IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

NOVARTIS PHARMACEUTICALS CORPORATION, *Plaintiff*, v. DIANA ESPINOSA, in her official capacity as ACTING ADMINISTRATOR, HEALTH RESOURCES AND SERVICES ADMINISTRATION and XAVIER BECERRA, in his official capacity as SECRETARY, UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, *Defendants*.	Civil Action No. 1:21-cv-01479

PLAINTIFF'S RESPONSE TO
DEFENDANTS' NOTICE OF SUPPLEMENTAL AUTHORITY

Defendants have submitted to this Court a recent decision from the Southern District of Indiana, arguing that the Indiana court's "plain holding" means "by implication" that Novartis's policy violates "the 340B statute itself." Defendants' Notice at 4 (citing *Eli Lilly v. Becerra*, No. 21-81 (S.D. Ind. Oct. 29, 2021). Novartis takes issue with that representation for a number of reasons.

First: The *Lilly* court's statutory analysis was premised on an assessment of what that court "believe[d] is the appropriate and correct interpretation of the 340B statute." *See Lilly*

Decision at 49 n.15. But the jumping-off point for an APA analysis is what the agency argued; and here, HRSA argued, both below and before this Court, that the 340B statute *unambiguously requires* manufacturers to honor all contract pharmacy arrangements. Novartis October 12, 2021 Hearing Tr. 42 ("HRSA does not seek to enforce any rule that was interpreted or is contained in the interpretive guidance here."), 37 ("[T]his enforcement process is based on a statutory obligation"), 44 (same), 49 (same) (attached as Ex. 1). The 340B statute contains no such unambiguous requirement. And where the agency has not invoked its interpretive authority, a reviewing court may not do that job for them. *See, e.g.*, *American Lung Ass'n v. EPA*, 985 F.3d 914, 944 (D.C. Cir. 2021) *(per curiam)* (regulatory action "must be declared invalid" if it is based on the "unjustified assumption that it was Congress' judgment that such a regulation is desirable or required" (cleaned up)), *cert. granted,* No. 20-1780 (Oct. 29, 2021).

In the usual APA case, the next question might be whether the agency *can* offer an interpretation that solves an ambiguity or fills a purported gap. But as we have explained, this is an unusual APA case, because HRSA is in an unusual position; *it lacks the authority* to gap-fill with requirements not found in the governing statute. *See Pharm. Research & Mfrs. of Am. v. U.S. Dep't of Health & Human Servs.*, 43 F. Supp. 3d 28, 42 (D.D.C. 2014) (noting that the 340B statute grants HRSA rulemaking authority only with respect to "(1) the establishment of an administrative dispute resolution process, (2) the 'regulatory issuance' of precisely defined standards of methodology for calculation of ceiling prices, and (3) the imposition of monetary civil sanctions"); Novartis Reply at 5 (explaining HRSA's limited authority); Novartis Hearing Tr. 56-57 (same). That is why the government has repeatedly taken the hard line it has in this case: Because of those statutory constraints, the government needs to argue that *the statute itself requires* manufacturers to accede to covered entities' directives that they deliver 340B-priced

drugs to non-covered-entity recipients. It has no other option. *See* AstraZeneca October 18, 2021 Hearing Tr. 51-52 (DOJ counsel conceding that HRSA may not interpret ambiguous statutory terms nor fill in legislative gaps, because that "would be [a] legislative act . . . and HRSA has not been expressly granted general rule making authority.") (attached as Ex. 2). Because the statute does not unambiguously require manufacturers to comply with covered entities' directives that they deliver 340B-priced drugs to tens of thousands of contract pharmacies, and because HRSA lacks the general authority to interpret or otherwise gap-fill the 340B statute, the proper outcome here is to decline to follow the *Lilly* decision and instead to enter summary judgment for Novartis.

Finally, even if this Court were inclined to follow the atypical analytical path set forth by the *Lilly* court, that court did not review—let alone purport to address—*Novartis's* contract pharmacy policy. *See Lilly* Decision at 59 ("We are not authorized or qualified to go beyond this role by presuming to speak for Congress, the agency, the regulated entities, or other federal district courts assessing similar but distinct policies of other drug manufacturers."). Even setting aside the other reasons why the *Lilly* opinion may not be an appropriate model for this Court to follow, there is no "implication" about Novartis's policy that can possibly be drawn from that decision in this case.

For the foregoing reasons, the Indiana court's decision has no bearing on the issues before this Court.

Respectfully submitted,

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Counsel for Novartis Pharmaceutical Corporation

Dated: November 4, 2021

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., .
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Defendants. .
- - - - - - - - - - - - - - - - - -
UNITED THERAPEUTICS CORPORATION, .
. Case Number 21-cv-1686
vs. .
.
DIANA ESPINOSA, et al., .
. October 12, 2021
Defendants. . 11:05 a.m.
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TRANSCRIPT OF MOTIONS HEARING
BEFORE THE HONORABLE DABNEY L. FRIEDRICH
UNITED STATES DISTRICT JUDGE

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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.

IN THE UNITED STATES DISTRICT COURT

IN AND FOR THE DISTRICT OF DELAWARE

- - -

ASTRAZENECA PHARMACEUTICALS LP,

Plaintiff,

v

XAVIER BECERRA, in his official capacity as Secretary of the U.S. Department of Health and Human Services; DANIEL J. BARRY, in his official capacity as Acting General Counsel of the U.S. Department of Health and Human Services; DIANA ESPINOSA, in her official capacity as Acting Administrator of the Health Resources and Services Administration; U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES; and HEALTH RESOURCES AND SERVICES ADMINISTRATION,

Defendants.

: CIVIL ACTION

: NO. 21-27-LPS

- - -

Wilmington, Delaware
Monday, October 18, 2021
Oral Argument by Zoom Conference

- - -

BEFORE: HONORABLE LEONARD P. STARK, Chief Judge

APPEARANCES:

- - -

McCARTER & ENGLISH, LLP
BY: DANIEL M. SILVER, ESQ., and
ALEXANDRA JOYCE, ESQ.

and

ARNOLD & PORTER KAY SCHOLER, LLP
BY: ALLON KEDEM, ESQ., and
JEFFREY L. HANDWERKER, ESQ.
(Washington, District of Columbia)

Counsel for Plaintiff

Brian P. Gaffigan
Official Court Reporter

APPEARANCES: (Continued)

U.S. DEPARTMENT OF JUSTICE
BY: KATE TALMOR, ESQ.
Trial Attorney
(Washington, District of Columbia)

Counsel for Defendants

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P R O C E E D I N G S

(REPORTER'S NOTE: The following Zoom Video Conference was held remotely, beginning at 3:19 p.m.)

THE COURT: Good afternoon, everyone. If you can't hear me, let me know. And if so, let's have the plaintiffs put their appearances on the record, please.

MR. ENGLISH: Good afternoon, Your Honor. Dan Silver from McCarter & English on behalf of AstraZeneca and I'm joined today by Allon Kedem, who you should be able to see, and also Jeffrey Handwerker from Arnold Porter.

THE COURT: Thank you. I can see Mr. Kedem. Let me make sure I can hear you.

MR. KEDEM: Can you hear me, Your Honor?

THE COURT: You can hear me; is that right?

MR. KEDEM: Absolutely.

THE COURT: Okay. Good afternoon to you.

And who is there for the government, please?

MS. TALMOR: Good afternoon, Judge Stark. This is Kate Talmor on behalf of the government.

THE COURT: Okay. And you can hear me all right as well?

MS. TALMOR: Yes, Your Honor. Can you hear me as well?

THE COURT: I can, yes. Thank you very much.

And thanks to all of you for arranging this.

So we're here for argument on your cross-motions for summary judgement.

And, Mr. Kedem, I take it you are going to

speak. Have you and Ms. Talmor conferred on how you might like to proceed today?

MR. KEDEM: We haven't, Your Honor; and we're happy to do it however you would prefer.

THE COURT: Okay. Does the government have a preference as to how we proceed?

MS. TALMOR: No, Your Honor. We also are happy to proceed as you would find most appropriate.

THE COURT: Okay. Well, why don't we hear from the plaintiff first. The issues, even though it's cross-motions, the issues overlap. And I will have questions for both of you, which I will feel free to throw at you any time I want; and you will each get, I'm sure, at least two opportunities to speak.

So with that, Mr. Kedem, why don't you begin when you are ready.

MR. KEDEM: Thank you, Your Honor. And may it please the court.

The May 17th letter and the advisor opinion reached the same conclusion based on the same errors identified in this Court's ruling.

Both attempt to locate a statutory requirement where none exists. Both make faulty claims of administrative inconsistency and both rely on one-sided administrative process.

The Department of Justice now seeks to brush aside the relevance of this Court's ruling with appeals to deference, a lengthy administrative record and above all, policy concerns.

But the basic interpretative question at the heart of this dispute remains the same: Does the 340B statute itself require manufacturers to provide unlimited discounts for contract pharmacy sales or is that a requirement that the agency is adding to the text? Or put in the language of the May 17th letter, is it true that AstraZeneca's policy is "in direct violation of the 340B statute."

The answer is still no.

Your Honor is imminently familiar with the 340B program and the relevant legal issues; and I'm happy to use our time together however would be most helpful. Subject to the Court's direction, I could sketch out what we take to be the three most straightforward errors reflected in the May 17th letter and then what we're asking the Court for, but, Your Honor, I'm happy to also just answer questions if you would prefer.

THE COURT: No, I think -- thank you for the offer. I think it would be helpful if you have the three most prominent, in your view, errors. And I did have questions about what actually you are asking me to do, so

why don't you start with all that.

MR. KEDEM: The first error, the most fundamental error is a textual one.

The May 17th letter says that AstraZeneca's policy directly conflicts with the 340B statute based on the "must offer" provision, which it says is not qualified or restrictive, and it's not at all surprising that the May 17th letter takes this position. As Your Honor will recall, the letter was issued while the advisory opinion was still on the books.

And the advisory opinion had been issued by the general counsel of the agency who speaks on the Secretary's behalf authoritatively on the questions that are applicable to the entire agency. So you could hardly expect the subagency like HRSA to take a different view.

But what Your Honor held is that such a requirement "is not contained in the statute and insofar as you look beyond the 'must offer' provision, beyond the provided by language, to other textual clues, they point against the government's reading and in favor of AstraZeneca's reading."

And so if Your Honor was correct about the text, then the May 17th letter is wrong about the text.

The second error is the government's unacknowledged change of position. What Your Honor called

the faulty premise that the agency has always taken the position that manufacturers are obligated to provide contracts, unlimited discounts for contract pharmacy sales.

And the way the May 17th letter puts it, is that the government has taken this position "consistently since issuance of its 1996 contract pharmacy guidance" but that runs head long into the simple observation that this Court made that AstraZeneca's policy complies with the 1996 guidance, and the way that the program worked between '96 and 2010 for most of its life-span.

And even with respect to the 2010 guidance which opened things up to unlimited contract pharmacies, that guidance required covered entities to maintain title to the drugs until they were sold to patients, which does not happen under the current replenishment model. So there has been a basic failure to acknowledge, much less to explain the agency's change in position, a classic APA error.

And the third is the government's one-sided process. An agency is required to consider all important aspects of a problem and yet not only does the May 17th letter make no findings, per se, it didn't even show AstraZeneca the allegations made against it by covered entities.

And that's probably because the agency knows that it doesn't really matter. What really matters is

whether this an obligation contained in the text of the statute itself. But insofar as you want to go beyond that and consider the process, it fundamentally undermines any confidence that you might have that the agency actually looked at all important aspects of the problem.

And this is a bit of a crude analogy, but I'd ask you to imagine an opinion from a Magistrate Judge who told you that they had considered all important aspects of some legal issue and concluded that the defendant had violated the law.

But then you discovered the Magistrate hadn't actually shown the allegations against the defendant to the defendant, didn't ask for an explanation, didn't try to see it from the other side as well.

I think you would not agree that they had looked at all important aspects of the problem, and it would not be the type of reasoning that you would be inclined to defer to.

