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BEFORE THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

NOVARTIS PHARMACEUTICAL COMPANY, .
 Plaintiff, . Case Number 21-cv-1479
 vs. .
 DIANA ESPINOSA, et al., .
 Defendants. .

 UNITED THERAPEUTICS CORPORATION, .
 vs. . Case Number 21-cv-1686
 DIANA ESPINOSA, et al., .
 Defendants. . October 12, 2021
 11:05 a.m.

TRANSCRIPT OF MOTIONS HEARING
BEFORE THE HONORABLE DABNEY L. FRIEDRICH
UNITED STATES DISTRICT JUDGE

APPEARANCES:

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United States District Court
for the District of Columbia
333 Constitution Avenue Northwest
Room 4704-B
Washington, D.C. 20001
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P R O C E E D I N G S

(All participants present via video conference.)

COURTROOM DEPUTY: Your Honor, we are in Civil Action 21-1479 and 21-1686, Novartis Pharmaceuticals Corporation versus Diana Espinosa and United Therapeutics Corporation versus Diana Espinosa.

If I can have the parties identify themselves for the record, beginning with plaintiffs' counsel.

MS. STETSON: Good morning, Your Honor. This is Kate Stetson, representing Novartis.

MR. PERRY: Good morning, Your Honor. This is Phil Perry, representing United Therapeutics.

MR. LOWENSTEIN: Good morning, Your Honor. This is Jody Lowenstein with the Department of Justice, representing the defendants.

COURTROOM DEPUTY: Now we can't hear you, Your Honor.

THE COURT: You cannot?

COURTROOM DEPUTY: Now we can.

THE COURT: My apologies. I recently moved chambers, so I don't know if that's the issue here. I will try to keep my voice up.

Is Ms. Stetson or Mr. Perry going to begin?

MS. STETSON: I am going to start, Judge.

THE COURT: All right.

MS. STETSON: This is an administrative procedure case

1 about the 340B statute, but I would begin by saying that this is
2 an unusual case in some respects, because usually when we're
3 here to talk about an administrative procedure issue we're
4 talking about what particular level of deference to give the
5 agency, whether the agency's expertise plays a role, the process
6 by which the record was compiled, public comments, and so forth.

7 This case is none of those things. This case is one in
8 which HRSA relies on the plain language of the 340B statute to
9 find an obligation that it's seeking to enforce now against
10 manufacturers. The statute does not require what HRSA says it
11 does. The 340B statute, the relevant portions of it for this
12 argument require drug manufacturers who contract with government
13 entities also to offer their products to a particular list of
14 covered entities at a set price, and those covered entities are
15 specified elsewhere in the statute.

16 The government maintains that the plain text of that
17 statute, which requires manufacturers to offer their drugs to
18 covered entities for purchase, also includes on its face a
19 requirement that manufacturers deliver their 340B products to
20 contract pharmacies, third-party contract pharmacies, wherever
21 they're located, however many of them there are, at the
22 discretion of the covered entities.

23 Everyone agrees --

24 THE COURT: Let me interrupt you there. If I agree
25 with you that the plain language does not support the

1 government's position, does the government lose here?

2 MS. STETSON: I think the short answer is yes, Judge
3 Friedrich. The government has --

4 THE COURT: Why is that?

5 MS. STETSON: For two different reasons, and maybe
6 they're kind of stacked in the menu. The first is, this is the
7 only argument the government has offered. You noticed in its
8 brief it makes kind of a stab at a Skidmore deference argument,
9 but of course, that is not what the violation letter that
10 Novartis received in May of 2021 says.

11 And the government is very clear in its briefs, and we
12 agree, that the statutory dispute here, quote, must be decided
13 on the basis of HRSA's reasoning contained, closed quote, in
14 that May 2021 letter. So the government is stuck with its plain
15 text argument.

16 So --

17 THE COURT: What about with the letter? So the letter
18 also includes information about complaints that the government's
19 receiving about Novartis and others overcharging for the price
20 of drugs. To what extent can they rely on that basis, which is
21 also stated in the letter?

22 MS. STETSON: I think --

23 (Simultaneous talking.)

24 THE COURT: -- the enforcement proceedings here.

25 MS. STETSON: Sure. So I think when the government

1 has essentially declared that the statute requires this of
2 manufacturers, the fact that they've received complaints from
3 covered entities -- and we can certainly talk about those
4 complaints as pertains to Novartis, because they are very, very
5 few and far between and not supported. But with respect to the
6 statute, if the statute requires this of manufacturers, the
7 complaints and the record is essentially beside the point.

8 But to your question about whether the government loses, we
9 think the government loses not only because it has offered only
10 the plain text interpretation that simply can't be supported by
11 the statutory text, but it also loses because even if this court
12 were to remand to the agency for some kind of exercise of its
13 expertise, which it has never said it could do or would do,
14 there is nothing to interpret in this statute. You know,
15 interpreting an ambiguous statutory provision requires the
16 agency to look at something identified as ambiguous and say
17 because this is ambiguous we are going to interpret this, we're
18 going to fill that statutory gap. There is no gap here.

19 The statute does not speak about contract pharmacies. It
20 does not speak about delivering to contract pharmacies. And it
21 certainly doesn't speak about requiring manufacturers to deliver
22 to contract pharmacies.

23 THE COURT: Why isn't that a gap that the agency can
24 fill? And if it were, though, to fill that gap, does it need to
25 do so through an actual rule rather than the interpretive rules

1 here in order to bring an enforcement proceeding?

2 MS. STETSON: I think that is the problem that HRSA
3 confronted when it issued its letter and when it issued that
4 advisory opinion last December that it then withdrew. HRSA
5 doesn't have the authority to issue a rule. HRSA, as explained
6 in our brief, has very limited authority. It can set up civil
7 monetary penalties. It can establish the methodology for
8 figuring out what the 340B price is and so forth. It cannot
9 make a rule. So because of that, I think HRSA found itself
10 constrained to interpret the statute as the statute exists.

11 Now, what HRSA ends up doing in its brief is to expand this
12 into a broader policy discussion about the merits of contract
13 pharmacies, why they are there, how they work, how hospitals use
14 them. And remember, with respect to Novartis, we're only
15 talking about contract pharmacies used by 340B hospitals. All
16 federal grantees, Subsections (a) through (k) of the 340B
17 statute, are all covered regardless under Novartis's policy.

18 So what the briefing turns into from the government's
19 perspective is a sort of lengthy policy discussion about the
20 merits of contract pharmacies. That's all well and good. I
21 think the venue to have that discussion is in Congress, and the
22 venue to enforce that discussion would be with HRSA, if and only
23 if Congress changes the statute and gives HRSA the
24 responsibility to enforce the statute.

25 But on the plain text of what the agency has brought to you

1 here today, Your Honor, there is simply no gap to fill. There's
2 a difference, I think, between a statutory sort of gap that the
3 agency can step in and say this connects these two concepts and,
4 therefore, we're going to regulate in the space. There's a
5 difference between that and just flat out statutory silence.

6 And it's the latter that we have here. The agency can't
7 point to anything in this statute to say well, clearly they're
8 making a reference to delivery, so therefore we're going to
9 interpret that to delivery to third-party contract pharmacies,
10 and thereafter we're going to interpret that to mean that
11 manufacturers are required to deliver to third-party contract
12 pharmacies. There's nothing to interpret and no gap to fill in
13 those circumstances.

14 And the D.C. Circuit and this court have been very clear
15 that when a statute is silent on something, the agency can't
16 just kind of exercise some sort of muscular opportunity to walk
17 into that space and say well, the statute is silent, therefore
18 we're going to legislate in this space.

19 So that's the reason -- all of those, I guess, are reasons
20 why if this court concludes that the statute doesn't say what
21 HRSA says it says, there's really nothing left for HRSA to do.
22 There's nothing left for HRSA to interpret.

23 HRSA has been very clear that it considers this statute
24 unambiguous. In fact, the advisory opinion says something like
25 it's difficult to imagine a less ambiguous phrase. So HRSA

1 would have to walk a lot of that back if it found some ambiguity
2 here, but there's no ambiguity as far as deliveries to
3 third-party contract pharmacies is concerned.

4 So on the plain statute, on what the government has brought
5 you with respect to a statutory argument, there is really
6 nothing more to say. The argument is deficient because the
7 statute doesn't say on its face what the agency maintains over
8 and over the statute says.

9 Let me mention one more thing about the statute, because
10 the agency mentions, I think in its violation letter and again
11 in its brief, that the statute doesn't talk about how the
12 covered entity chooses to distribute the covered outpatient
13 drugs that it purchases. Of course it does. There's an entire
14 statutory section, Section 256b(a)(5)(B), that prohibits
15 transfer of a covered outpatient drug that was purchased at the
16 340B price to a person not the patient of the covered entity.
17 So of course, there are restrictions what a covered entity can
18 do with its pharmaceuticals.

19 So trying to find some justification in that silence with
20 respect to that particular argument also runs the government
21 into that antitransfer provision which they're apparently
22 looking the other way on with respect to covered entities and
23 their contract pharmacies and this kind of odd replenishment
24 model that you read about in the briefs.

