometimes don't articulate is this desire to
4 equate the term "drug" in the IRA with the notion of a drug
5 product. They want to say "the drug" means product. Look, we
6 have many different products, therefore, they must be
7 different drugs. Neither the text nor the structure nor the
8 purpose of the IRA supports that interpretation. And there
9 are cases that I will get to in a minute that have rejected
10 the same kind of daisy-chaining efforts that plaintiffs made
11 here to tie FDA's practice to the Medicare context.

12 So, first, let's just turn to the text and talk about
13 the text. My friends have said that there's only one
14 provision, that this interpretation of the qualifying
15 single-source drug definition that CMS uses is based on one
16 statutory provision. That's not true, Your Honor. It's based
17 on three. We've cited them in our brief, but I think it's
18 worth walking through.

19 So, first of all, on the selection of
20 negotiation-eligible drugs, 42 U.S.C. 1320f-1(d)(3)(b), the
21 use of data. It says, "In determining whether a qualifying
22 single-source drug satisfies any of the criteria described in
23 the relevant paragraphs, the Secretary shall use data that is
24 aggregated across dosage forms" -- plural -- "strengths" --
25 plural -- "of the drug" -- singular -- "including new

1 formulations" -- plural -- "of the drug, such as an
2 extended-release formulation and based on the specific
3 formulation or package size or package type of the drug."

4 Second place there Congress references the idea of one
5 drug having multiple of these aspects is the negotiation of
6 price. When Congress directs the factors that the Secretary
7 is to consider in formulating its offer -- 42 U.S.C.
8 1320f-3(e), the factors (1)(D) -- this is the
9 manufacturer-specific data. It says that the Secretary shall
10 consider data on pending and approved patent applications,
11 exclusivity recognized by the Food and Drug Administration,
12 and applications and approvals -- plural -- under Section 355
13 of the FDCA for the drug -- singular. Again, applications and
14 approvals, multiple; the drug, singular.

15 Finally, the application of price provision. Once they
16 go through the process, they come up with a number, they come
17 up with the negotiated price, and they sign the agreement.
18 The Secretary then has administrative duties related to
19 compliance monitoring. We touched on some of these things.
20 The administrative duties include -- this is 41 U.S.C.
21 1320f-5(a)(2). The secretary's administrative duties include
22 the establishment of procedures to compute and apply the
23 maximum fair price across different strengths -- plural -- and
24 dosage forms -- plural -- of a selected drug and not based on
25 the specific formulation or package size or package type of

1 such drug. Right?

2 So throughout the statute we have multiple references
3 to dosage forms, different -- different formulations, new
4 formulations, extended-release formulations, all being
5 considered part of one drug.

6 Now, none of those statutory provisions would make any
7 sense under the interpretations that Novo is positing, and
8 here is how we know. We can look to the declarations that
9 they submitted. So the Hauda declaration, ECF 29 at paragraph
10 21, they say, "To change a product's dosage form or device
11 presentation, the manufacturer will create a new product that
12 must be evaluated, approved, and licensed by FDA."

13 So they view each of these different formulations, each
14 of these different presentations as a distinct drug. That's
15 the move they want to make. Product equals drug, drug equals
16 product. I previewed this a few minutes ago, but courts have
17 rejected similar attempts to import the FDCA into the
18 Medicare.

19 THE COURT: This is the daisy chain analogy.

20 MR. SVERDLOV: First time --

21 THE COURT: I'm still listening to you, Mr. Sverdlov.
22 It's late in the afternoon, but I'm still quick up here.

23 MR. SVERDLOV: Two cases I will cite to the Court
24 this afternoon on that point. The first, *Ipsen*
25 *Biopharmaceuticals v. Azar*. That's at 2020 Westlaw 3402344.

1 The Court says, quote, at page 9, star 9 specifically,
2 it says, "The Medicaid Act does not adopt the entire FDCA
3 wholesale." And then it goes on to reject the very type of
4 daisy chain that plaintiffs are positing here.

