

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE

3	ASTRAZENECA PHARMACEUTICALS	)	
4	LP AND ASTRAZENECA AB,	)	
		)	
	Plaintiff,	)	
5		)	C.A. No. 23-931
	v.	)	
6		)	
	XAVIER BECERRA, IN HIS	)	
7	OFFICIAL CAPACITY AS	)	
	SECRETARY OF THE DEPARTMENT	)	
8	OF HEALTH AND HUMAN	)	
	SERVICES, ET AL.,	)	
9		)	
	Defendants.	)	
10		)	

Wednesday, January 31, 2024  
9:10 a.m.  
Oral Argument

844 King Street  
Wilmington, Delaware

BEFORE: THE HONORABLE COLM F. CONNOLLY  
United States District Court Judge

APPEARANCES:

MCCARTER & ENGLISH  
BY: DANIEL M. SILVER, ESQ.

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APPEARANCES CONTINUED:

HOGAN LOVELLS US LLP  
BY: CATHERINE E. STETSON, ESQ.  
BY: SUSAN M. COOK, ESQ.

Counsel for the Plaintiff

UNITED STATES ATTORNEY'S OFFICE  
BY: JACOB LAKSIN, ESQ.

-and-

DEPARTMENT OF JUSTICE  
BY: BRIAN NETTER, , ESQ.  
BY: CASSANDRA SNYDER, ESQ.  
Counsel for the Defendants

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P R O C E E D I N G S

(Proceedings commenced in the courtroom beginning at  
9:10 a.m.)

**THE COURT:** All right. Please be seated.  
Before we get started, I understand there are a bunch of  
attorneys from D.C. who were precluded from coming in  
because they don't have bar cards but have electronic

1 equipment.

2 Does anybody know anything about the state of  
3 that? We tried to call down to the lobby to see if  
4 arrangements could be made to let those people --

5 **MR. SILVER:** Your Honor, Dan Silver for  
6 AstraZeneca. Our team, some of whom are from Washington,  
7 D.C., got in with no problem because they have bar cards.  
8 I don't know anything about the issue downstairs.

9 **THE COURT:** Does anybody else know? No. All  
10 right.

11 Why don't we have introductions.

12 Mr. Silver, do you want to start.

13 **MR. SILVER:** Thank you, Your Honor.

14 Good morning. Dan Silver from McCarter &  
15 English on behalf of AstraZeneca. And I'm joined by  
16 Catharine Stetson and Susan Cook from Hogan Lovells in  
17 D.C. And also with us today in the gallery, Your Honor,  
18 are Mariam Koohdary, "D.C.," Danelco Moxey, from  
19 AstraZeneca.

20 **THE COURT:** All right. Thank you. Good  
21 morning.

22 And Mr. Laksin.

23 **MR. LAKSIN:** Good morning, Your Honor. Jacob  
24 Laksin from the U.S. Attorney's Office. And with me at  
25 counsel's table is Mr. Brian Netter, Cassandra Snyder,

1 and Christine Coogle, all from the Department of Justice  
2 Civil Division and Matthew Campbell right behind them,  
3 from the Department of Health and Human Services, Your  
4 Honor.

5 **THE COURT:** All right.

6 Who's going to go first. Have you all figured  
7 that out?

8 Two things. So one, I just had my knee  
9 replaced relatively recently, Mr. Silver knows that, so I  
10 have to -- I can't sit for too long, so I might stand  
11 during argument. Just keep talking. Just ignore the  
12 fact that I'm standing.

13 And then, secondly, just give me a chance to  
14 get into the transcript for a second, please.

15 **MS. STETSON:** Certainly. While we are doing  
16 that, Your Honor, we have a small briefing book.

17 May I approach and hand that up? I have two  
18 copies.

19 **THE COURT:** Okay. That would be great. Go  
20 ahead.

21 Okay, great. Go ahead.

22 **MS. STETSON:** Good morning, Your Honor. May  
23 it please the Court, my name is Cate Stetson. I  
24 represent AstraZeneca.

25 We are here in a challenge to the Inflation

1 Reduction Act's Drug Price Negotiation Program and the  
2 guidance that CMS put in place to implement it.

3 We've made three claims. The first is, the  
4 statute provides that CMS may not select drug products  
5 for this negotiation process called qualifying single  
6 source drugs unless they have been on the market for a  
7 period of years. The guidance that CMS implemented lumps  
8 different drugs approved at different times together as  
9 one qualifying single source drug or QSSD subject to one  
10 price.

11 Second claim. The CMS -- the statute also  
12 prohibits CMS from approving a drug or continuing it in  
13 the price program if a generic of that drug has been  
14 approved and marketed. But CMS took that statutory  
15 directive and in the guidance implemented another  
16 requirement, which is that the marketing be, quote,  
17 robust and meaningful.

18 Third claim is of a constitutional valence.  
19 We say that the Inflation Reduction Act's combination of  
20 no comment on the front end to the guidance, no  
21 meaningful negotiation in the middle, and no judicial  
22 review on the back end combines to produce a due process  
23 violation for AstraZeneca.

24 So those are our three claims. The reason  
25 that we're here today --

1           **THE COURT:** Can I ask you on that last claim,  
2 so then you agree then the statute precludes judicial  
3 review?

4           **MS. STETSON:** I think the statute, as the  
5 Government interprets it, precludes judicial review. And  
6 I think in those circumstances, that would lead to our  
7 due process problem.

8           **THE COURT:** So I guess what I'm getting at, is  
9 it your position then, you only get to Claim 3 if I rule  
10 against you on Claims 1 and 2?

11           **MS. STETSON:** I think there is an independent  
12 basis for Claim 3. But I think it's narrower.

13           The independent basis for Claim 3 is that,  
14 even if you accept our argument that the judicial review  
15 preclusion only goes to the selection of the drug or to  
16 the determination of what drug qualifies, there's still a  
17 barrier to judicial review on even those -- on even those  
18 components. But our point is, the way the government is  
19 interpreting this, there --

20           **THE COURT:** But at that point, if I accepted  
21 that, then I presumably would have had to accept you have  
22 Article 3 standing, and so, then, you are not harmed,  
23 right, because if I accepted that argument, you're good  
24 to go.

25           **MS. STETSON:** I think if you accepted that

1 argument, then the guidance certainly would fail -- fall  
2 because our contention is that the guidance, as written,  
3 extends well beyond what the statutory mandate says.

4 So I think in those circumstances -- and the  
5 reason -- that's the reason we put our Constitutional  
6 argument last, to be candid. We think that --

7 **THE COURT:** So then, you do agree. I only get  
8 to Claim 3 for you if I find that you lose on Claims 1  
9 and 2 because of the absence of judicial review.

10 **MS. STETSON:** I think I can agree to that with  
11 one caveat, if I could, which is the reason that there's  
12 a due process valence in this case is because of that  
13 combination of factors that we're talking about.

14 Our challenges on the administrative procedure  
15 side are targeted and narrow, but they don't really get  
16 at the other failings, process failings of the program.

17 So with that caveat, I agree that if you rule  
18 for us on the administrative procedure claims, our  
19 problems with respect to this particular drug, Farxiga,  
20 that we're talking about, would be resolved.

21 **THE COURT:** Okay.

22 **MS. STETSON:** So the reason that we're here  
23 today -- and we thank you for your accommodation to the  
24 Government's and our expedited briefing and argument  
25 schedule -- is because we are on the clock.

1           The Government is due tomorrow to make its  
2 initial price offer for Farxiga, the drug that we're here  
3 to talk about. We have 30 days. AstraZeneca has 30 days  
4 after that point to make its counteroffer.

5           That's the reason that we put in place and  
6 you've accepted the expedited briefing schedule. It's  
7 the reason we are arguing at this point, rather than at  
8 some point later this spring, because that counteroffer  
9 is what supplies the basis for our standing.

10           A lot of the Government's brief has to do with  
11 whether or not AstraZeneca has standing to challenge the  
12 guidance that so plainly violates the text of the  
13 statute.

14           The answer is, of course, it does. You know,  
15 AstraZeneca, in order to make a counteroffer to the  
16 Government's price offer coming in tomorrow, AstraZeneca  
17 needs to know what is the value of this product that we  
18 have.

19           The value of that product, among other things,  
20 depends on a couple of key components. One of them is,  
21 what is coming down the pipeline, as our declarant says,  
22 that might, under the Government's construction of the  
23 guidance, be treated as the exact same drug and shunted  
24 into the same price? That's going to affect our  
25 valuation of the product right now, this product,



1 Farxiga.

2 The exact same calculus comes into play with  
3 respect to our other merits APA argument, which is the  
4 bona fide marketing requirement. If this drug, as should  
5 be, is taken back out of the price negotiation after  
6 generics come on the market, which 17 of them are poised  
7 to do as our declarant points out, that affects our  
8 valuation of the drug right now because we will  
9 understand that, in the world of the statute, this drug  
10 should be taken back out of the price program after a  
11 year.

12 But because the CMS has chosen to interpret  
13 the statute in two very faulty ways, we are not able to  
14 make that kind of valuation. We have no idea whether the  
15 value will be higher or lower because we don't know the  
16 impact of CMS's flawed guidance on our ability to  
17 negotiate.

18 So we, essentially, have to walk in over the  
19 next 30 days to this counteroffer, based on a flawed  
20 definition that affects our ability to value our product.  
21 That is the reason that we have standing.

22 **THE COURT:** All right. So I'm trying to  
23 figure out the timeline here, and so the way the statute  
24 is set up, as I understand it, is you're all to engage in  
25 this back and forth, the identification of the drugs, the

1 negotiation, the setting of the price, and that will be  
2 completed when? The setting of the price for January 1,  
3 2026 is completed -- is it in March of 2025?

4 **MS. STETSON:** No. I think -- let me turn -- I  
5 have some notes on the timeline, and I want to make sure  
6 I get it right.

7 **THE COURT:** Actually, is it September 1 of  
8 2024? That's when the final price offer is made?

9 **MS. STETSON:** Yes, that's the deadline for the  
10 secretary to publish the prices.

11 **THE COURT:** So at that point --

12 **MS. STETSON:** And then my notes have March of  
13 2025 as the deadline for the explanation of the prices.

14 **THE COURT:** Right.

15 **MS. STETSON:** So I --

16 **THE COURT:** I like that you get five months to  
17 explain your --

18 **MS. STETSON:** Explain themselves.

19 **THE COURT:** -- your decision. I should employ  
20 that more often.

21 But is it correct that that's it? I mean, as  
22 of 9/1/24 the price is set? Is that your understanding?

23 **MS. STETSON:** Oh, yes. And not only that, the  
24 price is set for three years. There is no further  
25 discussion --

1           **THE COURT:** When you say that it's set for  
2 three years, what three-year period?

3           **MS. STETSON:** '26, '27, '28. And then after  
4 that three-year period, there's an opportunity to  
5 renegotiate. But as you can imagine, the circumstances  
6 in which CMS will renegotiate the price are very limited  
7 indeed.

8           **THE COURT:** Right. But it's set -- just for a  
9 second. It's set for '26 and '27, but if a generic  
10 entered the market -- and just assume for argument's sake  
11 under the guidance, the revised guidance, and it was a  
12 bona fide marketing by the generic, as of, let's say  
13 January 2, 2026.

14           **MS. STETSON:** Uh-huh.

15           **THE COURT:** A generic entered the market. I  
16 guess there's no adverb for bona fide, but, you know,  
17 more than de minimis, right?

18           **MS. STETSON:** Right.

19           **THE COURT:** Such that it satisfied the revised  
20 guidance definition of marketing. And it does that on  
21 January 2nd. Then, am I correct that what happens is,  
22 you, basically, are stuck for a year plus whatever time  
23 it takes for CMS to do all its data analysis? Or is it,  
24 no, there's a bona fide marketing and there's some  
25 timeline by which that is adjudicated or determined by

1 CMS that we now have a bona fide --

2 **MS. STETSON:** It's --

3 **THE COURT:** And -- let me just finish up.

4 **MS. STETSON:** Sure.

5 **THE COURT:** And when is the next price that's  
6 affected by that? In other words, the way I understand  
7 this is, come September 1, 2024, you are stuck for sure  
8 with the price for 2026.

9 **MS. STETSON:** Correct.

10 **THE COURT:** And I'm going to ask the  
11 Government that too, but that's my understanding. But  
12 where I lose track of things is, what happens for what  
13 the price will be come January 1, 2027?

14 **MS. STETSON:** Yes. So let me -- the answer to  
15 your question is you asked if it was either one or the  
16 other. It's the former. It's the first part of your  
17 question, which was, when, if a drug, generic, comes on  
18 the market bona fidely in January of 2026, under our  
19 interpretation, we should be relieved from the program's  
20 price controls for 2027.

21 The cutoff for the generic determination is  
22 March 31 of that relevant year. So as long as CMS made a  
23 determination by March 31st of 2026, we'd be relieved  
24 from the program for 2027. If you remain in the program  
25 on April 1st, 2026, you are in it for 2027.

1           So the problem here is what you alluded to,  
2           which is CMS in its guidance had said we're going to look  
3           at robust and meaningful marketing, and we're going to  
4           look at 12 months of data in order to determine whether  
5           the marketing has been robust and meaningful. That data  
6           in itself takes, as you can imagine with the Government,  
7           a quarter to catch up.

8           **THE COURT:** Right.

9           **MS. STETSON:** So we're already --

10          **THE COURT:** Can I just interrupt?

11           And I'm going to let you go really -- I mean,  
12          we're here -- we're definitely here until 12:30 if you  
13          all want. I need to --

14           I'm not as up to speed as I would love to be  
15          just because I just concluded a trial last week and just  
16          our docket and whatnot.

17          **MS. STETSON:** Understood.

18          **THE COURT:** Because of the expedited nature, I  
19          want to try to give you all an opportunity to fully flesh  
20          out your arguments. But let me just interrupt though.

21           So given what you just said, it sounds like  
22          you're stuck at a minimum for the price for '26 and '27  
23          because a determination -- when it comes to bona fide.  
24          The bona fide marketing determination, you would say,  
25          well, look, it can't be made until the completion of

1 12 months of data, right? Can't be.

2 **MS. STETSON:** That's -- yes. That's the way  
3 the CMS has gone about this in its guidance, yes.

4 **THE COURT:** Right. And then on top of that,  
5 you have to the 12 months be concluded, then you have to  
6 have some period of time for CMS to make its  
7 determination.

8 **MS. STETSON:** Right.

9 **THE COURT:** Right. And then if you,  
10 AstraZeneca, remain in the market and it comes April 1 of  
11 2027, you are stuck for calendar year '27 as well.

12 **MS. STETSON:** We're stuck for calendar year  
13 '28.

14 **THE COURT:** Oh, '28 if it's April 1.

15 **MS. STETSON:** Yes. That's the kicker.

16 **THE COURT:** But if they make their  
17 determination -- so, if, under my hypothetical, on  
18 January 22, 2026, generic enters the market it's bona  
19 fide marketing, the worst case for you would be for two  
20 years, for '26 and '27, you pay the price that was  
21 determined or that was set as of September 1st, 2024.

22 **MS. STETSON:** I'm not sure that's the worst  
23 case. The only reason I'm thinking through the timelines  
24 here that we've been talking about --

25 **THE COURT:** When I say "worst case," assuming

1 CMS agreed with you. Like I said, assume as a matter of  
2 fact, it was bona fide marketing, right?

3 **MS. STETSON:** Yes.

4 **THE COURT:** So it's either going to be, again,  
5 January 2, right, right after you enter.

6 **MS. STETSON:** Uh-huh.

7 **THE COURT:** The day after, you have a bona  
8 fide entry by a generic.

9 **MS. STETSON:** Right.

10 **THE COURT:** Price is already set for 2006, so  
11 you're paying whatever was set in September 2024.

12 **MS. STETSON:** Correct.

13 **THE COURT:** Okay. Twelve months elapse. CMS,  
14 they're just the most diligent government bureaucrats  
15 that exist. They come January 3, 2027, they say this was  
16 a bona fide entry. Then the price doesn't change, or  
17 does it, for 2027 at that point?

18 **MS. STETSON:** It does not change for 2027.

19 **THE COURT:** Right.

20 **MS. STETSON:** That's the -- the relevant date  
21 is the previous April 1st.

22 **THE COURT:** Right.

23 **MS. STETSON:** So that's --

24 **THE COURT:** Maybe I should have phrased it  
25 "best," case. But come January 1, 2028, you are no

1 longer subject to being part of this program, right?

2 **MS. STETSON:** If CMS makes its determination  
3 after that 12 months of data, by January 2, 2027, that's  
4 before the April 1st cutoff. So we would be relieved, as  
5 in 2028. But, you know, harkening back to the timeline  
6 we were talking about earlier, let's say that CMS decides  
7 it's going to take five months to explain itself.

8 **THE COURT:** Right. Then you could --

9 **MS. STETSON:** Now, we're talking --

10 **THE COURT:** Now you're talking three years.

11 **MS. STETSON:** Exactly. Yes.

12 **THE COURT:** Right. Okay. But you're talking  
13 three years, and I take it the regs don't provide any  
14 requirement that CMS issue its decision about bona fide  
15 marketing under any timeline; is that right?

16 **MS. STETSON:** Oh, no, yeah. I mean, in fact,  
17 the opposite.

18 I think CMS went out of its way in the final  
19 guidance, I think it's Section 70 of the final guidance,  
20 to say what constitutes bona fide marketing is going to  
21 change. We're going to look at, you know, maybe we'll  
22 look at this particular type of data, maybe it's this  
23 data that matters. But they're not even willing to  
24 commit to a process that is categorical or uniform across  
25 the board.



1           And there's certainly no commitment to saying  
2 if something comes on the market on January 1st of 2026,  
3 in 90 days, we're going to give you our decision.  
4 There's no such commitment.

5           **THE COURT:** Okay. All right. Sorry I  
6 diverted you. Go ahead and pick up wherever you'd like.

7           **MS. STETSON:** Sure. I want to touch on the  
8 other threshold issues that the Government mentions  
9 because it spends so much of its brief talking about it.

10           And I just want to take maybe a couple minutes  
11 and lay out the array of cases on the preclusion of  
12 judicial review point because there's a lot of --

13           **THE COURT:** The statutory you're talking  
14 about.

15           **MS. STETSON:** Statutory preclusion on judicial  
16 review.

17           **THE COURT:** Okay.

18           **MS. STETSON:** There's a lot of back-and-forth  
19 in the briefs about, you know, these cases say X, these  
20 cases say Y. And I want to make one overarching point.

21           If you look at your briefing book at Page 12,  
22 you will see the judicial --

23           **THE COURT:** Now, this briefing book, this is  
24 like a supplemental brief you're giving me?

25           **MS. STETSON:** No, no. This is a collection of

1 the relevant statutory language. It's essentially the  
2 old-fashioned form of the PowerPoint that the Government  
3 will have. It's not a supplemental brief.

4 So on Page 12, you see at the top of the page,  
5 the statutory preclusion that we're talking about.

6 **THE COURT:** Hold on. I don't have a Page 12.  
7 Yes, I do. Oh, the Ader declaration starts, I see.  
8 Okay. Yes. On Page 12. Okay.

9 **MS. STETSON:** So you should have Page 12,  
10 limitation on administrative and judicial review. So  
11 this is not part of the Ader declaration. Right?

12 **THE COURT:** Right.

13 **MS. STETSON:** Okay. So at the top of that  
14 page, you see the statutory preclusion that we're talking  
15 about. No administrative or judicial review of the  
16 selection of drugs, the determination of  
17 negotiation-eligible drugs, a determination of qualifying  
18 single source drugs.

19 I want to start by comparing that to a  
20 relatively recent Third Circuit case containing a much  
21 different standard of review. This is the *United States*  
22 *v. Dohou* case that's just underneath that.

23 This has to do with an immigration statute.  
24 You can see here, notwithstanding any other provision of  
25 law, et cetera, et cetera, no clause or claim arising

1 from or relating to the implementation or operation of an  
2 order of removal, that is the language of the broad  
3 statutory preclusion provision.

4 What we are dealing with are understandably  
5 targeted statutory preclusion provisions. And I want to  
6 take a minute, just because of all of the cases that the  
7 parties have both cited, to try to break down, if it  
8 would be helpful, the cases that preclude judicial review  
9 and those that allow it because I think the distinction  
10 is really important here.

11 There are --

12 **THE COURT:** I will let you do it, but before  
13 you do, can you just -- I want to make sure you don't --  
14 are you going to come back to standing jurisdiction?

15 **MS. STETSON:** I'm sorry?