So moving now to what we are asking for.

Certainly, we are asking Your Honor to set the May 17th letter aside in the same manner that you set the advisory preponderance aside but -- and I say this with the greatest possible respect, it is not clear that the government gave literally any effect to your prior ruling.

There is no indication that the agency genuinely

rethought its position in light of the legal parameters that you identified. No indication that it even paused to consider whether another approach was possible. And perhaps Ms. Talmor will tell us today that if you set the May 17th letter aside that the agency would genuinely change gears, but all indications are to the contrary.

As we told Your Honor on September 22nd, the agency went ahead and referred AstraZeneca for imposition of civil monetary penalties.

And it didn't so much as acknowledge that after the May 17th letter but before September 22nd, there was something that happened that was really important in your ruling. No acknowledgment, much less any change of position as a result of it.

And so, Your Honor, we are asking you to make clear in your ruling that the government should not proceed -- the agency should not engage in any administrative proceedings premised on the faulty notion that the statute itself requires AstraZeneca to provide discounts for unlimited contract pharmacy sales. We think that is appropriate, but also flows directly from what you already held.

In other words, there cannot be a knowing intentional violation of a statutory requirement as would be necessary for civil monetary penalties if the statute itself

does not contain such a requirement.

And such a ruling would end the case. The government could appeal if they chose to do so. But absent that, it is hard to see how we don't end up back in front of Your Honor yet again at some point in the future when the government takes yet another step predicated on the same erroneous view of what the statute requires.

THE COURT: Okay. Thank you. Let me ask you some questions.

You did inadvertently, I think, mention the advisory opinion when you got to the relief and there is a footnote on this. Is there something more that you would ask me to do with respect to the advisory opinion in terms of any relief?

MR. KEDEM: No, Your Honor. I think that that is now in the past.

THE COURT: Okay. In terms of an ADR process, and you sent me a letter about that, do I have any claim in front of me from you relating to the ADR process? Is that something I should be concerned with or is that subsumed in what you've already said or should I have that out of my mind at this point?

MR. KEDEM: So I think it is subsumed in the relief that we have requested from the Court and I think Your Honor pointed out in your opinion -- it was a footnote;

I can't remember specifically which footnote -- where you pointed out in any ADR proceeding, the result is for a date because the only really disputed issue is the legal issue, which Your Honor has before you.

So if you thought it was technically necessary we could amend our complaint to add some sort of claim against the ADR specifically, but I do think that if you were to make clear in your ruling that any administrative proceeding predicated on the notion that there is this obligation in the statute that it cannot go forward, I would very much hope -- and this is a question you could pose to Ms. Talmor -- I would very much hope at that point that the government would not move forward with the ADR.

THE COURT: The government writes that based on your interpretation of the statute and probably they would say based on my interpretation of the statute, the inescapable conclusion would be that from 1992 until 2010, the pharmaceutical industry sold deeply discounted drugs to cover entities on a purely voluntary basis, to quote from one of their briefs at D.I. 93 at 13.

Are they right about that?

MR. KEDEM: I think they are right that we went beyond our statutory requirements. And, you know, it's not a legal point. It's maybe a reason that you might look more skeptically at one or the other side's views, but it had

no -- as far as I know, there is no estoppel principle under the APA if that is the argument.

THE COURT: But the logic seemed right. If, if your interpretation of the statute is correct, you did more than the statute required of you --

MR. KEDEM: That's correct.

THE COURT: -- for quite some time, and then for whatever reason you decided not to any longer. Is that a fair interpretation of the facts here?

MR. KEDEM: It is. Although I would point out, Your Honor, we are still doing more than we are required to. The statute requires us to provide discounts to contract -- to covered entities, and we do that in unlimited amounts.

But we have gone beyond that, even under our own reading of the statute to allow covered entities that don't have an in-house pharmacy to use one contract pharmacy.

And even under our own reading, we don't have to do that, but we do that because we want to encourage the use of the 340B program of which AstraZeneca is a proud member and participant.

THE COURT: So another thing the government suggests is that if your, if your interpretation is right, AstraZeneca, and of course other manufacturers in your similar position, could require each covered entity across the nation to physically pick up their purchased drugs from

your warehouse.

Is it right that nothing in the law would preclude you from requiring that?

MR. KEDEM: I don't think that is correct. There is an antidiscrimination provision, but maybe this is a good opportunity to just back up and explain a little bit about how AstraZeneca's sales transactions actually work and then maybe we can drill down on antidiscrimination if you are interested in that principle.

AstraZeneca does not sell to retail customers. We don't sell to hospitals or to pharmacies directly. We sell to wholesalers like AmerisourceBergen and McKesson.

And those wholesalers will often resell products in wholesale transactions to downstream purchasers but AstraZeneca is not involved in those transactions. We don't set the price of those transactions, we don't usually know that they're occurring.

There are, however, some instances where there is what you might call an indirect purchase through AstraZeneca and that's -- the two biggest examples of those are the 340B program and Group Purchasing Organizations or GPOs, which are basically just hospitals and others who band together to get discount pricing. And what happens for those indirect purchases is that they log on to a portal that the, that the wholesaler makes available. And they can

see there is preferential pricing there and they can choose the preferential pricing for the AstraZeneca products, the wholesaler will check with AstraZeneca to make sure they're eligible, and if they are told they are eligible, then they will ship that product to the retail customer.

And here is the key point. When that is involved, when AstraZeneca has that kind of indirect sale, it never offers bill-to, ship-to, with a single exception.

It never bills one entity but ships to another with the single exception of under AstraZeneca's 340B policy, we do bill-to, ship-to for a covered entity that doesn't have an in-house pharmacy. We will allow them to have it shipped to a contract pharmacy.

Now, when I say "shipped," I don't mean from AstraZeneca's warehouse. It still goes through the wholesaler, but we allow bill-to, ship-to only in that one situation. So there is no discrimination.

And, Your Honor, if I could, the government makes a representation to the contrary and I'll just read briefly from page 2 of their reply brief:

"Astra willingly ships its drugs to pharmacies when full commercial prices are paid. It's just newly refusing to ship those same drugs to those same locations when they are ordered and paid for by covered entities and statutory discounts."

And there is one piece of evidence from the administrative record that the government uses to substantiate that claim which, which is page 1842, which is an invoice where they say that there is a neighborhood pharmacy that paid wholesale prices for a bill-to, ship-to situation.

With Your Honor's permission, I'd like to share my screen and go directly to that piece of evidence?

THE COURT: That's fine. Go right ahead.

MR. KEDEM: Can you see, Your Honor?

THE COURT: Yes, I can see.

MR. KEDEM: So you can see 1842.

THE COURT: Okay.

MR. KEDEM: So this is the invoice in which AstraZeneca is allegedly under its policy allowing bill-to, ship-to at wholesale prices.

So we have here the sold to St. Joseph Medical Center, a covered entity, and shipped to Franciscan Pharmacy, which the government says is a neighborhood pharmacy except it's not a neighborhood pharmacy. It is, in fact, part of St. Joseph Medical Center.

And if you Google the street address, what you'll see is that it's just another building on the St. Joseph Medical Center campus. It is essentially an in-house pharmacy under AstraZeneca's policy and would be treated as

such.

The second thing to notice is the order date, September 1st, 2020. So that is one month before AstraZeneca's policy went into effect. So obviously this can't be evidence of what AstraZeneca is doing under its policy.

And then the final piece of the puzzle, if we look at the price of AstraZeneca's products, it's the Brilinta product here. You see here the wholesale price that the government points to except that is not the price that the pharmacy paid -- that the covered entity paid.

Instead they paid this, which is the covered -- the 340B price. And I checked with AstraZeneca's pricing team and they confirmed for me that that is in fact a little bit lower than the third quarter 2020 covered-entity 340B price.

And here, the extended amount is the amount actually paid.

So again, they're paying only the 340B price, not the wholesale price.

I think this is relevant in three respects:

First of all, this is -- I will stop sharing now unless Your Honor wants me to keep it up.

THE COURT: No, that's fine. You can take it down.

MR. KEDEM: So I think this relevant in three respects:

First of all, this is literally the only evidence the government points to, to the effect that AstraZeneca is discriminating under its policy and it's faulty on its face.

Second, I think it speaks to the process that was used by HRSA to determine that AstraZeneca violated statutory obligations. Had HRSA come to us and presented this to us, we could have explained to them, just like we explained to you just now, that this is not, in fact, evidence that we are violating our statutory obligations and yet that never happened.

And finally, I think this undermines any shred of argument that the government might have that its process is due deference because it is so thorough and well reasoned.

THE COURT: Notwithstanding this argument, the government said, at least in its brief, nowhere are you claiming that you don't already ship full price drugs to the various named pharmacies that you now refuse to ship discounted drugs. My language was slightly different but you get the idea.

Are you -- what is happening? Are you denying that that is happening?

MR. KEDEM: Absolutely. First of all, we don't ship drugs to pharmacies, period. The sales are made through wholesalers, and it may be that wholesalers will do bill-to, ship-to when they resell AstraZeneca's products, but that is not a transaction involving AstraZeneca. We don't have control over that.

The only retail transactions, which you might say directly involve AstraZeneca, are the indirect transactions that, as I just described, do not use bill-to, ship-to, unless it is an external contract pharmacy for a 340B covered entity that doesn't have an in-house pharmacy.

THE COURT: So there has been some back and forth on the legislative history including, in my opinion, the government is arguing that you are asking me to read into the statute precisely the constraints upon which were rejected in the legislative history, and we may have gone through this last time, but tell me now or again why that would not be the case from your perspective.

MR. KEDEM: Sure. So I think you can look to clues in the statutory text itself. You can look to the fact that the 340B statute distinguishes in other provisions between contract -- between covered entities and their representatives and people with whom they have an agency relationship.

The Veteran Healthcare Act, which is the statute

that enacted the 340B program, in other provisions authorizes contract purchases but not in the 340B statute.

And finally if you look at the legislative history, there was a provision that Congress considered, specifically considered that would have allowed contract purchases for pharmacies that operate on site.

Congress do not enact that language and so it was a pretty clear signal that even that was a bridge too far for Congress.

And it would be passing strain for Congress to enact such a huge change to the program in such an elite way as to simply not mention it at all. It's sort of a "elephants in mouse holes" principle.

THE COURT: But they, the government then interprets that legislative debate in a different way. I mean they say that, you know, there was, there was on the table at a certain point I think a reference to the contract pharmacies and something that would, you know, limit manufacturers obligations in the way that you say you're limited, but then that language wasn't included. And therefore, again, they say I'm putting something in the statute that Congress explicitly rejected.

Can you focus on that?

MR. KEDEM: Sure. So what you are referring to is the breadth of the provision which said that it was

limited to on-site contract pharmacy sales for drugs that were purchased and dispensed by covered entities, and Congress didn't enact any of that language.

So to some extent we're trying to read into a negative but the government focuses just on the purchase and dispensed by part and said, well, they didn't put in the word "dispensed by." But there was no need for the "dispensed by" language once you had eliminated the contract pharmacy provision because obviously if the only entity that is involved is the covered entity, then you don't have to specify that they're the ones doing the dispensing.

It is a far longer and more specific provision that we are pointing to, that Congress chose not to enact than just the sort of "dispensed by" words that the government is trying to read into, which is to say Your Honor had it right the first time.

THE COURT: So I have said, I think, that both sides have arguably at least a reasonable interpretation of the statute here. If I continue to feel that way, what does that mean for what happens next in this case on these motions?

MR. KEDEM: So I think it inclines you to two rulings.

First of all, the May 17th letter, no less than the advisory opinion is premised on the faulty legal

assumption that Congress has told the agency what the right result is.

Now, the government might point out that the May 17th letter, unlike the advisory opinion, avoids the word "unambiguous," but the American Lung Association doctrine that you pointed to is not about using the word unambiguous. And if you look at the cases that it cited, the *Prill* case, *PDK Laboratories* or the *Arizona vs. Thompson* case, none of those use the word "unambiguous" but they all stand for the same proposition, which is that when an agency is under the mistaken legal impression that Congress has told them what the right result is, if you determine that Congress did not so tell it that was the right result, then that is a legal error and it has to be vacated and sent back to the agency.

