BEFORE THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

NOVARTIS PHARMACEUTICAL COMPANY, .
. Case Number 21-cv-1479
Plaintiff, .
.
vs. .
.
DIANA ESPINOSA, et al., .
.
Defendants. .
- - - - - - - - - - - - - - - - - -
UNITED THERAPEUTICS CORPORATION, .
. Case Number 21-cv-1686
vs. .
.
DIANA ESPINOSA, et al., .
. October 12, 2021
Defendants. . 11:05 a.m.
- - - - - - - - - - - - - - - - - -

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

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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

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

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

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

Everyone agrees --

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

government's position, does the government lose here?

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

THE COURT: Why is that?

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

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

So --

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

MS. STETSON: I think --

(Simultaneous talking.)

THE COURT: -- the enforcement proceedings here.

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

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

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

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

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

here in order to bring an enforcement proceeding?

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

purchasers differently. That is simply not true.

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

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

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

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

THE COURT: (Distorted audio) anywhere across the

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

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

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

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

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

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

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

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

THE COURT: Go ahead.

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

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

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

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

Is that not true?

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

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

THE COURT: The hospital does; right?

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

exceptions all the time, I will tell you.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

THE COURT: Thank you, Ms. Stetson.

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

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

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

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

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

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

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

in the statute.

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

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

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

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

The response by the government to this can be found at

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

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

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

what we call here the "shall offer" provision.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Now, if I might --

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

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

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

THE COURT: Is that information you need to bring to

use the ADR process that's in the statute?

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Thank you.

THE COURT: Mr. Lowenstein?

MR. LOWENSTEIN: Thank you, Your Honor.

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

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

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

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

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

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

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

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

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

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

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

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

Yes, Your Honor?

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

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

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

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

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

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

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

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

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

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

be able to serve more patients with more comprehensive services.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

And then, Your Honor --

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

But in that very same guidance, HRSA acknowledged in 1994

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

THE COURT: What about United Therapeutics?

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

There is no regulatory act that HRSA can undertake, which

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

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

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

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

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

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

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

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

THE COURT: All right. Mr. Perry.

MR. PERRY: Thank you, Your Honor.

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

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

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

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

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

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

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

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

Thank you, Your Honor.

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

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

Thank you all.

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

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