16 **THE COURT:** Are you going to come back to the  
17 Article 3 standing or you just want to go right into --

18 **MS. STETSON:** I'm happy to take your lead,  
19 Your Honor.

20 **THE COURT:** Well, no. I think you should, at  
21 some point.

22 But let me just ask you a threshold question.  
23 So if you're me and you're really busy, you like to try  
24 to figure out the most efficient way to resolve things,  
25 do I get to Article 3 jurisdiction if I just conclude,

1 right off the bat, the statute precludes judicial review?

2 In other words, under Third Circuit law, do  
3 you think I have to address first Article 3 or can I go  
4 right to the statute?

5 **MS. STETSON:** I think it's *Trichy Steel*  
6 *Company* kind of question about which has to go first. I  
7 think because the statute purports to strip the Court of  
8 jurisdiction, that under *Steel Company*, would be  
9 considered equally on par with the Article 3  
10 jurisdictional issue.

11 So I don't think you need to favor one over  
12 the other in those circumstances.

13 **THE COURT:** Okay. All right.

14 **MS. STETSON:** But briefly on judicial review,  
15 and then I'm happy to turn back to standing.

16 If you break down the cases into, you know,  
17 the list of the cases that preclude review and the cases  
18 that don't, the cases that preclude review all share  
19 something in common, and they -- almost all of these, if  
20 not all of them, come up in the Medicare reimbursement  
21 context because this is where a lot of those statutory  
22 preclusions are hiding.

23 They all have to do with challenges to the  
24 numbers. You used the wrong data to calculate my  
25 reimbursement rate. You should have looked at this

1 particular set of disproportionate share data, not the  
2 2011 set of disproportionate share data.

3           The cases that find or allow judicial review  
4 ask different questions. They say, for example, in  
5 *American Clinical Laboratories Association*, your  
6 definition of laboratory, HHS, doesn't comport with what  
7 the statute tells you to do.

8           That's the kind of signal difference between  
9 the set of cases that preclude review and the set of  
10 cases that allow it.

11           Our case is, of course, in that latter  
12 category. We're not challenging, you know, you should  
13 have looked at this particular price data to choose  
14 Farxiga as your negotiation drug. You should have looked  
15 at this particular data. That's not our challenge.

16           Our challenge is, you have interpreted the  
17 statute in a way that is outside of your authority. And  
18 for the narrow preclusion of judicial review that we're  
19 talking about to bar that kind of basic legal  
20 definitional challenge, I think the statutory preclusion  
21 would have to look a lot more like the preclusion statute  
22 in *Dohou* than the narrow targeted preclusion we have  
23 here.

24           So circling back to standing, if there are no  
25 questions on judicial review, I think the --

1           **THE COURT:** I did have one.

2           **MS. STETSON:** Sure.

3           **THE COURT:** I just want to ask you one  
4 question. Let me get the briefs. Hold on a second.  
5 It's in your opposition brief, D.I. 58.

6           So can I just also say -- well, let me just  
7 ask you this question. So it's on Page 19 of the hard  
8 copy. So that's Page 27 of the electronic.

9           And you see at the top of the page there, it  
10 references Section 1192(d) and, then it says 1192(e).  
11 I'm assuming, like, that is from the original public law.  
12 I just want to make sure that's referring to 1320f-1(d).  
13 Right? It is, right?

14           **MS. STETSON:** Yes.

15           **THE COURT:** Okay.

16           **MS. STETSON:** That's -- a constant problem in  
17 this particular statute is that there's references to  
18 sections, and they don't translate into the actual code.

19           **THE COURT:** But in this one they do, right?  
20 This translate into 1192(d) does translate into  
21 1320f-1(d), right?

22           **MS. STETSON:** I believe that's correct. Yes.

23           **THE COURT:** And then the same thing, 1192(e),  
24 that is 1320f-1(e), right?

25           **MS. STETSON:** Yes.

1           **THE COURT:** I have to tell you, both sides,  
2 the briefing was just, it was outstanding. It was  
3 really, really good briefing. It's the best briefing  
4 I've read as a judge on both sides in five years.

5           Anyway, I thought that was the case, so I'm  
6 going to treat it that way. All right.

7           All right. Now, you want to address, then,  
8 Article 3 that had to do with the statutes. I want to go  
9 back now -- you want to address Article 3 standing; is  
10 that right, next?

11           **MS. STETSON:** Yes.

12           **THE COURT:** Okay. Go ahead.

13           **MS. STETSON:** Yes.

14           I think in addition to the point that I  
15 started with, which is the need for AstraZeneca to  
16 understand the value of the product that it has, right  
17 now, for its negotiation process for Farxiga, depends on  
18 a couple critical inputs. One of those inputs is what  
19 else is in development for this drug that we might value  
20 very highly, were it not for the Government's  
21 overreaching definition?

22           The other is, what generics are poised to come  
23 on the market that might actually temper our price offer  
24 if it weren't for the fact that this was going to stay on  
25 the market?

1           **THE COURT:** I mean, doesn't that open up just  
2 an incredible can of worms? You know, defense company  
3 wants to contract with the Government to sell it some  
4 product, sell the Government some product three years  
5 from now. And, clearly, if the defense company, the  
6 defense contractor, wants to figure out the value of what  
7 that product is three years from now, there's all sorts  
8 of things it would like to understand about different  
9 defense systems that the Government might be interested  
10 in the future, what's the state of the world affairs  
11 three years from now.

12           I mean, that just seems to me to be -- I can't  
13 even imagine where it would lead to. It would make  
14 everything a potential injury. I'd love to understand  
15 the value of my product in the future.

16           I guess -- and that's not really in your  
17 brief, right? I mean, I didn't get that theme from your  
18 brief, that that was the injury. I thought your injury  
19 was the loss of economic incentive.

20           **MS. STETSON:** I think that's definitely a  
21 component of it. I wanted to start with what I think of  
22 as the nearest term harm, which is we've got to make up  
23 our minds in the next month.

24           We have to decide, you know, among other  
25 things whether to even engage in this process. If the



1 Government is to be believed, this is a process. We're  
2 going to engage in that in good faith. And one of the  
3 things we need to figure out is what's the value of this  
4 product.

5 But I take your point that if you were to  
6 strip out some of the factual particulars here, and just  
7 talk about this in terms of, you know, I'm a regulated  
8 entity. I have a product. I'd love to forecast how the  
9 Government is going to regulate this in five years. That  
10 would be hugely problematic, I think, for standing.

11 But here, there's a couple of anchors that I  
12 think help. One of them is, we are talking about a  
13 particular drug, Farxiga.

14 The second is, with respect to drug  
15 development in particular, as Your Honor well knows, drug  
16 development is on a long fuse. And so there are in this  
17 industry, as our declarant points out, decisions that are  
18 made now that are designed to have impact a couple years  
19 from now.

20 So I don't think that you could take this to  
21 some other, you know, regulated industry and say, I'm  
22 going to forecast the Government's reaction in five  
23 years; and, therefore, I have standing now. There is  
24 some concrete decisions that have to be made now,  
25 including the negotiation process, including the

1 investment that you talked about, including whether to  
2 negotiate at all.

3 **THE COURT:** All right. But the Government  
4 would say, look, the guidelines could change between now  
5 and '26 or '27, '28, generics could come on the market.  
6 You know, they are also operating in the blind you could  
7 argue. In fact -- and, actually, I don't want to forget;  
8 I want to ask you about this, because I don't think this  
9 is in the briefs.

10 There was ANDA litigation over this drug,  
11 correct, with Judge Andrews?

12 **MS. STETSON:** I don't know the answer to that,  
13 but I'm happy to find out.

14 **THE COURT:** Well, I know the answer to that  
15 because there was a published decision. I think  
16 Mr. Silver participated in that case, right?

17 **MR. SILVER:** Correct, Your Honor.

18 **THE COURT:** Yeah. And I think there what was  
19 an appeal, and it was dismissed on appeal after Judge  
20 Andrews upheld on validity of the patent, right?

21 **MR. SILVER:** Yes, Your Honor.

22 **THE COURT:** So that would strike me that there  
23 must have been some settlement reached with at least one  
24 of the generics. Was there?

25 **MS. STETSON:** I don't know the answer to that,

1 Your Honor.

2 **THE COURT:** So isn't that really, really  
3 critical for us to know right now?

4 In other words, you are telling me that it's  
5 not mere speculation that generics will enter the market  
6 at the end of '25 and early '26, right?

7 **MS. STETSON:** That's correct. There are 17 of  
8 them to be clear.

9 **THE COURT:** Is that right?

10 **MS. STETSON:** Yeah.

11 **THE COURT:** And my guess is, just because we  
12 see a lot of ANDA cases here, that, because it looks like  
13 there's at least one settlement, that you might -- your  
14 client might actually have an agreement with at least one  
15 of those generics about when it enters the market. Do  
16 you?

17 **MS. STETSON:** Your Honor, I don't know the  
18 answer to that, but I think -- and the reason that I'm  
19 pausing is because I'm searching to figure out whether or  
20 how it's relevant to the timing question that we talked  
21 about earlier.

22 **THE COURT:** Well, here's why it's relevant.  
23 Because the Government is saying, look, one of the  
24 purposes of this statute is to avoid that situation.  
25 And, actually, I should say, especially one of the

1 purposes of the revised guidance and its definition of  
2 marketing is to avoid the situation where some kind of  
3 agreement is reached between the brand and the generic to  
4 allow for purely de minimis marketing, which would pull  
5 the -- under AstraZeneca's definition, pull AstraZeneca  
6 off the ten drug list, but not allow for true  
7 competition; and, therefore, cause Medicare to have to  
8 pay an exorbitant price for the drug.

9 And you should know, I have two -- do you know  
10 what *Actavis* is, the case? Yeah. I have two antitrust  
11 cases involving *Actavis* theories, right, where the  
12 allegation is precisely this.

13 **MS. STETSON:** Pay for delay.

14 **THE COURT:** And since you are saying on one  
15 hand, I'm to accept as a matter of fact, and it's not  
16 speculation, that 17 generics will enter the market at  
17 the end of '25 and in '26, why shouldn't we all have, you  
18 know, know as well, well, what are the terms of the  
19 agreements, if any, that you all have such that you can  
20 make that statement but not necessarily disclose what are  
21 the terms of those agreements?

22 Now, Mr. Silver is standing.

23 **MR. SILVER:** Your Honor, I apologize for  
24 interrupting, but it may be helpful to put some concrete  
25 structure around this. There is no settlement agreement.

1           **THE COURT:** Okay.

2           **MR. SILVER:** It was a compound patent case.  
3 Judge Andrews found that they failed to establish  
4 obviousness.

5           **THE COURT:** Right.

6           **MR. SILVER:** It went up on appeal. It was a  
7 very strong decision by Judge Andrews that they weren't  
8 even close, and then the appeal was dropped.

9           **THE COURT:** Without a settlement?

10          **MR. SILVER:** Without a settlement.

11          **THE COURT:** In that case?

12          **MR. SILVER:** In that case.

13          **THE COURT:** But, and, look, I don't mean that  
14 you have to answer this, but since you're standing. And  
15 I don't know that we can just accept an attorney proffer,  
16 but is it a fact, do you know, that there have been no  
17 settlement agreements reached with any generics?

18          **MR. SILVER:** I don't know that, Your Honor.  
19 What I do believe is that the other 16 generics did not  
20 challenge the compound patent.

21          **THE COURT:** And so, then, it's not going to  
22 expire until -- well, actually, when does the compound  
23 patent expire?

24          **MR. SILVER:** I don't know that offhand. But I  
25 think what we alluded to in the brief is when we expect

1 the generics to enter.

2 I don't want to get too far over my skis.

3 **THE COURT:** No, no. That's fair. And I  
4 appreciate that, Mr. Silver.

5 **MS. STETSON:** Thank you.

6 **THE COURT:** Go ahead.

7 **MS. STETSON:** So, Judge Connolly, maybe I can  
8 make one point here that I think is important based on  
9 what you mentioned a couple minutes ago.

10 As you pointed out, it's the Government's  
11 guidance that suggests that this concept exists. Of  
12 course, the statute just talks about approved and  
13 marketed.

14 But the other thing I want to point out --

15 **THE COURT:** But you can see, incidentally,  
16 look, let me -- I mean, we're getting into the merits  
17 here, right?

18 But what's "marketed"? Would AstraZeneca  
19 take the position that, you know, somebody sold ten  
20 pills, and now you're off the list?

21 **MS. STETSON:** I'm going to say, yes, but it  
22 doesn't matter. And the reason it doesn't matter here is  
23 that, remember, the guidance doesn't talk about sham  
24 marketing or de minimis marketing.

25 The guidance talks about robust and meaningful

1 marketing. "Is the generic" -- and this is the guidance  
2 at Page 68 -- "regularly and consistently available for  
3 purchase through the pharmaceutical supply chain,  
4 available in sufficient quantities at community retail  
5 pharmacies?" There is a lot of meat around the idea of  
6 marketing.

7 If CMS had put out guidance that said, we are  
8 going to be on the lookout for sham marketing, ten pills  
9 nationwide and that's it, that might be a different  
10 story. But that's not how CMS chose to interpret  
11 marketing.

12 And the other thing I would point out, just to  
13 return back to the statute is, there are circumstances  
14 where CMS has or where Congress in the statute has put  
15 some similar kind of guardrails around the idea of  
16 marketing. And we mentioned them in our brief.

17 The common understanding of marketing,  
18 including CMS's common understanding of marketing, is  
19 that when a generic goes on the market, it is marketed,  
20 full stop.

21 But the other problem, I think, with what CMS  
22 has done here isn't just that it's imposed this threshold  
23 that nobody knows when it's hid until they hid it, I  
24 suppose, but it's the conversation you and I had several  
25 minutes ago, which is, even under the best of

1 circumstances where generics come on the market, they are  
2 marketed robustly, there is robust uptake regardless of  
3 marketing -- I guess that's the real issue, are people  
4 buying this drug? -- we still have to wait 12 months for  
5 CMS to release us from these price commitments, so it's  
6 that it's almost a one, two punch.

7 **THE COURT:** And that's why I kind of asked you  
8 to walk me through the guideline.

9 Let's just assume as a given that you set the  
10 price September 1, 2024 for calendar year 2026, right?

11 **MS. STETSON:** Yes.

12 **THE COURT:** And it's set, and there's nothing  
13 that can change it; even though, if the facts existed, as  
14 you say they will in 2026, you would never have qualified  
15 for the QS -- what's that acronym you used?

16 **MS. STETSON:** QSSD.

17 **THE COURT:** QSSD. Right. So, but that  
18 happens all time with Government contracting, right? We  
19 set -- and private companies do the same thing. We set a  
20 price that is going to be in effect three years from now.  
21 And we just do that. And then, yeah, events change,  
22 circumstances change, and guess what? A year and a half  
23 from now, it turns out you wouldn't have qualified for  
24 the designation such that, come 2027 or 2028, we'll have  
25 a different price. And that happens all the time.



1           **MS. STETSON:** I think what's different here,  
2 and just to be clear, we are already in the CMS tractor  
3 beam.

4           **THE COURT:** Um-hmm.

5           **MS. STETSON:** You know, Farxiga was selected  
6 for negotiation. What we're talking about is how and  
7 whether we are able to negotiate understanding what the  
8 limits of CMS's authority are on how Farxiga and its  
9 relevant, you know, active moieties, which is the  
10 Government's phrase, are going to be treated down the  
11 road.

12           **THE COURT:** I get that. I mean, that sounds  
13 like an advisory opinion. You want to know how we are  
14 going to interpret down road, this guidance --

15           **MS. STETSON:** No, I --

16           **THE COURT:** -- to guide your decisions now.

17           **MS. STETSON:** I don't think that's accurate,  
18 Your Honor, for this reason: If we were just -- if we  
19 were able freely to price our product over the next  
20 several years, and we wanted to -- we came in to you, and  
21 we said, you know, we're curious about this new  
22 government regulation that's going to hit several years  
23 down the road where, you know, we would like you to just  
24 quickly eyeball what it means for us now, that's a  
25 different story. We have to make a price counteroffer

1 within the next month.

2 **THE COURT:** Yeah, but you still are -- the  
3 words you used -- I wrote them down -- "freely to price  
4 our product." When are you not free to price your  
5 product?

6 **MS. STETSON:** We are not free to price our  
7 product because we are deprived of a couple key inputs  
8 because of the way the Government has gone about  
9 interpreting the statute. We're essentially working on  
10 some guidance that is, I think, flatly, textually  
11 unlawful.

12 **THE COURT:** But you're still free to price it.  
13 In fact, you're free to sell it, right? In fact, that's  
14 like a big point I'm having a hard time with and if you  
15 can show me a case, I'd love to see it.

16 How is any of this involuntary? You're free  
17 to do what you want. You may not make as much money --

18 **MS. STETSON:** Right.

19 **THE COURT:** -- but you're free.

20 **MS. STETSON:** Sure. I'm happy to switch --

21 **THE COURT:** Yeah, go ahead.

22 **MS. STETSON:** -- over to the voluntariness  
23 issues.

24 **THE COURT:** Well, to me, they're the same  
25 issue. You just said, you know, when you just said you

1 are, you said, "Freely to price our product," and I'm  
2 trying to understand. You may not have all the  
3 information you want about what's going to happen in the  
4 future and what the Government's position will be. I get  
5 that.

6 **MS. STETSON:** I think there's a difference  
7 between not having -- not being omniscient and Farxiga  
8 and its development as our declarant says, subject to  
9 unlawful guidelines that impact our decision-making now,  
10 including the counteroffer, including our future  
11 investment. You know, there's sort of a tale of injury  
12 that starts now and extends into the future.

13 But on the voluntariness point, I want to make  
14 two observations. The first is, the Government has not  
15 made a voluntariness argument as I read their brief, when  
16 it comes to these administrative procedure, statutory  
17 authority arguments.

18 The voluntariness argument has to do with that  
19 due process argument. And I will say a couple of quick  
20 things on that. The first is, we point out in our reply  
21 brief, it is a tell, I think, that the Government's  
22 voluntariness cases all come from the takings world. And  
23 that makes some sense as a practical matter. If you're  
24 about to complain that the government should be paying  
25 you for something and you voluntarily engaged in what

1 you're giving the Government, you shouldn't expect  
2 payment for it.

3 But if you look at the Government's -- one of  
4 the Government's cases that it cites, that Supreme Court  
5 case long time ago, *Bowles v. Willingham*, 321 U.S. 503,  
6 the Government cites that case for the proposition that  
7 you can't claim a taking if you have voluntarily engaged  
8 in something. So in that circumstance, it was a  
9 landlord, and Court said, for takings purposes, the fact  
10 that the landlord voluntarily chose to make his property  
11 available for rent means it can't be subject to a takings  
12 claim.

13 And then you should look at Page 519, because  
14 what the Court went on to do was to make a due process  
15 analysis separate from the taking claim that had nothing  
16 to do with voluntariness.

17 So our point here is, to the extent that this  
18 is voluntary -- and there's a lot of, you know,  
19 discussion that we can have on that -- it is not relevant  
20 to a straight due process claim.

21 The only case that the Government cites for  
22 that purpose is that *Chamber, Dayton Chamber* case from  
23 the Ohio District Court, but the Government in that case,  
24 if you look at its briefing, explains that what the  
25 *Dayton Chamber* was doing there is really a takings claim

1 in due process clothing.

2 So really, on that side of the ledger, all  
3 they have is takings claims. On our side of the ledger,  
4 first, it's the dog that didn't bark; there's no due  
5 process case that talks about voluntariness.

6 And second, in the Government's own cases,  
7 *Bowles v. Willingham* shows that difference.  
8 Voluntariness is pertinent to a takings claim; it has no  
9 relevance whatsoever to a due process Claim.

10 **THE COURT:** Well, what's the property interest  
11 for due process? You need a property interest, right?

12 **MS. STETSON:** Yes.

13 **THE COURT:** Okay.

14 **MS. STETSON:** Yeah.

15 **THE COURT:** So what's the property interest?  
16 And you need a deprivation of the property interest,  
17 right?

18 **MS. STETSON:** We do.

19 **THE COURT:** So how does that differ from a  
20 takings issue, and then can you show me a -- can you just  
21 cite me a Supreme Court case or a Third Circuit case that  
22 addresses that?

23 **MS. STETSON:** Sure. So the Third Circuit  
24 case, I think I'd cite you to, I believe it's *Fein*,  
25 F-E-I-N. It's in our brief. But it stands for the

1 proposition that there is, you know, before the  
2 \depravation\deprivation of any property interest, you  
3 need a notice and a meaningful opportunity to be heard,  
4 so basic principles.