But there is another principle, which is the idea that what is being threatened here are civil monetary penalties for a knowing and intentional violation of a statutory requirement.

If Your Honor adheres to the position in your ruling that no such requirement is contained in the statute, then obviously there cannot be a knowing and intentional violation. And even if you think it is ambiguous, you have also held that insofar as the statute provides clues, they militate in favor of our reading. So ours is the better

reading regardless.

And even if ours were not the better reading, and we think that it is, it is still a good faith reading that we have engaged in and so that would make civil monetary penalties inappropriate.

And then just one final point. You are talking about an interpretation that the agency itself held between 1996 and 2010, and so it would not be appropriate for the agency to penalize AstraZeneca pretty severe penalties of potentially hundreds of millions dollars a month for a position that the agency itself held for the majority of the program's lifespan.

THE COURT: And then if I were to do that, if you vacate, I suppose maybe my case is over, but the government would be free to continue to pursue this and maybe come up with an interpretation on a different record? Is that correct?

MR. KEDEM: You know, I think it would depend a little bit on how you phrased it.

If you simply said that the statute does not contain this requirement, then I think that should and would foreclose the government from proceeding anything on any administrative position that depended on the existence of a statutory requirement that AstraZeneca was violating. So I think if you adhere to the position that it's simply not

there, it's not in the "must offer" provision, it's not in the "purchase by" language, and insofar as you can read the statute more broadly, it seems like it points in the opposite direction.

That I think logically means that the agency cannot impose penalties against AstraZeneca and insofar as you are asking, I think, about a situation where there is some ambiguity and sometimes agencies have the power to read ambiguity in a way that imposes new obligations on regulated parties, and gets *Chevron* deference, the agency could make that argument but that depends on a delegation of authority by Congress to impose new substantive requirements. That is really what we're talking about here.

Is this a requirement that already exists in the statute or is it something that the agency is adding newly?

If you want to add a new requirement on regulated parties that is not contained in the statute, number one, there has to be a genuine ambiguity.

And two, you have to have authority to do that. And they simply don't have such authority. But that could be a fight for a much later date.

THE COURT: So on the potential civil monetary penalties, the government says no matter what, that is premature, not an issue for me. And I guess I'm wondering if I were to go as far as what you have asked and order that

the letter be vacated because it's premised on the same misreading of the statute, isn't it premature? Shouldn't I leave it to you to make the argument that may be quite logical that you just made that we can potentially violate given the Court's understanding of the statute, but do I need to go so far as to say that?

MR. KEDEM: I think you do, Your Honor, and I think that is implicit in the fact that both sides agree there is final agency action here.

In other words, the government agrees that it has determined that there is a statutory violation in the May 17th letter and there will be consequences for that. And I don't think either side contemplates that there are future proceedings in which this issue, the agency will genuinely reconsider its position. I don't think the government is prepared to say that.

And if Your Honor doesn't set the May 17th letter aside, but you agree with us, it's not clear what other form of relief the government thinks you could ever grant that would have any effect.

In other words, if you were to rule in our favor and adhere to the position that there is no such obligation in the statute, you might put it to Ms. Talmor, what is it the government thinks that you can do, and will they continue on as if Your Honor never made that ruling?

THE COURT: There is a suggestion from the government that if I adopt your view, that means that the statutory regime adopted by Congress is, is meaningless in practice, that basically Congress knew the 340B program would only effect roughly 5 percent of the covered entities, and that that is meaningless and it is implausible to think that that's what Congress had in mind.

Could you respond to that?

MR. KEDEM: Sure. What Congress was dealing with, and this is very clear if you read the entirety of the report that both sides rely on, is making sure that both the Veterans Affairs office, because it was part of the Veterans Healthcare Act, and also 340B covered entities weren't paying too much out of pocket for drugs that they were turning around and giving for free or selling at a steep discount.

And so it was dealing with the problem of those covered entities that were spending a lot on outpatient drugs, subsidizing or providing them entirely for free for their patients.

So it's true that most covered entities didn't have in-house pharmacies, but the ones that did have in-house pharmacies are precisely the ones who Congress was concerned about in much the same way that they were concerned about the Department of Veterans Affairs was

spending too much on drugs that it was giving away for low or no cost to its own -- to its -- to our veterans.

THE COURT: And I can find that in the report somewhere, in the legislative history?

MR. KEDEM: You can. I think it's pretty clear starting from the very first page and even the sentence that the government harps on, which talks about stretching scarce resources, it talks about stretching scarce resources in the context of making sure that both the Department of Veterans Affairs and covered entities have access to drugs at relatively cheap prices.

And, you know, one reason that I have harped on that so many times at this last hearing and then again today, the fact that this is -- the same program was implemented with respect to the Department of Veterans Affairs, is that no one thinks that Congress wanted the Veterans Affairs office to upsell to its veteran clientele and to make profit through drug price arbitrage.

THE COURT: I think you all sent a letter, too, telling me about the New Jersey litigation and --

MR. KEDEM: Yes.

THE COURT: -- Chief Judge Wolfson said something I saw about a ruling may be imminent.

What, if any, overlap does that have with the issue in front of me? How should I think about that and

just overall the urgency of the decision from your perspective?

MR. KEDEM: You know, I think her order reflects the same urgency that we feel. Sanofi, who moved for emergency relief, had pointed out that they were expected to respond to the ADR petitions by November 5th. We believe our deadline could be as early as November 4th. And so what you saw as the judge there expressing her view that it would be appropriate for them to request perhaps an extension, but she would in all events make sure to rule before that date. And, you know, we would never tell Your Honor when to rule by, but we feel the same sense of urgency that those parties and that judge did.

THE COURT: And are the issues in front of her overlapping with the issues you have placed in front of me?

MR. KEDEM: Yes. The contract pharmacy issue is there as well.

THE COURT: Okay. That was my questions for now. I will probably have more for you before I'm done, but anything else before I turn it over to the government?

MR. KEDEM: No, Your Honor.

THE COURT: Okay. Thank you very much.

Then we will turn it over to Ms. Talmor to proceed when you are ready.

MS. TALMOR: Thank you, Your Honor.

THE COURT: Good afternoon again.

MS. TALMOR: Good afternoon.

Your Honor, we're here today in a very different posture than the last time the parties appeared before you.

Before the Court now is a voluminous record containing evidence that it is covered entities, not contract pharmacies making the purchases that is at issue here and that Astra's policy has resulted in both overcharges to covered entities and unlawful denial of access to 340B drugs.

Yet in its papers and in its presentation a few moments ago, Astra largely ignores this evidence. It continues to mischaracterize the covered entities purchases as contract pharmacy sales and is hanging its entire argument on the theory that Your Honor's previous opinion controls the disposition of the May 17th letter.

That theory is flawed.

Astra is ignoring the fact that this Court found that HHS's current interpretation is permissible, albeit not the sole reasonable interpretation. But the violation letter does not repeat the same flaw that Your Honor found with regard to the advisory opinion.

Most importantly, as shown in our briefs, HRSA's determination is correct. The 340B statute contains what really is a simple, though broad, statutory command, which

is that the 340B statute requires covered entities, requires Astra, to ensure that purchases by covered entities do not exceed the ceiling price and that its drugs are available on terms comparable to those in the commercial market.

HRSA correctly found that Astra is overcharging those covered entities, and that determination should be upheld.

So this case ultimately will turn on what this Court determines is the best reading of the statute, of course. But before turning to the soundness of HRSA's statutory interpretation, I'd like to start with just walking through some of the factual evidence in the record that backs up HRSA's determination.

So on page 14 of its reply brief, Astra claims that the record does not show that covered entities themselves have paid above 340B prices and Astra also claims on page 6 of its motion that HRSA is requiring it to resume sales to contract pharmacies.

Now, the record demonstrates that those claims are inaccurate and that covered entities are both the purchasers and are being overcharged.

So just to walk through a little bit of this evidence, I have here -- all these are VLTR, the administrative record for the violation letter.

So I have here VLTR, and I apologize, I don't

have the -- my technology is a bit more rudimentary and I can't easily share my screen.

THE COURT: That's fine. If you give us the references, we can find it.

MS. TALMOR: I will give the references.

So this is VLTR 6396, which couples with a spreadsheet that is just after that, it's 6404 and -05, and that shows that a hospital, Strong Memorial Hospital, paid $2 million in actual overcharges on purchases from five manufacturers, including Astra.

And the spreadsheet shows the actual units, how many units of Astra drugs it purchased at up to $565 per unit.

Similarly at 6229, we have another medical center, which I may mispronounce, but Arnot Ogden, which shows it had $360,000 in overcharges in just a few months from the manufacturers imposing restrictions, and it was paying $830 per unit of Astra drugs, and it also includes an actual spreadsheet showing how many units it purchased of which different drugs.

We have adjusted 9556 through -58, another similar spreadsheet, which shows actual purchases with both the drugs and the number of units purchased. And here in just the month of October, this covered entity paid $8,956 in overcharges on Astra drugs.

At 6117, we have a spreadsheet showing actual purchases totaling $43,000 in overcharges of Astra drugs and there are many more.

So these are not just covered entities who unlawfully been denied access, which is also reported and evidenced in the record. These are overcharges with actual spreadsheets showing the units that were purchased and the amounts that they paid for Astra's drugs.

Now --

THE COURT: Let me ask, is there anything in the record about whether any of those purchasers tried to get the Astra drugs through their own internal pharmacy or through a single designated contract pharmacy?

MS. TALMOR: Yes, Your Honor. There is a lot of evidence about what covered entities have done to try to, to try to continue their business models in light of the manufacturer's restrictions.

So we have different types of covered entities that work on very different models and some of them have an in-house pharmacy. Some do not.

So one piece of evidence that I think is, is really telling here. So at VLTR 7281, we have a covered entity that submits a sworn declaration saying that it serves 80,000 patients around Chicago, that it writes 115,000 prescriptions annually, and it is unable to serve

all of those patients in all of those prescriptions through just one location.

So the ability to designate a single location doesn't work because they have patients that would need to travel six hours roundtrip on Chicago public transit in order to reach one designated location.

I have here --

THE COURT: Okay. I understand the logic of that, but I guess with respect to any of the entities you're talking about, the ones you have listed now or you may yet have, do we have a record of any single instance where the entity said to Astra, you know, we -- here is the drugs we need, since their new policy has been adopted and here is where we want it to go. And it was something more than one designated contract pharmacy or internal pharmacy and Astra said no.

MS. TALMOR: So just to confirm. I believe I have here what you are asking for but specifically an instance where a covered entity tried to purchase an Astra drug and was unable to make the purchase as opposed to did make the purchase but was charged too much?

THE COURT: I think it's more I'm understanding what you are arguing now to be, hey, it would be totally impractical for Covered Entity X to get all of the 340B drugs it needs through just a single contract pharmacy, but

that seems to me potentially different than they tried to get it, they tried to work with Astra, Astra said forget it, we're not going to send it to XY&Z place. And, you know, and then problems ensued.

So I'm not -- I apologize if I'm not being clear. What is your best instance of an actual violation? Because in part, the argument we are hearing today is you didn't really follow a careful process or the agency didn't follow a careful process and didn't get any input from Astra on any of these alleged violations.

MS. TALMOR: Your Honor, I would be happy to address that, but I, I believe that each of these are evidences of actual violations, and I think any kind of complaints as to the process HRSA followed are meritless.

HRSA spent many months here compiling a very detailed administrative record that shows it gathered information of the facts on the ground. And so if Astra is suggesting that HRSA somehow committed an APA violation by not specifically engaging with Astra before finding it to violate the statute, that requirement simply isn't found in the Administrative Procedure Act.

But as for what Your Honor is asking about, as I understand with regard to violations, I think there are two different types of violations here, and I would be happy to point to evidence of both types.