5 Another case, *Baker Norton Farms versus FDA*, 132
6 F. Supp. 2d 30 from CDC in 2001. It does something even more
7 relevant here. It says, even within FDA's practice, the term
8 "drug" doesn't mean one thing. So in that case, the Court is
9 looking at the orphan drug, which establishes certain types of
10 exclusivities, eligibilities. And the plaintiffs in that case
11 come in and they say, no, no, no. The word "drug" for
12 purposes of the Orphan Drug Act means the same thing as what
13 it means for FDA's other practice. And the Court explains why
14 that's not correct. You have to read the statutory provisions
15 within the context in which they are presented, not across
16 broad swaths of agency practice, much less across two
17 completely different agencies, as we have.

18 The -- I said at the top that neither of the text nor
19 the structure nor the purpose of the IRA supports Novo's
20 position. I think my point on the structure and purpose can
21 be summarized pretty quickly. I can refer the Court to the
22 revised guidance at page 12 where CMS explains why the kind of
23 interpretation that Novo was positing here doesn't work. But
24 the short answer is that if it were the case that CMS went
25 through the process of selecting the drug, negotiated the

1 price, and then were only applying the established price to
2 one dosage form, one package type, one presentation, it would
3 be trivially easy for a manufacturer to just shift production
4 of the same -- what is essentially the same drug, the same
5 active moiety, the same active ingredient, depending on
6 whether you're dealing with a biologic or the drug product,
7 have doctors prescribe the new drug and the -- or the new
8 product, rather, and the entire regime becomes -- becomes
9 vitiated, becomes a nullity. The maximum fair price that was
10 established, that was just for this pill container. That's
11 clearly not what Congress intended. CMS explained that's not
12 Congress's interpretation. I think our briefs lay out in
13 detail responses on some of the other points that my friend
14 made about the high-spend requirements and such. I wanted to
15 reiterate those.

16 I think I have been up here long enough. I'm happy to
17 address any questions.

18 THE COURT: I thank you for your time. I appreciate
19 it, Mr. Sverdlov.

20 Mr. Parrish, do you want to respond to some of these
21 comments, arguments?

22 MR. PARRISH: I would, Your Honor. I'm going to be
23 very quick. I've got three points on jurisdiction. I've got
24 one point on notice and comment, and I've got three points on
25 the merits, and they're all very short and to the point.

1 THE COURT: Build your record.

2 MR. PARRISH: I hope that you and your clerks picked
3 up on opposing counsel's first argument.

4 THE COURT: They picked up on it. I don't know if I
5 have. They're much smarter than me. I hire very well.

6 MR. PARRISH: My ears perked up because he said the
7 merits and the jurisdictional issues are intertwined. He said
8 they overlap. Well, Your Honor, I'm going to refer you to the
9 *AJ* case in the D.C. Circuit from 2020, 964 F.3d 1230, because,
10 Your Honor, I'd like to say we close the day on a very
11 positive note. When things are intertwined and the merits are
12 melded with a jurisdictional question, you skip the
13 jurisdictional bar and you go right to the merits.

14 So, Your Honor, we've got one step based on his
15 concession today that makes it easy for you to go to the
16 merits. If you don't believe that, though, Your Honor, we
17 still win because it's clear that whatever you think about
18 what he says we're challenging, we are not challenging the
19 selection decision under Subsection B. We are challenging the
20 publication of the list under Subsection A and specifically
21 the idea that there are ten negotiation-eligible drugs, not
22 15, or whatever number the government wants to make up.
23 Subsection A is not covered by the judicial review bar. If
24 you take a look at the *American Clinical Laboratories*
25 *Association* case in the D.C. Circuit --

1 THE COURT: Mr. Parrish, just so I'm not confused,
2 because there's a lot of statutory language, but here in
3 Subsection B, doesn't it begin with him in carrying out
4 Subsection A? Isn't that the first line of Subsection B?