5 As far as our property interest, we cite  
6 Supreme Court cases going back 100 years for the  
7 proposition that a patent held in a particular product, a  
8 drug product, is a property interest.

9 And I would pause here and say that one of the  
10 gaps in the Government's briefing is that, by putting all  
11 of its eggs in the voluntariness basket, it really didn't  
12 contest that there was a property interest, that this  
13 quasi negotiation process deprives AstraZeneca of the  
14 opportunity to sell this particular patented drug product  
15 at a price that it would get in the market.

16 So those -- the interest and the  
17 \depravation\deprivation are all things that the  
18 government glossed over in favor of this overarching  
19 voluntariness theory.

20 **THE COURT:** All right. Let me ask you, then,  
21 I do see, to be candid, a bit of a moving target.

22 What's the property interest that you allege  
23 AstraZeneca is being deprived of without process?

24 **MS. STETSON:** It is the -- it's two parts.  
25 It's the interest in our patented product being sold on a

1 fair market at a price that the product would command.

2 **THE COURT:** Doesn't the patent expire in 2026?  
3 I mean, didn't you just say that? Didn't Mr. Silver --  
4 he didn't say an exact date, but don't your briefs  
5 effectively say that?

6 **MS. STETSON:** I think there are patents and  
7 exclusivities that expire in 2026, yes. But we're here  
8 talking about a patented product now in 2024.

9 If I could make one other point on due process  
10 and voluntariness, just because I don't want the  
11 voluntariness issue to get lost completely. To the  
12 extent that voluntariness plays any role in the due  
13 process inquiry, which for all the reasons and for *Bowles*  
14 and everything else, it doesn't. If it does, I would  
15 like to ask the Court to consider what I think of as the  
16 immense disproportionality between what AstraZeneca is  
17 being asked to do here and the consequences if it walks  
18 away.

19 So, you know, unlike a situation where a  
20 doctor can say, I choose not to treat Medicare patients,  
21 this is the situation where we can't just say, I choose  
22 not to offer Farxiga into this program. If we walk away,  
23 all of our products nationally come with it. We cannot  
24 participate in either Medicare or Medicaid with respect  
25 to any AstraZeneca drug products. And it's that seismic

1       disproportionality that I think makes this coercive.

2                You know, there's a difference between  
3       engaging in a negotiation with the Government where, you  
4       know, the government is pinching your arm a little bit;  
5       this is breaking your arm. And if you look at the  
6       Government's briefing in the Supreme Court, in the *NFIB*  
7       case on the Medicaid issue -- because there's lots of  
8       briefing in the Supreme Court in that case.

9                The Government's response brief on the  
10       Medicaid issue makes exactly the same arguments that it's  
11       making here. Medicaid is voluntary. A state can choose  
12       to walk away from it. The fact that it might hurt a  
13       little bit is really irrelevant because Medicaid is a  
14       voluntary program.

15               And what the Supreme Court majority said was,  
16       there's voluntariness, and then there's coercion. And  
17       where you have a Government hammer that is going to,  
18       essentially, deprive AstraZeneca, as our declarant says,  
19       of a vast percentage of its drug consumers -- to their  
20       detriment as well I might add -- that is coercion. That  
21       is not a voluntary --

22                **THE COURT:** Coercion happens all the time.  
23       Taxes are coercion, right? We have sin taxes; they're  
24       not unconstitutional. I mean, that's coercion.

25                **MS. STETSON:** I'm trying to think about a



1 quick analogy to that. So let's suppose that you have a  
2 sin tax. I go and buy a bottle of bourbon. The bourbon  
3 costs \$10. The tax is \$100,000. That's coercive.

4 **THE COURT:** Yeah.

5 **MS. STETSON:** That's what we're talking about  
6 here. If you have a circumstance where we can pull our  
7 drug from this negotiation only at --

8 **THE COURT:** Is there any case that says, that  
9 has held that a tax violates due process because it's too  
10 high?

11 **MS. STETSON:** I don't know the answer to that  
12 exact question, whether a tax violates a due process  
13 because it's too high. I think the analogy here is to  
14 *NFIB* because what we're talking about is a coercive  
15 Government program that essentially hammers a participant  
16 if it attempts to exit the program.

17 And what the Supreme Court in *NFIB* said was  
18 that is over the line. Wherever the line is, this is  
19 past it I think is how the majority put it. And I think  
20 it's telling that the Government, in its *NFIB* brief,  
21 makes the same flavor of arguments that it makes here.

22 Now, Mr. Netter is going to stand up, and he's  
23 going to say *NFIB* is different. That involved a state,  
24 this involved a private entity. That's nowhere in the  
25 Supreme Court's decision.

1           The Supreme Court didn't say, this is a  
2 special coercion rule only available to states. Coercion  
3 is coercion when you're dealing with the Government. So  
4 on that due process point, I think the two takeaways are  
5 voluntariness isn't relevant to due process and even if  
6 it is, this is not voluntary. This is coercive.

7           **THE COURT:** All right. Can you go back, you  
8 know, I'm still at -- the property interest -- I think  
9 I've got -- I'll go back and look at the transcript.

10           Did you want to say anything else about what  
11 the property interest is of AstraZeneca? At the  
12 beginning, you were talking -- you led off, really,  
13 saying that the injury, which I think is essentially the  
14 same thing as the property interest, right, that you are  
15 talking about?

16           **MS. STETSON:** Uh-huh.

17           **THE COURT:** -- is the inability to assess the  
18 value of the products to make a counteroffer.

19           **MS. STETSON:** Yeah. That's the nearest term  
20 injury. You know, then there's the injury you mentioned  
21 as well.

22           **THE COURT:** I think you should give me the  
23 universe. Because, like I said, you know, I came away  
24 from the briefs that the first injury was this loss of  
25 economic incentive to develop the product. And,

1 basically, you know, for other uses. But am I wrong on  
2 that?

3 **MS. STETSON:** No. I think there is an  
4 allegation of that injury as well. You know, I had a  
5 mentor who used to say, Nothing sharpens the mind like  
6 argument preparation.

7 **THE COURT:** Right.

8 **MS. STETSON:** The thing that struck me about  
9 the nearest term injury is this need for AstraZeneca to  
10 understand the value of what it is holding right now in  
11 order to negotiate right now.

12 But you're absolutely right. There is, as I  
13 think of it, a longer tail injury, and that is how are we  
14 going to make investment decisions, including in  
15 products, as our declarant says, that we are currently  
16 developing, with the same active moiety as Farxiga if we  
17 understand -- why would we invest if we understand at the  
18 end of the day, if that product makes it all the way  
19 through the gauntlet, subject to a separate NDA, it  
20 immediately gets shunted into the maximum fair price  
21 program.

22 **THE COURT:** And how is that not pure  
23 speculation and -- maybe not even speculation, but not  
24 tied to current reality?

25 I mean, this is what your witness, Mr. Ader --

1 is that how you pronounce it?

2 **MS. STETSON:** Yes, I believe so.

3 **THE COURT:** Right.

4 He says in Paragraph 23, "While clinical  
5 trials are currently focused on combination product  
6 therapies that would not be impacted by the agency's  
7 definition of qualifying single source drug, there are  
8 other ongoing drug development efforts involving the same  
9 active moiety as Farxiga, where one development pathway  
10 could result in the product being treated as the same  
11 QSSD as Farxiga, under CMS's position."

12 I mean, the second part of that sentence, I  
13 would -- my take on it is there's some possibility, you  
14 know, it could result. That's speculation.

15 **MS. STETSON:** Right.

16 **THE COURT:** But the killer for you, I think,  
17 is the first part, which says the clinical trials  
18 current, the current ones, wouldn't be impacted. What  
19 you're developing right now, currently, would not be  
20 impacted by the agency's definition.

21 Not only are you, basically, as I understand  
22 your theory you are articulating this morning, which is,  
23 we want to be able to value the product, your current  
24 plans for the product aren't going to be impacted at all  
25 by the agency's current guidelines.

1           **MS. STETSON:** I don't think that's entirely  
2 accurate.

3           **THE COURT:** All right.

4           **MS. STETSON:** This is something the Government  
5 fastens in on that I don't think is relevant.

6           The first part of that sentence talks about  
7 clinical trials. Second talks about other ongoing  
8 development efforts.

9           So what we're talking about are two things  
10 that are both currently going on. One is just further  
11 down the pike than the other.

12           **THE COURT:** But you said "could result." And,  
13 incidentally, should I hold it against you?

14           I mean, you don't -- it's a very vague  
15 sentence. Quote, "ongoing drug development efforts  
16 involving the same active moiety." Right, so that's  
17 vague. And then, quote, "could result in the product  
18 being treated," unquote.

19           I mean, I'm supposed to say that's a concrete  
20 harm that gives rise to jurisdiction?

21           **MS. STETSON:** I hear you on the "could," but  
22 let me make this observation.

23           The declarant, of course, is not a lawyer.  
24 From the declarant's perspective, you know, the declarant  
25 is not able to point out what we can point out, which is

1 a drug involving the same active moiety as Farxiga is,  
2 under the Government's guidance, going to be treated as  
3 the same QSSD. The fact that Mr. Ader couldn't make that  
4 legal determination is understandable.

5 **THE COURT:** Am I supposed to accept that he's  
6 not a lawyer and that's probative? I mean, my personal  
7 experience as a lawyer and as a judge is, would suggest  
8 there's a good chance a lawyer drafted or certainly  
9 participated in the drafting of his declaration.

10 I mean, should I infer any facts about that,  
11 that he's not a lawyer? I mean, doesn't say he's not a  
12 lawyer either.

13 It's summary judgment, right? You're asking  
14 me to make some kind of -- I'm supposed to assume the  
15 facts are not in dispute. I don't know. I mean, should  
16 I really place any value, to use your word, on the fact  
17 that you just said he's not a lawyer?

18 **MS. STETSON:** No. I don't want you to over --  
19 you don't need to overemphasize that. My point was that  
20 could result in those circumstances is not some kind of a  
21 weaselly hedge word.

22 But, you know, for our purposes, and for  
23 AstraZeneca's purposes valuing Farxiga right now, the  
24 takeaway from that Paragraph 23 is that there are  
25 development efforts underway. Even if we take the

1 "could," that could result in this being treated as the  
2 same qualifying single source drug, and that affects our  
3 decision right now to negotiate, to negotiate offering a  
4 particular price, and to accept that price. That's the  
5 immediate harm.

6 And then the longer term harm, as you  
7 mentioned earlier, is the idea that, depending on the  
8 Government -- whether the Government's unlawful  
9 definition sticks, we are forced to make investment  
10 choices now about what products to pursue, what  
11 indications to pursue, in what order, all because the  
12 Government has taken it upon itself to interpret drug,  
13 not through the pathway that the statute directs in terms  
14 of definition, but to introduce a brand-new phrase that  
15 you will look in vain through the statute to find, which  
16 is this idea that the active moiety controls, regardless  
17 of how many NDAs get lumped in together. That is a  
18 complete aberration when it comes to what the statute  
19 directs.

20 **THE COURT:** But the statute does refer to  
21 plural approvals, right?

22 **MS. STETSON:** It does, but I -- short answer  
23 is yes. But it refers to plural approvals. But, of  
24 course, approvals can also be an approval of an SNDA, a  
25 supplemental NDA, as the Court knows.

1           **THE COURT:** But the particular passage in  
2 question doesn't refer to supplemental. It just says  
3 "approvals," right? I mean, it's -- let me see if I can  
4 find it.

5           So I'm looking at 1320f-3(e)(1)(D).

6           And so the manufacturing-specific data that's  
7 supposed to be submitted for consideration includes,  
8 quote, "data on pending and approved patent applications,  
9 exclusivities recognized by the Food and Drug  
10 Administration, and applications, plural, and approvals,  
11 plural, under Section 355(c) of Title 21 or  
12 Section 262(a) of this title." Right? Now, that could  
13 include supplemental NDAs. That's your point, right?

14           **MS. STETSON:** It's one of my points.

15           **THE COURT:** Yeah.

16           **MS. STETSON:** The other one is, and you'll see  
17 this, this is a harbinger of Slide 14 in the Government's  
18 presentation.

19           That provision that you just read begins with,  
20 "The following data with respect to such selected drug,"  
21 singular.

22           And what it ends with, right after it says  
23 "under Section 355(c) or 262(a) of this title for the  
24 drug."

25           So what the Government is doing is essentially



1 moving the lens away from how do we define the drug, and  
2 looking at everything after that. There's --

3 **THE COURT:** Actually, drug -- Sorry.

4 **MS. STETSON:** -- approvals?

5 **THE COURT:** Sorry. Go ahead.

6 **MS. STETSON:** No. Please.

7 **THE COURT:** Is drug defined in the statute?

8 **MS. STETSON:** Yes.

9 **THE COURT:** Okay. And what does it say?

10 **MS. STETSON:** So if you look at our briefing  
11 book, we -- this is a classic congressional navigational  
12 exercise, but Page 3 of your briefing book, Qualifying  
13 Single Source Drugs. This is 42 U.S.C. 1320f-1(e).

14 For purposes of this part, the term  
15 "qualifying single source drug" means, with respect to an  
16 additional price applicability ear subject ... a covered  
17 Part D drug as defined in Section 1395w-102(e) of this  
18 title.

19 **THE COURT:** Right.

20 **MS. STETSON:** So turn the page.

21 Page 4. Covered Part D drug defined. The  
22 term "Covered Part D drug," means a drug that may be  
23 dispensed only upon a prescription. And that's described  
24 in subparagraph (A) (i), (ii), or (iii). Turn the page  
25 to Page 5.

1 "Covered outpatient drug means," it lists a  
2 number of drugs. And then turn to Page 6, Single source  
3 drug, which, of course, is part of qualifying single  
4 source drug, means a covered outpatient drug, already  
5 defined.

6 And then if you look about five lines down,  
7 "which is produced or distributed under a new drug  
8 application approved by the FDA."

9 So that's perhaps not as long a path as some  
10 congressional paths, but what you get to the -- when you  
11 get to the end of that, the takeaway is --

12 **THE COURT:** Wait. Actually, hold on. Hold  
13 on.

14 Where is it limited to a single new drug  
15 application? Can you show me that?

16 **MS. STETSON:** If you look at Page 6 of the  
17 briefing book, it's subprovision 7(A)(iv), single source  
18 drug. Four lines down a covered outpatient drug, which  
19 is produced or districted under a new drug application.

20 **THE COURT:** This is a definition -- hold on --  
21 for a single source drug.

22 **MS. STETSON:** Correct.

23 **THE COURT:** Okay. But I asked if there was a  
24 definition of "drug."

25 **MS. STETSON:** So the definition of drug is

1 everything that we discussed preceding that. It reduces  
2 down to covered outpatient drug and --

3 **THE COURT:** Right. So how does it get from  
4 covered outpatient drug to single source drug?

5 **MS. STETSON:** I think it gets to single source  
6 drug by way of what -- of course what we're talking here  
7 is only single source drugs. Those are the only things  
8 that qualify.

9 So we first define "drug," and then we look at  
10 single source drug. And let me make, maybe, a more  
11 important point.

12 **THE COURT:** No. No. Actually, I want you to  
13 make the point about drug.

14 Because here's the thing, again, we do ANDA  
15 cases here all the time. The reality is people refer to  
16 "drug" in multiple ways. And a lot of times, everybody  
17 knows what people are talking about when they refer to  
18 "drug," both for legal and for medical reasons, it means  
19 the active moiety. And so that's why I actually would  
20 like to see the definition of drug.

21 I think your best argument is, and I'll wait  
22 for the Government, but I'm really trying just to explore  
23 this to learn, but where is the definition of "drug"  
24 anywhere in the statute or in a reg, that limits it to a  
25 product covered by a single NDA?

1           **MS. STETSON:** I think the best I can show you  
2 for the textual analysis is what we just walked through.

3           **THE COURT:** All right.

4           **MS. STETSON:** So Pages 3 through 6 of that  
5 briefing book. The qualifying single source drug is  
6 defined with reference to another statute, which is  
7 defined with reference to another. And that drug  
8 product, when you're talking about single source drug,  
9 means an NDA.

10           But let me make two other points on this, if I  
11 could. The first is, that's not the only textual clue  
12 that we have in the Inflation Reduction Act about how  
13 this is supposed to read.

14           **THE COURT:** Right.

15           **MS. STETSON:** Right? One of the other  
16 provisions -- this is 42 U.S.C. 1320f-1(e)(1)(B).

17           Statute talks about if FDA approves a new drug  
18 under Section 355(c) and at least 7 years have elapsed  
19 since the date of such approval, or with respect to a  
20 BLA, such licensure.

21           **THE COURT:** Right. This is (1)(A),  
22 incidentally. This is not (1)(B). Right? (1)(B) is  
23 biological product.

24           **MS. STETSON:** Oh, that might be --

25           **THE COURT:** But I think this is your best

1 argument, right? It's talking about the date, singular,  
2 of such approval.

3 **MS. STETSON:** Yes.

4 **THE COURT:** So we're talking about one  
5 approval.

6 **MS. STETSON:** We're talking about one  
7 approval, the date, such approval, the drug.

8 **THE COURT:** Right.

9 **MS. STETSON:** What the Government is doing, I  
10 think -- there's a couple of different things at work.

11 Remember first, that the guidance is talking  
12 all about active moieties. However you choose to pick  
13 your way through those provisions that we just talked  
14 about, the words "active" and "moiety" appear nowhere in  
15 those statutes. So that's problem Number 1.

16 Problem Number 2 is when the Government tries  
17 to make a textual argument, what they're doing, as I  
18 alluded to before, is looking at things that are  
19 happening after the selection of the drug. The drug  
20 subject to such approval. They're looking at, you know,  
21 what are the drugs -- the drugs approvals, what are, you  
22 know, the forms and dosages of the drug. But all of that  
23 depends on the question about what's the drug that you're  
24 talking about.

25 And our point here is when you line up the

1 statute against the guidance, which you also have a few  
2 pages further in your briefing book, there's simply kind  
3 of an undeniable cognitive dissonance between talking  
4 about the drug, such approval, and talking about active  
5 moiety regardless of the number of NDAs and so on and so  
6 forth.

7 The whole idea behind this, of course, is to  
8 try to lump in as many different products as possible  
9 under that maximum fair price. But that's not the way  
10 that Congress chose to write this.

11 There is, as you've mentioned, a role for  
12 active moiety in some certain drug product discussions  
13 and when that occurs, the FDA's statutes talk about  
14 active moiety having a role. But here, the way that the  
15 IRA, Inflation Reduction Act, chose to go about it, the  
16 Inflation Reduction Act puts its emphasis on "the drug"  
17 and "such approval." That's what creates that statutory  
18 overreach that we're arguing about.

19 **THE COURT:** All right. So here's your last  
20 chance, I just want to make sure. Give me the universe  
21 of the property interests that you say is at issue such  
22 that AstraZeneca has a cognizable harm that gives rise to  
23 subject matter jurisdiction.

24 **MS. STETSON:** It is our property interest in  
25 our patented drug Farxiga.

1           **THE COURT:** And when do the patents expire for  
2 Farxiga?

3           **MS. STETSON:** I think the patents and  
4 exclusivities expire two years hence, if I remember  
5 correctly.

6           **THE COURT:** All right. And then, you know,  
7 you all decided to present this to me in this procedural  
8 posture of competing summary judgment motions. And as I  
9 understand the stipulation, it was to forego preliminary  
10 injunction litigation. Is that a fair summary?

11           **MS. STETSON:** That is fair. Yes.

12           **THE COURT:** Now, if we were in a preliminary  
13 injunction posture and you asked specifically for  
14 preliminary injunctive relief in your complaint, I would  
15 be looking, among other things, at irreparable harm, or  
16 alleged irreparable harm, and I would think in such  
17 situation, I'd probably have affidavits that told me how  
18 much money AstraZeneca is spending to these -- in  
19 furtherance of these, quote, "ongoing development  
20 efforts." There's none of that.

21           I mean, there's no -- the harm you're pointing  
22 to is, it's broadly, if not vaguely, stated. It's  
23 conclusorily stated. And I'm almost tempted to, you  
24 know, question, well, why that lack of supporting fact  
25 that I would expect to see in a preliminary injunction

1 proceeding isn't enough just to say, yeah, where's the  
2 harm? And did you meet your burden to establish a harm?

3 **MS. STETSON:** Two responses, Your Honor. The  
4 first is, we and the Government, with thanks to the  
5 Government, agreed not to light your busy docket on fire  
6 a few months ago. And we were able to negotiate and  
7 agree on this expedited posture precisely to avoid having  
8 to go through the rigmarole, for you and for us, of a  
9 preliminary injunction hearing.