So these are different types of covered entities that work in different models. And so some of these covered entities have continued to purchase 340B drugs but are being charged prices over the ceiling price. And some of these covered entities have been unable to complete the purchases at all.

So right here, I have VLTR 1596. This is a screenshot of the, it says PHS account, which is Public Health Service account. And it shows that when this covered entity seeks to purchase AstraZeneca drugs, what is loaded in the account -- and it's the column that I have highlighted on my column -- the purchase price is the wholesale acquisition cost rather than the 340B cost. That's with the wholesaler McKesson.

And here is a different wholesaler. It's a similar screenshot. This is 1591. So on this particular wholesaler, Cardinal Health, when a covered entity goes in to request to purchase Astra's drugs, they're just marked as ineligible. So this first column, all the way down, says "ineligible" and the covered entity isn't even able to purchase.

So we have some covered entities who are completing actual purchases of Astra drugs and paying too much, paying over the ceiling price. We have other covered entities who are seeking to make the purchases and being

blocked from doing so at all.

So I do think this is a different point from what we were discussing a moment ago that many covered entities simply cannot serve their patients through just one pharmacy. And I think that shows how Congress intended this program to work, which I will turn to in a moment. But I think that each of these are instances showing where covered entities are actually being denied access or paying over the ceiling price.

Just one other I have here, 1463, which is a printout from October 2020. And it shows a hospital, all of the purchases from October 2020 from various manufacturers and they're being charged the wholesale acquisition cost for Astra's drugs of up to 725 per unit, so they show over 126,000 in overcharges in just one month.

So these are a combination of the covered entities who did not make a purchase because the price would have been the wholesale acquisition cost and those covered entities who did complete the purchase and paid too much.

I also would just mention this is not in the administrative record because it only newly became available. But in the administrative record at 7937 and surrounding pages, there were a number of graphs that showed steep and stark changes to volume of 340B sales when Astra's policy went into effect.

We describe that in the brief as showing 340B sales just falling off a cliff when they put their restrictions into effect.

HRSA has been working to update that data and compile that data since the violation letter issued. And the most newly released data shows that covered entities are continuing to purchase AstraZeneca's drugs at wholesale acquisition costs in their 340B account and for the most recent amount, data is available in August. There were over $2 and a half million in overcharges. Those are just 340B accounts, purchases by covered entities effectuated at the wholesale acquisition cost.

So these are real overcharges that continue every month.

THE COURT: Are you relying on the document that Mr. Kedem showed us today? And, if so, how does that support your contentions?

MS. TALMOR: Thank you, Your Honor. I would like to address that.

Now, I apologize if there was any lack of clarity in the briefs as to how we were using that document. We certainly were aware that this invoice -- it's from September and that Astra's policy went into effect in October, so we were not suggesting that the Astra drugs on here were purchased at the wholesale acquisition cost

because as Mr. Kedem pointed out, this was before their policy went into effect.

The reason we pointed to this is because the last time the parties appeared before you there were a lot of questions about how these transactions actually work? Who pays for the drugs? How the dispensing models work? Who retains title? All of that.

And so most of the covered entities submitted spreadsheets of overcharges rather than the invoices themselves. And because this covered entity submitted an invoice, we wanted to merely point out that this is the way that these transactions are effectuated, where there is a sold-to line and a covered entity is billed, pays for the medication and is the true purchaser of the medication and there is a ship-to location where the drugs are sent. And that ship-to location is often a contract pharmacy.

But we did not suggest that this showed an overcharge. This is illustrative of how these transactions take place.

THE COURT: Okay. Thank you for that.

Now, you already said the case turns on statutory interpretation.

If I continue to view the statute the way I did, do you have evidence of a violation or does all of this evidence, whether it constitutes a violation, turn on me

having a different statutory interpretation than I did the last time we were together?

MS. TALMOR: I have two responses to that, Your Honor.

For one, I do think that this is a very different type of decision. And so whereas Your Honor's previous opinion really I think kind of began and ended with the text because that is what the advisory opinion focused on, and the advisory opinion was very focused on setting forth that it viewed there to be only one unambiguous reading of the statute, here HRSA has conducted holistic analysis with a lot of evidence.

So we would encourage Your Honor to take a fresh look at all of the tools available to determine the Congressional meaning, but we also think even if Your Honor does not view the statute differently than what was set forth in the previous opinion, that certainly does not warrant setting aside the violation letter.

THE COURT: All right. Yes. Why would that be? The second part.

MS. TALMOR: Why would it not require setting aside?

THE COURT: Yes.

MS. TALMOR: Because, Your Honor, I think that what Astra is doing with its statutory interpretation here

is really mis-framing the proper inquiry, so I think the inquiry before the Court today is not whether Section 340B contains any explicit delivery instructions on manufacturers but really whether Astra is violating Congress's command to sell discounted drugs to covered entities.

So Astra's focus on a lack of a statutory delivery instruction is just a contrived technicality that it is using to kind of skirt past the basic statutory obligation to honor these purchases and we think that violates bedrock canons of interpretation.

So a statute should only, according to Supreme Court precedent, a statute should be considered ambiguous only when a court has exhausted all the tools of statutory conduct, structure, history and purpose and cannot determine Congressional intent.

And we think here that those factors point toward this being the intent, the working of the statute that Congress intended.

So Mr. Kedem has argued and Your Honor asked him about our assertion that if Astra's interpretation were accepted, then manufacturers would have been voluntarily providing these discounts since 1992.

We think that strains credulity but it also wouldn't be a permissible reading with the statements made by the Supreme Court when Astra petitioned it in a case

regarding the 340B program.

I'm referring to *Astra v Santa Clara County*, which can be found at 563 U.S. 118.

Now, the question before the Supreme Court was very different than the question before this Court, but that was a case where Astra petitioned for review of whether covered entities could directly sue manufacturers like Astra for violations.

And in holding that covered entities can't sue another program, the Supreme Court explained what the 340B program does by saying that it imposes ceilings on prices drug manufacturers may charge for medications sold to specified healthcare facilities.

Again, that is 563 U.S. 118.

So that is the broad statutory command that is written in 340B, a ceiling on prices that a drug manufacturer may charge. So each of those instances that I just walked through are instances where Astra is directly violating that command.

I think that the flaw in Astra's approach to the statute is really illuminated by *Bostock v Clayton County*. We discuss that in our briefs so I won't walk Your Honor through all of it. But I would like to point out, if it's okay, why we think that case really shows how this Court should approach interpreting a broad statutory command such

as that found in 340B.

So as I'm sure Your Honor is aware, there, the Supreme Court held that there was no ambiguity that Title VII's prohibition on discrimination because of sex includes transgender or sexual orientation discrimination, even though Title VII spells out a list of protected characteristics and those aren't on the list. And that was because the Supreme Court explained that when Congress writes a broad rule and chooses not to include any exceptions, courts must apply the broad rule.

Title VII was unambiguous there, despite not containing the actual words "transgender" or "sexual orientation."

We think that analysis is directly analogous here because Astra's focus on the absence of any express command to deliver the drugs that covered entities' purchases is analogous to that argument that Title VII didn't contain those exact words.

So I believe that Congress often writes in starkly broad terms such as this. And where Congress writes a broad legislative command or prohibition, an entity can't devise its own workaround and evade Congress's desired result just because it didn't expressly prohibit what the entity is trying to do.

So I think this is where the Court explains that

there is no such thing as a "canon of donut holes" where Congress must speak directly to a specific case with a general statutory rule.

So what Astra is essentially asking to do here is asking for this Court to insert the phrase "except when delivered to neighborhood dispensers" after the command in the statute that the amount required to be paid to a manufacturer for drugs purchased by the covered entity not exceed the ceiling price. And we just think that is the not permissible under governing Supreme Court precedent.

THE COURT: So the violation letter is very short and has very little legal analysis.

On the procedural status of this case, am I permitted to consider all of these arguments that you are making now or am I limited to the analysis that is provided in the violation letter itself?

MS. TALMOR: Your Honor, I think that here the question before the Court is whether HRSA correctly interpreted the statute itself. And what I mean by that is this is not a case where an agency has issued a legislative rule or engaged in broad policy making and has to explain all the different factors that went into it.

This is an instance where an agency is taking an enforcement action. The agency is charged with implementing

and enforcing the statute. It determines that Astra is violating the statute, and it doesn't need to engage in the type of balancing of different factors and all of this that Astra alleges that it does.

This is a different type of agency action. And so I think that it's very clear in APA case law that an agency's decision must be upheld if its path can be reasonably ascertained.

Here, the agency was very clear in the letter in stating that Astra's policy violates the 340B statute, that it also violates its PPA. Contrary to Astra's assertion, the agency did not rely only on the must-offer language at all. The agency was very clear that Astra is violating its PPA.

And there just isn't any requirement in the APA for the agency to have gone through the type of full-throated statutory interpretation that a court might engage in or frankly that we engage in in our brief. What is required is that the agency set forth the basis for its decision, such that a court can determine whether or not it interpreted the statute right.

And so the short answer is yes, Your Honor, you are permitted to look at the statutory interpretations set forth in our briefs, which simply expounds on the grounds stated by the agency.

THE COURT: But it is true with respect to the text of the statute that the agency and the violation letter only cites to the shall-offer language; correct?

MS. TALMOR: I think that really is a red herring that Astra offers, Your Honor. Because first of all, first and foremost, there is no requirement that an agency action, that an agency quote every relevant provision in the statute that it is opining on. There's simply -- the agency action could have been perfectly reasonable and could be upheld without it having quoted the statute itself as long as it sets forth the correct interpretation.

But more importantly, the letter says that HRSA has determined that Astra's actions are in violation of the 340B statute and then goes on to discuss its PPA and how it violates the PPA.

And what the Supreme Court explained in the decision I was discussing a moment ago, *Astra v Santa Clara County*, the Supreme Court was very plain in saying that the PPA was not a bargained-for contract or transactional in any way, but it is just a uniform agreement that recites the responsibilities imposed by the statute on manufacturers.

So by the agency discussing that Astra is violating its PPA, it was under that Supreme Court reading just discussing that Astra is violating its contract which attests that Astra will adhere to its statutory obligations.

THE COURT: If I conclude that the letter is based on the same legally flawed statutory interpretation as the advisory opinion, do I have any choice other than to vacate the letter and remand?

MS. TALMOR: Certainly, Your Honor, but two answers to that.

One, I would point out that the letter in no way suggests that its conclusion is compelled by the statute. There is nothing in this letter that suggests that Astra thinks that -- I'm sorry, that HRSA thinks its hands are tied or that its action was compelled by Congress.

On the other contrary, it is well known that agencies are vested with considerable discretion especially when it comes to an enforcement actions. And I think that it would be, it would be very problematic to assume that an agency thought its hands were tied with regards to mounting an enforcement action when the agency did not so state.

But even putting that aside, even if Your Honor thought that this letter somehow conveyed the idea that its decision was compelled by Congress, Your Honor still can't set aside the letter without affirmatively finding that Astra's policies permissible under the statute and that is why I think it is so important that this is a different type of agency action.

Because this is an enforcement action, because

this is HRSA says Astra you are violating the statute, what matters here is whether or not Astra got -- HRSA got the statute right. And so the only grounds to set aside the violation letter would be a finding that it interpreted the statute wrongly and that Astra's policy is permissible.

THE COURT: So was I wrong that Astra's policy was entirely consistent with the agency's own interpretation of the statute through at least 2010?

MS. TALMOR: Yes, Your Honor. And I would like to address that, if that is okay.

THE COURT: Sure. Go ahead.

MS. TALMOR: I think this actually is a critical point. The point is that Astra's claim that its policy would be entirely lawful under the 1996 guidance, we think that is flatly incorrect for several reasons. And we recognize that not all of this was put in the briefing before Your Honor before, which we did brief on an emergency basis. So we apologize for, you know, having a bit more fulsome briefing here of that here.

But the reasons why Astra's policy would not be lawful under the '96 guidance are first and foremost, the 1996 guidance was explicit that contract pharmacy use is not limited to covered entities that lack an in-house pharmacy. That is at 61 FR 4351.