25 Let me talk also about the letter itself, the basis for the

1 agency's decision, because even if you get past the idea that
2 there's some ambiguity in the statute and that it's available
3 for you to pass on when the government hasn't argued ambiguity,
4 there are independent deficiencies with the May 2021 Novartis
5 letter that I want to point out. And this also goes, I guess,
6 to the ambiguity issue as the government plans to invoke
7 Skidmore deference.

8 One of the things, of course, that Skidmore deference asks
9 is, what was the nature of the pronouncement? Was it thorough?
10 Was it well-considered? Did it depart from other previous
11 statements? The letter that Novartis received in May didn't
12 even identify the right policy, the right contract pharmacy
13 policy. It identified the policy that Novartis had quoted last
14 August that it retracted last October in an e-mail that HRSA
15 received.

16 So the fact that it didn't identify even the right policy
17 means that all of the material in the brief that talks about
18 some kind of evidentiary response to what Novartis's policy
19 actually is -- and remember, it also guarantees all contract
20 pharmacies anywhere they are, however many, all contract
21 pharmacies within a 40-mile radius, which I went back to math
22 and did the math and it's 5,000 miles around a particular
23 hospital-covered entity. All contract pharmacies within that
24 space are also covered, and then there's an exception mechanism.

25 So all of the work that DOJ counsel had to do in its brief

1 to talk about that policy is something that's new in the briefs,
2 precisely because the May 2021 letter doesn't even address the
3 right policy.

4 The government also, with respect to its statutory
5 analysis, focuses on one statute clause in its May letter and
6 another in its brief. And again, you know, that kind of
7 dissonance is not something that this court tolerates in its
8 Administrative Procedure Act proceeding. The clause that the
9 government fastened on in its May letter, the clause that HRSA
10 fastened on in its May letter was the "shall offer" clause,
11 manufacturers shall offer drugs at the 340B price to that list
12 of covered entities.

13 What it then pivoted to in its brief is that the really
14 operative clause is the "purchased by" clause. That's the
15 beginning of the 340B(a), which talks about the Secretary being
16 required to enter into agreements with manufacturers that
17 provide, among other things, that manufacturers have to ensure
18 that the amount required to be paid to the manufacturer for
19 drugs purchased by a covered entity doesn't exceed the ceiling
20 price.

21 So again, I think that is a sort of process foot fault on
22 the part of the government, because it's now focusing on a
23 different piece of statutory text that it says obviously
24 contains the delivery requirement that it wants to impose here.
25 So that's another kind of cognitive dissonance in the letter.

1 The letter also talks about how its statement to the effect
2 that manufacturers are required to deliver drugs to any contract
3 pharmacies anywhere has been consistent since 1996. And these
4 are the references to the 1996 and 2010 Federal Register
5 guidances, which of course are guidance, not binding on anyone,
6 didn't even purport -- and they say this in there -- to create
7 any new obligations or anything.

8 I think the issue the government has is that of course
9 there is a departure from the 1996 guidance. The 1996 guidance
10 talked in terms of covered entities being permitted to contract
11 with one outside pharmacy if the covered entity didn't have an
12 in-house pharmacy of its own.

13 So the fact that the government is now maintaining that the
14 statute requires manufacturers to deliver to any contract
15 pharmacy, no matter how many, no matter where, no matter if the
16 covered entity has an in-house pharmacy or not, goes flatly
17 against what the government's understanding of that statute was
18 in 1996, which the contract pharmacies were not contemplated.

19 The other problem with relying on the 1996 and 2010
20 guidance is, of course, that guidance wasn't directed to drug
21 manufacturers at all. It was directed to covered entities to
22 set out kind of the metes and bounds of their ability to
23 contract with contract pharmacies. What the regulations do say
24 is that manufacturers have to sell to covered entities that
25 contract with contract pharmacies. We have no quarrel with

1 that. We do sell to covered entities that have contract
2 pharmacies.

3 Where we part ways and where the regulations don't speak to
4 with respect to imposing any kind of statutory obligation on a
5 manufacturer is this idea that the covered entity gets to
6 unilaterally direct delivery to as many contract pharmacies as
7 it wishes. And you will remember, I think, from the brief,
8 we're talking about 47,000 different pharmacies that are now a
9 part of the contract pharmacy arrangements of covered entities.
10 Direct delivery to any of those 47,000, no matter how many, no
11 matter where, that is not something that either the statute or
12 the regulatory sort of bagging that the government is looking to
13 contemplates.

14 THE COURT: Sorry again to interrupt. But what about
15 the agency's point that Novartis is discriminating against
16 covered entities relative to just, you know, purchases of
17 regularly priced drugs across the country for which Novartis and
18 the other manufacturers put no limits on the use of pharmacies?
19 What about that provision, and doesn't that have a statutory
20 base?

21 MS. STETSON: That is precisely what I was about to
22 turn to. So the problem with the discrimination argument is
23 that you will notice the government doesn't cite anything for
24 it. It is an uncited, unsupported statement to the effect that
25 this is discriminatory because Novartis treats its commercial

1 purchasers differently. That is simply not true.

2 Novartis would not permit, in any reasonable contract
3 arrangement, a commercial purchaser to unilaterally direct
4 delivery of its drugs to any number of third-party locations.
5 So there is no discrimination whatsoever.

6 And in fact, that answers -- one of the hypotheticals in
7 the government's brief that I paused on is this notion that our
8 theory of the statute, which is the statute says what the
9 statute says, would suggest that manufacturers could just direct
10 all covered entities to drive to one warehouse to pick up the
11 340B drugs that they purchased.

12 Of course that's not true, and it's precisely because of
13 the nondiscrimination point that Your Honor just made. That
14 would be an instance where a manufacturer would be treating a
15 340B entity different than it would treat another commercial
16 purchaser. So that hypothetical, I think, kind of explodes in
17 the face of the government's own sort of nondiscrimination
18 argument.

19 But in any event, there is simply no basis on which the
20 government can suggest that this is somehow a differential
21 treatment from a commercial purchaser. We wouldn't permit
22 commercial purchasers to exercise the kind of unilateral
23 directives that the contract -- that the covered entities are
24 attempting to exercise here.

25 THE COURT: (Distorted audio) anywhere across the

1 country? There aren't geographical limitations on where they
2 can get the drugs?

3 MS. STETSON: So commercial purchasers, just like
4 covered entities, can certainly purchase the drugs anywhere
5 across the country. I think one of the differences here and the
6 difficulties here is that with respect to contract pharmacies,
7 what you see -- and this is this replenishment model that's
8 discussed in the briefing. What you see is, a pharmacy that has
9 a contract with the 340B entity dispenses a drug. There is
10 later work done by some third-party administrator to determine
11 whether or not that particular person may or may not be a 340B
12 entity patient. And you will see also from the briefing that
13 there's a lot of disagreement among even contract pharmacies
14 about when that call is made.

15 At that point, after a certain amount of 340B patients
16 receiving a certain drug is kind of aggregated, the covered
17 entity puts in a call to the manufacturer and says, please send
18 this 340B price drug to this particular pharmacy at the 340B
19 price. It essentially replenishes what was previously given
20 out, but then those drugs get dispensed to literally anyone who
21 walks in the door.

22 And Your Honor raises a question that I think is important
23 to kind of emphasize here. There is a -- there is a suggestion
24 underneath the briefing -- it's never made kind of in the brief
25 for the reason I'm about to say -- that this somehow harms

1 patients who are looking for their medications. Any patient
2 anywhere of any hospital can walk into any pharmacy and get the
3 prescription that she needs.

4 So the pricing that we're talking about is --

5 THE COURT: Help me understand that. Why is that the
6 case? Why can a patient walk into a pharmacy a thousand miles
7 away and get the drug he or she is entitled to?

8 MS. STETSON: Why can she? Because she does -- sorry.

9 THE COURT: Go ahead.

10 MS. STETSON: If the question is why can she or even
11 why can't she, you know, in either case the patient is holding a
12 prescription that entitles her to be dispensed a particular
13 drug. So from the patient's perspective, all of this colloquy
14 and all of this case is kind of invisible to them in all but the
15 most extraordinary circumstances, because the patient pays
16 whatever the patient pays. She pays a copay, she pays a cash
17 pay, what have you.

18 All of this has to do with the pricing that the
19 manufacturer offers to the covered entity. So there is no
20 impact on patient purchases of pharmaceuticals in this case.
21 And as I said, there's a suggestion underneath the briefing that
22 that might be the case. That's simply not the case, which is
23 why the suggestion isn't made more full-footedly.

24 With respect -- have I answered your question, Judge
25 Friedrich?

1 THE COURT: I guess so. I thought that was what the
2 government was saying, that a patient who lives a far distance
3 away from a covered entity can't get the drug from that
4 location, that home location.

5 Is that not true?

6 MS. STETSON: That is not true. A patient who lives a
7 far distance away -- let's take one of the government's favorite
8 examples, UC Davis. Let's say a patient actually lives, you
9 know, over 40 miles away from UC Davis and she has a
10 prescription that she wants to fill. She can walk into a
11 pharmacy and fill that prescription, and she pays the
12 appropriate price that she pays for that prescription under her
13 insurance contract, under whatever kind of health insurance
14 arrangement she has, or the cash price, or what have you.