10 So that's why we don't talk about it in terms  
11 of irreparable harm anymore. It was in our complaint, of  
12 course, because that was the first thing we filed. But  
13 we're past that juncture.

14 **THE COURT:** Wait, wait. We're past prelim- --  
15 You're still seeking permanent injunctive relief.

16 **MS. STETSON:** Yes.

17 **THE COURT:** Okay. So I still have to address  
18 irreparable harm under that, right?

19 **MS. STETSON:** Yes. So as to harm, I think  
20 what I would point you to, again, is the Ader  
21 declaration. We are, you know, it is difficult for us on  
22 a public record to talk about, you know, the amount of  
23 investment in a particular product, but our point is, our  
24 choices about investment are being damaged by the  
25 Government's statutory overreaches here.



1           And irreparable harm, you know -- or let's  
2 say, "harm," since we are past irreparable, it doesn't  
3 have to be for standing purposes much. It just has to be  
4 something.

5           So for these purposes, to the extent we're  
6 going to look at the monetary investment side, we  
7 shouldn't have to come in and say, you know, we're  
8 investigating X hundreds of millions of dollars in a  
9 particular line of research.

10           It should be enough to say we are making these  
11 choices because we are forced to make them based on the  
12 Government's statutory overreach.

13           **THE COURT:** Right. But the order that you've  
14 submitted me to sign calls for you -- calls for a  
15 permanent injunction.

16           It says, "The Court further orders that  
17 defendants and their officers, agents, servants,  
18 employees, and attorneys, and other persons who are in  
19 active concert or participation with the foregoing  
20 persons are permanently enjoined from implementing or  
21 enforcing the Drug Price Negotiation Program."

22           So, you know, you're asking for a permanent  
23 injunction, but nobody is telling me or offering me any  
24 ability to address a specific element of what you need to  
25 have to get a permanent injunction, which would be

1 irreparable harm.

2 **MS. STETSON:** So that is one form of the  
3 relief that we are seeking; you are right. And that's  
4 the broadest form of the relief that we're seeking.

5 And that, in a way, circles all the way back  
6 to the beginning of our conversation, which is, you know,  
7 if we are at the point where you are considering  
8 enjoining the implementation of the entire Drug Price  
9 Negotiation Program, we are at the point where we have  
10 registered a constitutional harm. And that is the harm  
11 that we would be talking about in that injunctive  
12 circumstance.

13 The other relief that we seek in that same  
14 proposed order is vacate the guidelines; vacate the  
15 guidelines, declare this interpretation of qualifying  
16 single source drug as beyond the statute, just as a plain  
17 legal matter. Declare the interpretation of "marketing"  
18 as bona fide --

19 **THE COURT:** Hold on. Sorry. I think you said  
20 the relief is I vacate the guidelines, but that's not the  
21 relief you've asked for. It's you want -- so you've got  
22 a declaratory judgment.

23 **MS. STETSON:** Yes.

24 **THE COURT:** Which is I would declare it  
25 unconstitutional, or I would declare the regulations to

1 be in violation of the APA. I get that, okay. And that  
2 is part of what the complaint seeks as relief. And I get  
3 how these summary judgment briefs tee up those issues. I  
4 get that. And I think there's enough for me to make some  
5 determinations about those and whether there's  
6 jurisdiction, right?

7 **MS. STETSON:** Right.

8 **THE COURT:** Okay. And from the Government's  
9 point of view, it would be -- I don't have the order in  
10 front of me, but I'd dismiss for lack of jurisdiction the  
11 whole complaint, right?

12 I assume is that what you're asking for? Is  
13 that in your order, sir?

14 **MR. NETTER:** It is, Your Honor, except we are  
15 asking for dismissal only on the APA claims.

16 **THE COURT:** And, actually, that's true. So it  
17 would be a partial dismissal. I would just get rid of  
18 Counts 1 and 2. So I just want to figure out the  
19 procedural posture of the case.

20 Because I think you all are assuming I'm going  
21 to rule and this is going up to the Third Circuit right  
22 away. But I don't know that you'd have a final order to  
23 go to the Third Circuit, even if I granted your side of  
24 the ledger is what I'm getting at. Because you are  
25 seeking an injunction, and I don't think you've really

1 teed that up issue up for me. And if you think  
2 otherwise, let me know.

3 I see where you've teed up the declaratory  
4 judgments that you are asking for. And so if I only  
5 ruled on the declaratory judgment action, assuming I  
6 ruled your way, so what then?

7 I mean, is the case still ongoing on the  
8 injunction, the injunction relief you've asked for? I  
9 mean, where does it stand procedurally?

10 **MS. STETSON:** I think there's probably a few  
11 different combinations and permutations --

12 **THE COURT:** Right.

13 **MS. STETSON:** -- of the answer. If you were  
14 to rule in our favor on -- meaning you would grant us  
15 summary judgment on our APA claims, but decline --

16 **THE COURT:** You keep saying that. So granting  
17 summary judgment, what do you mean, right? Summary  
18 judgment on what? I mean, summary judgment on a  
19 declaratory judgment? Summary judgment on a permanent  
20 injunction?

21 **MS. STETSON:** Summary judgment on a  
22 declaratory judgment with respect to the APA claims.

23 **THE COURT:** Okay. So let's say I issued an  
24 order, and I said that the APA -- or rather the QSSND  
25 is -- well, A, I would have to say I have jurisdiction;

1 B, the statute doesn't preclude judicial review; and, C,  
2 you prevail on Claim 1 insofar as it seeks a declaratory  
3 judgment.

4 All right. Let's say I stop there. What  
5 next?

6 **MS. STETSON:** If we prevail on Claim 1,  
7 insofar as it seeks a declaratory judgment, and you find  
8 that we haven't established sufficient harm to warrant an  
9 injunction --

10 **THE COURT:** Well, you haven't even -- where is  
11 any briefing on an irreparable harm?

12 **MS. STETSON:** I think the Ader declaration  
13 contains the best factual averments as to that. Because  
14 we, in terms of harm, what we are alleging is harm to our  
15 investment decisions. We are not meaning to quantify it  
16 in that respect.

17 **THE COURT:** Okay. So it goes back to  
18 unquantified investment decisions?

19 **MS. STETSON:** Yes.

20 **THE COURT:** Okay. But they're unquantified;  
21 you admit that?

22 **MS. STETSON:** I do, yes.

23 **THE COURT:** All right.

24 All right. Let's hear from the other side.

25 **THE COURT:** Actually, does the court reporter

1 want a break?

2 Let's take a break. We will come back in  
3 about eight minutes or so.

4 (Whereupon, a recess was taken.)

5 **THE COURT:** Please be seated. Before you  
6 start, I just want to do a follow-up question.

7 So the property interest is the patented  
8 product, right?

9 **MS. STETSON:** Correct, yes.

10 **THE COURT:** The patents, according to the  
11 declarations, expire '25, late '25 or 26; is that right?

12 **MS. STETSON:** The patents expire, yes. And I  
13 think --

14 **THE COURT:** So your property interest -- is it  
15 fair to say, then, as I understand your position, your  
16 property interest goes away when those patents expire  
17 sometime in '25, '26. Is that what you are saying?

18 **MS. STETSON:** I'm not going to go so far as to  
19 say that for two reasons, if I could.

20 The first is, you know, that puts us really  
21 between a rock and a hard place, because one of the  
22 things that the Government is saying is that we don't yet  
23 have standing to complain about our property interest  
24 being compromised.

25 And the second is, it's the patented product,

1 it's the drug product that we own. We're still going to  
2 own the product even if the patent goes away. And --

3 **THE COURT:** Well, then why did you say,  
4 "patented" if it's just the drug product.

5 **MS. STETSON:** Well, because, I think for -- as  
6 I mentioned, for a hundred years, the Supreme Court has  
7 said the patent, in particular, is also a separate  
8 property interest.

9 But I think it's -- if you think of it as the  
10 typical bundle, it's a bundle of interests. It's the  
11 patent. It's the product. It's the patented product.

12 If I could while I'm here.

13 **THE COURT:** Well, hold up. But see, now,  
14 there's an Orange Book, right, and there are lots of  
15 patents that are listed for this drug in the Orange Book  
16 that don't expire until way after 2026, right?

17 **MS. STETSON:** Yes, I believe that's correct.

18 **THE COURT:** And isn't the real property  
19 interest, it's the -- or what you are hoping will be a  
20 property interest is that you would be able to develop  
21 further exclusivity through new NDAs that would extend,  
22 or that would extend your exclusivity, and, in fact, as  
23 part of that, it's because you've -- right now you've  
24 said the only two patents or the patents at issue expire  
25 in '25, '26. What you are hoping to do is to develop new

1 uses of drug that might be covered by other patents in  
2 the Orange Book that would extend your exclusivity beyond  
3 2026.

4 **MS. STETSON:** I don't think that's an argument  
5 that we've made with respect to our property interest.

6 **THE COURT:** Well, isn't -- see, that's what  
7 confuses me, because I, again, I didn't hear, I didn't  
8 see in your briefs the argument you made at the outset  
9 about the property interest is, the value to negotiate  
10 this month or in the coming 30 days. I thought it was  
11 loss of economic incentive. And the loss of economic  
12 incentive is to go out and develop further exclusivity  
13 for the drug, isn't it?

14 **MS. STETSON:** I see. I see. So I think there  
15 are two different concepts. And if you think about them  
16 like a Venn diagram as I often do, maybe they overlap a  
17 little bit. When we talk about standing and we talk  
18 about harm, our harm is that set of circumstances we've  
19 talked about: \depravation\deprivation of information we  
20 need to negotiate right now. \depravation\deprivation of  
21 our incentive to further invest.

22 The property interest -- for purposes of our  
23 due process argument, our property interest is in the  
24 drug product, the drug product that we hold right now.

25 So it should not matter to this, you know,



1 property interest due process discussion whether or not  
2 there's going to be some point way down the road where we  
3 have a different bundle of property interests in Farxiga  
4 than what we hold right now. So standing and property  
5 interest, I think, are two slightly different concepts.

6 If I could make one more point just where we  
7 left off on the injunction issue, I want to make sure  
8 we're clear here. If you look at the end of our  
9 complaint, we ask for a declaration that the  
10 interpretation of "qualifying single source drug" is  
11 unlawful. We ask for a declaration that the  
12 interpretation of "bona fide marketing" is unlawful. We  
13 ask for -- and that's Sub C, I think, of our remedies --  
14 we ask for vacatur of the --

15 **THE COURT:** You ask for that in your  
16 complaint. You don't ask for that in your order for  
17 summary judgment, I don't believe, did you?

18 **MS. STETSON:** I think we do in the proposed  
19 order.

20 **THE COURT:** All right. Let me look at it  
21 because I didn't see it, so hold on. Oh, okay, "the  
22 guidance documents be set aside and vacated." Okay.

23 **MS. STETSON:** Yes. And that pertains to our  
24 administrative procedure claims. Then the injunction  
25 comes into play only if you declare the IRA

1 unconstitutional for due process reasons. And that  
2 injunction, just in an APA case, the injunction involves  
3 from that declaration of unlawfulness. There's no  
4 separate inquiry that has to occur. The injunction, as  
5 an administrative procedure matter, follows from that  
6 declaration. So that's what makes it a somewhat  
7 different animal, I think. But on the last point, I just  
8 wanted to tie that up in a knot before we left off.

9 **THE COURT:** I'm not sure that helps me  
10 understand things. The complaint seeks preliminary  
11 injunctive and permanent injunctive relief barring  
12 defendants from applying the drug pricing provisions of  
13 the IRA to AstraZeneca.

14 So, for instance, even if I agree with you on  
15 Claim 1 and Claim 2, but I disagree with you on  
16 Claim 3 -- well, wait.

17 **MS. STETSON:** Then we --

18 **THE COURT:** They're not moving to dismiss --  
19 see, they're not moving to dismiss Claim 3.

20 **MS. STETSON:** Correct, yes.

21 **THE COURT:** So --

22 **MS. STETSON:** So if you -- I'm sorry to  
23 interrupt.

24 **THE COURT:** No.

25 **MS. STETSON:** If you agree with us on Claim 1

1 and 2, that would mean that you would grant summary  
2 judgment for us on the administrative procedure claims.  
3 And the remedy that follows from that is the vacatur of  
4 the guidance.

5 **THE COURT:** Okay.

6 **MS. STETSON:** If you disagree with us on the  
7 due process argument --

8 **THE COURT:** Hold up. But I think you've  
9 already said if I agree with you on Claims 1 and Claim 2,  
10 you're saying I don't get to Claim 3.

11 **MS. STETSON:** I don't think you need to get to  
12 Claim 3. I think -- I think --

13 **THE COURT:** Okay.

14 **MS. STETSON:** I think then -- the work that  
15 the due process argument is doing -- this is what I was  
16 trying to articulate before -- there is almost an  
17 overarching constitutional violation here, that we get no  
18 comment on the front end, as I said, no discussion in the  
19 middle, no challenge on the back. But in our -- the way  
20 that we have narrowly targeted this case, that due  
21 process violation is pertinent to AstraZeneca right now  
22 because of what AstraZeneca is being asked to do right  
23 now.

24 So if you agree with us that the guidance is  
25 unlawful and should be vacated, I don't think you need to

1 reach that constitutional question. That's why we  
2 ordered it in the way that we did.

3 I think it's relevant to your thinking about  
4 this case to understand the highly unusual nature of it,  
5 but I don't think you need to get to it. And even if you  
6 do, at the end of the day, the only reason that  
7 injunction would come into play is actually if you agree  
8 with us that there's a due process violation.

9 So that's the permutation I mentioned earlier.  
10 You would have to disagree with us on both administrative  
11 procedure counts, agree with us on due process, declare  
12 the IRA unlawful because it does not permit sufficient  
13 process to the regulated entity, and then the injunction  
14 would flow from that. And I'm sorry to sidetrack us back  
15 again, but it felt like we left off on an unfinished  
16 note.

17 **THE COURT:** It's not finished in my mind, at  
18 least, even with this. So I give you the declaratory  
19 judgment you're seeking in Counts 1 and Count 2, I order  
20 the guidance documents to be set aside and vacated, and I  
21 don't address Count 3. All right.

22 **MS. STETSON:** Yes.

23 **THE COURT:** Because under your theory, I don't  
24 have to. And the Government is not moving to dismiss  
25 Count 3.

1           So you're saying I only issue an injunction if  
2 I get to Count 3. That's what you're saying?

3           **MS. STETSON:** Correct.

4           And I think what Mr. Netter would say if he  
5 were here is that they're not moving to dismiss Count 3,  
6 but they're moving for summary judgment on Count 3.  
7 They're not moving to dismiss on standing grounds, but  
8 they are moving for summary judgment. They have filed a  
9 cross-motion that seeks to dispose of all of the claims,  
10 two of them on standing or judicial preclusion grounds,  
11 one of them on its merits, the constitutional ground on  
12 its merits.

13           **THE COURT:** All right. So then your proposed  
14 order, you would actually revise it. I would just delete  
15 the paragraph that says, "The Court further orders that  
16 the defendants and their officers are permanently  
17 enjoined."

18           You would say, don't do that, if I agree with  
19 you and would sign the order of the first four  
20 paragraphs. Is that what you're saying?

21           **MS. STETSON:** I think you could, yes.

22           **THE COURT:** What do you mean I could? Of  
23 course, I could.

24           What do you want me to do?

25           **MS. STETSON:** I'm hedging. I'm hedging only

1 because of what I mentioned earlier.

2 For AstraZeneca's purposes, the due process,  
3 the immediacy of this entire procedure is what  
4 constitutes the due process violation. We, of course,  
5 had no opportunity to comment on this unlawful guidance.  
6 We're in the, as I said earlier, the tractor beam of this  
7 negotiation process.

8 **THE COURT:** So let me just ask you, if I set  
9 aside the guidelines, what happens next?

10 Do they need guidelines to -- do they have to  
11 have guidelines before they pick these ten drugs?

12 **MS. STETSON:** Yes.

13 **THE COURT:** They do.

14 **MS. STETSON:** The statute requires them to  
15 issue guidelines to implement the drug price negotiation  
16 process.

17 **THE COURT:** They cannot issue without  
18 guidelines. Okay. And then the guideline period, the  
19 review period is how long? Is that in the statute?

20 **MS. STETSON:** No. There's no review period, I  
21 think, set forth in the statute.

22 **THE COURT:** So they could issue guidelines an  
23 hour after I ruled that these guidelines are vacated?

24 **MS. STETSON:** They could, yes. And if the  
25 guidelines hued to the statute, we would have more of a

1 problem.

2 **THE COURT:** Okay. And let's say they issued  
3 the guidelines, and they said, oh -- because there's no  
4 other NDA for Farxiga, right?

5 **MS. STETSON:** There's no other NDA for Farxiga  
6 right now, yes.

7 **THE COURT:** Well, you've got the only clinical  
8 trials that you have that are ongoing according to the  
9 Ader declaration wouldn't impact the guidelines, right?  
10 It wouldn't have any impact on this case?

11 **MS. STETSON:** I think that's that distinction  
12 we were talking about earlier between focusing on the  
13 clinical trial stage and focusing on the development  
14 stage.

15 **THE COURT:** But let's focus on the clinical.  
16 The clinical trial is the last stage of a development,  
17 right?

18 **MS. STETSON:** Correct.

19 **THE COURT:** So if you've got no ongoing  
20 clinical trials and I were to vacate the guidelines  
21 tomorrow, all right, and an hour later after I issued my  
22 opinion, they tweaked something about the guidelines.  
23 And let's say they said, oh, yeah, the drug has to be  
24 limited to a single NDA. You win Claim 1. Let's say  
25 they said it.

1           **MS. STETSON:** Right.

2           **THE COURT:** All right. Farxiga falls under  
3 that; they only have one NDA. So you could be picked an  
4 hour after I issue my ruling.

5           **MS. STETSON:** That would be the Government's  
6 argument, yes.

7           **THE COURT:** Well --

8           **MS. STETSON:** The Government's argument is  
9 Farxiga is already in there.

10          **THE COURT:** Actually, can you disagree with  
11 that argument?

12          **MS. STETSON:** If we're in this counter-factual  
13 world where the guidance hues to the statute, then I  
14 don't think I could disagree with the argument. The  
15 reason we're --

16          **THE COURT:** Well, okay. And don't you admit  
17 that -- I mean, under your reading of the statute, the  
18 drug has to be limited to a single NDA, right?

19          **MS. STETSON:** Yes.

20          **THE COURT:** Okay. And Farxiga, undisputedly,  
21 is limited to a single NDA, right?

22          **MS. STETSON:** Yes.

23          **THE COURT:** All right. So I issue my order  
24 tomorrow. AstraZeneca, that Stetson, she's amazing, she  
25 persuaded me, I'm good. For claim 1, she wins, DJ on



1 that count. I'm going to vacate the guidance on that  
2 part of it.

3 And an hour later, they switch the guidance to  
4 say, yep, it's got to be a single NDA; Farxiga you are  
5 still on the list. Right?

6 **MS. STETSON:** I think that would be a rare  
7 thing, indeed, for the Government --

8 **THE COURT:** To move that quick.

9 **MS. STETSON:** -- to issue guidance the  
10 following day.

11 **THE COURT:** But they could. So doesn't that  
12 show you're not harmed? There's no harm for Claim 1 for  
13 you.

14 **MS. STETSON:** I don't think that's accurate.  
15 I think the fact that harm could be remedied at some  
16 point after the fact is a completely different issue.  
17 But we are harmed right now because of the unlawful  
18 interpretation right now.

19 If the Government were to do that, and let's,  
20 you know, put aside the fact that, you know, as you and I  
21 talked about a while ago, the Government is taking five  
22 months even to explain why it set the prices where it is.  
23 But let's assume the government comes back the day after  
24 tomorrow and says, here's new guidance that's completely  
25 in concert with the law. There's nothing to see here.

1 If we were to come back at that point and file another  
2 lawsuit making the same allegations, we wouldn't have  
3 standing because, for these purposes, the statute, you  
4 know, we fit the statute, and the statute, you know, the  
5 guidance doesn't go beyond the statute.

6 But that's a -- I mean, talk about  
7 speculation. That's a future-looking set of  
8 circumstances that might diminish some future allegation  
9 of harm. It has no bearing on the current set of  
10 circumstances. It's the -- I don't want to say, as  
11 lawyers often do, that's just a hypothetical, but, you  
12 know, our present circumstances are that the guidance is  
13 unlawful in two different ways for the same reason, they  
14 go outside the statute.