On the contrary, that guidance said that "there

is not a bar to the use of the mechanism," meaning contract pharmacies, "by any covered entity." It even went on to say that covered entities have the choice of using different types of purchasing and that the use of in-house purchasing doesn't preclude the use of a contract pharmacy.

Second, the guidance explicitly said that covered entities have a right to contract with retail pharmacies for the purpose of dispensing 340B drugs in the absence of any federal guidelines.

That's at 61 FR 43550.

So HRSA was saying that it was not creating a new right for covered entities, but that if it had spoken at all, covered entities already have the right under state law to use contract pharmacies.

Third, the '96 guidance explicitly described its contract pharmacy provisions including the limitation to one contract pharmacy as "a suggested model agreement" that it encourage covered entities to use.

That is at 43555.

So in other words, HRSA said the guidance is nonbinding on covered entities, and they did not have to follow its model agreement format. But it just as clearly stated that manufacturers simply cannot deny the purchases.

HRSA explained that if a covered entity using contract pharmacy services requests to purchase a drug, the

statue directs the manufacturer to sell the drug at that discounted price and that there is no basis to conclude that the statute exempts the manufacturer from complying.

So those provisions coupled together show that while HRSA recommended covered entities used just one contract pharmacy while it evaluated the feasibility of multiple, multiple sites, it told manufacturers explicitly that they may not deny those sales.

And just as importantly, two years later in '96, HRSA already had confirmed that the use of contract pharmacies was a common business practice and that manufacturers cannot restrict those sales without violating the statute.

So all of that shows that Astra's policies would have been just as unlawful in 1996 as it is today.

THE COURT: So it follows from that, that you believe that HRSA could have brought this same violation-type enforcement action against Astra in, say, 1999 when the '96 guidance was offered to them.

MS. TALMOR: Certainly, Your Honor. And I think that's critical because, first of all, agencies can't base an enforcement action guidance. They have to base an enforcement action on the statute.

But agencies are free to issue interpretive rules that set forth for the public how they interpret the

statute. And that is what HRSA has done in these guidances because it has repeatedly set forth how it interprets the statute.

And it could have based an enforcement action against Astra in 1998 on the statute itself because it had already explained that manufacturing in those conditions are unlawful, but HRSA could not have brought an enforcement action against a covered entity for say using two contract pharmacies because it had been explicit that that was not compelled by the statute, but was a recommendation for facilitating access without allowing diversion.

THE COURT: So is it now HRSA's view that the May 17th letter is based on unambiguous statutory text or is that not HRSA's view?

MS. TALMOR: The violation letter does not make any claim to be interpreting unambiguous statutory texts, and so I think that the letter is not subject to being set aside for the same reason as I understood Your Honor to have set aside the advisory opinion.

In other words, we don't believe that the violation letter thinks -- that HRSA has explained that it thinks what it is doing is compelled by a statute.

At the same time, we do believe that each of the tools of statutory interpretation, especially considering legislative history, context and Congressional purpose point

toward a view where Congress intended for the statute to work in practice the way that it does work today. And we would encourage Your Honor to reconsider the finding that it was ambiguous because we think that each of these tools does point to there being a plain meaning of the statute.

THE COURT: Astra's interpretation of your letter -- for instance, it's in the reply brief D.I. 95 at 8 -- is that you do not purport to fill any statutory gaps to interpret ambiguous terms or to impose requirements besides those contained in the statute itself.

Do they accurately characterize the government's position?

MS. TALMOR: I think that they are correct that HRSA is not purporting to be interpreting ambiguous terms because for HRSA to be purporting to fill in the gaps and in an ambiguous term, that would be legislative rulemaking, and we don't believe there is any legislative rulemaking required here.

What is important to take away, I think, is that the statute doesn't need to say Astra must deliver its drugs to where covered entities direct them to be delivered. Congress wrote a clear but broad rule that Astra cannot charge over the ceiling price to covered entities, period, and Astra can contrive exceptions to that, that allow it to skirt. So it is based on the statute and the rule that it

creates.

THE COURT: So you are not purporting to fill any statutory gaps?

MS. TALMOR: We are not -- what the agency did here is not purporting to fill statutory gaps. What the agency did in its 1996 guidance, it did acknowledge that the statute was broad and that it was engaging in "gap filling." I think read in context, that comment from the 1996 guidance about gap filling said that the statute didn't spell out how covered entities are to dispense drugs without engaging in diversion and duplicate discounting.

And I think the gap filling comment was very clearly pointed toward the suggested model agreement it encouraged covered entities to use, but it didn't suggest that the language from the 1996 guidance, which is very firm, stating that manufacturers cannot impose conditions. It didn't suggest that that was a gap in the statute.

THE COURT: So I think it follows, you don't think that HRSA is imposing a requirement besides requirements that are already contained in the statute itself; is that right?

MS. TALMOR: Yes, Your Honor.

THE COURT: Because you agree that HRSA can't add to the statutory obligation; is that right, too?

MS. TALMOR: Yes, Your Honor.

THE COURT: That would be a legislative act and you can't do that or at least haven't done that; right?

MS. TALMOR: It would be legislative act, Your Honor, and HRSA has not been expressly granted general rule making authority.

THE COURT: Okay. So -- and I think we talked about this, but I just want to make sure I understand your position.

Can I rely on an argument that it is not the grounds that were actually relied on by the agency?

MS. TALMOR: Your Honor, framed in that way, no, I think that would be a general violation. We think a ground not relied on by the agency cannot be relied on, but I don't think that is at all what we're doing here.

I think that day in and day out agencies issue decisions that are then challenged in courts and lawyers at the Department of Justice brief why those decisions are correct.

And the grounds set forth by the agency can't be expanded in litigation briefs, but the, the statutory analysis certainly can go into more depth and use case law. In other words, there is no requirement that in interpreting a statute that the agency itself ran a legal brief. And I think that the grounds that we have defended the agency action on here are the grounds invoked by the agency, which

is that the statute requires Astra not to overcharge and that Astra is both discriminating against covered entity sales and charging in excess of the statutory price.

THE COURT: If I do consider Congressional intent and purpose, what do you point to for your contention that the purpose here was to shift some amount of drug manufacturer profits to subsidize healthcare for, you know, vulnerable individuals and institutions?

MS. TALMOR: Respectfully, Your Honor, I think that would slightly mis-frame -- would be slightly different than the way we would frame it. What we think Congress did here was create a program where certain safety net healthcare providers that serve the poorest and most vulnerable individuals can buy drugs at a discount and stretch scarce federal resources and to expand services.

That is not the same as explicit -- you know, my friend Mr. Kedem mentioned arbitrage profits. We don't think the covered entities here are engaging in arbitrage profit making. These are nonprofits serving the sickest and poorest individuals.

So I think what Congress did here was create a program where they can buy drugs at steep discounts and they can, and very often do, pass on those discounts to uninsured patients, especially those below the poverty line, but they also can charge a higher price and then reinvest that in

patient care.

So we cited the House Report that talks about -- that has the language about stretching scarce federal resources, but I also have here the Senate Report that both sides have briefed for the legislative history and at the outset, that says that "it is the purpose of this section to ensure that certain entities funded under Public Health Service Act receive a discount on prices for prescription drugs comparable to the Medicaid rebate amount and with a minimum of administrative costs and burdens."

So Congress was trying to create a program where these entities receive a discount on purchases paid. We think that is clearly what happened here.

Mr. Kedem mentioned that there is no reason to believe that Congress wanted the Department of Veterans Affairs to claim arbitrage profits. We think that is inapposite and doesn't make a lot of sense here.

The Department of Veterans Affairs is a healthcare provider for veterans and is not turning around certainly and up-charging drugs purchased to veterans. It's in a different position from these nonfederal but grantee covered entities.

These covered entities that serve individuals that are not part of the Federal Government are able to buy drugs under the same statutory formula that may apply to the

Department of Veterans Affairs, but that doesn't mean that Congress created the program for the same purpose.

THE COURT: The policy concerns you raise and which largely dominate the first third of your first brief at least, and they're very serious and valid policy concerns and I think even AstraZeneca at least says that they agree with that, but I mean, you saw my earlier opinion. Why are those not issues for Congress as opposed to an issue for the court?

MS. TALMOR: Because Congress has already spoken to this issue, Your Honor. I think that is the critical point here.

Congress doesn't need to fix something that Congress created in 1992 and that has worked without incident in a particular way for nearly 30 years before six drug manufacturers decided to upend the way they've always operated under the program.

Your Honor, there are somewhere around 600 manufacturers that participate in the 340B program. There are now eight that have followed the lead of Eli Lilly by imposing contract pharmacy restrictions. When we briefed this matter, it was six. All of the rest of these manufacturers are continuing to comply with their statutory obligations.

So we don't think Congress needs to go back and

fix something that is working properly.

And I think that those policy concerns, it's not a matter of the agency engaging in policy making or this Court needing to weigh the policy of how it should work. We think that the policy concerns and, in particular, we have a lot of evidence of how completely unworkable Astra's view is in practice, we think what those do is bolster the agency's reading of what Congress intended from the outset.

So we've pointed out that when Congress created this program from whole cloth in 1992, only 5 percent of covered entities had a pharmacy in-house.

Now, Congress knew when it created the program how most individuals received their prescription drugs every month. You don't go to your doctor's office to pick up a refill. You go to your doctor's office, typically, to get a prescription and then you take it to a pharmacy to get the drugs.

So in 1992 when Congress devised this program, it didn't need to spell out that the program shall apply where patients actually get their drugs, particularly since only 5 percent of these entities even had a pharmacy. Congress is able to legislate against the backdrop of real-world fact and say the program is going to work in a particular way and it doesn't need to spell out the minutia of how these transactions will work. So this policy

evidence just really bolsters how it has always worked.

THE COURT: AstraZeneca points to parts in the reports and legislative history that suggests Congress really was concerned with just the approximately 5 percent covered entities on their view benefit, as well as the Veterans Administration.

I think -- I'm still trying to understand where it is you think I can find this clear Congressional intent and conclude that Congress already did what you're saying. I mean, it seems like it's, you know, it's the one provision in the statute, which I have already said I don't see it there, and the statutory language hasn't changed and then some of these broad statements in the legislative history, which may be amenable to both interpretations, I'm hearing.

So I mean what, where can I look to find what you are saying Congress has already clearly told us they wanted?

MS. TALMOR: I have two hopefully brief answers to that, Your Honor.

First, looking back at the legislative history. Respectfully, Your Honor, I think it is important that this legislative history came from 1992 and not 2010 because this is the language that Congress was considering when it first drafted the program from whole cloth.

And so this language that, it's very small but I have highlighted on my copy of the Senate report, I think it is clearly written as a restriction. This is Section 2141B on Senate Report 102-259 from 1992.

And what it does is it is a definition, spelling out what covered entities -- which drug purchases by which covered entities are included in the program. And so the way Congress originally drafted this program, it says under covered entities, "a drug of the type described in Subsection A" -- which is the program itself -- "as defined in Section 1927(K)(2) of the Social Security Act, and to any over-the-counter drug, birth control device or vaccine that is purchased and dispensed by or under a contract entered into for on-site pharmacy services with."

So what that does is it clearly restricts the drugs that a manufacturer must discount to only those that are purchased and dispensed by or under a contract entered into for pharmacy services on site.

It explicitly defines the drugs that will be discounted as only those drugs that are dispensed by or on site.

When Congress removed those words, what it did is omit from the statute any restriction on which drugs the covered entity has to purchase.

Now, Congress clearly prevented a covered entity

from taking those drugs and turning around and selling them to other healthcare providers or using them for in-house services by including the prohibitions on diversion, specifying that they're outpatient drugs. So it doesn't allow a covered entity to turn into its own drug wholesaler.

But what it did do, very knowingly and explicitly I think, is remove from the statute a restriction that would have said, hey, AstraZeneca, you only have to provide the discount if the covered entity is going to dispense these drugs itself. And by removing that restriction, it is saying that the covered entity does not have to dispense the drug itself and it doesn't have to do so on site.