15 The issue for the contract pharmacy is that when it seeks
16 to replenish that particular drug that it prescribed, under
17 Novartis's policy, which again loops in every contract pharmacy
18 within 5,000 miles, but on this hypothetical, it would not be
19 able to purchase that replacement at the 340B price. So the
20 patient doesn't suffer anything. The patient can go anywhere.

21 THE COURT: The hospital does; right?

22 MS. STETSON: The hospital does in the event that
23 we're talking about, again with respect to Novartis, outside the
24 40-mile radius and it's sought an exception and then denied.
25 This is not in the record, but Novartis entertains and grants

1 exceptions all the time, I will tell you.

2 So that kind of theory again starts -- not starts -- it is
3 a discussion of policy. It's a discussion of why it might be
4 helpful or additionally helpful on the margins to hospitals that
5 have patients that are filling prescriptions over 40 miles away
6 in some circumstances, why it might be helpful for hospitals to
7 be able to profit from that spread between the usual price and
8 the 340B price. But that's all policy. There is nothing in the
9 statute that requires it.

10 THE COURT: But why -- (distorted audio) your
11 statutory point on the text, but why should the covered entity
12 be penalized in that situation? Is that not treating it
13 differently than you would in a regular commercial arrangement?
14 And to the extent the statute suggests that you can't
15 discriminate, is that not -- does that not violate that
16 statutory provision?

17 MS. STETSON: I think that goes back to the back and
18 forth we had a few minutes ago, Judge Friedrich, which is, we
19 would -- Novartis would not permit a commercial purchaser to
20 exercise the kind of directive and the unilateral directive that
21 a drug be sent to a third-party pharmacy, you know, X thousand
22 miles away. It just wouldn't happen.

23 So it's not so much a penalty on the covered entity, you
24 know. The plain fact of the matter is that, you know, because
25 the statute does not speak to contract pharmacies at all,

1 manufacturers flatly don't have to do anything. That sounds
2 stark to say, but it's the reality of the statute.

3 What Novartis has strived to do with this policy is to
4 strike that balance between ensuring that 340B hospitals have
5 all the resources they need, all the contract pharmacies within
6 that radius, however many they contract with, any exceptions
7 that are necessary to be baked into that system, that federal
8 grantees have all the contract pharmacies they need, because a
9 lot of those grantees operate in rural places where you're
10 talking about more than 40 square miles away, that all of those
11 things are essentially a bolster to the 340B program.

12 That is something that Novartis has voluntarily put in
13 place precisely because the statute doesn't speak to this issue,
14 and it's trying to find a reasonable accommodation and a
15 reasonable landing for these covered entities that are
16 contracting with these contract pharmacies.

17 But none of that is in the statute, and it's certainly not
18 a penalty to suggest that a hospital has to stay within those
19 very modest bounds when it seeks replenishment of drugs at the
20 340B price. It's not a penalty because it's not measured
21 against anything different that Novartis would do on the
22 commercial purchaser side.

23 Let me make one more point, because I know I've been going
24 on for a while. This has to do just with the record briefly.
25 On a basic arbitrary and capricious level, we've already talked

1 about the fact that the letter offers a challenge to the wrong
2 Novartis policy and, therefore, everything in the DOJ brief
3 talking about the right Novartis policy really isn't supported
4 by the letter.

5 I would urge you also to look at the joint appendix that
6 was filed in this case, because what you will find on close
7 examination is that huge swaths of it have nothing to do with
8 Novartis. I will point you in particular to sort of midway
9 through -- there are four volumes of the JA. Leafing through
10 volume 2, page 7255, all the way through the end of volume 3 all
11 have to do with declarations and complaints made by federal
12 grantees about the potential inability to obtain covered
13 outpatient drugs.

14 Federal grantees are covered by Novartis's program. And
15 yet the government's brief in this case -- and this is part of
16 the "one size fits all" problem with the government filing a
17 very similar brief in each case, but the government's brief in
18 this case from pages 15 to 17 goes on at great length about
19 those federal grantee declarations. None of those have anything
20 to do with Novartis. Even the 20-odd pages of the joint
21 appendix that do speak to Novartis, they assume the conclusion.

22 What you see in those -- once you wade through the JA and
23 find the stuff that talks about Novartis, what you see are
24 hospitals saying, we have been told we can't access 340B drugs.
25 That is assuming that the hospitals are entitled to access 340B

1 drugs by directing Novartis to send them to their contract
2 pharmacies, no matter where located, no matter how many.

3 So all of the material in the record, which of course
4 Novartis was not able to comment on before this was filed, has
5 precious little, if anything, to do with Novartis's policy and
6 certainly is not any kind of support to one of your very first
7 questions, Judge Friedrich, about how the statute can be backed
8 up by any evidence in the record.

9 So the statute says what it says. It doesn't require what
10 HRSA requires. The letter is deficient for all the reasons
11 we've talked about. There's a significant departure from prior
12 practice. And the record itself just doesn't bear out any of
13 HRSA's concerns with respect to Novartis, unless, of course, you
14 assume the conclusion that Novartis is required to deliver the
15 covered -- to contract pharmacies no matter where they are.

16 If you have no further questions, I will stop talking.

17 THE COURT: Thank you, Ms. Stetson.

18 Mr. Perry, can you start by answering the question -- I
19 think I posed this for Ms. Stetson, but can an enforcement
20 proceeding be based solely on interpretive rules of HRSA if I
21 disagree with the government on the plain language of the
22 statute?

23 MR. PERRY: I don't think they have authority to
24 proceed against my client under any grounds, certainly not on
25 anything that might be an interpretive rule.

1 I take by your question that you mean the guidance itself
2 rather than any type of actual rule. They've taken to calling
3 that guidance some type of interpretive exercise explaining what
4 the statute means, but they've in fact taken a very different
5 view of what the statute means since they put that guidance out.

6 You can see that in a number of the citations that we have
7 in our brief, including the 2020 GAO study that we cited where
8 HRSA's wing that does audits was quoted as saying the 340B
9 statute does not address contract pharmacy use. And in
10 addition, there are public statements since the guidance back in
11 1996 and 2010 that show that HRSA has taken a very different
12 position since then.

13 So now they're saying, we always had the same position, it
14 was always based on this interpretive exercise that we played
15 through in the guidance, but in fact, they've not always had
16 that position. And that guidance itself has long been thought
17 of by HRSA as being unenforceable, that it doesn't actually
18 compel manufacturers to do anything.

19 Now they're in a tough spot now where they're trying to
20 rehabilitate something they did in the guidance and call it an
21 interpretive rule, but I don't think it's fair to call it that.
22 It's not.

23 THE COURT: Let's back up and let's just assume
24 there's not this history of interpretive guidance. Let's just
25 say this is the first occasion that the agency interpreted a gap

1 in the statute.

2 Would that -- if it were a reasoned analysis, would that be
3 sufficient basis on which to bring an enforcement action?

4 MR. PERRY: Well, Your Honor, I don't think the
5 statute would allow them to do what they're doing here. So if
6 you'll permit me, there are a few very specific provisions that
7 I would like to walk through in the statute. And I will say
8 generally that I agree with almost everything Ms. Stetson said
9 about the statute. But here are some very specific problems
10 that the government has under the statute.

11 First, as Ms. Stetson indicated, there are multiple
12 relevant provisions here, including (a)(1), (a)(4), and (a)(5).
13 (a)(5)(B) is something she specifically focused on, and I am
14 just going to read a small portion of this. It's
15 called "Prohibiting the Resale of Drugs" and reads that "a
16 covered entity" -- this would be the hospital in the types of
17 examples that Ms. Stetson gave -- "shall not resell or otherwise
18 transfer," and then it goes on, "the drug to a person." Person,
19 of course, is a very broad term. The dictionary defines it as
20 including and it surely encompasses a contract pharmacy who is
21 not a patient of the entity.

22 In other words, there's a direct statement Congress put in
23 the statute that should be read to prohibit this exercise of
24 using contract pharmacies. All right. So that's point 1.

25 The response by the government to this can be found at

1 page 8 of their second brief filed in our United Therapeutics
2 case and footnote 8. And their response to that plain statutory
3 language is not to explain what "otherwise transfer" means but
4 to ignore "otherwise transfer." What they say instead is,
5 Congress could not have meant that, that there is legislative
6 history that suggests they did not mean that. But those are the
7 plain words of this statute. That's what applies. That's what
8 prevented them from enforcing some idea that there was an
9 interpretive rule and guidance from 12 years ago.

10 Now, if I might, Your Honor, there is another relevant
11 point I would like to make related to a question that, I think,
12 you asked and Ms. Stetson addressed. The question is, is there
13 some nondiscrimination provision baked into this statute
14 somewhere. I mean, like Ms. Stetson's clients, we do not have a
15 relationship that's analogous to what HRSA is attempting to get
16 us to do for contract pharmacies. We just don't do that in the
17 commercial world. There is no analogue. So even if there were
18 a discrimination provision or nondiscrimination provision, there
19 is nothing that can be used to prove that we're discriminating.

20 But let's look for a moment, if we might, Your Honor, at
21 what they claim is the origin of a nondiscrimination obligation.
22 If I might, it's 256b or 340B(a)(1). Now, that provision has
23 two long sentences in it, and they're both predicated on the
24 Secretary entering an agreement that requires manufacturers to
25 do specific things. The second sentence at its tail end has

1 what we call here the "shall offer" provision.