15 **THE COURT:** Right.

16 **MS. STETSON:** And Farxiga is subject to that  
17 unlawful interpretation because of all of that work that  
18 we need to do around value and investment that we've  
19 talked about.

20 **THE COURT:** Okay. Thank you.

21 **MS. STETSON:** Thank you, Your Honor.

22 **THE COURT:** Let me hear from the other side.  
23 Good morning.

24 **MR. NETTER:** It is still the morning. Good  
25 morning, Your Honor. May it please the Court, my name is

1 Brian Netter. I am counsel for the defendants in this  
2 case.

3 We have a slide deck that we have put on the  
4 screen. I have hard copies here if I may approach.

5 **THE COURT:** Please. Thank you.

6 Go ahead.

7 **MR. NETTER:** Your Honor, Congress adopted the  
8 negotiation program as part of the Inflation Reduction  
9 Act, to curb runaway spending caused by a small number of  
10 drugs reimbursed by Medicare. Under the terms of  
11 statute, ten drugs were selected as part of initial price  
12 applicability, year 2026. And all ten of those drugs are  
13 involved in one way or another in a pending lawsuit  
14 seeking to upend the implementation of this program.

15 **THE COURT:** Can you tell me what the status of  
16 the cases are?

17 Like, in other words, the timing you expect of  
18 decisions. Has anybody else had an early summary  
19 judgment motion like this teed up before them?

20 **MR. NETTER:** So there are other case that have  
21 fully briefed summary judgment motions. This is the  
22 first hearing in a summary judgment case.

23 **THE COURT:** Does anybody else have a target  
24 date like I do, that the parties asked for a target date?

25 **MR. NETTER:** I don't believe that there is a

1 target date as soon as this Court's target date.

2 **THE COURT:** Why was it set in this case?

3 **MR. NETTER:** Excuse me, Your Honor?

4 **THE COURT:** Why this case?

5 **MR. NETTER:** I think that that's probably a  
6 better question directed to the plaintiffs, in terms of  
7 why they think an answer needs to be given within the  
8 next month. We don't share that assessment.

9 **THE COURT:** I got that. But I don't know  
10 who -- it was presented to me as a stipulation from both  
11 sides, so I don't know how it got there how and how it  
12 ended up or what began the discussions that led to it.

13 So, I guess I can ask them. But you're  
14 telling me that none of the other cases have a target  
15 date of March 1st?

16 **MR. NETTER:** That's correct, Your Honor.

17 **THE COURT:** Let me just ask you this, just  
18 procedurally, too.

19 I assume you all had discussions back and  
20 forth to figure out how to frame this for summary  
21 judgment; is that right?

22 **MR. NETTER:** Discussions with --

23 **THE COURT:** With the other side, AstraZeneca.

24 **MR. NETTER:** Yes, Your Honor.

25 **THE COURT:** All right. Did you guys talk

1 about standing before the briefing started?

2 **MR. NETTER:** Your Honor, I was not involved in  
3 such conversations. I don't believe that we had  
4 substantive conversations about the arguments the parties  
5 would be making.

6 The nature of the discussions was to decide to  
7 do this in a cross-motion format with four briefs.

8 **THE COURT:** Okay. All right. Go ahead.

9 **MR. NETTER:** So as the Court is well aware,  
10 the issues that have been laid before the parties here  
11 are standing, the statutory bar on judicial review, and  
12 the merits issues, and we have slides that walk us  
13 through these issues. Of course happy to jump around,  
14 should the Court prefer.

15 But to begin with standing, I think the  
16 critical point, which the Court was just alluding to, is  
17 that AstraZeneca's claims here have no bearing on  
18 Farxiga's status as a selected drug for price  
19 applicability year 2026. Even were they to prevail on  
20 their legal theories as to the definition of a qualifying  
21 single source drug or as to the rule pertaining to when a  
22 generic is going to result in a drug being deselected,  
23 they still would be part of the program now. All of the  
24 facts are potentially future facts that we would deem to  
25 be speculative.

1           And that's critical because we're here at  
2 summary judgment and, as the Court knows under *Lujan*, the  
3 plaintiff's burden to establish standing rises with the  
4 level of the case, and at summary judgment, they need to  
5 come forward with actual facts, not mere allegations, not  
6 mere speculation, actual concrete facts. And the facts  
7 that have been presented in the Ader declaration and are,  
8 in our view, far too thin and far too speculative to  
9 support an exercise of this Court's jurisdiction as to  
10 the APA claims that the plaintiffs have presented before  
11 the Court.

12           Now, in your colloquy with counsel for the  
13 plaintiffs, I think you already looked here at  
14 Paragraph 23, where AstraZeneca acknowledges that there  
15 are no clinical trials currently involving the same  
16 active moiety as Farxiga. And that's notable, not just  
17 because they acknowledge here that, at most, there are  
18 ongoing drug development efforts that are in a  
19 preclinical phase, but in Paragraph 7 of this same  
20 declaration, Mr. Ader acknowledges that the likelihood  
21 that a drug in preclinical testing or a product in  
22 preclinical testing is actually going to result in an  
23 approved drug product is 1 in 5000.

24           So speaking from a standpoint of speculation,  
25 if there is a 1 in 5000 chance that a product in

1 preclinical investigation is actually going to be  
2 approved, that can't be the basis for the Court to enter  
3 imminently a ruling on whether these rules are actually  
4 applicable.

5 Now, the governing standard here comes from  
6 *Clapper v. Amnesty International*, and that was a case in  
7 which the plaintiffs came to the Court and said, We  
8 anticipate that in the future we're going to withstand an  
9 injury, and as a result of that future expectation, we're  
10 going to take prophylactic steps now. We're going to  
11 introduce antisurveillance protocols that are going to  
12 cost us money now because we think in the future we're  
13 going to be surveilled under this program.

14 The Court rejected -- the Supreme Court  
15 rejected that theory of standing, finding that it was not  
16 certainly impending that Amnesty International would  
17 actually be subject to the surveillance that it feared  
18 and that, as a result, any cost that they incurred in the  
19 present day were simply self-inflicted wounds. And that,  
20 in our view, is the circumstance here, too. That in  
21 order for AstraZeneca to be able to say to the Court that  
22 they're experiencing injury now as a result of their  
23 expectation of how the guidance might be applied in the  
24 future, and I should pause to note that the guidance that  
25 we're here discussing is only the guidance for this first

1 year of the program. There's going to be new guidance  
2 issued for the subsequent, the ensuing two years, that  
3 aren't presently before the Court. But even with respect  
4 to --

5 **THE COURT:** But this guidance applies for a  
6 three-year period.

7 **MR. NETTER:** No. This guidance -- well,  
8 insofar as it covers through 2026, yes.

9 **THE COURT:** Well, but -- so you disagree that  
10 it also sets the price for '27 and '28?

11 **MR. NETTER:** It sets the price, Your Honor,  
12 yes, but there will be new guidance for initial price  
13 applicability year 2027.

14 **THE COURT:** And you're saying that that  
15 guidance could address things like what happens if a  
16 generic emerges on the market January 2, 2026?

17 **MR. NETTER:** Yes, Your Honor.

18 In terms of the time, I should note also that  
19 many of the timing considerations about when a  
20 determination has to be made by the agency and when that  
21 determination has an effect on the price for the drug,  
22 those are baked into the statute. So those -- you can't  
23 have an APA claim as to the nature on the statute,  
24 obviously.

25 So the fact that there is an eight-month delay



1 or nine-month delay, between when the agency makes a  
2 determination that there is a bona fide marketing of a  
3 generic, and when that actually affects the pricing,  
4 that's baked into the statute. That's not a matter of --

5 **THE COURT:** Right. But is there anything  
6 baked in the statute that would -- and I think the answer  
7 is no -- but that would require you to address, within a  
8 certain amount of time after January 2, 2026, the fact  
9 that there's a generic on the market?

10 **MR. NETTER:** So I don't believe that's in the  
11 statute, Your Honor, but there is a provision in the  
12 revised guidance, I think I flagged here, that indicates  
13 that the agency is going to review the market data on a  
14 monthly basis. So the suggestion that we don't know how  
15 often they're going to look at the data or what the cycle  
16 that's going to be, is inaccurate.

17 **THE COURT:** So your point -- go ahead and look  
18 for it and give it to us. But while you're looking for  
19 it.

20 So are you saying, then, that if, in fact, on  
21 January 2, 2026, the generics came on the market with  
22 more than de minimis market, they met the bona fide  
23 definition, right, that -- are you saying within one  
24 month of that you would have to do the 12-month  
25 retrospective data analysis is that what you're saying?

1           **MR. NETTER:** Yes, Your Honor.

2           **THE COURT:** Okay.

3           **MR. NETTER:** The 12-month period, that's just  
4 identifying the window of data that --

5           **THE COURT:** Right.

6           **MR. NETTER:** -- CMS is going to look at.  
7 Right? It doesn't say you need to wait for a year. And  
8 I think that that is to the benefit of the drug  
9 companies. Right?

10           **THE COURT:** Because your point would be it  
11 doesn't have to include times when the generics were on  
12 the market.

13           **MR. NETTER:** Correct.

14           **THE COURT:** In fact, if -- within 30 days, is  
15 it, you say you have to conduct this analysis?

16           **MR. NETTER:** That's Page 165 of the revised  
17 guidance.

18           **THE COURT:** All right. So is this a factual  
19 dispute that would preclude summary judgment?

20           **MR. NETTER:** I don't think so, Your Honor. I  
21 don't believe there is any other factual information in  
22 the record as to the cycle on which the data are going to  
23 be reviewed. But in any event --

24           **THE COURT:** Hold on. I want to make this  
25 clear.

1           So to the extent you all differ -- because,  
2           for instance, there is some differences on, you know, the  
3           length of time that will pass, right, before a remedy. I  
4           think there's one instance where I think you say 30 days,  
5           they say 11 months. Maybe it's this issue in your  
6           briefing, where you address this.

7           But you would say that's not a factual  
8           dispute; that's interpreting the guidance, which is a  
9           legal dispute I can make. Is that right?

10           **MR. NETTER:** That's right, Your Honor. And I  
11           would refer the Court to Page 166 of the revised  
12           guidance, which has a pretty helpful chart about when,  
13           you know, various determinations would have the real  
14           world effect in terms of deselection or the price, the  
15           negotiated price no longer applying as to a specific  
16           drug.

17           **THE COURT:** Okay.

18           **MR. NETTER:** But I don't want to get us too  
19           far off target with respect to the core standing  
20           question, which is whether there is a certainly impending  
21           injury that stems from what exists right now, the facts  
22           that are in the record right now.

23           And with respect to the definition of  
24           "qualifying single source drug," all that AstraZeneca has  
25           put into the record is the possibility there's some

1 unidentified ongoing drug development efforts that they  
2 don't even say that drug development efforts would result  
3 in a different NDA. They say only that it could result  
4 in the product being treated as the same QSSD as Farxiga,  
5 which, now, it would also be the case if their  
6 investigation resulted in a product that were approved  
7 under the existing NDA.

8 So from our standpoint, the factual record  
9 here is so sparse that it can't support an exercise of  
10 the Court's jurisdiction under the summary judgment  
11 standard.

12 Likewise, with respect to "bona fide  
13 marketing." The Ader declaration identifies that there  
14 are 17 generic versions of Farxiga that have received  
15 tentative approval, and that, in AstraZeneca's views, are  
16 poised to enter the market.

17 Now, in order for AstraZeneca to be able to  
18 obtain standing on the basis, they would have to  
19 establish that the bona fide marketing standard wouldn't  
20 matter. And if are 17 generic versions sitting on the  
21 sidelines waiting for the exclusivity periods to end,  
22 then AstraZeneca has to establish that the delta, that  
23 there's some difference in the pricing of Farxiga that is  
24 going to result from the bona fide marketing standard.

25 So what I think that means is that, of these

1 17 generics, they would have to establish that at least  
2 one of them is going to make it to market, but that all  
3 17 of them are not going to be on the market and marketed  
4 in a bona fide manner such that the difference between  
5 whether their drug is selected or not hinges on the  
6 interpretation of the bona fide marketing standard that  
7 has been adopted in the revised guidance.

8           There certainly doesn't seem to be any facts  
9 in the record to establish that that standard is met.  
10 And as the Court acknowledged, it's AstraZeneca that has  
11 all the factual information about any agreements that  
12 they may have with the generic companies, any agreements  
13 they may have to delay market entry, to partition the  
14 market in some way. Such agreement may or may not be  
15 appropriate or lawful under the antitrust laws. But  
16 insofar as the thrust of claim here, is that AstraZeneca  
17 is seeking this Court's preapproval for what I think we  
18 would call "gamesmanship" to engage in some sort of an  
19 agreement with a generic manufacturer so that it would be  
20 nominally marketed, but not marketed in a bona fide sense.

21           Any facts that they would like to put before  
22 the Court, those are in AstraZeneca's possession. The  
23 facts they introduced here, the existence of 17 generic  
24 versions, does not suggest that the bona fide marketing  
25 standard is going to be implicated.

1           Now, the plaintiffs in their brief say, well,  
2 this established that the bona fide marketing standard  
3 certified going to be applied. On Page 8 of their  
4 opposition reply brief, they say they, "soon will be  
5 subject to the unlawful bona fide marketing test."

6           But the standard for standing is not whether a  
7 party is subject to the law; it's whether it's injured by  
8 the law. And that's where there is the absence of  
9 evidence here.

10           Now, it didn't come up in Ms. Stetson's  
11 presentation, but there are a few paragraphs in the Ader  
12 declaration that speak to other drugs too. There's a  
13 drug other than Calquence that's mentioned in the briefs.  
14 It may only being Calquence that's mentioned here in the  
15 Ader declaration.

16           We think all the questions, all the issues  
17 with this being speculative, not knowing whether a drug  
18 is going to be selected, not knowing whether there's  
19 going to be this issue with multiple NDA, they haven't  
20 established the factual predicate for any of this. And  
21 as a result, we think the easiest way for the Court to  
22 resolve the APA claims is just to identify the lack of  
23 factual support as a basis for granting summary judgment  
24 under the standing.

25           **THE COURT:** All right. So let me ask you

1 that, you know, I asked this to Ms. Stetson.

2 So you think the easy way is Article 3, not  
3 the statutory provisions that address judicial review?

4 **MR. NETTER:** So, Your Honor, I said that, and  
5 I immediately regretted it because I do think that the  
6 bar on statutory reviews is an extremely straightforward  
7 way to resolve the case, and I don't want to suggest  
8 otherwise.

9 It so happens here that we think the factual  
10 record is so sparse that an opinion could be written  
11 quite easily to say it's the plaintiffs burden. They  
12 haven't identified why these issues need a decision right  
13 now such that this would be, effectively, an advisory  
14 opinion.

15 I agree with Ms. Stetson's answer that the  
16 Court could, in its discretion, decide either of these  
17 threshold issue first because they are both of a judicial  
18 character.

19 **THE COURT:** Okay. And then, let's just -- I  
20 want you to go to the statutory argument, but before you  
21 do, I want to just flesh this out. I try to be practical  
22 about things, and let's just say.

23 So let's say I went either under Article 3 or  
24 under the statute and said, I don't have jurisdiction  
25 under Claims 1 and 2, so they are dismissed, right?

1           **MR. NETTER:** Yes, Your Honor.

2           **THE COURT:** And then you are not moving to  
3 dismiss Claim 3?

4           **MR. NETTER:** That's correct, Your Honor. We  
5 don't have standing or jurisdictional bar arguments as to  
6 Claim 3.

7           **THE COURT:** Right. Are you asking for summary  
8 judgment, though, on Claim 3?

9           **MR. NETTER:** We are.

10          **THE COURT:** Right. And so you do anticipate  
11 that there will be a final judgment.

12           I mean, isn't that -- because what I'm getting  
13 at is, you guys reached this stipulation.

14           Was it your expectation that I would issue a  
15 judgment that would be final? Because, in other words,  
16 your thought is, if I dispose of this either in favor of  
17 AstraZeneca or in favor of you, or even if I, I don't  
18 know, come up with some partial thing, there will be a  
19 final judgment that will be subject to appeal? Is that  
20 your understanding?

21          **MR. NETTER:** That is our expectation, Your  
22 Honor. There's always the theoretical possibility that  
23 the Court could find that we are in this middle space  
24 where a trial needs to be held on some factual issues. I  
25 don't think we are in a place where there is an actual



1 dispute of material fact such that there can't be a  
2 determination.

3 **THE COURT:** Well, I mean, you go -- you made  
4 this point. I mean, it's summary judgment. The burden  
5 is on them to put forth facts that would be sufficient to  
6 establish harm that would give rise to jurisdiction.  
7 Right?

8 **MR. NETTER:** That's right, Your Honor.

9 **THE COURT:** Yeah. So, I mean, they had their  
10 chance. So I'm not going to allow for -- you're saying  
11 we don't need further opportunity to -- we don't need a  
12 trial on that.

13 **MR. NETTER:** Right. The only reason that we  
14 would need a trial was if we disputed Mr. Ader's  
15 assertion that there are drugs in the predevelopment  
16 phase that use the same active moiety as Farxiga. That's  
17 a matter that could require a trial. But we're not  
18 disputing those facts.

19 So the question is whether the factual record  
20 that the plaintiffs have introduced, whether that's  
21 sufficient to invoke the Court's jurisdiction.

22 **THE COURT:** All right. And then what do you  
23 do with all this injunctive -- the fact that they've  
24 asked for, though, an injunction in their order. What  
25 does that -- what do you think about that?

1           **MR. NETTER:** So we certainly agree, Your  
2 Honor, that an injunction is a remedy that invokes the  
3 Court's equitable authority. And in order to invoke that  
4 authority, the party seeking the injunction has an  
5 obligation to demonstrate that the equities are in their  
6 favor. And the lack of factual support for those  
7 equities is rather telling. Now, we don't --

8           **THE COURT:** Factual support. There's no legal  
9 argument from either of you, right? I mean, nobody says  
10 here are the four prongs of an injunction and weigh the  
11 public interest or engage in this. I don't think. Was  
12 that in the briefs?

13           **MR. NETTER:** It wasn't, Your Honor. And I  
14 think, in part, that's because as strategic matter or  
15 however, most of the briefing in this case focuses on the  
16 APA claims.

17                       Sometimes claims end up at the end of the  
18 brief, and they don't get the same amount of development  
19 as a result of -- there are strategic reasons why things  
20 end up at the end of the brief.

21                       We certainly think, though, that the Court, as  
22 an exercise of its authority, would have an obligation to  
23 consider the equities before entering an injunction,  
24 certainly in a public law context like this.

25           **THE COURT:** All right. But what I take from

1 your comments is that both sides want and expect a final  
2 judgment to be issued by me that would be subject to an  
3 immediate appeal, correct?

4 **MR. NETTER:** That's correct, Your Honor. I  
5 think we differ as to how urgent we think the Court needs  
6 to rule, but insofar as this being the end of the case,  
7 we both agree with that.

8 **THE COURT:** Okay. So, just to flesh that out,  
9 in other words, the only one who's asked for the March 1  
10 target date is AstraZeneca?

11 **MR. NETTER:** Right. We agreed to brief the  
12 case so as to facilitate that schedule. We're not asking  
13 for a March 1 date.

14 **THE COURT:** Right. Okay. Is everybody else;  
15 i.e., the other -- I don't know if there's nine  
16 pharmaceutical companies. But for the other nine drugs,  
17 that those pharmaceutical companies, they're all involved  
18 in litigation with you right now; is that right?

19 **MR. NETTER:** So either the pharmaceutical  
20 companies, themselves, are involved in litigation or, as  
21 was the case in the *Dayton area Chamber* case, there's a  
22 case brought by Pharma, the industry group also. They  
23 are claiming, as members, the other manufacturers and  
24 relying upon injuries to the drugs for their assertions  
25 of standing.

1           **THE COURT:** Okay. And is the timing exactly  
2 the same for all of the other pharmaceutical companies?  
3 In other words, their counteroffer is due March 1st; is  
4 that right?

5           **MR. NETTER:** Yes. The schedule is the same  
6 for all ten drugs.

7           **THE COURT:** But nobody else is asking a Court  
8 to issue an opinion before March 1st?

9           **MR. NETTER:** I'll look at my team here again.

10          **MS. SNYDER:** No. We had one PI in one of the  
11 other cases, but otherwise, no.

12          **THE COURT:** Was that the Ohio case, the PI?

13          **MS. SNYDER:** Yes.

14          **THE COURT:** Right.

15          **MS. SNYDER:** And the PI was denied --

16          **THE COURT:** Right. Okay.