5 MR. PARRISH: Absolutely, Your Honor. What I say is
6 when you look at judicial review bars, because of the fact
7 that if there's any interpretation that's reasonably
8 susceptible, what they often do is apply these formalisms
9 where they say if it's in one section but not another, that's
10 significant. So all I'm saying, Your Honor, is that the ten
11 negotiation-eligible drugs in A is not covered by the bar.
12 And, Your Honor, you are absolutely right that you look, then,
13 and say, well, what's going on in B?

14 What is interesting -- this goes to my point -- my two
15 points -- one is look at the letters, and the second one is
16 look at the verbs. If you go into B, the agency has not been
17 given discretion to redefine. It's been given discretion to
18 select based on high spend. And then the other provision is
19 to make determinations based on high spend or low spend.

20 So what Congress was clearly doing is it was saying --
21 this is always the case -- it gives the parameters by which
22 the agency gets to act. In this case, ten must be the types
23 of things that FDA has licensed or approved only 7 or 11
24 years, and then within that, agency has discretion to
25 determine which one of those things are high spend and low

1 spend to select.

2 On the question of which drugs, they get the discretion
3 no judicial review, but they can't in the way to do that
4 rewrite the plain statutory mandates.

5 THE COURT: Mr. Sverdlov is saying, look, this is
6 kind of a toothless tiger, this whole thing, if we have all
7 these different modifications of basically the same drug, and
8 you all want them to be considered separate and independent
9 drugs. So you have one drug, it's within the IRA. You have a
10 very similar drug, some modification, and that one you were
11 selling outside of this program. Is that really the intent of
12 Congress that it would be circumvented that way where you
13 could have different ideations of the same product? I keep
14 using "drug," but I'm going to get corrected by somebody. The
15 same product, and then doesn't that circumvent the whole
16 purpose of what Congress was intending with the IRA here?

17 MR. PARRISH: No, Your Honor. I'm so glad you asked
18 that because there's three things that really explain what
19 Congress wanted. So, first, what Congress was saying was that
20 we want this to phase in, and this gets to the most common
21 argument, but it didn't give the agency any rulemaking
22 authority for three years. After three years, it has
23 rulemaking authority. Now, if there was a product-hopping
24 problem, the agency could address that through proper
25 rulemaking through notice and comment. So the agency would

1 have an ability to do that.

2 Second, Your Honor, remember the deference here is not
3 to the inexperience CMS that has never regulated these things
4 before. It's to FDA's determination of what our individual
5 product to be approved and licensed. Product hopping can't
6 happen that quickly because it has to go through the FDA
7 approval process. Of course, what we're talking about is
8 products that have been on the market for 7 or 11 years.

9 Remember, Your Honor, when you and I were talking
10 earlier, Congress didn't want to blow up the system. It
11 wanted to move in. So what it does it goes ahead and says,
12 There will be some products that are priced subject to price
13 controls. The idea that several years down the road --

14 THE COURT: Baby steps.

15 MR. PARRISH: Baby steps. The idea that there might
16 be product hopping will give the agency rulemaking authority
17 in three years' time.

18 Finally, Your Honor, whatever I think about probably
19 doesn't matter because I'll just return to my friend, who I
20 agree with. It is Congress's prerogative, and nowhere in the
21 statute does it say product hopping. That, of course, if you
22 looked at the legislative history, too, they talk about it all
23 the time, but they didn't address it here because Congress --
24 as you said -- baby stepping, not going ahead and sweeping
25 everything in.

1 Your Honor, I think the judicial review bar,
2 notwithstanding concession, the question is can this Court
3 reasonably read that provision as being related to which
4 products meet the high spend, low spend, and other
5 determinations that were within the agency's discretion but
6 doesn't give the agency the ability to redefine and to change
7 10 to 15, and the answer is clearly yes there.