2 And there, the Secretary shall require in this agreement
3 that the manufacturer offer a covered entity outpatient drugs at
4 or below the applicable ceiling price. The first sentence
5 addresses that ceiling price. And then it says "if such drug is
6 made available to any other purchaser at any price." That's not
7 a nondiscrimination provision as broad as the government paints
8 it. That tells you when you have to offer -- which drugs on
9 which you have to offer a covered entity something at the
10 patient ceiling price.

11 The government knows and Congress knows, of course, what a
12 nondiscrimination provision looks like. In our brief we cite
13 several, including from the same act, and they are written quite
14 differently. In fact, we could write this like a
15 nondiscrimination provision, but it is not one itself. All it
16 tells you is which drugs you must offer at the ceiling price to
17 a covered entity.

18 If I might, Your Honor, like Ms. Stetson, my client is
19 quite aggrieved by the letter we got on May 17th, and I would
20 like to explain why that's so.

21 First, our policies are somewhat different than Novartis.
22 We sell a series of outpatient drugs -- this is all set forth in
23 enormous detail in the declaration of David Barton, where he
24 explains this. We sell them essentially through specialty
25 pharmacies as a commercial matter.

1 So what's a specialty pharmacy? Well, it's a pharmacy that
2 has the capability to educate patients about the special needs
3 for taking a drug. In other words, you have to be exceptionally
4 careful when you use our drugs, that you take them in accordance
5 with the instructions. And so we use specialty pharmacies in
6 the commercial world to do that. As Mr. Barton's declaration
7 says, we use Accredo, and there's another.

8 Now, we also in our policy -- so that's only one pharmacy,
9 and they deliver by mail. There is no geographic issue here.
10 They deliver by special delivery, Federal Express, UPS, or by
11 mail. This is not a situation where somebody has to go to a
12 neighborhood pharmacy and they're deprived of some capability.

13 Now, our policy, and this is all laid out in enormous
14 detail, is if a covered entity has a pharmacy that's capable of
15 doing that, well, then, they should use their own pharmacy.

16 Now here, what the letter says to us is, after review of
17 this policy -- that's our policy -- and analysis of the
18 complaints received from covered entities, first, it has to
19 determine that United Therapeutics has resulted in overcharge.

20 You know what? There are almost no complaints in this
21 record regarding United Therapeutics. There are three, or you
22 might say four if you count duplicates. And the government has
23 identified exactly what they're relying on on page 14 of their
24 second brief. And you know what? These are -- Ms. Stetson used
25 this example -- from UC Davis outside Sacramento and from UCLA.

1 You know what? UC Davis and UCLA have their own specialty
2 pharmacies that dispense by mail. There's not a single patient
3 that's going to be deprived of any drug by virtue of our policy.

4 For these particular entities in the record, there's is not
5 any record information supporting a claim that's written here in
6 our letter, which by the way is a form letter with language
7 identical to Novartis's language and nearly identical to the
8 other manufacturers. Again, how do those result in an
9 overcharge? They haven't looked to see. They don't know. They
10 may not have even known what our drugs were or how we dispensed
11 them. There's nothing in the record --

12 THE COURT: Isn't it just a matter of time with the
13 way in which this is going to operate that there will be covered
14 entities who are going to be paying more than they should be
15 under the statute?

16 MR. PERRY: I don't think so, Your Honor, because I
17 think there's a way to make sure through our policy that every
18 covered entity that has an in-house pharmacy can dispense by
19 mail in the way that meets our policy. And we make exceptions,
20 Your Honor, when we need to, just like Ms. Stetson's client
21 does. I do not think that will ultimately happen.

22 But the important point for my client now and this letter
23 is there's nothing in the record that supports this. Zero.

24 Now, let me just focus for a moment, if I might, on
25 UC Davis. It says in the half-page e-mail -- they didn't fill

1 out the special form, by the way, but in the half-page e-mail,
2 they say our patients live across northern California and rely
3 on pharmacies closer to their homes. We dispense by mail.
4 That's not an issue. This complaint has nothing to do with us.

5 In the UCLA complaints -- and again, you can find these by
6 virtue of the citations at page 14 of the government's second
7 brief -- there are forms that are filled out, but those forms
8 also instruct that HRSA might reach out for additional
9 clarifying information. They have not. They have no idea how
10 this particular policy affects us.

11 Now, as Ms. Stetson indicated, and you'll find in our
12 brief, too, there are pages and pages, about 8,000 pages in the
13 administrative record that the government thinks are important.
14 This is just a few pages that are relevant to us, and these
15 pages don't tell you anything. They don't tell you that any
16 patient has been deprived of a drug with 340B pricing or that
17 the covered entities have been deprived of those drugs.

18 So there's a real problem with their letter. It's not
19 based on any sufficient record to justify what they've done.

20 Now, we have another policy, Your Honor, which is different
21 than Novartis's policies and perhaps unique, and it's what we
22 call our claims data policy. It's outlined in the declarations
23 of David Barton. And what it basically does is require, for
24 accessing our drugs through the 340B program, that you provide
25 us with some very basic information. So let me tell what you

1 that information is. It's the identity of the prescriber and
2 the covered entity and some other pieces of information that
3 allow us to make sure we are dealing with genuine covered-entity
4 prescriptions.

5 To give a sense of what's actually going on in this world,
6 Your Honor, and why all these companies are taking these
7 actions, I might recommend -- and it's a quick read. We cite it
8 on page 35 of our second brief. It's the hearing conducted by
9 the Committee of Health, Education, Labor and Pensions in the
10 U.S. Senate, where Assistant Inspector General Ann Maxwell
11 testified. She's with OIG for HHS.

12 And if you take a look in that document, you will find at
13 pages 10 through 12 her description of how this replenishment
14 model that you've read so much about in these briefs works for
15 the contract pharmacy. She will explain what's going on. The
16 contract pharmacies, their third-party administrators are
17 looking for -- not in the way that you might present a
18 prescription and see if it's a qualified prescription before you
19 dispense. But after the fact, they're getting paid a fee or
20 they're being compensated in another way to go through and data
21 mine prescriptions from the past, that have already been filled,
22 and see if they can make an argument that any of those are
23 340B-eligible. That's after the fact, and that is what is
24 driving a lot of the concern here, is that there is an unknown
25 problem with opportunistic behavior here.

1 Now, if I might --

2 THE COURT: By after the fact, are you suggesting that
3 they really aren't entitled to the discount for those purchases
4 of the drug?

5 MR. PERRY: If you look at the Maxwell prepared
6 testimony, she gives examples. One pertinent example, and
7 there's many other citations in our brief with others, of
8 problems that have arisen from this practice, where really what
9 they're doing is claiming -- and we don't have this information.
10 We need it. But they're claiming that these drugs are being
11 dispensed to non-340B patients, and she explains one scenario in
12 some detail where that's happening.

13 Now, here's what our claims data policy does. And I'm
14 going to reference some of HRSA's past guidance because I want
15 to identify why our policy is rooted in something HRSA already
16 thinks is reasonable. We want to know some very basic
17 information. It will take, our declarant says, an hour a year,
18 so 15 minutes to set up, and then an hour a year for these
19 covered entities or contract pharmacies or third-party
20 administrators to get this information, but it lets us know if
21 there are duplicate discounts, and it will help us understand if
22 the prescription that we're giving a 340B discount to is
23 generally from a covered entity or some prescriber who is not
24 working for the covered entity when it sees the patient.

25 THE COURT: Is that information you need to bring to

1 use the ADR process that's in the statute?

2 MR. PERRY: Important question, and here's the answer.
3 We need to audit before we go to the ADR process. We need to
4 know when to audit. This information tells us enough to know
5 when to audit.

6 Here's what is particularly important about the history of
7 this particular program. Back to the 2010 guidance -- so 1996
8 guidance is first put out, 2010 guidance. Those two pieces of
9 guidance from long ago have one thing in common. They identify
10 the essential elements of a contract pharmacy policy. We, of
11 course, think that was not consistent with the statute, but this
12 is how HRSA did it in their guidance. And they also identified
13 suggested contract terms, you know, what is needed -- and we
14 touched on this in our brief, what is needed up on the front end
15 prior to actually telling a 340B discount for a contract
16 pharmacy to have to justify that discount. It's a prior
17 verification system in both the 1996 guidance and the 2010
18 guidance.

19 The information we're asking for here in our claims data
20 policy is essentially the same as HRSA said the contractor
21 pharmacy has to have to call it a 340B discount. We're not
22 talking about anything unreasonable. We're talking about the
23 same type of information HRSA thought was reasonable for the
24 patient to supply to the 340B contract pharmacy before they said
25 it was eligible for a discount.

1 THE COURT: But this is information you don't require
2 in the regular commercial context; correct?

3 MR. PERRY: Your Honor, there are many other things in
4 play in the regular commercial context. We're not giving a
5 deeply discounted price. And what we're trying to do here, for
6 example, is make sure that these folks are eligible in the same
7 way that HRSA did in its own guidance. It's not much of an
8 imposition. There is no nondiscrimination requirement in the
9 statute. And it's a part of the normal commercial contract that
10 we would employ with all of the covered entities in this
11 context.