17          **MR. NETTER:** Right. We'll talk about that  
18 later. That was limited to the due process issue. And  
19 in that case, the chamber asked for a ruling before the  
20 negotiation process would even begin, before the  
21 negotiation agreements would need to be signed.

22                 But this seems as good a time as any for us to  
23 move on to the statutory bar on judicial review.

24                 So I put the statute up here. This is  
25 codified at 1320f-7, and the critical language here in

1 subsection 2 says that "There shall be no be  
2 administrative or judicial review as to the selection of  
3 drugs under F1B, the determination of negotiation  
4 eligible drugs under F1D, and the determination of  
5 qualifying single source drugs under F1E."

6 Now, the plaintiffs seem to take it for  
7 granted that the definition of the words "selection" and  
8 "determination" are so narrow that they are only  
9 referring to the things selected or what is determined.  
10 So I just wanted to start by quickly putting on the  
11 screen actual dictionary definitions. And I'll zoom in  
12 on the critical part here. This is the American Heritage  
13 dictionary, but the Oxford English dictionary has the  
14 equivalent definition.

15 So "determination" means either the  
16 ascertaining or the result of the ascertaining, either  
17 the act of making and arriving at the decision or the  
18 decision that's reached. Same thing for "selection."

19 "Selection" means either the act of selecting  
20 something or what is actually selected.

21 So if we put the statutory bar on judicial  
22 review back up here, the determination, the act of  
23 identifying the qualifying single source drugs under  
24 Section 1320f-1(e), that's precisely what the plaintiffs  
25 are seeking to challenge here.

1           Now, Ms. Stetson discussed with the Court the  
2 Third Circuit's decision in the *Dohou* case. I think she  
3 said, "Dohou," so I'll go with her pronunciation. It's  
4 D-O-H-O-U. That's a 2020 decision. And they included in  
5 their little booklet here, one of the statutes that was  
6 at issue in that case.

7           That's 8 U.S.C. Section 1252(a)(2)(A). So I  
8 think it's important to put that case into context. So  
9 in the immigration world, there are various circumstances  
10 in which, when the relevant agency makes a determination  
11 that a noncitizen is subject to removal and enters a  
12 removal order, sometimes that's immediately reviewable  
13 and sometimes it isn't immediately reviewable.

14           And the issue before the Court in *Dohou* was  
15 whether a removal that was within the category of  
16 8 U.S.C. Section 1252(a)(2)(C) was subject to a  
17 collateral attack in a subsequent criminal prosecution  
18 for an individual who failed to willfully -- who  
19 willfully failed to depart after being subject to an  
20 immigration removal order.

21           So what's important here is that 8 U.S.C.  
22 Section 1252(b)(7) says expressly that you haven't had a  
23 chance to challenge your removal order already, you can  
24 file a motion in the criminal case that collaterally  
25 attacks the removal order as part of the explanation for

1 why you shouldn't be criminally liable for willfully  
2 failing to depart the country.

3 So the Court was comparing two different  
4 subprovisions of 8 U.S.C. 1252(a)(2). Now, the one that  
5 Ms. Stetson put in the book here says, "No Court shall  
6 have jurisdiction to review or to entertain any other  
7 cause or claim arising from or relating to the  
8 implementation or operation of an order of removal that  
9 is subject to" the conditions set forth there.

10 By contrast, the provision that was an issue  
11 in *Dohou* said only, "No Court shall have jurisdiction to  
12 review any final order of removal."

13 So what the Third Circuit said in *Dohou* was,  
14 Congress has told us that you can't have immediate  
15 judicial review of the order of removal under the  
16 circumstances, but they haven't said that you can't have  
17 a collateral attack on the order of removal when the  
18 noncitizen is subsequently prosecuted for willful failure  
19 to depart.

20 And the distinction between two subsections,  
21 between 1252(a)(2)(C) and 1252(a)(2)(A) is so stark that  
22 it identifies the fact that 1252(a)(2)(A) was intended to  
23 bar, not just initial judicial review, but any future  
24 claim that could be based on the fact of that removal  
25 order.

1           So the dichotomy between (a) (2) (C) and  
2           (a) (2) (A) is what was at issue there. There's obviously  
3           nothing similar to that here.

4           Rather, I want to mention, also, one of the  
5           other cases that the plaintiffs invoked. And this was  
6           the decision of D.C. Circuit in *American Clinical*  
7           *Laboratory Association versus Azar* from 2019. This was a  
8           case that the plaintiffs described as perhaps most  
9           closely resembling the claims that they raise here.

10           And in the *American Clinical Laboratory*  
11           *Association* case, the Court did indeed find that a  
12           judicial preclusion bar did not cover the claims in that  
13           case. There was a judicial preclusion bar that covered  
14           pricing, like the actual amount that was being determined  
15           by the agency, and the lawsuit was challenging data  
16           collection.

17           And in order to find that data collection was  
18           not part of pricing, the Court noted that the data  
19           collection procedures were laid out in a totally  
20           different part of the law from the pricing, and the data  
21           collection procedures themselves were subject to their  
22           own notice and comment procedure that was particular only  
23           to the data collection proceedings, and that a specific  
24           notice and comment procedure is suggestive of their being  
25           judicial review, because that's ordinarily why notice and



1 comment would be required.

2 That's obviously not the case here. All of  
3 the text that we are looking at is within f-1(c), (d) and  
4 (e). They're the provisions that -- sorry -- f-1(b), (d)  
5 and (e), the provisions that Congress has identified as  
6 being part of the judicial bar.

7 **THE COURT:** What's left to review by the  
8 courts as far as the implementation of this program under  
9 your reading of 1320f-7?

10 **MR. NETTER:** So I don't think we can survey  
11 the scene, but the answer may be not much. And I think  
12 that that's fine because Congress has the authority to  
13 determine the jurisdiction of Federal District Courts  
14 with respect to statutory claims. And there's good  
15 reason when Congress --

16 **THE COURT:** Well, when you say, "district  
17 courts," what about just Federal? I mean, this is not  
18 limited to district courts, right? This is judicial  
19 review, period, right?

20 **MR. NETTER:** Oh, absolutely. I was just  
21 trying to separate off --

22 **THE COURT:** Well, listen. Do they have the  
23 authority to preclude the Supreme Court?

24 **MR. NETTER:** Yes, with respect to statutory  
25 claims, certainly.

1           **THE COURT:** Okay.

2           **MR. NETTER:** And, you know, Congress -- it's  
3 sensible for Congress to have precluded judicial review  
4 as to key aspects of this program, because, otherwise, it  
5 would be very difficult for the program to launch. And  
6 we see that from the existence of all these lawsuits  
7 filed trying to challenge every aspect of program.

8           **THE COURT:** Right. But, you know, let's say  
9 you have an agency that promulgated guidance, which is  
10 just absolutely clearly inconsistent and contradicts, not  
11 just inconsistent, contradicts the explicit statutory  
12 text. All right?

13                   For argument's sake, let's say I agree on the  
14 merits with the first claim. All right? That the  
15 language referring to the date of approval makes clear  
16 that you can only have a drug qualify as a QSSND --is  
17 that right? Yeah. QSS --

18           **MR. NETTER:** No N.

19           **THE COURT:** No N. QSSD. Can only qualify if  
20 there's a single NDA. All right?

21                   So CMS comes along, promulgates this guidance,  
22 and when can that possibly be reviewed?

23           **MR. NETTER:** Well, it wouldn't be, Your Honor,  
24 and that is Congress's determination, that the frame of  
25 analysis here is not to determine whether the agency has

1 made a mistake and then to figure out some way to review  
2 it. Right?

3 The first question is, does Congress permit  
4 the Court to review this question.

5 **THE COURT:** Right.

6 **MR. NETTER:** Now, there may be circumstances  
7 where the ultra vires standard comes into play if an  
8 agency is doing something that is so far beyond the scope  
9 of the statute.

10 **THE COURT:** Let's say this is. I read the  
11 statute. It's clear as a bell. I'm not saying it is  
12 clear as a bell by any stretch. But there's language,  
13 though, clearly in 1320f-1(e)(1)(A) which refers to the  
14 date of such approval. So it's singular date, singular  
15 approval. That says to me, there's a single approval.  
16 There's one. And it's talking about a drug. Right?  
17 That's defining a drug that would -- or the drug products  
18 that would be subject to this.

19 So let's just say I agree with AstraZeneca on  
20 that. When would a drug company be able to challenge  
21 your designation of its blockbuster product? Let's say  
22 it only makes one product. When can it do that?

23 **MR. NETTER:** So it wouldn't be able to, Your  
24 Honor.

25 **THE COURT:** Ever?

1           **MR. NETTER:** Ever? Well, unless they could  
2 try to convince Congress to change the statutory bar.  
3 But it's Congress' prerogative.

4           **THE COURT:** That doesn't bother you, that you  
5 could have -- again, imagine it was, again, that there  
6 was no other ambiguity in the statute to shed doubt on  
7 AstraZeneca's interpretation.

8           So you're saying that an agency can come along  
9 and can issue a regulation that absolutely contradicts  
10 the explicit statutory text of Congress? And here -- and  
11 you're saying, tough noogies, there's no review?

12           **MR. NETTER:** That is the outcome of the  
13 standard analysis on judicial bars. Now, were it the  
14 case that the judicial preclusion bar were implicit,  
15 that's where the ultra vires discussion could take place.  
16 But here, it is explicit that Congress didn't want there  
17 to be review of the determination of what constitutes a  
18 qualifying single source drug.

19           And if the agency is interpreting it wrong,  
20 well, Congress had the authority to give the agency this  
21 power and Congress has the authority to wrest that power  
22 back. And I --

23           **THE COURT:** I guess -- I thought you might  
24 tell me that, well, there's going to be in the future  
25 some period to review it, but you're not going there.

1           **MR. NETTER:** No. This is not a judicial  
2 review provision.

3           **THE COURT:** For instance, maybe if AstraZeneca  
4 decided, you know what, we're going to take the risk. We  
5 will go get a second NDA.

6           Would they be able to challenge it if they had  
7 two NDAs that covered this drug?

8           **MR. NETTER:** Well, that would take away the  
9 standing issue; that would not remove the bar on judicial  
10 review.

11          **THE COURT:** It would not.

12          **MR. NETTER:** That also would arise in the  
13 subsequent period where there could be different  
14 governing guidance. That certainly wouldn't be --

15          **THE COURT:** No, I agree.

16          **MR. NETTER:** Right.

17          **THE COURT:** I just want to make sure, your  
18 point, so what you're saying is if they did decide if  
19 they didn't have Ader's declaration and they had another  
20 declaration which said, you know, we've got these  
21 clinical trials, we're ready to go, we're about to go  
22 seek a new NDA, but your point would be, no, doesn't  
23 matter, you can get the second NDA; you can never  
24 challenge this in the courts. That's right, right?

25          **MR. NETTER:** That's correct, Your Honor. And

1 I would refer the Court to the Second Circuit's recent  
2 decision in *Yale New Haven Hospital versus Becerra*.

3 Because that was a situation in which the Court thought  
4 that the -- what was being challenged was a few steps  
5 removed from what was covered in the statute.

6 The plaintiffs were trying to challenge the  
7 rule-making procedures that would set the policies that  
8 would result in an estimate. And the statute said there  
9 was a bar on judicial review of any estimate.

10 And the court's conclusion was it didn't  
11 matter that this was, you know, a procedural challenge as  
12 to the mode of administrative process, and it didn't  
13 matter that it was as to the procedure, even though the  
14 procedure was going to lead to the estimate.

15 They described the distinction as nearly  
16 metaphysical as between these two steps. And I think  
17 that's the case here, that if this judicial preclusion  
18 provision were interpreted so as not to cover plaintiff's  
19 challenges, then it would convert the judicial bar, the  
20 judicial review bar into a creative or artful pleading  
21 standard. Whereas all of the precedents in this space  
22 say that both the plain language, which we think plainly  
23 covers their claims here as to Claims 1 and 2, also,  
24 steps that are inextricably linked with the plain text  
25 here. And at a very minimum, the process for

1 determining, you know, how one counts drugs or what  
2 marketed means, that is all bound up in the ultimate  
3 determinations of what constitutes a qualifying single  
4 source drug.

5 **THE COURT:** All right. Give me a second.

6 **MR. NETTER:** Your Honor, while we are  
7 transitioning to the merits of this case, my colleagues  
8 just noted that the plaintiffs in the *Chamber* case in  
9 Ohio did ask for an order by a specific date on  
10 dispositive motions, but the Court denied that request.

11 **THE COURT:** Clearly a smarter judge than I,  
12 I'll say that.

13 Just give me a second.

14 Okay. Now, your motion, your proposed order  
15 says, "Upon consideration of the parties' cross-motions,  
16 it is hereby ordered plaintiff's Motion for Summary  
17 Judgment is denied, and it's further ordered that  
18 defendant's cross-motion for Summary Judgment is  
19 granted."

20 And in your motion, you just say, "We move for  
21 summary judgment on all claims."

22 So what's the judgment you're seeking on  
23 Claim 3? How would the judgment read on Claim 3?

24 **MR. NETTER:** We're just seeking judgment on  
25 the merits. So we are seeking a determination that

1 plaintiff's claim fails as a matter of law. We don't  
2 think there are any facts that play into that decision.

3 And the conclusion section of our brief  
4 probably describes the relief that we are seeking more  
5 precisely.

6 **THE COURT:** Where is it? So which brief, the  
7 opening brief? The memorandum of law and support?

8 **MR. NETTER:** I think that's what I'm referring  
9 to.

10 **THE COURT:** D.I. 22?

11 **MR. NETTER:** Memorandum Support is ECF 21-1.

12 **THE COURT:** Yeah. So you dismiss -- you say  
13 you want to enter judgment for defendants on Count 3.

14 **MR. NETTER:** Right.

15 **THE COURT:** All right. So then -- but, you  
16 know, so they're seeking a declaration that the IRA's  
17 drug price control program is, therefore,  
18 unconstitutional under the Fifth Amendment, should be  
19 enjoined.

20 All right. Now, is it as applied? I mean,  
21 what am I supposed to declare? That's what I'm trying to  
22 understand, and what judgment am I entering? I'm  
23 supposed to say that the law is constitutional?

24 I mean, I think, generally, we don't issue  
25 judgments like that. You know, we say that the plaintiff



1 failed to establish that the law was unconstitutional,  
2 right? What's the judgment you're looking for?

3 **MR. NETTER:** So, Your Honor, we think of this  
4 as a facial challenge to which *Salerno* would apply. And  
5 the plaintiffs burden has established that there's no set  
6 of circumstances in which the law would be kept  
7 constitutional. Because there isn't a price at the end  
8 of day, they don't know what the price is going to be,  
9 such that the procedural claims are, in a sense, unripe.

10 So the judgment that we would ask the Court to  
11 enter would say that the plaintiffs have not met their  
12 burden to establish a facial constitutional violation,  
13 and as a result the defendants are entitled to judgment  
14 as a matter of law.

15 I would note also --

16 **THE COURT:** Give me a second.

17 **MR. NETTER:** Sorry, Your Honor.

18 **THE COURT:** All right. So you just think the  
19 order should say, judgment entered in your favor on  
20 Count 3.

21 **MR. NETTER:** Yes, Your Honor.

22 **THE COURT:** And by the way, why don't you  
23 address this. Well, what do you think the -- what's  
24 your -- and I know I'm putting you kind of in their  
25 shoes, but what do you understand their property interest

1 to be?

2 **MR. NETTER:** We struggled with this question  
3 also, Your Honor. It sounds to us like they are saying  
4 they have a right to enter into contracts to sell their  
5 products to the Government on the terms that they want.  
6 That is the thrust of their claim. The suggestion that  
7 they have a patent interest doesn't make sense, because  
8 we aren't seizing the patent. We aren't demanding they  
9 sell products to us under the patent. This is a  
10 voluntary program. They get to choose whether they want  
11 to sell Farxiga to Medicare beneficiaries or they don't.

12 So, you know, we think what they are trying to  
13 say is that they want this commercial relationship to  
14 occur under terms that they think are suitable for them,  
15 but that's not a basis on which any Court, to our  
16 knowledge, has ever found there to be a protected  
17 property interest.

18 And so long as we are discussing due process,  
19 the --

20 **THE COURT:** Wait. Hold on. And then, you  
21 know, you do have a lot of takings cases. What's your  
22 response to, oh, well, they're not due process cases;  
23 they're takings cases?

24 **MR. NETTER:** So this issue came up in the  
25 *Chamber* case also. And what we said there and what I'll

1 say here is that the due process clause and the takings  
2 clause are adjacent in the Fifth Amendment, and they both  
3 have the same predicate, which is the government can't  
4 deprive an individual of a protected property interest  
5 unless certain steps are followed.

6 So the cases about due process and the cases  
7 about takings, they refer to each other. For these  
8 purposes, right, there are places where the clauses  
9 diverge. For purposes of determining whether there is a  
10 protected -- a property interest that has constitutional  
11 protection, those standards are coextensive and have been  
12 understood as such by the case law.

13 **THE COURT:** All right. Go ahead. You want to  
14 address something?

15 **MR. NETTER:** So I was going to note before we  
16 move on that I just don't want to leave the impression  
17 with the Court that we think that any review of anything  
18 happening under this program is barred by the judicial  
19 preclusion provision.

20 **THE COURT:** Oh, so you're going to change your  
21 answer, then, is what you're saying?

22 **MR. NETTER:** No, I'm not. I'm not. It's just  
23 that the statutory claims are precluded. And that means  
24 that, of all the cases we have been briefing in this  
25 space, there have been two cases where we've raised a

1 statutory bar defense. A lot of other cases raise other  
2 constitutional claims as part of their challenges, and  
3 those aren't circumstances where we think the  
4 constitutional claims are barred.

5 **THE COURT:** Those other two cases are part of  
6 the ten, of the nine or ten?

7 **MR. NETTER:** Right, yes. So most of cases  
8 don't have --

9 **THE COURT:** Well, that's weird because I  
10 thought -- we'll go back. I'll have to look at the  
11 transcript.

12 I thought I kind of invited you to tell me  
13 when you would have judicial review, and I thought you  
14 said, "There is none."

15 **MR. NETTER:** As to statutory claims. So the  
16 claims that are being raised in the other cases are  
17 things like excessive fines, Eighth Amendment claims, the  
18 due process claim that exists here.

19 So the constitutional challenges can proceed,  
20 but the challenges to the mechanics of the statutory  
21 operation, that's what Congress barred from review.

22 **THE COURT:** Okay.

23 **MR. NETTER:** So let's move on to the merits,  
24 the definition of "qualifying single source drug."

25 Now, Ms. Stetson already walked through the

1 how the statutes connect, but there's one point that I  
2 want to clarify. So we start here with 1320f-1(e)(1),  
3 which incorporates the definition of a covered Part D  
4 drug in 1395w-102. And the definition of a covered  
5 Part D drug under 1395w-102 says, "A drug that may be  
6 dispensed only upon a prescription and that is described  
7 in Subparagraph (a)(1), (a)(2), or (a)(3) of  
8 Section 1396r-8(k)(2) of this title."

9 And I am specifically focusing on the text  
10 that applies to drugs as opposed biologics; it's all  
11 parallel, though.

12 So then she led you to r-8(k)(2), which says  
13 that the drug has to be dispensed only upon prescription,  
14 and that it has to be approved for safety and  
15 effectiveness.

16 But then after that, she read a different  
17 provision of r-8(k); it was r-8(k)(7). That was a  
18 definition for single source drug under the Medicaid  
19 statute.

20 **THE COURT:** Yeah, I lost her. My questions, I  
21 think, pointed out I kind of lost that connection.

22 **MR. NETTER:** Precisely. Congress didn't  
23 incorporate that definition into the IRA. So even if  
24 that, you know, leant some clarity to the question of  
25 what constitutes a drug for the purposes of the

1 definition of qualifying single source drug, Congress did  
2 not incorporate r-8(k) (7). So if any inference is to be  
3 drawn from r-8(k) (7), it's that Congress did not want  
4 that to be a part of the IRA.

5 Instead, we think there are a couple of other  
6 statutory provisions that are a part of the IRA that are  
7 probative here. The first one the Court referenced,  
8 that -- and identifying the data the agency is supposed  
9 to consider, it refers to applications and approvals,  
10 plural, pertaining to a drug, singular.

11 **THE COURT:** Go back on that.

12 **MR. NETTER:** Yeah.

13 **THE COURT:** You know that they've got an  
14 explanation for this; it's supplemental. Supplemental  
15 applications, which the code allows for, right?