8 So, Your Honor, that takes us to the notice and comment
9 point. I'm just going to highlight this. This is one of the
10 most extraordinary things in this case that really highlights
11 the constitutional problems. I mean, usually everybody knows
12 that a guidance doctrine is supposed to only be nonbinding.
13 It's supposed to be, at most, an expression of the agency's
14 views to be done later. But they've conceded in their brief
15 that this is binding substantive, and yet they also tell you
16 that they didn't have to go through APA notice and common
17 rulemaking proceedings, and there's no judicial review. Your
18 Honor, it's extraordinary revolution since 1946 that they can
19 wipe out the APA like this, and all the cases they talk about
20 where the APA doesn't apply, it's because Congress has imposed
21 similarly constitutionally required procedures to displace the
22 APA, but they're very similar. There's a chance to be heard.
23 There's an opportunity to make sure the agency is just not
24 making it all up. But their position here, Your Honor, is
25 that for purposes of all these things, the amount of data

1 we've had to turn over, that has nothing to do with the
2 statute itself. All of the things they've done to add to the
3 agreement, their redefinition of what type of manufacturers
4 have to provide materials, all of these things that they say
5 they can make up is completely -- you know, courts -- get
6 away, courts. We get to do this on our own. There's no check
7 from Congress. There's no check from courts. Everybody is
8 just at our mercy. Your Honor, that can't be the law.

9 That takes me to the merits, Your Honor, which is just
10 a few points. Your Honor, I hope you noticed -- because I did
11 -- the twist that I was trying to warn you about. The word
12 "drug" is not the operative term because the word "drug" means
13 lots of different things in different contexts. He's
14 absolutely right. There's no doubt about it.

15 He cites cases all day long that talks about drugs and
16 refers to the drug substance. In fact, that's often what you
17 see in the patent context, but we're not talking about drug in
18 the abstract. We're talking about it in two specific places.
19 One is how is it defined by Congress in the statute here? And
20 there it specifically refers to the approval and licensing
21 decisions by FDA.

22 And we know from the Supreme Court for the last 35
23 years that in that context, not in the patent context, not in
24 another context, but in the approval and licensing process, it
25 is a product-by-product decision. And, you know, he even

1 admits that in his brief.

2 So, Your Honor, the idea that there are distant
3 definitions of drugs makes this statute a little confusing
4 because it does refer to drug, but it isn't confusing what it
5 means when it talks about a negotiation-eligible drug.

6 And, Your Honor, I've never been accused of
7 daisy-chaining before, but it's not particularly difficult
8 because, remember, he stood up and he said, Your Honor, I
9 don't know -- it's so disoriented, I don't understand where
10 they came up with this idea that it's product.

11 And, Your Honor, the question is do you believe my
12 friend or do you believe the text of the statute? You take a
13 look at page 7, qualifying single-source drug, and what is the
14 definition? It says drug products, a drug that is approved by
15 FDA for seven years on the market and is not a listed drug.

16 Every one of those things only applies to products.
17 There is no FDA approval process here that says if you've got
18 an active ingredient, you can just go ahead, put it in any
19 form that you want, and sell it. You have to get it approved
20 and licensed if it's something new.

21 So, Your Honor, the daisy-chaining, it may take a
22 little while to go through two or three statutory provisions,
23 but all you have to do is look at what the text says, and the
24 idea that we're coming up with something crazy with products
25 is belied by the fact that it says it there in the statute.

1 Your Honor, also he went on about those provisions. I
2 told you he would, and he's absolutely right. There are
3 aggregation provisions, and remember, he focused on strengths
4 and dosage forms.

5 But, Your Honor, you remember -- let's take a look at
6 the NovoLog products. We have Fiasp and we have NovoLog.
7 Those are two products, separately approved, different
8 clinical uses. Those are not different strengths and dosage
9 forms. Those are totally different products.

10 And then, Your Honor, you remember that within those
11 products, we have three of them. Again, we have the
12 injection, we have the Epipen, and we have the pump. Those
13 are not dosage forms and strength.

14 And all three provisions that he referred you to, the
15 ones that he says, well, that means we must -- "drug" must
16 mean something else than what negotiation-eligible drug is
17 defined. None of them go beyond dosage form and strength, and
18 the problem is that our products, which are differentiating by
19 device presentation, different things all together,
20 innovations that go from putting it in your arm to having a
21 very high-tech pump that has just been recently approved as of
22 2023. Those are different things.