12 The pricing agreement, the pharmaceutical pricing agreement
13 that the Secretary's entered with manufacturers doesn't make
14 this illegal. It's perfectly --

15 THE COURT: Is this a role for HRSA to take on rather
16 than every pharmaceutical come up with its own way in which to
17 be able to audit and police this? Isn't that a role for the
18 agency rather than companies?

19 MR. PERRY: HRSA doesn't think it has authority to
20 audit contract pharmacies and third-party administrators. This
21 takes me back to that Ann Maxwell testimony and takes me back to
22 the 2020 GAO report where they say they didn't have authority to
23 look at this. There is an independent entity, independent of
24 the covered entities, that are determining through data mining
25 what is going on in the past and then claiming a new 340B

1 discount. The covered entities don't necessarily know what's
2 going on with that.

3 So our problem is, can HRSA even do it? And if you look at
4 our brief, we show through these GAO reports HRSA has not been
5 doing it, and our audit rights, to the extent we can employ
6 them, may be useless to solve this problem.

7 So we certainly want to know what to try to audit, and
8 that's why we have this entire claims data policy. But we
9 designed it very specifically to parallel what HRSA has asked
10 for in the past and to not be unduly burdensome. And it's a
11 reasonable -- we think a reasonable thing to ask for. And the
12 reasonableness is apparent when you look back at the guidance
13 from 2010 and 1996 and the suggested contract terms from those
14 documents.

15 I've been going for a while -- I'm sorry, Your Honor.

16 THE COURT: I don't mean to cut you off. You can have
17 a few more minutes if you're not done.

18 MR. PERRY: To wrap up, I would say at this point that
19 we in other respects agree with what Ms. Stetson said, including
20 about her -- the changes that HRSA has walked through as it's
21 implemented this program. It has said many times it's got the
22 same position that it's always had, but it's transparently clear
23 that it's changed positions from 1996 to 2010 and now again.

24 Let me make that point again about the contract terms from
25 the 2010 guidance. Those contract terms require

1 preverification. That's the suggested contract terms at the end
2 of the guidance, require preverification by the contract
3 pharmacy that are dealing with a genuine prescription.

4 Now, as Ms. Maxwell's testimony describes, we're not
5 talking about preverification at all. HRSA is trying to bless a
6 data mining exercise that involves none of those safeguards.

7 Thank you.

8 THE COURT: Mr. Lowenstein?

9 MR. LOWENSTEIN: Thank you, Your Honor.

10 I think it would be helpful to step back here and to look
11 at the context with which this case has come to the court.

12 Late last year, Novartis and United Therapeutics joined a
13 handful of other drug companies in designing policies that are
14 unprecedented in the history of the 340B program. And these
15 policies, what I didn't hear from either of my colleagues on the
16 other side is that they place extra statutory restrictions on
17 the ability of certain safety net healthcare providers to
18 purchase 340B drugs based simply on the fact that those
19 providers rely on outside pharmacies to deliver those drugs to
20 their underprivileged patients.

21 And this is a dispensing practice that has been widely used
22 for nearly 30 years in the 340B program. And consistent with
23 that long-standing operation of the 340B program, HRSA, who --
24 the part of HHS that administers the 340B program and has for
25 decades, informed plaintiffs in May of this year that their

1 extra statutory restrictions violate their statutory obligations
2 to honor 340B purchases by covered entities.

3 And I would like to begin why that determination, that
4 violation determination to both United Therapeutics and Novartis
5 is consistent with the statute and why the plaintiffs' contrary
6 reading of their own statutory obligations are -- is simply
7 inconsistent with basic principles of statutory interpretation.

8 I think it would be helpful to start with the text, and the
9 text must be read in context and with a view of its place in the
10 overall statutory scheme.

11 So what Congress thought to do in 1992 with the 340B
12 program was to condition a drug manufacturer's access to
13 Medicaid coverage or drug on its willingness to enter into a
14 pharmaceutical pricing agreement as described in Subsection
15 (a) (1) of the 340B statute. And under that PPA, a manufacturer
16 would be obligated to ensure -- and I'm quoting Subsection
17 (a) (1) here, the first provision -- would ensure that the amount
18 required to be paid to the manufacturer or covered outpatient
19 drug purchased by the covered entity does not exceed the
20 statutory ceiling price.

21 And since 1992, drug manufacturers have understood that in
22 order to uphold their PPAs, they would need to comply with that
23 straightforward, textually unqualified statutory demand to honor
24 discounted 340B drug purchases by covered entities.

25 But what plaintiffs do here is they try to create from that

1 broad obligation an implicit exception to their statutory
2 obligations to honor purchases by suggesting that they have the
3 discretion to deny 340B purchases any time those purchases would
4 be dispensed to patients through an outside contract pharmacy.
5 And they reach that conclusion based chiefly on the fact that
6 the 340B statute does not expressly note anything about the
7 terms of deliveries or the dispensing mechanism that can be
8 used.

9 But that's not how courts interpret broad statutory
10 command. When a statute contains broad language to define a
11 mandate, it's presumed that Congress is seeking to achieve
12 general coverage under that broad mandate and not to leave room
13 for regulated parties to create ad hoc exceptions to that broad
14 mandate.

15 And that is precisely the principle that the Supreme Court
16 applied in the *Bostock* case, where it explained that Congress's
17 failure to speak directly to a specific case that falls within a
18 more general statutory rule does not create a passive exception,
19 that that court should apply the broad rules as they're written.

20 Yes, Your Honor?

21 THE COURT: Here, it seems like there's a really big
22 gap in the statute. The statute says nothing about contract
23 pharmacies, and over time, the agency has put out these
24 interpretive rules that you argue are fairly, you know,
25 consistent over time, the plaintiffs argue are inconsistent.

1 And my question is just, can the agency begin these
2 enforcement actions based solely on interpretive rules when
3 there's nothing that I see in the statute -- I agree with the
4 *AstraZeneca* court that the plain text doesn't speak to this.
5 The agency is really filling a gap, and doesn't it need to do
6 formal rulemaking in order to do so?

7 MR. LOWENSTEIN: Your Honor, no, because this
8 enforcement process is based on a statutory obligation, and it
9 seeks to enforce that statutory obligation. It does not seek to
10 enforce an obligation that was -- that contained an interpretive
11 guidance or a substantive rulemaking by the agency itself. It
12 seeks to enforce a straightforward statutory obligation, and
13 that is to honor 340B purchases by covered entities.

14 And while yes, it's true that the statute does not
15 expressly say anything about contract pharmacies, we don't think
16 that is a reason why drug manufacturers can try to superintend
17 this program by imposing their own conditions on 340B purchases.

18 Again, it's important, both plaintiffs here admit that if
19 their conditions are not complied with, they will deny or refuse
20 to fill 340B purchases by eligible covered entities that
21 otherwise are mandated to be filled under the statute.

22 And I think it would be helpful to look at -- well, first,
23 to just note that a statute is not ambiguous simply because the
24 text might not expressly address an issue, but when considering
25 ambiguity under D.C. Circuit precedent, a court should look at

1 all of the tools of statutory interpretation. One of those
2 helpful tools here is the legislative history to help illuminate
3 what this broad mandate was trying to do.

4 And we know from clear indications in the legislative
5 history that Congress specifically chose not to condition the
6 eligibility of 340B purchases based on the dispensing mechanism
7 that would be used by a covered entity. And in 1992, Congress
8 considered in a prior version of the bill that would become the
9 340B statute a provision that would have restricted eligible
10 purchases of 340B drugs to only those that would be sent to a
11 covered entity or on-site at a covered entity.

12 And on its plain terms, that provision would operate almost
13 precisely how the plaintiffs here think that the current version
14 of the 340B statute ought to operate. That is, that a
15 manufacturer has no obligation to sell 340B drugs unless it's
16 going to be dispensed by the covered entity itself.

17 But critically, Congress chose not to enact that provision
18 but instead wrote a statute containing no dispensing-based
19 restrictions on a covered entity's ability to dispense 340B
20 drugs. And I think it's clear why Congress chose to do that
21 when one also considers Congress's legislative objective here.
22 And it's undisputed in this case that Congress's goal -- and a
23 number of courts have acknowledged this, that Congress's goal in
24 designing the 340B program was to enable covered entities to
25 stretch their resources as far as they possibly can in order to

1 be able to serve more patients with more comprehensive services.

2 And Congress said in -- that quotation comes from a House
3 report. In that same House report, Congress explained exactly
4 how it sought to achieve that purpose, by enabling covering
5 entities to actually obtain the lower prices on the drugs that
6 they provide to their patients.

7 And I think this is actually a critical point that Your
8 Honor asked, I believe, Novartis's counsel, that Novartis's
9 counsel said that patients can fill their prescriptions at any
10 pharmacy in the country, no matter how far away it is from the
11 covered entity and nothing about Novartis's policy restricts
12 that. But those drugs are not going to be drugs purchased by a
13 covered entity at the discounted price. It would also prevent
14 those covered entities from extending those discounts to that
15 patient.