16 **MR. NETTER:** The code does allow for  
17 supplemental applications.

18 **THE COURT:** And they're different than new  
19 drug applications?

20 **MR. NETTER:** They are. Right. I don't want  
21 to suggest that this provision in and of itself is  
22 completely dispositive and airtight. I think, if  
23 anything, the next provision I'm going to put on the  
24 screen explains more as to why we think that the  
25 definition adopted by the agency is appropriate here.

1           **THE COURT:** Right.

2           **MR. NETTER:** And that's f-1(d) (3) (B), which  
3 says that, "In identifying the data, the secretary shall  
4 use data that is aggregated across dosage forms and  
5 strengths of the drug, including new formulations of the  
6 drug."

7                       Now, this is significant because there is  
8 long-standing agency guidance -- this is dated  
9 December 2004. And the guidance for industry says that  
10 different dosage forms should be submitted in separate  
11 original applications unless the products are identical,  
12 in the case of drugs, in a quantitative and qualitative  
13 composition.

14           **THE COURT:** Right, but that happens all the  
15 time.

16           **MR. NETTER:** So I don't think that it happens  
17 with respect to, for example, you know, necessarily. You  
18 know, our understanding is that it is commonplace, that  
19 commonly, immediate and extended-release formulations are  
20 submitted in distinct applications because they wouldn't  
21 satisfy the standard of being identical and quantitative  
22 and qualitative compositions.

23           **THE COURT:** Wait, wait. What did you just  
24 say? Sorry?

25           **MR. NETTER:** So what I said is that extended

1 and immediate-release formulations are commonly submitted  
2 in distinct applications. So they have separate NDAs.

3 **THE COURT:** Okay. So they're commonly, but  
4 aren't there NDA that cover multiple dosages? I think I  
5 see them all the time.

6 **MR. NETTER:** They could cover multiple  
7 dosages. That's not uncommon.

8 **THE COURT:** Okay.

9 **MR. NETTER:** What we're talking about are  
10 different formulations, one of which has immediate  
11 release, and one of which is extended release.

12 **THE COURT:** But this is not -- the language  
13 you are focusing on is not limited to different  
14 formulations. And it's not so limited, in fact, that the  
15 clause that follows that's not highlighted, "including  
16 new formulations," and "such as an extended-release  
17 formulation" would suggest that they're -- this is much  
18 broader.

19 **MR. NETTER:** So here's how we interpret this,  
20 Your Honor. You know, because this says the secretary  
21 has to aggregate data across dosage forms and strengths,  
22 including across an extended-release formulation, and  
23 given that extended-release formulations are commonly  
24 submitted in different NDAs --

25 **THE COURT:** But they're commonly; they're not



1 required to be, right?

2 **MR. NETTER:** Well, I'm not sure that's  
3 correct. And I don't want to stand up hearing offering  
4 chemical -- or pharmacological expertise. But the  
5 long-standing guidance is that dosage forms should be  
6 submitted in separate original applications unless the  
7 products are identical in quantitative and qualitative  
8 composition.

9 And just intuitively, the way that a drug  
10 product, you know, has a release period that extended as  
11 opposed to immediate is, there necessarily has to be some  
12 difference there. Right? So we identified in Footnote 7  
13 of our opening brief circumstances in which the  
14 extended-release formulations are submitted in distinct  
15 NDAs. The record doesn't contain any counter-example.

16 So if it is the case, which we think it is,  
17 that extended-release formulations are commonly -- and  
18 there are no counter-examples that we have before the  
19 Court -- submitted in separate NDAs, then Congress's  
20 directive to aggregate data, including extended-release  
21 formulations, necessarily means that Congress anticipated  
22 aggregating across -- excuse me -- across NDAs, so long  
23 as the same active moiety is involved.

24 **THE COURT:** Does this raise a factual issue?  
25 Because they dispute it. They say, you know, they don't

1 agree with you on this.

2 **MR. NETTER:** Well, they don't agree with the  
3 legal interpretation. They didn't introduce any facts.

4 **THE COURT:** Well, no, but you said "commonly."  
5 This is commonly done before the FDA. That sounds like a  
6 fact, factual assertion.

7 **MR. NETTER:** So the legal source here, Your  
8 Honor, which I think we can presume that Congress is  
9 aware of, is this requirement that different dosage forms  
10 be submitted in separate original applications unless  
11 they're identical.

12 **THE COURT:** So I've got to tell you, I've had  
13 ANDA cases where experts dispute what guidance means.  
14 It's guidance. It's not mandatory.

15 Is this really a legal determination for me to  
16 make?

17 **MR. NETTER:** So I don't think it's a legal  
18 determination, Your Honor. I think that the Court can  
19 draw the inference that because of the common industry  
20 practice --

21 **THE COURT:** But, again, that's a fact, isn't  
22 it? What the common industry practice is, is a fact.  
23 And it sounds like you guys disagree about it.

24 Is this something that is a material fact that  
25 precludes summary judgment?

1           **MR. NETTER:** So I don't understand there to be  
2 any evidence in the record from the plaintiffs as to  
3 whether it's commonplace for extended-release  
4 formulations to be introduced under the same new drug  
5 application.

6           **THE COURT:** Well, there's none from you  
7 either.

8           **MR. NETTER:** No, we do -- we do cite, in  
9 footnote 7, the examples, and we offered into the record  
10 also this guidance for industry.

11           In any event, the relevance of this is the  
12 inference that it wouldn't have been sensible for  
13 Congress to direct the secretary to aggregate across  
14 dosage forms, including extended release formulations, if  
15 those extended release formulations arise under a  
16 different new drug application.

17           And I think, also, if we take a step back and  
18 look to the purpose of the statute more broadly, that a  
19 lot of the record here is concerns about product hopping,  
20 about the gamesmanship that results in periods of  
21 exclusivity stretching out and having unchecked prices  
22 being paid by Medicare as a result. And provisions like  
23 this are responsive to that concern.

24           Adopting an interpretation of the statute that  
25 requires -- that would effectively turn the drug maker's

1 decision on whether to submit something as a separate new  
2 drug application is having consequences for pricing, I  
3 think that would be surprisingly inconsistent with the  
4 nature of the statute.

5 And I wanted to move on, also, because the  
6 plaintiffs suggested in their briefing that the  
7 government previously had a different interpretation as  
8 to the relationship between the meaning of "drug" and the  
9 existence of multiple new drugs applications. And they  
10 cited a D.C., district court, decision in a case called  
11 *Ipsen Biopharmaceuticals*.

12 Now we, in our final brief in this sequence,  
13 indicated that we thought that they were misinterpreting  
14 what happened in that case. But I wanted to put up on  
15 the screen here -- this is from the joint appendix in  
16 that case, which is part of the record. This is what CMS  
17 actually said. They said, while Section 1927(k)(2) --  
18 that's 1396r-8(k)(2) in the codified version -- while  
19 that defines a covered outpatient drug based on FDA  
20 approval, we find no indication that Congress intended  
21 that FDA approval status be used for determining whether  
22 a drug qualifies as a new drug for purposes -- for the  
23 Medicaid pricing purposes that were at issue in that  
24 case.

25 So the interpretation that the agency

1 adopted -- let's see -- this stamped 2017. I think the  
2 letter is actually 2016. You know, before the Inflation  
3 Reduction Act was adopted, it's entirely consistent with  
4 the agency's approach here, which we certainly think is  
5 significant.

6 I do want to address, also, the part of the  
7 statute that the Court questioned Ms. Stetson about.

8 **THE COURT:** The date, right?

9 **MR. NETTER:** Right.

10 **THE COURT:** Yeah.

11 **MR. NETTER:** And the date of approval is  
12 addressed in the revised guidance in Section 30.1. And  
13 the way that the agency has construed the statute is the  
14 date of approval means the date at which the drug, as a  
15 unit, encompassing all of its products, was approved, the  
16 first date at which it was approved.

17 Now, the counterargument, I suppose, is, well,  
18 there could be multiple dates. But there could be  
19 multiple dates if there are grants of a supplemental NDA  
20 also. So in any circumstance, there has to be a relevant  
21 date. And the date of approval, the date that the drug  
22 was approved is the first date that a drug containing  
23 that active moiety was approved. And that seems to us  
24 perfectly sensible and consistent with the other  
25 provisions of the statute.

1           Unless the Court has further questions on that  
2 issue, I would move on to the bona fide marketing  
3 standard. So I'll throw the text up here. This says  
4 that a drug that is not the listed drug for any drug that  
5 is approved and marketed under Section 355J of such  
6 title -- that's referring to the ANDA process.

7           So I alluded to this earlier, and I think we  
8 should be clear on what effectively is being asked of the  
9 Court here. The plaintiffs are asking for what we would  
10 describe as an advisory opinion that they can engage in  
11 transactions with the generic manufacturers that will  
12 result in a drug being offered in some de minimis  
13 capacity such that it's nominally available for sale  
14 somewhere, but not truly marketed as the way that anybody  
15 would understand that concept in the real world.

16           They say that if Congress had intended to mean  
17 real marketing, they would have added that qualifier. I  
18 think that that instinct, that intuition is inconsistent  
19 with the way the law ordinarily functions. There are  
20 plenty of circumstances in which courts will disregard  
21 transactions that have no bona fide purpose. The sham  
22 transaction doctrine in the tax context. Here in  
23 Delaware, there's a whole body of law as to when one can  
24 breach the corporate veil because there is, effectively,  
25 a sham relationship between a parent and a subsidiary.

1 There's also the sham affidavit rule that applies with  
2 respect to summary judgment.

3 Now, I think that Ms. Stetson -- I think I  
4 heard her say that she would have been more comforted if  
5 the words "de minimis" applied in the guidance. So I do  
6 want to highlight --

7 **THE COURT:** They're both, you know,  
8 italicized, de minimis, bona fide. I don't find that  
9 argument compelling. I mean, just for what it's worth, I  
10 just don't. But go ahead.

11 I mean, I do want to be a little bit mindful  
12 of time, so -- but go ahead.

13 **MR. NETTER:** Of course, Your Honor. I just  
14 wanted to refer to the fact --

15 **THE COURT:** Not your argument. I meant I  
16 don't find their argument compelling. In other words,  
17 what I'm trying to say is if you put the words in de  
18 minimis, you put as opposed to bona fide, I mean, you  
19 know, they're qualifiers of what marketing means, to  
20 bring clarity to what is meant by "marketed."

21 **MR. NETTER:** Right. Entirely agreed, Your  
22 Honor. And I would just refer the Court to Page 72 of  
23 the revised guidance, which says that the alternative,  
24 the opposite of having a bona fide marketing standard is  
25 permitting, quote, "a token or de minimis amount of

1 generic drug to be allowed."

2 **THE COURT:** Right. All right. Thank you. So  
3 it's actually in there is what you're saying.

4 **MR. NETTER:** Exactly.

5 **THE COURT:** Gotcha.

6 **MR. NETTER:** So I think that leaves only the  
7 due process claim, which we touched on briefly. I would  
8 put up here just this quote from the Supreme Court in  
9 *American Manufacturers Mutual Insurance Company v.*  
10 *Sullivan*, that the first inquiry in every due process  
11 challenge is whether the plaintiff has been deprived of a  
12 protected interest in property or liberty.

13 Our reading of their arguments is that they're  
14 basically skipping that step. They are assuming that  
15 there's been this \depravation\deprivation and then are  
16 complaining about the processes that are required once  
17 there has been a \depravation\deprivation of a protected  
18 property interest.

19 Because we don't believe that to be the case,  
20 we find that to be dispositive of their due process.

21 **THE COURT:** I mean, it's somewhat funny,  
22 right? I mean, on one level you can say, well, really  
23 they're arguing a liberty interest, their freedom to  
24 contract. But they want total freedom, where they have  
25 all information, including information in the future.



1                   **MR. NETTER:** Yes, Your Honor.

2                   And your Honor alluded earlier to defense  
3 contractors, and that feels like an apt comparison here  
4 because there are plenty of defense contractors who would  
5 like to have greater control about the military products  
6 that they're selling to the United States Government.  
7 And one can only imagine the chaos that would result from  
8 applying a due process standard there instead of treating  
9 these as market transactions where the parties can decide  
10 either they want to transact with the United States in  
11 this commercial manner or that they don't.

12                   Now, the plaintiffs try to suggest that this  
13 isn't just an ordinary market transaction because  
14 Medicare and the United States is such a big player in  
15 the market, but --

16                   **THE COURT:** They are the only player in the  
17 defense market.

18                   **MR. NETTER:** Only player in the defense  
19 market. Absolutely.

20                   But there are plenty of cases out there that  
21 say that Medicare and Medicaid are voluntary, despite the  
22 fact that these programs are so essential. There are  
23 Eighth Circuit cases that talk about both nursing homes,  
24 which are obviously dependent on Medicare and Medicaid,  
25 and hospice facilities, which are obviously dependent on

1 Medicare and Medicaid.

2 In those contexts, the courts have said this  
3 is still a voluntary program for purposes of the law.  
4 And that's why, in the Chamber case, the Court said the  
5 law established in the Sixth Circuit and beyond is clear.  
6 Participation in Medicare, no matter how vital it may be  
7 to a business model, is a completely voluntary choice.

8 The plaintiffs tried to invoke the NFIB  
9 decision, and I think that Ms. Stetson anticipated what  
10 our response to that would be, which is, *NFIB*, by its  
11 terms, is speaking to the relationship among  
12 counterparts' sovereignty, not about commercial  
13 transactions in which one party can say yes or say no.  
14 There is such a robust body of case law establishing the  
15 voluntariness of Medicare and Medicaid that that seems to  
16 us entirely dispositive.

17 **THE COURT:** None of the penalties that they  
18 deem coercive affect the price that they can sell to a  
19 private citizen or anybody other than Medicare, right?

20 **MR. NETTER:** That's correct, Your Honor. They  
21 are not obligated to sell to Medicare. They can  
22 withdraw, they can divest the drug. There are things  
23 that they can do. And they can always sell to private  
24 parties on whatever terms they want.

25 **THE COURT:** Or foreign governments.

1           **MR. NETTER:** Or foreign governments. I don't  
2 want to speak to --

3           **THE COURT:** Although the price might be lower  
4 if they sell to a foreign government.

5           Let me ask you a couple of things. There's a  
6 disagreement, it appears, between how quick you can  
7 withdraw, whether it's 30 months or 11 months. Can  
8 you -- and you guys, the Government, says it's one month.

9           Can you just direct me to where -- what's the  
10 support for that position.

11           **MR. NETTER:** So that position is within the  
12 revised guidance. And maybe one of my colleagues can  
13 find the page number in the revised guidance that says  
14 that.

15           **THE COURT:** While they're looking for that,  
16 let me give you another question I have.

17           You know, you brought up this idea of product  
18 hopping, right?

19           Is there anything that you can point me to in  
20 the statute or -- I don't generally resort to legislative  
21 history, but in the legislative history -- suggesting or  
22 indicating or confirming that Congress was aware of that  
23 and that that's part of what it was trying to accomplish  
24 here in restraining such agreements?

25           **MR. NETTER:** Your Honor, this isn't a

1 circumstance in which all the purposes of the statute are  
2 laid out in the statutory provision.

3 **THE COURT:** Right.

4 **MR. NETTER:** So I think that it would require  
5 a resort to the legislative process.

6 **THE COURT:** Okay.

7 **MR. NETTER:** But, also, just the -- what is in  
8 the ether. The public discussion about the need for this  
9 law.

10 **THE COURT:** Right. And you both resort to  
11 that. You both do this, you refer me to websites and  
12 whatnot that talk about various things to support your  
13 policy positions. All right?

14 When does CMS, when will it release guidance  
15 for 2027?

16 **MR. NETTER:** That's a fair question, Your  
17 Honor. I don't recall -- my colleague from HHS may have  
18 the precise date over there.

19 **THE COURT:** It's required to release the  
20 guidance by a date certain, is that right under the  
21 statute or not?

22 **MR. NETTER:** So the statute requires the  
23 agency to operate by program guidance for the first three  
24 years of the program. So we do construe that as  
25 obligating the agency to issue guidance prior to the

1 start of the next negotiation cycle.

2 As to what the precise date certain is for  
3 issuance of that guidance, I don't have that offhand.

4 **THE COURT:** But your understanding is the  
5 requirement is that the guidance must be issued prior to  
6 the beginning of the negotiation cycle.

7 So you would say the 2027 guidance has to be  
8 issued before the negotiation period for that year, 2027,  
9 not when the year begins, but rather when the negotiation  
10 for that period begins.

11 **MR. NETTER:** Right. Right. That would be the  
12 guidance that will govern that initial price  
13 applicability, Your Honor.

14 So that guidance has to be issued prior to  
15 when the drugs are selected because the guidance, as  
16 before the Court right now, dictates the rules that the  
17 agency's going to follow to identify which drugs get  
18 selected.

19 **THE COURT:** All right.

20 **MR. NETTER:** Your Honor, we may not have  
21 identified where the 30-day period exists. We could make  
22 a supplemental filing that directs the Court to the  
23 particular cite.

24 I think the thrust of that dispute is that the  
25 statute says that the secretary can -- direct withdraw

1 within 30 days upon good cause shown. And the revised  
2 guidance defines "good cause shown" to say, well, if you  
3 want to get out of this program because you don't want to  
4 participate in the negotiation, that's good cause shown.

5 The plaintiffs are effectively saying, at this  
6 more generous interpretation that the agency has adopted,  
7 that it wouldn't be their interpretation. As a result,  
8 it isn't governing. But I don't think that they have  
9 standing to say that the Government has done something  
10 that is too much in their favor.

11 Just like that, here it is. I believe this is  
12 going to be on Page 34 of the revised guidance.

13 **THE COURT:** Page 34 of the revised guidance?

14 **MR. NETTER:** Yes.

15 **THE COURT:** Okay. Now, do you dispute whether  
16 AstraZeneca would be harmed if, on January 2, 2026,  
17 generics enter the market?

18 **MR. NETTER:** We would dispute that because  
19 their challenge is as to the bona fide marketing  
20 standard. So they would have to demonstrate not just  
21 that the generics entered the market, but that the  
22 presence of the bona fide marketing standard dictated  
23 whether Farxiga remained a selected drug that was subject  
24 to the maximum fair price. Right? So it's one step  
25 further from that.

1           **THE COURT:** I guess what I'm getting at is,  
2 well, let's assume it was bona fide. Let's assume, as a  
3 factual matter, on January 2, 2026, 17 generics began  
4 bona fide marketing of generic drug products. Do you  
5 dispute that for the remainder of that year they would be  
6 harmed? "They" being AstraZeneca. Excuse me. That it  
7 would be harmed.

8           **MR. NETTER:** Yes, Your Honor, we do dispute  
9 that. Because the harm that they would suffer there  
10 would be harm coming from the statute.

11           **THE COURT:** That's my point is, you don't  
12 dispute that they'd be harmed in the sense that, yeah,  
13 they'd have competition, but the point is, it's not  
14 attributable to the statute is what you would say.

15           **MR. NETTER:** Right. So their legal claim,  
16 they wouldn't have injury that is traceable to their  
17 legal claim.

18           **THE COURT:** Right.

19           **MR. NETTER:** They would be objecting to the  
20 statute, but that's not one of the claims they have.

21           **THE COURT:** Right. But they would be having  
22 to sell to Medicaid at a price that private people  
23 wouldn't tolerate on the market for the remainder of that  
24 year, right?

25           **MR. NETTER:** Potentially.

1           **THE COURT:** Right. And your point would be,  
2 goes back to my point, I think, earlier on, is,  
3 Government contracts all the time, agree way ahead in  
4 advance to certain prices in the future. So I'm a  
5 defense contractor. I agree to build certain planes.  
6 I'm going to sell them to you five years from now --  
7 takes a long time to build these planes -- at a certain  
8 price. Titanium goes up a hundred percent the next year,  
9 tough luck for the defense contractor. It's not going to  
10 make as much money as it anticipated it would have when  
11 it sells, consummates a sale five years from day.

12           **MR. NETTER:** Correct.

13           **THE COURT:** I kind of think in Joe 6-pack-type  
14 terms, right. I mean, that's, when you really boil it  
15 down to it, isn't that their position, is, I mean -- or  
16 it's not their position, but it's the reality is that  
17 folks contract with the Government all the time for a  
18 future price.

19           **MR. NETTER:** Yes. And in this context, that's  
20 perfectly sensible because insurance plans are going to  
21 be contracting with drug formularies. And all of the  
22 contracts that depend on the pricing of particular drug  
23 products that are downstream, those can't be updated on a  
24 day-to-day basis is either. So it's perfectly sensible  
25 for the price to be fixed for one price applicability



1 year, and then, you know, potentially to be changed in  
2 the subsequent year.