23 So, Your Honor, let me just close up because I think I
24 speak on behalf of all the plaintiffs of thanking the Court
25 for taking the exception of having oral argument. We are very

1 grateful for that.

2 I would just say, Your Honor, that the government
3 challenge here is that this statute is unprecedented. There
4 has never been a statute like this that combines so many
5 attempts to get around basic constitutional protections,
6 whether it's a forced sale, whether it's a forced compelled
7 speech, whether it's a \$2 billion fine or even larger.

8 There has never been anything like that combined with
9 the idea that there's no principle from Congress, and on top
10 of no principle from Congress, there's no judicial review and
11 no procedures.

12 But if you disagree with us on that, Your Honor, and I
13 really hope you don't because it's very important that we
14 uphold the Constitution, I, at least, urge you to agree with
15 us on the idea that CMS has gone completely off of what the
16 statute is. It does not have authority to rewrite the
17 statute, and it's trying to do that, and we would urge you, at
18 least, Your Honor, to hold the agency to the language that
19 Congress imposed and the statute Congress chose to write.

20 And with that, unless you have questions, I'm grateful
21 for the Court's time.

22 THE COURT: I don't. Thank you, Mr. Parrish.

23 MR. PARRISH: Thank you, sir.

24 THE COURT: Is there anything further on behalf of
25 the plaintiffs first? Is there anything further we had to

1 address today?

2 It looks like we covered all the issues. I know it's
3 been a long day.

4 Mr. Chiesa, anything on behalf of this team on my right
5 over here?

6 MR. CHIESA: No, nothing, Your Honor. Thank you.

7 THE COURT: All right. Mr. Netter, who's speaking
8 for the government here? Do you have anything further?

9 MR. NETTER: We have nothing further, Your Honor.

10 THE COURT: All right. I will be brief because
11 you've been here for a long time, but I think it's worth
12 mentioning this on the record.

13 I will tell you that today I witnessed absolutely
14 outstanding lawyering from the attorneys here in this
15 courtroom, and I say that from both sides.

16 I think it's worth mentioning on the record -- I think
17 it's mentioning even for the public who are still here:
18 Mr. Chiesa, Mr. Roth, Mr. Deger-Sen, Mr. King, Mr. Parrish,
19 Mr. Netter, Mr. Gaffney, Mr. Sverdlov, I say this because -- I
20 think I mentioned this off the record before, and I think it's
21 worth mentioning now.

22 This district is not known to be generous in offering
23 oral argument on particular motions or applications, at least
24 not in civil matters, and I am not one personally who is
25 generous offering oral argument.

1 I find that many times it's redundant, and it's a waste
2 of time, and I will tell you absolutely that was not the case
3 today.

4 We've had this discussion with the federal bar, and
5 that's a discussion we'll continue to have with members of our
6 bar about encouraging oral argument when it can be informative
7 to the Court, but here -- two things I think are worth
8 mentioning:

9 One, I found that the oral argument was absolutely
10 informative to the Court. These are complex issues. Many of
11 these issues, I don't have clear-cut law before me. So I
12 appreciate the written submissions but also the oral argument.

13 But I also want to say I think you all did a bit more
14 today. You also offered a unique educational opportunity for
15 the newer attorneys that are in my courthouse. We have
16 judicial law clerks. We have judicial interns that have been
17 sitting here observing your advocacy today from this courtroom
18 and in an overflow courtroom across the way in Judge Kirsch's
19 courtroom, and he was gracious to offer that to us. I think
20 that is an important opportunity for them to witness effective
21 advocacy and professionalism.

22 So I do want to thank the lawyers for your preparation,
23 and with that, this matter is adjourned. Thank you.

24 THE DEPUTY COURT CLERK: All rise.

25 (Court concludes at 4:03 p.m.)

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FEDERAL OFFICIAL COURT REPORTER'S CERTIFICATE.

I certify that the foregoing is a correct transcript from
the record of proceedings in the above-entitled matter.

I

/s/ Megan McKay-Soule, RDR, CRR March 7, 2024

Court Reporter

Date

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