16 So it's incorrect to say that Novartis's policy of a
17 40-mile geographic restriction does not impact patients who
18 would have to fill those medications at a pharmacy that is
19 beyond that 40-mile restriction.

20 So with Congress seeking to actually have covered entities
21 be able to obtain discounted drugs for the medications that
22 their places fill, I think it's important to look to the
23 administrative record. And the administrative record is replete
24 with evidence that covered entities' ability to access 340B
25 discounts which they're statutorily entitled through their

1 contract pharmacy arrangement has enabled them to do exactly
2 what Congress sought for them to do, to stretch resources, to
3 remain in operations, to expand critical healthcare services,
4 and to permit patients to actually access medications.

5 And plaintiffs' contrary argument that they need not honor
6 any 340B purchases that are made through -- that are going to be
7 dispensed by a contract pharmacy is predicated on an
8 interpretation of the statute that would have meant that the
9 340B statute was, in large part, a dead letter when it was
10 passed. What we see from the record is that without the 340B
11 program, more than 95 percent of covered entities have the
12 ability to dispense drugs in-house, and a large number of them
13 were already relying in those early years of the 340B program on
14 outside dispensing services.

15 So in order to accept plaintiffs' view of the statute, I
16 think one would need to also accept that Congress designed the
17 340B program to put the vast majority of its intended
18 beneficiaries to a choice, and that choice would be to invest
19 severely limited resources and infrastructure into developing
20 their own in-house pharmacies, which for a good number of them
21 would have been impossible and would have defeated Congress's
22 intent to help them stretch their resources to provide critical
23 healthcare service to underprivileged patients, or their other
24 choice would have been to simply forego participation in the
25 340B program altogether, which would clearly defeat Congress's

1 intent to enable covered entities to actually access the
2 medicine. And some of those same choices still face covered
3 entities today.

4 THE COURT: Is there any limit under the statute as to
5 what HRSA can do?

6 So between 1996 and 2010, HRSA has changed its view
7 interpreting the text of the statute from requiring just one
8 contract pharmacy to now unlimited contract pharmacies. Is
9 there any limit?

10 Because the statute does require the manufacturers to
11 provide these drugs at below the applicable ceiling price to
12 these patients, but it also is concerned about other things like
13 double-dipping and audits, and there's a concern about these
14 things not being done fraudulently, too.

15 It just seems like HRSA has expanded the program to a
16 degree that those statutory provisions are not being honored,
17 based on what I read in the OIG report and the -- I forget the
18 other report discussing the fraud.

19 MR. LOWENSTEIN: I believe that was some extra record
20 evidence that perhaps United Therapeutics might have brought in,
21 or it's from the GAO report.

22 THE COURT: GAO report. So that's not in the record?

23 MR. LOWENSTEIN: There's one GAO report in the record
24 and another cited in the briefs by plaintiffs that I don't
25 believe is in the record.

1 THE COURT: All right. Anyway, back to the question,
2 is the text -- the government's position is that the text
3 requires its interpretation, and I just have a hard time
4 following that textual argument. And if the government loses on
5 the textual argument, can it still win on the reasonableness of
6 its interpretive rules that it issued in '94, '96, 2010, and
7 later?

8 MR. LOWENSTEIN: So Your Honor, I will first address
9 that last point. I don't believe that -- well, HRSA does not
10 seek to enforce any rule that was interpreted or is contained in
11 the interpretive guidance here. And I think this is -- I think
12 there's multiple points to address to Your Honor's question, and
13 I would like to take them in reverse, because this is really, I
14 think, the chief contention of Novartis in this case, is that
15 the violation letter, that HRSA began and initiated its
16 enforcement action and interpreted the statute because it felt
17 that it was compelled by unambiguous statutory text. That's
18 nowhere contained within HRSA's violation letter. It does not
19 depend and hinge itself on the assumption that its statutory
20 interpretation is compelled by unambiguous text.

21 The question for the Court, if the Court -- in the event
22 the Court thinks the statute is unambiguous -- or is ambiguous,
23 the question then for the Court is, who has the best reading
24 here? And we would posit that HRSA's reading is the best
25 reading of in this event an ambiguous statute. And all Novartis

1 points to to assert its position that HRSA's enforcement action
2 and HRSA's statutory interpretation is going to hinge on whether
3 or not the text is unambiguous is that HRSA's letter says
4 that -- or that the 340B statute, quote, requires manufacturers
5 to honor 340B purchases. But the point of interpretation,
6 whether it's based on an unambiguous statute or an ambiguous
7 statute, is always to determine what Congress requires.

8 So I think I disagree with Novartis's counsel that the
9 validity of HRSA's statutory interpretation and violation
10 determination hinges on whether there's no ambiguity in the
11 text.

12 And then, Your Honor --

13 THE COURT: Sorry to interrupt there. Let's say I --
14 well, two questions. One, you did argue in your brief that the
15 agency's interpretation is entitled to deference. But let's put
16 that aside. You seem to be not advancing that here. You're
17 saying that it's the best reading.

18 But let's say I do agree with you that it is the best
19 reading. Can HRSA base an enforcement action based on its best
20 reading that is reflected in an interpretive guidance document
21 as opposed to some sort of regulation?

22 MR. LOWENSTEIN: Well, Your Honor, yes, HRSA can
23 enforce a statutory obligation and base that enforcement action
24 on its interpretation of what it believes that statutory
25 obligation means. I think that is proper here. I think that's

1 a proper role of HRSA in exercising its delegated authority to
2 enforce this statute.

3 And again, I want to go back to, I think, a piece that is a
4 part of this question. And that is that in the 1994, 1996, and
5 2010 guidance documents, HRSA does not change or modify its
6 statutory interpretation. The limitation in the 1996 guidance
7 that HRSA designed to help create a working framework for
8 covered entities to help them participate in the program and to
9 also help them comply with their obligations was not -- that was
10 not -- HRSA nowhere in that guidance suggests that that was a
11 product of a statutory interpretation but of administering a new
12 program, a very novel program here, and to help the intended
13 beneficiaries access the benefits.

14 What was a matter of statutory interpretation in the 1996
15 guidance was HRSA's very clear statement that the statute
16 directs manufacturers to honor 340B purchases when they are
17 directed to be dispensed through contract pharmacies. And the
18 fact that HRSA as the -- as administering the 340B program
19 sought to set some guidance for covered entities and the number
20 of contract pharmacies they could engage does not in any way
21 suggest that manufacturers are able to superintend the program
22 themselves with self-help restrictions where they can police
23 covered entities' compliance.

24 In the *Astra v. USA* case before the Supreme Court, the
25 Supreme Court said very clearly that Congress gave oversight of

1 compliance to HHS. And both plaintiffs here are seeking to do a
2 run-around, to bypass the proper administrative course for
3 addressing their concerns with diversion and duplicate
4 discounting at contract pharmacies, and they're trying to get
5 around what is -- yes, Your Honor.

6 THE COURT: What about United Therapeutics's point
7 that they can't even use the enforcement mechanisms they have in
8 the statute, the ADR process, for example, without this sort of
9 information?

10 MR. LOWENSTEIN: Well, United Therapeutics has --
11 there is an auditing process, that United Therapeutics can
12 engage in auditing guidelines to help them engage in that
13 process, and that is a process that Congress directed
14 manufacturers to take. And United Therapeutics's pharmaceutical
15 pricing agreement says if they have concerns with compliance
16 issues with covered entities who are the ones who are subject to
17 the statutory prohibitions of the divergence in discounting,
18 they can, as Congress pointed out in the statute, act to conduct
19 a manufacturer-based audit. So they are able to audit.

20 And that's precisely what their claims data restriction on
21 340B purchases attempts to do, is to get around that requirement
22 and that orderly administrative process by trying to use
23 purchases as a means of getting information themselves outside
24 of the orderly administrative process that Congress directed
25 these manufacturers to utilize.

1 THE COURT: But to their point, as the program's
2 currently being administered, can it be audited effectively?

3 MR. LOWENSTEIN: Your Honor, I believe so. I believe
4 that these manufacturers are able to -- they have a statutory
5 ability to use the audit guidelines that HRSA has created for
6 them and to audit covered entities for the information that they
7 are trying to extract from them through holding up their ability
8 to purchase the 340B drugs that they're statutorily entitled to.

9 And Your Honor, I would like to also note that another
10 chief point that particularly United Therapeutics relies on is
11 their attempt to find a statutory prohibition on dispensing 340B
12 drugs anywhere but by covered entity. And they find this
13 prohibition lurking, you know, for about 30 years now unnoticed
14 in Subsection (a) (5) (A) of the 340B statute. And this prohibits
15 the reselling or transferring of 340B drugs to nonpatients.

16 This prohibition has never been understood, never been
17 interpreted, never been applied to prohibit the use of
18 outside -- of contract pharmacies to dispense drugs to a covered
19 entity's patients. And I point the Court's attention to the
20 1994 guidance, which explains that this prohibition on
21 diverging, which is just another term for unlawful transfer or
22 reselling of drugs, typically would take place where drugs are
23 being dispensed to ineligible patients or used in ineligible
24 services.