3 **THE COURT:** All right. Anything else?

4 **MR. NETTER:** No, Your Honor.

5 **THE COURT:** All right. Thank you.

6 All right. Briefly here, AstraZeneca. Just  
7 very brief. Just rebuttal. Go ahead.

8 **MS. STETSON:** Thank you, Your Honor. I am  
9 mindful of the 12:30.

10 **THE COURT:** Well, don't. You don't have 25  
11 minutes. No.

12 **MS. STETSON:** I understand.

13 **THE COURT:** You need to go. I said that was  
14 the absolute latest.

15 **MS. STETSON:** I won't need it. I have one  
16 point, essentially, on each of the points of discussion.

17 The first thing is on standing. I actually  
18 would encourage you to look closely at *Clapper* if you  
19 haven't already. So that was a circumstance where the  
20 plaintiffs were coming in and saying, we might talk to  
21 people who might be wiretapped pursuant to one of several  
22 programs, and that particular wiretapping program we had  
23 problems with.

24 The Court found that that kind of cascade of  
25 possibilities was simply too remote to establish

1 standing. Here, we have a drug that has been selected  
2 for this program, that the piano has already falling on  
3 us. This is not a piano might fall someday. We have a  
4 drug that has been selected for this program. We have to  
5 operate, you know -- unlike your government contractor  
6 example where the government contractor wasn't having to  
7 operate with legally flawed definitions that governed its  
8 ability to negotiate, we have having to value something  
9 right now, taking into account the fact that the  
10 Government has way overstepped its legal authority with  
11 respect to the guidance. That kind of immediacy is what  
12 grounds the standing here.

13 I want to make one more point that the bona  
14 fide marketing standing in particular, I thought I heard  
15 Mr. Netter say that there was something in the guidance  
16 that suggested that the Government would take care of the  
17 question about whether something was bona fide marketed  
18 within 30 days. The guidance, it's Page 165, of the  
19 revised guidance, and I think Page 62 of the initial  
20 guidance. The guidance says, every 30 days CMS will take  
21 a look at bona fide marketing, but remember what you and  
22 I talked about earlier. It is going to be looking at 12  
23 months of data. And unless Mr. Netter is prepared to say  
24 that the 12 months of data proceeding an entry of generic  
25 on the market is going to suffice for their determination

1 about whether a generic would be robustly and  
2 meaningfully marketed, that delay is what is causing the  
3 harm.

4 This is not an advisory opinion about whether  
5 something is or is not going to be subjected to de  
6 minimis marketing. This is the delay that is occasioned  
7 by the Government saying we're going to look at 12 months  
8 of data about this marketing and then decide whether to  
9 let you out of the program.

10 Point three. The judicial review ban. The  
11 fact that Mr. Netter put those competing dictionary  
12 definitions -- it could mean -- selection could mean  
13 this; it could mean this -- I think, is exactly the  
14 problem with their argument. You begin, when you talk  
15 about a preclusion of judicial review, with the strong  
16 presumption, as the Supreme Court has said, that there is  
17 judicial review.

18 And what the Supreme Court has also said in  
19 the *Gutierrez de Martinez* case, 510 US at 434. This is  
20 cited in the *American Clinical Laboratories* case. If the  
21 judicial review provision is reasonably susceptible to  
22 two competing interpretations, then you rule in favor of  
23 the traditional understanding that administrative actions  
24 are subject to judicial review. And as you pointed out,  
25 this is not --

1           **THE COURT:** Well, wait. Let's do this.

2           **MS. STETSON:** Sure.

3           **THE COURT:** Let's assume you're right about  
4 that. Let's take "selection." Go under either  
5 definition of "selection." How would it make a  
6 difference in this case?

7           **MS. STETSON:** I think it would make a  
8 difference in this case, because we're not -- as I  
9 mentioned earlier, we are not contesting the selection of  
10 Farxiga for negotiation. We're not saying, oh, we  
11 shouldn't have been in the top ten list because our  
12 revenues are actually X versus Y.

13                   What we are contesting is the definition of  
14 "qualifying single source drug," which is -- and I  
15 encourage you to look at the cases that provide against  
16 judicial review. That is a completely different animal  
17 than the cases that hold against judicial review,  
18 including *American Clinical Laboratories Association*,  
19 which turns on the question of the definition of  
20 "laboratory."

21           **THE COURT:** All right. Well, let's hold on.  
22 How would the determination of qualifying single source  
23 drugs go under either determination definition that was  
24 put up on the screen?

25           **MS. STETSON:** That would be my point.

1           **THE COURT:** Explain the two. Like why that  
2 difference? Which determination, first of all, do you  
3 want? Which definition that he gave?

4           **MS. STETSON:** We would like the definition of  
5 qualifying single source drug --

6           **THE COURT:** No, no, the definition of  
7 "determination."

8           **MS. STETSON:** Oh, determination.

9           **THE COURT:** Isn't that what you just said?  
10 You said that's what -- that's what he was pointing out.  
11 That's what you took issue with. So which definition of  
12 "determination" does AstraZeneca want me to use for the  
13 statute?

14           **MS. STETSON:** I'm going to answer that in  
15 two -- I'm going to answer your question and then  
16 explain.

17                         We want the narrower definition.

18           **THE COURT:** Which is what?

19           **MS. STETSON:** Which is the act of decision,  
20 the deciding. We want --

21           **THE COURT:** The determining?

22           **MS. STETSON:** Determining. Yes, the  
23 determination.

24           **THE COURT:** The determining.

25           **MS. STETSON:** Yes. The determination.

1           **THE COURT:** All right. We'll using use "the  
2 determining." So you're saying that it's not the fact  
3 that Farxiga was determined. You are saying it was the  
4 determination, the process of determining Farxiga. How  
5 does that make a difference in this case? Whether I use  
6 either one, I don't understand how it makes a difference.

7           **MS. STETSON:** I think that's my point, though.

8           **THE COURT:** Well, just explain it to me if you  
9 want to make it your point.

10          **MS. STETSON:** Sure. The reason that that is a  
11 point in our favor is because of that *Gutierrez de*  
12 *Martinez* language that I just said. If you have --

13          **THE COURT:** Well, wait a second. Before you  
14 even get there, you said, "that was a point." What do  
15 you mean by "that"? So that's why I go back to, how  
16 did -- let's just do this. Let's start with the language  
17 of the statute: "The determination of qualifying single  
18 source drugs."

19                 All right. What does determination mean in  
20 that statute, in that sentence, that clause from the  
21 statute?

22          **MS. STETSON:** The identification of a drug.  
23 The determination of a qualifying single source drug.

24          **THE COURT:** I don't think he disputes that.  
25 Where is the dispute?

1           **MS. STETSON:** I think he does. I don't want  
2 to speak for Mr. Netter either, but my point with respect  
3 to judicial review is that what you didn't hear  
4 Mr. Netter say was that, when you begin that inquiry --  
5 do I or do I not have the power to look at this unlawful  
6 guidance? -- that you begin with the strong presumption  
7 in favor of review. If, as Mr. Netter demonstrated with  
8 those two competing definitions: Determination could  
9 mean this; it could mean this.

10           If it's competing definitions like that, that  
11 means that it's reasonably susceptible to an  
12 interpretation where we get judicial review of this  
13 predicate definition that we're talking about. That's  
14 the point of construing judicial review provisions  
15 narrowly. That was the point I wanted to make on how and  
16 whether to construe this judicial review provision to  
17 preclude us, or, apparently, anyone, from ever making a  
18 statutory challenge to us. That's not the way that the  
19 presumption works.

20           **THE COURT:** All right. To try to flesh this  
21 out, the determination of qualifying single source drug  
22 in this case was already done, correct?

23           **MS. STETSON:** Correct.

24           **THE COURT:** You're challenging the manner in  
25 which the determination was made, or are you challenging

1 the fact that it was made?

2 **MS. STETSON:** We are challenging the manner in  
3 which it was made, and we are challenging the definition  
4 that kind of sits behind it. So like the *Baxter* case --

5 **THE COURT:** The definition of qualifying --

6 **MS. STETSON:** Of qualifying --

7 **THE COURT:** -- single source drug.

8 **MS. STETSON:** -- single source drug. Yes.

9 **THE COURT:** Okay.

10 **MS. STETSON:** Not the determination of a  
11 particular drug. We're not saying you shouldn't have  
12 chosen Farxiga. That would walk us right into the  
13 judicial review bar. What we are saying is, there is a  
14 definition that you are using of "qualifying single  
15 source drug" that impacts our ability to figure out how  
16 to value Farxiga. Because if you, Government, are right,  
17 that despite what the statute says, qualifying single  
18 source drug actually sweeps in anything with the same  
19 active moiety, no matter when or how it's proved, that  
20 affects our ability to value our product --

21 **THE COURT:** All right. Now you're back to  
22 "affecting our ability to value our product," which I  
23 didn't see in your brief at all. But I'm not saying that  
24 matters, and the argument is very good, and I'll go back  
25 and look.



1           I mean, do you think "determination of value"  
2 is anywhere in the brief?

3           **MS. STETSON:** I want to say at Page 12 of our  
4 reply brief in particular, we talk about needing to make  
5 decisions now that impact our ability to negotiate later.  
6 And that's, of course, why we're here. You mentioned the  
7 March 1st deadline.

8           **THE COURT:** That's what I do want to spend the  
9 remainder of the argument on, why you're here. You know,  
10 I just signed the stipulation. I knew this was an  
11 important act. And I've got the Government and the  
12 lawyers on this case, who come with a lot of credibility  
13 to the Court and say, stipulation, hey, let's take it up.  
14 I'm going to do it.

15           I have to say as I sit here, I'm thinking why  
16 did I ever agree to this? I probably should have had you  
17 all brief it. I mean, but the Government agreed to do  
18 it. And, frankly, I thought at the time it was because  
19 it was in the Government's interest as well.

20           In other words, it was both parties, it was in  
21 both of your interests to get this decided here, get it  
22 to the Court of Appeals, and get it decided. And you  
23 avoid a preliminary injunction, and that's attractive to  
24 me, so I was like, sure, I'll sign the stipulation. And  
25 you avoided a preliminary injunction proceeding and

1 briefing and that kind of thing.

2 But I'm even just thinking, so I issue my  
3 decision by March 1. You say your response is due  
4 March 2; is that right?

5 **MS. STETSON:** That's correct.

6 **THE COURT:** So how is my decision going to  
7 influence anything you do between now and March 2, and  
8 now the biggest -- what you are saying today, which was  
9 not in your briefs, that you need a decision now so you  
10 can get involved or -- and you can meaningfully give a  
11 counter-proposal.

12 You're not going to get it. Even if I get you  
13 a decision by March 1, you're not going to get it in time  
14 to accomplish what you need.

15 **MS. STETSON:** Oh --

16 **THE COURT:** I agreed to get it by March 1; I  
17 didn't agree to get it before.

18 **MS. STETSON:** Understood. I think there are a  
19 couple of different answers.

20 The first is, the reason that we asked for  
21 March 1st and none of the other cases did, to my  
22 recollection, is because, as Mr. Netter mentioned, all of  
23 those other cases with one distinguishable exception, are  
24 making constitutional claims. There's one other case  
25 that is bringing a procedural --

1           **THE COURT:** You are making a constitutional  
2 claim.

3           **MS. STETSON:** They are, but they're not  
4 bringing APA claims. And for these purposes, the APA  
5 claims are what are driving the decision-making here for  
6 all the reasons we've talked about, the need to  
7 understand whether we are operating under lawful or  
8 unlawful guidance.

9           At the very least, if you are able to render a  
10 decision by March 1st, we will at least have a judicial  
11 imprimatur of whether or not in your view this is lawful  
12 or this is unlawful. That's helpful information to us.

13           **THE COURT:** That's an advisory opinion.

14           **MS. STETSON:** No, it is not. It is not  
15 because it's what we are intending to do with valuing our  
16 product under the negotiation that we are compelled to  
17 enter into.

18           If I could make two more quick points.

19           **THE COURT:** Just give me one second.

20           Okay.

21           **MS. STETSON:** So the first is on qualifying  
22 single source drug. I want to point out a couple of  
23 things that Mr. Netter said. When we, he and I both,  
24 walked through the definition, Mr. Netter concluded his  
25 definition by adding the phrase -- and I wrote this

1 down -- "so long as the same active moiety is involved."  
2 And that, of course, is the problem. That appears  
3 nowhere in the statutory definition.

4 I want to point out what Mr. Netter put up on  
5 the screen with --

6 **THE COURT:** Hold on, hold on.

7 Go ahead.

8 **MS. STETSON:** What Mr. Netter put up on the  
9 screen with respect to the *Ipsen* joint appendix, I'd  
10 encourage the Court to look at that entire document.  
11 Because I think is, unfortunately, one of those things  
12 what happens when you look at the 23 words that are good  
13 for you and not for the rest. That letter has to do with  
14 *Ipsen's* request in that case for a different price based  
15 on a supplemental NDA approval. That was what that  
16 language was about.

17 So the fact that the Government is reaching  
18 that far to pull 23 words from a completely inapposite  
19 letter suggests that maybe what we should be doing is  
20 looking at the statute for the definition.

21 Last thing I'll say is what you didn't hear  
22 Mr. Netter say on the due process arguments. You didn't  
23 hear a response to my point about *Bowles*, which is that  
24 *Bowles* said you don't get a taking claim because your  
25 participation is voluntary, but we're going to look at

1 due process.

2 You didn't hear a response with respect to the  
3 coercion, the absolutely -- "seismically" was my word --  
4 disproportionate penalty that comes from us having to  
5 withdraw all of our drugs from the program based on  
6 withdrawing one drug from negotiation.

7 **THE COURT:** You don't have a case that says  
8 it's -- you don't have a case that talks about the  
9 withdrawal from Medicaid being a due process violation,  
10 do you?

11 **MS. STETSON:** No, but I have *NFIB* that says  
12 when the penalty is so disproportionate to the  
13 withdrawal, that is coercive. And, you know, I did  
14 anticipate Mr. Netter's response, which is that involved  
15 a state.

16 **THE COURT:** But it does, and that's a pretty  
17 big thing.

18 **MS. STETSON:** But the Court's ruling did not  
19 say, we're finding this coercive because it involves a  
20 state; they said, we are finding this coercive because  
21 the penalty for withdrawal is so harsh.

22 One last point on due process if I could, you  
23 and I and you and Mr. Netter spent some time today  
24 talking about the property interest. I'd encourage to  
25 you to go back and look at the government's briefs,

1 opening brief and reply brief. What the Government  
2 argued today about the property interest is nowhere in  
3 its briefing.

4 The Government's brief on due process begins  
5 and ends with the argument that our participation is  
6 voluntary. It is not voluntary for both of the reasons  
7 that we've already talk about. It either doesn't --

8 **THE COURT:** Not voluntary? You're going to  
9 have to -- how is it not voluntary?

10 **MS. STETSON:** I, actually. Let me --

11 **THE COURT:** And that seems a brand-new  
12 argument at 12:22.

13 You're saying your participation in Medicare  
14 is involuntary?

15 **MS. STETSON:** No, no. Let me bite that back.

16 What I meant is the only argument the  
17 Government made in its brief was that our participation  
18 was voluntary.

19 **THE COURT:** Correct. And because it's  
20 voluntary, you don't have a property interest. It's not  
21 your property interest, I mean, that you're being  
22 deprived of. You said your property interest is the  
23 patented products.

24 **MS. STETSON:** My point was the Government  
25 didn't make a separate argument that we didn't have a

1 property interest, even if you included either, as we've  
2 argued, that the voluntariness inquiry has no relevance  
3 to the due process question, or that this actually isn't  
4 voluntary.

5 So the Government is now arguing that, you  
6 know, setting aside the voluntariness, there's no  
7 property interest. That is not in their briefing. Their  
8 brief rises and falls on this argument that there's no  
9 due process violation because our participation is  
10 voluntary, not relevant to due process and, in any event,  
11 not voluntary. Those are our two arguments.

12 **THE COURT:** So are you saying they've waived  
13 their argument that you don't have a property interest?

14 **MS. STETSON:** Yes, I am. We're here on  
15 summary judgment, as you pointed out. And what they have  
16 argued, in its entirety, if you look at the header of the  
17 brief, is no due process because it's voluntary.

18 **THE COURT:** Have you waived ultra vires, then,  
19 your argument?

20 **MS. STETSON:** No. There's the third Circuit  
21 case we cite in our brief, the name of which escapes me,  
22 it begins with a B, but it talks about how ultra vires  
23 means contrary to statutory command under the APA.

24 **THE COURT:** Okay. Interesting.

25 **MS. STETSON:** There are no further questions.

1           **THE COURT:** All right. Thank you very much.

2           I enjoyed the argument very much. It's very,  
3 very helpful. I am a little taken aback by the March 1  
4 deadline now.

5           You're not going to be able to get an appeal  
6 in time, it seems to me, to affect any of the ongoing  
7 negotiation over this price.

8           I mean, you know, the Third Circuit, on an  
9 expedited basis, just realistically, wouldn't have an  
10 opinion for you before September 1 of 2024. And even if  
11 they did, at that point, your counterproposal is already  
12 given. So why the March 1 deadline?

13           **MS. STETSON:** I think the March --

14           **THE COURT:** I mean, in other words, why didn't  
15 you come to me and say, hey, we need this decided by  
16 December 1? Nobody did that. You didn't bring a  
17 preliminary injunction.

18           **MS. STETSON:** I think we were trying to  
19 give -- two things. We were trying to give you as much  
20 time as possible, and the second is --

21           **THE COURT:** But as much time as possible --  
22 hold on. And I appreciate any time somebody gives me as  
23 much time as possible. But to issue an opinion on a  
24 deadline that would be ineffectual. What advantage does  
25 it serve to get the opinion out?



1           In other words, why didn't you bring a  
2 preliminary injunction to me in the fall? It would have  
3 been -- it's always difficult to address preliminary  
4 injunctions, but I do. I am a little, as I say, taken  
5 aback.

6           **MS. STETSON:** I think what we were -- what we  
7 were thinking about is this. March 2nd is our  
8 counteroffer deadline. Depends on whether -- March 2 is  
9 a Saturday, so I'm hesitating only because maybe it's  
10 March 4 -- the March 1st deadline was designed to give  
11 you as much time as possible and us at least some time to  
12 take a judicial decision into account.

13           We understand that neither side is going to be  
14 able to sort of run the complete gauntlet before  
15 March 1st or March 2nd. This at least gives us some  
16 further certainty about what we're negotiating for and  
17 why. That's the line we were trying to navigate.

18           **THE COURT:** All right. Well, and I suppose in  
19 your favor, you could argue -- well, plus, if you won,  
20 you don't have to submit a bid, at least potentially.  
21 Depends how an order would be framed.

22           **MS. STETSON:** True also.

23           **THE COURT:** But that would be an issue.

24           **MS. STETSON:** Yes.

25           **THE COURT:** All right. Yeah. I can see that.

1 Okay.

2 **MS. STETSON:** Thank you, Your Honor.

3 **THE COURT:** Thank you. Maybe I'm not as taken  
4 aback as much as I thought I was.

5 Okay. All right. Thank you very much.

6 I will say one other thing. It's possible, as  
7 I write this, I may have follow-up questions. I did not  
8 get to prepare for this, given my trial last week, you  
9 know, and given the complexity of the issues, you could  
10 spend weeks and days. And I'm sure some Court of Appeals  
11 will one day.

12 So as I write and formulate further questions,  
13 I make issue oral orders asking for immediate responses.  
14 And because you've put me on a clock, I'm going to put  
15 you on one.

16 Just be ready. You have a lot of lawyers. I  
17 can see issuing an order saying, you know, you have 24  
18 hours to let me know what the answer to X is. Okay?

19 **MS. STETSON:** Understood.

20 **THE COURT:** And if I ever do something like  
21 that, it would be -- I will give both -- even if it's  
22 directed to one party, both parties will have the same  
23 time frame to respond to whatever question I have. I may  
24 not have any questions, but just be ready for that. All  
25 right?

1 Thank you. Take care.

2 (The proceedings concluded at 12:26 p.m.)

3  
4  
5  
6 CERTIFICATE OF COURT REPORTER

7  
8 I hereby certify that the foregoing is a true and  
9 accurate transcript from my stenographic notes in the  
10 proceeding.

11  
12 /s/ Bonnie R. Archer  
13 Bonnie R. Archer  
14 Official Court Reporter  
15 U.S. District Court  
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