And so I think this language that was removed here, this "the drug is purchased and dispensed by or for on-site pharmacy services," I think that is exactly what Astra wants you to read back into the statute.

And just as importantly, I think that what Astra is doing when it focuses on the statute "not including delivery restrictions," I think that it's asking of Congress something that case law just doesn't support.

I think you can look at other statutory regimes where Congress has written broad prohibitions or broad commands and courts have interpreted those not to include exceptions. That is why I discussed *Bostock* earlier.

I would also point to the antitrust statutes,

which have, you know, broad prohibitions on anticompetitive conduct that courts have interpreted over time to include a lot more than just price fixing.

And so I think when Congress uses a broad statutory command to say, hey, AstraZeneca, you must not charge over the ceiling price for these drugs, Astra doesn't get to say except when they're dispensed by a pharmacy, any more than it can say, okay, I'll only honor the sale if you pay in a foreign currency, or I'll only honor the sale if you buy 100 units at a time. You know, Astra can't create these conditions itself that Congress didn't write in, in order to restrict covered entities' volume.

THE COURT: You made reference to certain reliance interests of the covered entities and the patients that they serve, and certainly I think that is all really important, at least from a policy perspective, but what, if any, relevance does it have to the issues in front of me?

MS. TALMOR: I think it has a lot of relevance, Your Honor.

I think that the agency has been plain ever since the 1994 guidance in saying manufacturers, you cannot impose restrictions on covered entities.

And if manufacturers thought that that was an unlawful interpretation of the statute, they could have sued

the agency over that then. The agency could have been sued by drug manufacturers in 1994 or 1996 or 2010 or any time since.

And since then covered entities have created these arrangements where they serve their patients through neighborhood pharmacies and restricting this as having real impacts on patient care and on the providers themselves.

And I think that also, just as importantly, what you I think were describing as kind of policy concerns that we briefed, I think they show why it just strains credulity that Congress could have meant this in the first place.

I mean here at VLTR 7256 we have a covered entity sworn declaration saying yes, we have an in-house pharmacy, which means that under Astra's policy they will not deliver anywhere else. And this in-house pharmacy can only serve 40 percent of the covered entity's 90,000 patients because it's only opening to five and presumably because of volume and space considerations.

And so they have a very large geographic area where their patients need to be able to go to neighborhood pharmacies.

There just -- there isn't any doctrine that I am aware of that will support a reading the statute where just because Congress didn't spell out every single minutia of how these transactions work that Astra is able to skirt its

obligations in this way.

THE COURT: And I guess I just -- I don't see how it is that the agency's own guidance for at least 2010 would entirely allow these policies. I know you say it wouldn't, but the manufacturers would have been fine with limiting the use of covered or contract pharmacies to at most one through 2010.

I mean you have said that that is not true, but it explicitly happened through 2010, didn't it?

MS. TALMOR: I'm not sure that is exactly correct, Your Honor.

For one thing, I would point out that Astra takes the position strongly, I think, that it's one contract pharmacy allowance is not required by the statute. And so if Your Honor were to rule that Astra doesn't have to honor even one contract pharmacy, nothing would prevent Astra from removing even that allowance immediately thereafter under their reading. And so I, I don't think that covered entities can safely rely on Astra doing something that it thinks is voluntary.

But more importantly, the 1996 guidance is very clear in saying that covered entities have a preexisting right to use contract pharmacy services without any federal guidance. And it describes the one pharmacy limitation as part of a suggested model agreement. So I don't think it's

fair to say from that, that covered entities are explicitly limited.

Moreover, the 2010 guidance says that they had been allowing and approving different covered entities to use multiple pharmacies under pilot programs and that had worked so well, but they issued additional guidance telling covered entities that they may do that more broadly. So it seems clear there were multiple pharmacy agreements before 2010.

THE COURT: You are contending that the agency could have brought a violation enforcement action against a drug manufacturer at the time that was complying and trying in good faith, let's just stipulate for the sake of argument, to do what the agency itself described as a model agreement.

MS. TALMOR: I think they absolutely could have brought a violation and the reason is because the 1994 guidance is very clear in saying that a covered -- a manufacturer cannot impose restrictions on covered entities' access to 340B drugs.

The 1994 guidance is so plain that it says that a manufacturer cannot single out covered entities from other customers for restrictive conditions. And that the manufacturer cannot even require that the covered entity sign a contract saying that it will comply with its own

statutory obligations.

So that guidance just makes it clear that manufacturers cannot deny sales. It also says that even where the manufacturer has proof that the covered entity has violated the statute that the manufacturer still has to honor the 340B sales.

So I think what the guidance --

THE COURT: Doesn't the 1994 guidance also say it is not imposing any requirements on drug manufacturers?

MS. TALMOR: It says that it's not imposing new obligations not found in the statute, Your Honor. I don't think it's -- and it's not. What it's doing is interpreting a statute to say manufacturers, you have to honor these sales and you can't place restrictions on what covered entities do.

THE COURT: If it's unclear from the record that HRSA considered either AstraZeneca's views and responses to the complaints or the replenishment model and who takes title to the drugs and when or some other material issue, must I vacate and remand?

MS. TALMOR: No, Your Honor, for three reasons.

One, we cite a lot of information in the record that shows that HRSA did have before it and did look at evidence about both the replenishment model that Astra speaks about in detail, who takes title to drugs, et cetera.

I won't read that for you but I would direct Your Honor in particular to VLTR 7279, which I think has a really good explanation of how covered entities are actually using the replenishment model, who takes title, how they ensure compliance.

I would also point out the declaration similar starting at VLTR 7260. So I think that evidence is in the record.

But as far as Astra's views, once again, this is not the agency engaging in policy making and balancing of different factors. This is an enforcement action. And so when an agency issues an enforcement letter, a violation letter, under various statutes through a regulated entity, they're not required to engage that alleged violator or regulated entity first and hear their views why they may or may not be violating the statute. An agency charged with enforcement by Congress is able to issue an enforcement action against a regulated entity and then defend that in court. So that is simply not an APA requirement.

And finally, I think that it is important to focus on that type of action with the final question about vacating because here, I think the only ground to vacate the violation letter would be if Your Honor thinks that HRSA wrongly interpreted the statute, because if Your Honor thinks that HRSA's interpretation either is correct or that

the statute is unclear that it's a reasonable interpretation, then HRSA receives -- or should receive discretion under the APA and Astra can't get away with violating the statute, even if Your Honor thinks that a more robust explanation would have been preferable.

THE COURT: Astra says if, if the May 17th letter merely articulated what the statute so plainly requires, which I think is your position, then you can't rely on your supposed expertise in an administrative statute and can't give any deference. Is their logic wrong there?

MS. TALMOR: Yes, Your Honor. I think that an agency charged with implementing and enforcing a statute is plainly able to rely on its expertise and its, you know, its history implementing a statute to determine the way that that statute should work and to determine a violation.

I think that we, we did not make an appeal for *Chevron* deference here because this isn't a legislative rulemaking. This is an interpretative rule. But under *Skidmore*, we think that the agency is entitled to deference to the extent that it has the power to persuade, and we think that for the reasons we've briefed here that HRSA's determination is very persuasive, both on the legislative analysis and on the evidence that they gathered.

You know, I think that what Astra is asking for here is something that the APA doesn't require. They're

asking for the agency to have gone through and really summarize an 8,000 page record and detail every bit of it. That is just not required in an enforcement action.

THE COURT: Astra makes a distinction between silence in a statute and ambiguity in a statute, and says here the statute is silent but not ambiguous.

Do you agree with that analysis?

MS. TALMOR: I think that argument from Astra is very hard to square with its near complete reliance on the advisory opinions holding because Your Honor previously found that the statute was ambiguous.

So I'm, I'm not sure exactly how they thread that needle, but we do think that a statute should only be held to be ambiguous when a court is unable to arrive at the plain meaning. And we do think here the plain meaning is not that Astra has a delivery obligation, that contract pharmacies participate in the program. None of that is in our position. We think that it's clear that what Congress intended was that Astra can't deny sales or overcharge covered entities, and that is what it's doing, so in that way we don't think it is ambiguous.

THE COURT: Do you want to say anything about the New Jersey action and about whatever the ADR response state may be for AstraZeneca and the urgency that they have seemingly that maybe I make the decision quickly again?

MS. TALMOR: Yes, Your Honor. As I believe Your Honor pointed out, Astra has not challenged the ADR rule promulgated by the agency.

The court in New Jersey that is hearing the case brought by Sanofi, that has a direct challenge to the ADR rule. So they have brought a challenge to the ADR rule and originally in the case filed a preliminary injunction arguing that the ADR rule violates the constitution.

And so they have a live claim making that, and they recently filed a motion for an emergency stay, arguing that they would be irreparably harmed by being held before an unconstitutional tribunal. We opposed that, and the court denied their emergency motion while indicating it will rule quickly.

But the important thing is that all that is premised on a claim challenging the ADR rule that it violates Articles 2 and 3 of the Constitution.

Astra hasn't challenged the ADR rule here, so I don't think it has any relevance to these proceedings whatsoever.

I also don't think that Astra providing either a motion and response to the claims of ADR or even a motion requesting a stay of those proceedings, I don't think that those would prejudice it at all, but it hasn't, it hasn't challenged the ADR rule, so it doesn't really have any

relevance.

THE COURT: So is there a mechanism within the ADR process for them to ask to delay their response?

MS. TALMOR: They certainly can ask. The ADR rule explicitly says that it's governed by the Federal Rules of Civil Procedure, so they can file a motion in those proceedings and request it.

THE COURT: And I know with respect to this CNP issue, you believe I shouldn't engage with them at all, but it has been put on the table.

What is your response to the contention that at least one court, at least me, at least the last time I looked at this, said what AstraZeneca is arguing is at least a reasonable interpretation, if not the better interpretation of the statute? How could it be under that scenario that the agency could be reserving the right to try to prove intentional violations if they are in compliance with the interpretation that at least one judge on one day said was reasonable?

MS. TALMOR: Respectfully, Your Honor, I don't think that issue is on the table because there is no jurisdiction over that issue in this court.

So the way that the civil monetary penalties work in this instance is a little bit different in this agency, but HRSA does not impose the CNPs and HRSA is

obviously is a party before this court. All HRSA does is refer the matter to the Office of Inspector General to review and make its own determination.

So OIG, it's not only a separate process, but they're not a party in this litigation, nor have they made a determination, but most importantly, OIG will conduct its own investigation. There is no way for me to predict how long that will take.

And if OIG determined that they thought there was evidence of knowing and intentional violations, then under its own regulations, OIG would approach AstraZeneca and attempt to seek a resolution.

If it was unable to reach a settled resolution, then OIG would bring an action seeking to impose monetary penalties before an agency ALJ, and AstraZeneca would have a chance to defend it before the ALJ.

If the ALJ imposed sanctions as OIG was requesting, then AstraZeneca would have an appeal within the agency to the departmental appeals board.

And if that body still ruled against Astra, then Congress is granted direct review of that decision in the Court of Appeals.

So even if the agency imposed sanctions, it's simply not reviewable in District Court. So there isn't jurisdiction for Your Honor to rule on that issue, even

putting aside its premature nature.

But most importantly, Astra has asked for relief here that we think is just really impermissible under the APA.

The APA allows Your Honor to review the May 17th letter. And if a violation is found to set it aside, but the APA doesn't allow Your Honor to issue the broad sort of sweeping injunctive relief that Mr. Kedem asked for, that would basically bar any administrative action based on interpretation of the statute. That is simply beyond what the APA authorizes.

THE COURT: All right. Thank you. Your time is up. I will give you an extra five minutes but I'm going to save it for you until after we heard from Mr. Kedem again; all right?

MS. TALMOR: Thank you, Your Honor.

THE COURT: Okay. Thank you.

So, Mr. Kedem, back to you.

MR. KEDEM: Thank you, Your Honor.