25 But in that very same guidance, HRSA acknowledged in 1994

1 and has stayed true to this interpretation that the use of
2 contract pharmacies is not only permissible, but it was a custom
3 dispensing mechanism and could not be used as a basis to limit
4 340B transactions. And really, to adopt United Therapeutics's
5 reading of the statutory prohibition on divergence, one would
6 have to accept that the 340B program in that instance would have
7 been operating in a fundamentally unlawful manner for nearly
8 three decades. And the drug manufacturers, including
9 plaintiffs, have long honored those purchases that would have
10 apparently been unlawful this entire time by honoring purchases
11 made through contract pharmacies.

12 Now, Your Honor, you asked both plaintiffs here about the
13 antidiscrimination provision that was codified in the "shall
14 offer" provision. The "shall offer" provision was codified --
15 or sought to codify in 2010 versus a prior interpretation that
16 is contained in the 1994 guidance that manufacturers must offer
17 discounted 340B drugs and, in doing so, may not single out
18 covered entities from their other customers or restrictive
19 conditions. And this mandate was really necessary to impose on
20 manufacturers, particularly in part to prevent them from giving
21 preferential treatment to full-priced commercial sales in a time
22 where there might be a drug shortage or a scarcity.

23 As HRSA also explained in its civil monetary penalty rule
24 from 2017, the provision is consistent with HRSA's long-standing
25 antidiscrimination policy in that manufacturers are expected to

1 provide the same opportunity for 340B covered entities and
2 non340B covered entities when drugs are distributed through a
3 certain avenue or dispensed through, for instance, specialty
4 pharmacies, that they are giving that same -- same
5 opportunities.

6 And plaintiffs' suggestion that really the full extent of
7 their obligation under the "must offer" provision is just simply
8 to offer their drugs for sale at discounted prices really kind
9 of strains credulity, because that obligation to offer their
10 drugs for sale and to honor purchases existed since 1992 and
11 didn't need to be codified in 2010. And to suggest that the
12 full extent -- and I think United Therapeutics leans into this
13 more than Novartis. To suggest that the full extent of their
14 obligation to actually offer drugs is just in the "shall offer"
15 provision and not in the first provision of Subsection (a)(1), I
16 think one would have to accept an exceedingly improbable
17 premise, and that is, for the first 18 years of the 340B
18 program, a drug manufacturer could formally sign a PPA, reap the
19 entire benefits of Medicaid coverage for its drug, which
20 Congress sought to condition on their participation in the 340B
21 program, and yet refuse to sell a single drug to a single
22 covered entity.

23 I think it's highly unlikely that Congress would have
24 enacted such a meaningless piece of legislation, and I think
25 it's also highly unlikely that Congress would have relied

1 entirely -- in order to try to have covered entities actually
2 obtain discounted drugs for their patients, rely entirely on the
3 pharmaceutical industry to voluntarily sell drugs at deeply
4 discounted prices when it has no incentive to do so.

5 So that reading of the "shall offer" provision is really
6 implausible, and it had to have enacted an additional
7 requirement, and it's clear that its codification was to codify
8 that basic understanding that commercial purchases should be
9 treated on par with covered entity purchases.

10 THE COURT: Mr. Lowenstein, can you address
11 plaintiffs' argument that the record here doesn't show either
12 one of them has actually violated the statute in not offering
13 drugs at discounted prices to covered entities?

14 MR. LOWENSTEIN: Yes, Your Honor. I think this case
15 is really a case of pure statutory interpretation. Drug
16 manufacturers are obligated under statute to honor 340B
17 purchases by covered entity, and they cannot impose extra
18 statutory restrictions on those purchases that result in
19 purchases being denied, which they both concede that that is how
20 their policy, that's how their restrictions operate. They deny
21 purchases when their conditions that Congress did not impose on
22 the statute, when their conditions are not met.

23 Your Honor, so there's really no serious argument that this
24 record doesn't support that conclusion, that both plaintiffs
25 here impose extra statutory restrictions on 340B purchases which

1 are, as a matter of law, unlawful under the 340B statute.

2 And Your Honor, I think it's important to note that HRSA
3 did not need to wait around until plaintiffs' specific
4 restrictions caused widespread harm to covered entities or their
5 patients before HRSA could inform plaintiffs that their
6 restrictions are unlawful under the statute. And that's
7 particularly true where HRSA had already collected ample
8 evidence of widespread harm to covered entities and their
9 patients when they're unable to purchase drugs through the
10 covered entities that they have relied on.

11 And those extra statutory restrictions, I think, subvert
12 the purpose of the statute in the same manner as those other
13 restrictions. It creates the same basic harm for individual
14 covered entities and their patients. And they equally violate
15 plaintiffs' statutory obligation.

16 At any rate, the record does show that Novartis's and
17 United Therapeutics's restrictions have led to specific covered
18 entities either purchasing 340B drugs above the ceiling price or
19 being denied access to 340B discounted drugs. And with regard
20 to Novartis, covered entities have provided specific
21 transactions where they purchased Novartis's drug above the
22 ceiling price, and they pin that on Novartis's restrictions on
23 the ability to purchase drugs and dispense them through contract
24 pharmacies.

25 And I will just point the Court's attention to a few record

1 cites at VLTR 1468, VLTR 1474, VLTR 6243 through 44, and VLTR
2 6410 through 11. And these are specific transactions that are
3 noted where Novartis's drugs are being purchased by covered
4 entities that are entitled to those drugs at the discounted rate
5 but are purchasing above the ceiling price. That is a clear-cut
6 violation of their statutory violation to ensure that that does
7 not happen.

8 THE COURT: What about United Therapeutics?

9 MR. LOWENSTEIN: United Therapeutics's covered
10 entities have explained that 340B prices had become unavailable
11 or would become unavailable for use of these drugs for these
12 covered entities. And I will point the Court to VLTR 5714,
13 5756, and 5769.

14 THE COURT: Are they all prospective, or are there
15 some that have already occurred with respect to United
16 Therapeutics?

17 MR. LOWENSTEIN: One covered entity stated that 340B
18 pricing had become unavailable to it, and we know that relates
19 to United Therapeutics. It appended United Therapeutics's
20 two-step policy restricting 340B purchases that are going to be
21 dispensed to contract pharmacies. And that unavailability of
22 the 340B price is again a clear-cut violation of United
23 Therapeutics's statutory obligations.

24 And Your Honor, if I may, I just want to address a few of
25 the contentions that have been made by Novartis and United

1 Therapeutics. With respect to the replenishment model -- and
2 this really comes up in both plaintiffs' attempt to try to
3 justify their extra statutory restrictions, their resorting to
4 self-help mechanisms to police the 340B program because they're
5 concerned about what is occurring through the replenishment
6 model.

7 And both plaintiffs state with a lot of confidence that
8 340B eligibility for dispenses that are made through the
9 replenishment model at a contract pharmacy are always
10 determined -- well, United Therapeutics says it's up for debate
11 whether eligibility is ever determined. But it is never
12 determined at the time a prescription is dispensed.

13 And I would point the Court to the OIG report, VLTR 7972
14 and 7977, where OIG found that the majority of the covered
15 entities that it had surveyed were capable of determining and
16 did determine eligibility at their contract pharmacies under the
17 replenishment model at the time drugs were dispensed, and they
18 did that so that they would be able to give these discounts,
19 give up -- to pass on the discounts to their patients at the
20 time the prescriptions are filled. And that was through the
21 replenishment model. They could do that through providing their
22 patient's card or a coded prescription.

23 So it's just not correct that eligibility is not able to be
24 determined at the time a prescription is filled. And the OIG
25 report says that all the covered entities either determine

1 eligibility of a 340B dispensed at the time of prescription or
2 after the fact. And it makes no legal difference because, as
3 HRSA has shown in the record and with the declaration appended
4 to our motion submitted by the director of HRSA's Office of
5 Policy Affairs, that all 340B purchases by covered entities are
6 tied to eligible 340B dispenses at their contract pharmacies.
7 And HRSA puts in place recordkeeping requirements, and it
8 conducts audits to ensure that is taking place.

9 So it's just simply not true what plaintiffs say in their
10 briefing that once drugs are sent to the contract pharmacies
11 that utilize this virtual inventory or this replenishment model,
12 that they're just being sold to patients and nonpatients alike.
13 340B purchases are being tied to 340B eligible dispenses. And
14 so plaintiffs' concerns with the replenishment model are simply
15 not -- at the end of the day, it's simply not a justification
16 for creating these extra statutory restrictions to deny 340B
17 discount covered entities to purchase those drugs.

18 THE COURT: Do covered entities always remain entitled
19 to the drugs?

20 MR. LOWENSTEIN: Your Honor, under -- as the record
21 shows, and I will provide Your Honor with a few record cites,
22 that covered entities do maintain title to 340B drugs that
23 they've purchased, at least until they reach -- under the
24 replenishment model, until they reach the neutral inventory of
25 the contract pharmacy from which the 340B eligible dispenses

1 were dispensed. And at VLCR 7261 and 7279, these are two sworn
2 declarations by covered entities explaining that they maintain
3 title under a virtual inventory or replenishment model system.

4 And your Honor, I would also just like to identify that
5 retention of title, as United Therapeutics admits in its brief,
6 is not a statutory requirement when covered entities through --
7 through the dispensing process when covered entities are
8 dispensing their 340 purchased drugs to their patients.

9 THE COURT: The government would concede, I take it,
10 based on the GAO report, the OIG report that the likelihood of
11 fraud increases or double-dipping increases with this regime
12 that's currently in practice? Is that fair?

13 MR. LOWENSTEIN: Your Honor, I don't think we would
14 concede that, that there's anything inherently about the
15 contract pharmacy arrangement that necessarily leads to more
16 abuse in the system. Covered entities have statutory
17 obligations just like our manufacturers do, and they put in
18 place -- and HRSA has helped put in place guidance for them to
19 comply with those statutory prohibitions on divergence in
20 discounting, and they are -- and HRSA has created oversight
21 mechanisms to oversee contract pharmacy arrangements through --

22 THE COURT: You wouldn't agree, though, that it's
23 harder for you to police these arrangements than before?

24 MR. LOWENSTEIN: I'm not sure, Your Honor. If I did
25 say that, it's necessarily harder to conduct oversight of a

1 contract pharmacy arrangement than maybe an in-house pharmacy.
2 I just want to note, Your Honor, there's never really been a
3 before with respect to contract pharmacies, because contract
4 pharmacies have really been an integral part of how covered
5 entities have been able to dispense drugs for nearly the entire
6 340B program.

7 THE COURT: But regardless, the government's position
8 is even if it's harder to police, it's the role of the
9 government and not the entities, not the manufacturers, to play
10 that role under the statute?

11 MR. LOWENSTEIN: That's precisely right, Your Honor,
12 and I think that's what the Supreme Court said in saying that
13 Congress specifically gave oversight of compliance in the 340B
14 program to HHS, and it is not the place of drug manufacturers to
15 try and police the system by holding 340B purchases hostage from
16 covered entities.

17 THE COURT: Ms. Stetson and Mr. Perry, I'm going to
18 give each of you five minutes. Unfortunately, I have a 12:30.
19 So I'm going to have to cut you short here.

20 Ms. Stetson, if you would like to make any remaining
21 points.

22 MS. STETSON: Sure. Let me make three quick points.
23 I'm sure Mr. Perry will want to talk about the title colloquy
24 you were having, among others. So I will leave that to him.

25 The first on text, where Mr. Lowenstein started is where we

1 would start. He says it's helpful to start with the text. We
2 agree. But what he then says was a long kind of discursive
3 argument using the word "purchase" as much as possible but
4 ending up in a lot of kind of convoluted phrases like, you know,
5 manufacturers are impermissibly exercising discretion to deny
6 purchases to the extent that drugs are dispensed by a contract
7 pharmacy.

8 That kind of gymnastical interpretation is, I think, what
9 led to Your Honor's comment, that with respect to the statute,
10 the statute says nothing about contract pharmacies.

11 Mr. Lowenstein's response was that HRSA just seeks to
12 enforce straightforward statutory obligations. So again, I
13 think there is a passing of ships in the night here. Your
14 Honor, and we agree, pointed out that the statute doesn't speak
15 to contract pharmacies. Mr. Lowenstein consistently has said
16 the straightforward statutory obligation says what it says.

17 He has to say that, let me add, because DOJ understands as
18 we do that HRSA doesn't have the kind of rulemaking authority
19 that you alluded to, Judge Friedrich. There is no gap to fill
20 to begin with, but even if there were, HRSA's authority is
21 limited -- and you can find this on page 5 of our reply brief --
22 to the establishment of an ADR process, the issuance of
23 methodologies for determining ceiling prices, and even the
24 imposition of monetary civil sanctions.

25 There is no regulatory act that HRSA can undertake, which

1 is why HRSA has so unusually kind of latched itself to the mast
2 of the plain text of the statute here, because that is the only
3 path that it has to enforcement.

4 Second point on legislative history. Mr. Lowenstein made
5 the point about how you should consult legislative history in
6 statutory constructions. That legislative history is always
7 kind of the last ditch when it comes to statutory construction.
8 But even so, the legislative history to which he referred, and I
9 will point you to the 1992 Senate report that he mentioned, what
10 didn't come through, I think, in Mr. Lowenstein's argument is
11 that that language initially included reference to pharmacies
12 with whom covered entities had contracted. That was taken out.
13 So if anything, the legislative history here bears out our
14 point. The statute now says nothing about contract pharmacies.

15 The third point I will make is one on policy. A lot of
16 what you heard from DOJ today, understandably, because it's the
17 same as in its brief, has to do with the policies underlying the
18 340B statute. But as I said at the front of my argument, the
19 policy debates are debates that Congress gets to have, not this
20 Court with counsel within the context of talking about the plain
21 text of the statute.

22 With respect to the policy on extending discounts to
23 patients, I want to make this very clear. First of all, as the
24 government knows, the 340B program is not designed to require
25 340B covered entities to give discounts to patients. And in

1 fact, that is rarely done. If a patient, however, in that rare
2 circumstance walks into a pharmacy with a 340B discount card or
3 some other offering like Mr. Lowenstein was talking to, she gets
4 the prescription filled at that cost. This is all about the
5 covered entities kind of profiting from that back-end spread
6 between the 340B price and the other, you know, available price.
7 This is not about failing to give discounts to patients.

8 The last thing I will say is, Mr. Lowenstein mentioned a
9 couple of times the manufacturers taking upon themselves to
10 superintend this process. Manufacturers are not doing anything
11 except trying to impose some modest restrictions on a runaway
12 contract pharmacy program that has grown by thousands of percent
13 in the last 10 years. There were 193 contract pharmacies in
14 2010. There are 43,000 of them now. And as a result of that,
15 Your Honor pointed out, there are issues that the GAO and OIG
16 have both pointed out with duplicate discounts, with diversion,
17 with other issues with transfer.

18 Mr. Lowenstein couldn't concede any of that. I think he
19 could have because the OIG has said what it said, but the fact
20 is, this is perfectly within the manufacturers' abilities as a
21 contracting party with these covered entities, because the
22 statute says nothing about contract pharmacies.

23 And I will leave it there. Thank you, Your Honor.

24 THE COURT: All right. Mr. Perry.

25 MR. PERRY: Thank you, Your Honor.

1 The government's counsel said a few times that it's
2 material that these policies that they're attempting to enforce
3 are longstanding. That really doesn't matter. It's the
4 statutory text that matters. And his response where he gave
5 that answer was, I think, relating to a question about
6 (a) (5) (b), which is the "otherwise transfer" provision. They
7 have no answer to that provision. And all they are doing here
8 is citing legislative history. There is no answer to that
9 provision. It's a clear prohibition on what they're attempting
10 to do, and it doesn't matter how long they've been trying to do
11 it.

12 The *Eagle* case, *Eagle Pharmaceuticals* in the D.C. Circuit,
13 is premised on that same thing, essentially found that
14 regulation that had been longstanding were inconsistent with the
15 statute. The recent *Catalyst* case in the Eleventh Circuit, same
16 thing. The fact that an agency has been doing something wrong
17 for a long time does not matter.

18 And here, of course, they've been doing something wrong,
19 but they keep changing what they're doing, which undermines
20 their argument, too.

21 On the GAO and OIG reports, we cited many of them, but
22 here's the salient facts for our record. If you look at the
23 Barton declaration, Your Honor, and in particular the sections
24 that describe all programs, they explain how the replenishment
25 system is working for us, for our client on our record. This

1 letter to us on May 17th should have been about our client and
2 our record. The GAO findings are troubling. The OIG findings
3 are troubling. And we are in the -- in a situation where the
4 replenishment model is really hurting us.

5 Finally, Your Honor, the statute and Section (a)(1) talks
6 about the Secretary implementing these requirements through an
7 agreement. That's the pharmaceutical pricing agreement. It
8 says nothing about contract pharmacies at all. What it does
9 say, and this is in Section 4, it's VLTR 54, is that HRSA
10 recognizes that the pharmaceutical pricing agreements provisions
11 which are pricing provisions coexist with a whole realm of
12 commercial contracts. And those are commercial contracts
13 between manufacturers and covered entities or manufacturers and
14 distributors and covered entities.

15 And here's what it says on that page. "Disputes arising
16 under a contract between a manufacturer and a covered entity
17 should resolve according to the terms of that contract."

18 This PPA is not a license to try to enforce against us for
19 these types of common-sense commercial provisions like those
20 Ms. Stetson mentioned. What we're trying to do here is stem the
21 tide of this abuse that the replenishment model is inflicting
22 upon us, and we're doing so in a really reasonable and
23 nonburdensome way.

24 Thank you, Your Honor.

25 THE COURT: All right. I wish I could take longer,

1 but I do have a status hearing, and I will endeavor to get out
2 an opinion shortly. I know the parties have been waiting some
3 time for this. So I will do my best. I'm not going to give you
4 a date exactly, but it is at the top of my list.

5 Thank you all.

6 (Proceedings adjourned at 12:40 p.m.)

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CERTIFICATE OF OFFICIAL COURT REPORTER

I, Sara A. Wick, certify that the foregoing is a correct transcript from the record of proceedings in the above-entitled matter.

Please Note: This hearing occurred during the COVID-19 pandemic and is, therefore, subject to the technological limitations of court reporting remotely.

/s/ Sara A. Wick

October 18, 2021

SIGNATURE OF COURT REPORTER

DATE