So both sides agree on one thing, which is at the heart of this dispute is a textual question about whether the 340B statute imposes obligations on manufacturers to provide discounts for contract pharmacy sales.

One of the most remarkable things, however, about the government's presentation and its briefing is that

although it says that there is this broad statutory command, they never actually identify what that command is.

It's not in the "must offer" provision. It's not in the "purchase by" language. And as Your Honor pointed out, if you look more broadly at the statute, it points away from the government's interpretation rather than towards it.

Now, the May 17th letter itself locates the requirements, supposed requirements in the "must offer" provision. It quotes the provision and then says "this requirement is not qualified or restricted."

It's reaches the conclusion that because AstraZeneca takes a different interpretation, its policy is "directly in violation of the 340B statute."

So I don't think that you have to guess what it is that the May 17th letter is relying upon and generally says you look solely on the ground that the agency articulates at the time of its decision.

But there simply is no broad statutory command that the government identifies. And Your Honor's ruling was correct on this. You pointed to several different conforming factors. The fact that there was a list of covered entities that was specified for taking particularity, including distinguishing parts of hospitals that the 340B statute elsewhere distinguishes between covered entities and

their representatives and agents that other provisions of the Veterans Healthcare Act authorized contract purchases but 340B does not. And that Congress specifically considered but rejected language that would have allowed contract purchases for on-site sales.

I'd add to that one more provision, and that is Subsection (a)(5)(B), the anti-diversion provision, which says that covered entities may not transfer or sell 340B discount drugs to anyone other than patients of the covered entities, except under the replenishment model that is used today for multiple contract pharmacies.

That is exactly what happened. Even on the government's telling, title is maintained by the covered entity only while it is in transit to the contract pharmacy, to the CDS. At that point, it goes into the general stock of the contract pharmacy and it can be dispensed to any patient, whether 340B or not.

And so the government would have you believe that Congress has authorized, has required manufacturers to provide discounts for sales under a replenishment model that almost always leads to diversion, that is beyond implausible.

Turning now -- and I would be happy to talk more about that, Your Honor, but --

THE COURT: Why don't you move on to the next

topic.

MR. KEDEM: Okay. So the next point to make is the record that the government relies on, which I think is, to put it lightly, in some contradiction to the government's point that this is really all about whether AstraZeneca has and is complying with the statutory requirement, whether the requirement is contained in the statute itself.

That is the one thing that the parties all agree on: That HRSA cannot add requirements to the statute. They don't have legislative rulemaking authority and so the obligation has to be contained in the statute. Otherwise, there can be no violation.

All of the government's evidence is predicated on the same legal position. Namely, that AstraZeneca is required to provide discounts for contract pharmacy sales, and if it fails to do so, that that is an overcharge.

They have two general categories. First, they point to open market transactions where a covered entity goes to a wholesaler and purchases AstraZeneca's drugs, but from the wholesaler without involving AstraZeneca directly.

And the other category are instances where covered entities attempt to purchase drugs and have them shipped to contract pharmacies under an account listed by the contract pharmacy's number.

And I want to be very clear about this. The

obligation under the 340B statute is to offer drugs to covered entities. AstraZeneca's policy does that in 100 percent of cases. Any covered entity can purchase AstraZeneca's products in whatever amount they want at 340B prices.

What they can't do is to use a contract pharmacy to make the purchase if they haven't designated that contract pharmacy under the policy, and that is what all of the government's evidence points to.

And AstraZeneca has been refusing covered entities who have been trying to make these purchases, not on their own behalf, but in order to have the drugs sent to and through contract pharmacies.

And I can get into the minutia of how this works. Basically, every covered entity has its own identifying number and every pharmacy also has its own identifying number. And if it is a covered entity placing the drugs, they get it no matter what. But if they attempt to use the number ID for the contract pharmacy and it's not a contract pharmacy who has been approved under AstraZeneca's policy, then what you will see is they don't get access to the discounts.

And if the government is right about the statutory interpretation, then that would be a problem. But if we are right about the statutory interpretation, then

it's not a problem. And all of the government's evidence points to that same central fact.

They don't identify any instance, either of a covered entity that wants to buy the drugs for itself on its own account or under a designated contract pharmacy under AstraZeneca's policy who is not able to do so.

Turning to the 1996 guidance.

Your Honor pointed out that it was maybe a little bit implausible that under our reading of the statute, pharmacy -- manufacturers were doing more than they had to.

I don't think that it's actually implausible. First of all, we're still doing that. AstraZeneca allows every covered entity, whether they have an in-house pharmacy or not, to participate, and we don't have to under our reading of the statute. But we also just didn't have the explosion of contract pharmacies until after the 2010 guidance, so there really wasn't a problem.

The government would have you believe, however, that every manufacturer in the country between 1996 and 2010 was violating its obligations to provide discounts to unlimited contract pharmacies and moreover that no covered entity said anything.

A person never got involved, no covered entity complained. This is not a group of shrinking violets. If

they thought there was this obligation to provide discounts for unlimited contract pharmacy sales, either for himself or the covered entities themselves, they would have said something. No one did because everyone understood the '96 guidance as being limited to one contract pharmacy see.

Turning to the *Bostock* case very briefly.

You know, I think the obvious difference between this case and *Bostock* is there, there was an express command that said employers may not discriminate against employees on the basis of sexual -- on the basis of sex. And what the Supreme Court determined is that that prohibition literally covered discrimination against transgender or gay employees.

And obviously, here there is no such language that the government can point to. But I think the case is actually on point in two respects because the Supreme Court there rejected two arguments that are almost identical to the ones that the government makes here.

One is an argument about what the legislators could have intended, and the argument in that case, the employer said the legislators could not have intended to protect gay and transgender employees when Title VII was passed in the '70s. And the Supreme Court said we don't care what Congress intended, what was in the mind of the legislators, what we care is what Congress said. And that is the best evidence of what Congress intended.

Second, the employers made all sorts of policy arguments about why it would be better if Title VII did not apply to transgender and gay employees. And the Supreme Court said those are arguments to be made to Congress.

Now, the government makes a lot of arguments as to why it would be unworkable or impractical for the program to go back to the way it existed between 1996 and 2010. They may or may not be right about that. We don't think that they are. We think the program worked okay.

But we're not asking Your Honor to give a position on that. That is a question for Congress, that is not a question for the Court. The question for the Court is does the 340B statute itself impose an obligation on AstraZeneca that AstraZeneca is violating?

And I would like just to return to the question of remedy.

If the government disagrees with the way that Your Honor reads the statute, the government is free to appeal and take its arguments to the Third Circuit. What it cannot do is repeatedly take additional actions against AstraZeneca predicated on the same interpretation that Your Honor has already rejected and, if you adhere to your position, would reject for a second time.

Now, my friend Ms. Talmor says that the inspector general process for civil monetary penalties are

separate.

I confess, I don't fully understand that because we have sued not just HRSA, but the Secretary of Health and Human Services, and every relevant HHS official that we could think of. And all of the proceedings are conducted in the name of the Secretary of Health and Human Services.

So if you were to issue a ruling that binds the Secretary stating the statute does not impose the obligation that is a premise of the CNP proceeding, then that should stop the government from proceeding with that.

But if the government is now telling us that such a ruling by you would not stop them from moving forward, that is exactly why it would be appropriate for you to take the additional step of making that clear in your ruling, that the government cannot and should not proceed administratively on the basis of an interpretation that adds requirements that are not, simply not contained in the statute.

THE COURT: Okay. Does the APA require that AstraZeneca be part of the process leading to the violation letter?

MR. KEDEM: So there is no formal participatory requirement under the APA, but what there is, is a requirement that the agency consider all important aspects of the problem. And we are simply suggesting that when all

the agency does is solicit complaints from one side, doesn't ask for any explanation or clarification, never asked us whether we were denying these drugs to the covered entities themselves or only in the contract pharmacy scenario, then it is not considering an important aspect of the problem.

And I turn you back to the analogy that I made about the Magistrate Judge. If you saw a Magistrate Judge who simply said I'm going to just accept as true all of the complaints made by the plaintiff without so much as showing them to the defendant, I don't think you would believe that that Magistrate had considered all important aspects of the problem, especially if you found out that from 1996 to 2010, the Magistrate had taken the exact opposite position.

THE COURT: Where in the APA or case law would I find that requirement that they consider all important aspects of the problem?

MR. KEDEM: Your Honor, we quoted in this round of briefing. I think we quoted it last time as well. I apologize, I don't have a case cite for you off the top of my head.

THE COURT: All right. And if I find that they did not consider all important aspects of the problem, is the remedy vacate the letter and remand?

MR. KEDEM: So that's vacate and remand, but only if you don't also take on the textual issue. If you

decide that we have the better reading the statute, then it moots out all of the process of APA obligation, the failure to acknowledge the change of position and everything else like that.

But if you don't take on the statutory issue and just want to go for process, then yes, you would vacate and remand.

THE COURT: The violation letter does refer to your PPA, as well as the statute and the government is emphasizing that today.

How does that fit into the analysis here?

MR. KEDEM: So the PPA just, it basically just copies the words of the statute. It doesn't purport to impose any new obligation, and certainly the government hasn't identified any provision of the PPA separate from the statutory terms that AstraZeneca supposedly is violating.

THE COURT: Speak about the *Santa Clara* decision. Did you or someone in the industry on your behalf say something that is binding on you and perhaps stopping you from taking the interpretations you are taking now?

MR. KEDEM: No, and I would point out first of all the *Santa Clara* case was about whether covered entities had a cause of action to enforce contract provisions under the PPA, and the Supreme Court said no. What we said, and what we will continue to say because the statute also says

it, is that manufacturers are obligated to offer their drugs at discounted rates to covered entities. That is what we said in Santa Clara. That is what we'll say now. That is what the "must offer" provision says.

It does not say or suggest that discounts also have to be extended in the contract pharmacy scenario.

THE COURT: *Chenery* deference, have you cited a case where that is applied to an agency enforcement action?

MR. KEDEM: So *Chenery* I think is an APA-wide principle, and it's really just a basic principle. It is actually older than the APA itself, and it just says agency action has to be judged on the basis of the justification offer by the agency at the time of its decision. It's really a doctrine of judicial modesty.

It says if the court identifies some error, gap in reasoning, gap in the record, it is not up to the judge or certainly not to the lawyers to fill that in. The agency has to identify its own arguments and its justifications have to stand in full on their own.

So I would urge Your Honor to look closely at the May 17th letter and the arguments that are contained there and see whether the government is correct that it provides an adequate basis to just CNPs.

THE COURT: But it does -- the principle embedded in *Chenery* does apply when an agency acts in an

enforcement contract; is that right?

MR. KEDEM: Yes, absolutely.

THE COURT: With respect to the ADR process, is it correct that you could seek a stay or some sort of extension of time from them? And why should the -- why should I treat this as my emergency as opposed to theirs through yours?

MR. ENGLISH: So the answer is -- to your first question is I don't know. We don't know because this has never been used before. We've sent now two emails to the ADR panel, to HRSA, asking it about procedures and when our response was due, whether we would be able to seek an extension and we got no response. We asked them to respond by the end of last week, so that we would be able to speak to Your Honor intelligently about what was going on. We have not heard literally anything from them.

And I understand that we haven't directly challenged the ADR proceeding, but as Your Honor pointed out, that proceeding is based on exactly the same interpretation issue that is at issue here.

I would also point out that the CNP process, inspector general process, as far as we know, that is going to go forward. The government certainly has not represented that they're going to hold off until Your Honor rules.

So again, we would never presume to tell you

when you need to rule, but we do personally feel a pretty strong sense of urgency.

THE COURT: So the way the government wants me to frame the issue is whether HRSA correctly found that Astra's contract pharmacy restriction violates the statutory provision -- prohibition on overcharging covered entities.

And we heard that really framing emphasized a lot I think today. Should I not view that as the way to frame the issue? And if I do frame it that way, how do you prevail?

Again, the way they frame it is whether HRSA correctly found that Astra's contract pharmacy restrictions violate the statutory prohibition on overcharging covered entities.

MR. KEDEM: The overcharge argument depends on the same assumption, that we have an obligation to provide discounts for contract pharmacy sales on and are failing to do so. So when a covered entity goes on to the open market and buys from McKesson or AmerisourceBergen at wholesale prices that we are therefore overcharging them, or when it is unavailable for them to get discount pricing for the contract pharmacy purchases that we are overcharging them. It is again tied directly back to the same interpretative question before Your Honor.

In other words, there is no separate argument

that they make that doesn't depend on their being right rather than us being right about what our obligations are.

THE COURT: You repeatedly say that AstraZeneca is sensitive to the policy concerns that the government has raised and you want everyone to be able to afford their medications. But I meant to ask you, I think it is undisputed that there has been something of a nosedive in the 340B sales since you and some of your counterparts adopted this policy. That is empirically correct, isn't it?

MR. KEDEM: It is, and I think there are sort of two reasons.

One is that not every covered entity had designated a contract pharmacy under our policy even when they were eligible to do so.

But the second reason, and I think this is what you are getting at, there was an explosion of contract pharmacy use following the 2010 guidance, more than a tenfold increase. It was actually closer to a 20-fold increase.

So there will be covered entities who are using a dozen or more contract pharmacies and they can't place purchases through those contract pharmacies.

I don't want to duck away from that, but we are sensitive to that. We will work with a contract pharmacy to make sure that any of their patients who need AstraZeneca's

medications can afford it. We have patient assistance programs, among other things.

And, you know, Ms. Talmor pointed to evidence of overcharges from a covered entity called Erie. You know, on 7281, Erie is in communication with AstraZeneca regarding designating one contract pharmacy. This process is not yet finalized.

So we are willing to work with covered entities to make sure that they can participate in the 340B program under our policy.

THE COURT: All right. But -- and fair enough to say I should not worry about this, it's outside my lane, if that is your view. But you know, the government says, it seems plausible that there is a certain covered entity in Chicago and they cover 70,000 patients and it takes six hours roundtrip on the public transportation.

What could AstraZeneca possibly do if it's going to limit itself, whether required by the statute or not, to dispensing the drugs only within the in-house pharmacy and possibly one contract pharmacy?

I mean it -- that seems like a compelling problem. Again, it may not be my problem but it seems like a problem.

MR. KEDEM: So I think that there are things that AstraZeneca can and does do as a matter of policy.

I just want to be clear about one thing. It is not the case that a patient of a covered entity can only access AstraZeneca's drugs through one pharmacy or in-house.

AstraZeneca's drugs, as far as we're concerned, we don't place any limitations where it can be sold. So you can go to any CVS and get it.

There are instances where maybe you don't get access to a discount because you are not going through the covered entity's in-house pharmacy and there we have patient assistance programs. So, again, we're willing to work with covered entities if they have a lot of patients who are need help accessing and affording AstraZeneca's products.

That is our policy response and something that we care very much about, but as Your Honor pointed out eloquently in your opinion, that is a question as a matter of policy for Congress, not for a court.

THE COURT: Okay. Is there anything else you want to add at this point?

MR. KEDEM: I don't think so, Your Honor.

THE COURT: All right. Thank you.

We'll turn it back to Ms. Talmor to add whatever she likes.

MS. TALMOR: Thank you, Your Honor. I have just a few points I'd like to touch on. But first, are there any additional questions that Your Honor would like me to

address?

THE COURT: Not yet, but go ahead.

MS. TALMOR: Thank you, Your Honor.

My friend Mr. Kedem just stated that we have failed to identify the broad statutory command that we say is imposed.

I'd like to strongly resist that point. I think we have identified that. And I'll briefly go back to the language of the statute. The statute does discuss the Secretary entering into a PPA, but it says that what that PPA is going to require is that each manufacturer of covered outpatient drugs shall -- the agreement shall ensure that each manufacturer, under which the amount required to be paid to the manufacturer for covered outpatient drugs purchased by a covered entity, does not exceed the ceiling price.

So now we've addressed how Congress later added the separate nondiscrimination requirement, but that broad command is that under the PPA, the manufacturer must ensure that the amount required to be paid by the covered entity doesn't exceed the ceiling price. That is a clear and broad statutory command.

And so what we have -- what I discussed earlier today, these are evidence of actual overcharges, actual spreadsheets submitted by covered entities where they are

paying thousands, sometimes millions of dollars in overcharges above the ceiling price. So that is a clear violation of the statutory command to ensure that the purchase price does not exceed the ceiling price.

We think that is an affirmative command by Congress that manufacturers must honor these purchases not exceeding the ceiling price.

As far as the continuing agency action. I did mention that the agency has compiled additional evidence showing that Astra is continuing to overcharge covered entities every month. And I think that really has a bearing on the fact that, as Mr. Kedem pointed out, the Inspector General's Office is analyzing whether there is a basis for monetary penalties, and that is because every single month there are millions of dollars that the agency has documented, where covered entities are paying over the celling price in their 340B account.

So these are accounts set up for covered entities to purchase directly under the 340B account, under the 340B program, and they're paying millions of dollars over the ceiling price every single month. So that is why that process is ongoing.

Going back to the statute itself.

We think that it really is important to focus on the fact that when Congress created this program, it would

have known that 95 percent of covered entities could not access this program who were covered entities not able to operate in the way they operate now. And there simply isn't any requirement for Congress to have written out the ins and out of how these transactions work. It was enough for Congress to create the broad rule that you can't charge a covered entity over the ceiling price.

We think that Astra's offer, as Mr. Kedem was speaking about, offer to sell drugs to each covered entity is really a small comfort to patients in covered entities, such as ones in the record, like at VLTR 7261. That is the covered entity in Michigan's Upper Peninsula that says it served a 10,000-square-mile service area.

So in an area like that where patients presumably would need to charter -- get on a plane in order to all visit one location to fill their prescriptions each month, Astra's contention that it is offering drugs to that covered entity really is small comfort to the patients who can't access the drugs in practice.

Mr. Kedem pointed out that Astra voluntarily has a patient assistance program where it purports to make medications available for some individuals who can't otherwise afford them.

Astra voluntarily engaging in a charity program just can't make up for its nonstatutory restriction that are

preventing access to deeply discounted drugs by safety net providers and their vulnerable patients. So it really doesn't matter whether Astra is giving some of these patients access to discounts if it is denying the ones that Congress told it it must give.

Mr. Kedem brought up that there was no -- the way that the program operated between 1996 and 2010 and that there was no evidence for covered entities having brought claims that manufacturers were denying these purchases.

I think what is important there is that there isn't any evidence that between 1996 and 2010 that manufacturers were denying purchases under 340B. In fact, there isn't evidence that manufacturers were denying any purchases under 340B until 2020, so that simply doesn't help Astra's case here.

MS. TALMOR: I think that Mr. Kedem's reliance on *Chenery* is unavailing here because HRSA has made clear that what it is doing is enforcing the PPA. And so as I had mentioned earlier, HRSA doesn't have to go through, provide a robust legal brief of how it interprets the statute. It's enough that HRSA has said that it finds Astra to be in violation of the statute and its analysis -- sorry, this court's resolution of the challenge has to rise and fall with whether you think that Astra got -- I apologize -- that HRSA got the statute right.

Finally, Mr. Kedem spoke a good bit about how it is wholesalers are actually engaging in the transactions directly with covered entities.

And I had a couple of printouts earlier that show how covered entities access these drugs through the wholesalers' accounts.

I would point out that it is entirely Astra's choice to provide it drugs to both commercial and 340B purchasers through these wholesaler accounts, and it's certainly entitled to do so. But there is no current 340B or contract pharmacy litigation being brought by or against any wholesaler because the wholesalers here not only don't have the statutory obligation, but they're not the ones imposing these restrictions.

So up until Astra put its policy in place in October of 2020, Cardinal Health, McKesson and the other wholesalers were honoring the 340B price for covered entities when they purchased Astra's drugs. And these wholesalers are continuing to honor the 340B price for the drugs of other manufacturers that haven't put their restrictions in place.

So Astra can't hide behind the fact that it is Cardinal Health and McKesson that are actually effectuating these transactions delivering the drugs, et cetera. Because it is Astra that has the obligation. And HRSA explained in

the '94 guidance that if a manufacturer wants to rely on wholesaler agreements, it can, but it has to make sure that the discount is equally available.

So the takeaway there is that these restrictions are entirely being imposed by Astra. And if Astra were reserve its contract pharmacy policy, there's no reason to believe that the wholesalers wouldn't immediately provide the 340B price covered identities as they always have.

And Mr. Kedem has spoken a good bit about how Astra is offering each covered entity the ability to access its drugs through one contract pharmacy. We'll just point out that again I don't understand Mr. Kedem to be saying that Astra will always continue to have that policy and it thinks it is not required to by statute, so it can revoke that policy at any time and render the vast majority of the covered entities access the program. And that simply can't be what the Congress intended.

THE COURT: Okay. Just a couple quick questions.

What, if anything, does the PPA add that is not already in the statute?

MS. TALMOR: Nothing whatsoever. And I think that is critical, Your Honor. That is what the *Astra v Santa Clara* county case, the reason I brought that up.

Because the Supreme Court was explicit in saying

that the PPA is not a bargained-for contract. All it does is record that Astra has opted into the program and agreed to abide by the statute. And so when HRSA invokes the PPA in the violation letter, what it is doing is saying that the PPA is Astra's promise to abide by the statute.

THE COURT: Okay. And do you agree that the APA requires HRSA to consider all important aspects of the problem?

MS. TALMOR: I think that is really inapposite here.

When Mr. Kedem points to that case law, and it is in their brief, they're relying on case law that deals with agency rulemaking. It deals with challenges to agency policy in the context of rulemaking. And so when an agency is -- in the brief, Astra relies on *FTC v Fox Television* stations, which is a case talking about agency reversals of policy.

That case law has no bearing here at all. Because in the violation letter, HRSA isn't reversing a previous policy. HRSA isn't engaging in policy making, and it isn't engaging in rulemaking.

So I am not aware and I don't believe that Astra has provided in its papers any authority that would say that when an agency is launching an enforcement action that it has to balance competing policy considerations and consider

important aspects of the problem.

That is just completely inapposite to this type of agency action because an enforcement proceeding, all an agency is saying is you are violating the statute. There aren't competing policies to weigh, there aren't aspects of a problem to consider because it is not a policy decision.

THE COURT: Okay. Thank you. We're well beyond your time. I appreciate you answering all the questions. They have been very helpful.

Mr. Kedem, anything you want to add?

MR. KEDEM: No, Your Honor. Thank you.

THE COURT: All right. Well, thank you both again for the helpful argument and the responses to my questions. I'm not, I'm not here yet to say that -- first of all, I'm not here to say that I'm persuaded there is any urgency.

I understand AstraZeneca views that differently. And if there is urgency and were I to determine there is urgency, I'm not in a position to say to you that I can meet anything like the November 4th or 5th deadline.

But I do want to give that more thought and have some more input from you. So I would like, and I guess I hereby am ordering, a joint status report a week from today. Just tell me anything you want to tell me, but in a single letter that you both had a chance to review about, in

particular, your perspectives on the urgency or have there been any developments in the ADR process? Has there been any response to the inquiries that AstraZeneca has made?

And it may well be you have got nothing to say, but at least submit something that tells me you have got nothing to say or to add to what you told me today.

Are there any questions about that or anything else, Mr. Kedem?

MR. KEDEM: No, Your Honor.

THE COURT: Okay. And, Ms. Talmor, same. Any questions?

MS. TALMOR: No, Your Honor.

THE COURT: Okay. Thank you all again. It's a very helpful argument. Everybody stay safe, and we'll be in recess. Good night.

(Zoom video conference ends at 5:23 p.m.)

I hereby certify the foregoing is a true and accurate transcript from my stenographic notes in the proceeding.

/s/ Brian P. Gaffigan
Official Court Reporter
U.S. District Court

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