

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

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NOVARTIS PHARMACEUTICALS))	
CORPORATION,))	
))	
<i>Plaintiff,</i>))	
))	
v.))	Civil Action No. 1:21-cv-01479
))	
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,))	
))	
<i>Defendants.</i>))	
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**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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Dated: November 4, 2021

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BEFORE THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

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

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

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

APPEARANCES:

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Official Court Reporter: SARA A. WICK, RPR, CRR
United States District Court
for the District of Columbia
333 Constitution Avenue Northwest
Room 4704-B
Washington, D.C. 20001
202-354-3284

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

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

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

20 Yes, Your Honor?

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

12 And then, Your Honor --

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

8 THE COURT: What about United Therapeutics?

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

24 THE COURT: All right. Mr. Perry.

25 MR. PERRY: Thank you, Your Honor.

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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.)**

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

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

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

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

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

12 MR. KEDEM: Absolutely.

13 THE COURT: Okay. Good afternoon to you.

14 And who is there for the government, please?

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

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

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

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

22 And thanks to all of you for arranging this.

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

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

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

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

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

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

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

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

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

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

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

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

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

13 The answer is still no.

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

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

1 why don't you start with all that.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

19 So moving now to what we are asking for.

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

25 There is no indication that the agency genuinely

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

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

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

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

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

1 does not contain such a requirement.

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

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

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

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

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

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

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

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

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

21 Are they right about that?

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

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

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

6 MR. KEDEM: That's correct.

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

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

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

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

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

1 your warehouse.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

10 MR. KEDEM: Can you see, Your Honor?

11 THE COURT: Yes, I can see.

12 MR. KEDEM: So you can see 1842.

13 THE COURT: Okay.

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

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

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

1 such.

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

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

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

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

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

21 I think this is relevant in three respects:

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

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

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

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

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

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

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

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

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

7 The only retail transactions, which you might
8 say directly involve AstraZeneca, are the indirect
9 transactions that, as I just described, do not use bill-to,
10 ship-to, unless it is an external contract pharmacy for a
11 340B covered entity that doesn't have an in-house pharmacy.

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

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

25 The Veteran Healthcare Act, which is the statute

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

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

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

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

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

23 Can you focus on that?

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

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

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

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

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

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

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

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

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

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

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

1 reading regardless.

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

6 And then just one final point. You are talking
7 about an interpretation that the agency itself held between
8 1996 and 2010, and so it would not be appropriate for the
9 agency to penalize AstraZeneca pretty severe penalties of
10 potentially hundreds of millions dollars a month for a
11 position that the agency itself held for the majority of the
12 program's lifespan.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

8 Could you respond to that?

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

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

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

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

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

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

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

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

21 MR. KEDEM: Yes.

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

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

1 just overall the urgency of the decision from your
2 perspective?

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

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

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

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

21 MR. KEDEM: No, Your Honor.

22 THE COURT: Okay. Thank you very much.

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

25 MS. TALMOR: Thank you, Your Honor.

1 THE COURT: Good afternoon again.

2 MS. TALMOR: Good afternoon.

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

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

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

17 That theory is flawed.

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

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

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

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

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

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

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

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

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

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

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

5 MS. TALMOR: I will give the references.

6 So this is VLTR 6396, which couples with a
7 spreadsheet that is just after that, it's 6404 and -05, and
8 that shows that a hospital, Strong Memorial Hospital, paid
9 \$2 million in actual overcharges on purchases from five
10 manufacturers, including Astra.

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

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

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

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

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

9 Now --

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

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

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

21 So one piece of evidence that I think is, is
22 really telling here. So at VLTR 7281, we have a covered
23 entity that submits a sworn declaration saying that it
24 serves 80,000 patients around Chicago, that it writes
25 115,000 prescriptions annually, and it is unable to serve

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

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

7 I have here --

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

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

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

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

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

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

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

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

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

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

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

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

1 blocked from doing so at all.

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

10 Just one other I have here, 1463, which is a
11 printout from October 2020. And it shows a hospital, all of
12 the purchases from October 2020 from various manufacturers
13 and they're being charged the wholesale acquisition cost
14 for Astra's drugs of up to 725 per unit, so they show over
15 126,000 in overcharges in just one month.

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

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

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

4 HRSA has been working to update that data and
5 compile that data since the violation letter issued. And
6 the most newly released data shows that covered entities are
7 continuing to purchase AstraZeneca's drugs at wholesale
8 acquisition costs in their 340B account and for the most
9 recent amount, data is available in August. There were over
10 \$2 and a half million in overcharges. Those are just 340B
11 accounts, purchases by covered entities effectuated at the
12 wholesale acquisition cost.

13 So these are real overcharges that continue
14 every month.

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

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

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

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

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

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

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

20 THE COURT: Okay. Thank you for that.

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

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

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

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

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

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

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

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

23 THE COURT: Yes.

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

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

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

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

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

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

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

1 regarding the 340B program.

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

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

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

14 Again, that is 563 U.S. 118.

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

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

1 as that found in 340B.

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

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

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

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

25 So I think this is where the Court explains that

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

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

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

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

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

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

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

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

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

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

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

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

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

12 But more importantly, the letter says that HRSA
13 has determined that Astra's actions are in violation of the
14 340B statute and then goes on to discuss its PPA and how it
15 violates the PPA.

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

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

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

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

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

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

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

25 Because this is an enforcement action, because

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

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

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

11 THE COURT: Sure. Go ahead.

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

20 But the reasons why Astra's policy would not be
21 lawful under the '96 guidance are first and foremost, the
22 1996 guidance was explicit that contract pharmacy use is not
23 limited to covered entities that lack an in-house pharmacy.
24 That is at 61 FR 4351.

25 On the contrary, that guidance said that "there

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

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

10 That's at 61 FR 43550.

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

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

19 That is at 43555.

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

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

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

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

9 And just as importantly, two years later in
10 '96, HRSA already had confirmed that the use of contract
11 pharmacies was a common business practice and that
12 manufacturers cannot restrict those sales without violating
13 the statute.

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

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

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

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

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

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

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

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

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

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

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

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

11 Do they accurately characterize the government's
12 position?

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

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

1 creates.

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

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

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

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

22 MS. TALMOR: Yes, Your Honor.

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

25 MS. TALMOR: Yes, Your Honor.

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

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

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

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

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

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

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

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

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

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

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

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

1 patient care.

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

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

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

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

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

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

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

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

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

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

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

1 fix something that is working properly.

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

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

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

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

1 evidence just really bolsters how it has always worked.

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

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

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

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

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

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

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

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

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

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

25 Now, Congress clearly prevented a covered entity

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

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

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

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

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

25 I would also point to the antitrust statutes,

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

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

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

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

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

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

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

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

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

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

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

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

1 obligations in this way.

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

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

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

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

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

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

3 Moreover, the 2010 guidance says that they had
4 been allowing and approving different covered entities to
5 use multiple pharmacies under pilot programs and that had
6 worked so well, but they issued additional guidance telling
7 covered entities that they may do that more broadly. So it
8 seems clear there were multiple pharmacy agreements before
9 2010.

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

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

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

1 statutory obligations.

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

7 So I think what the guidance --

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

7 Do you agree with that analysis?

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

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

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

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

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

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

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

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

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

1 relevance.

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

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

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

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

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

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

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

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

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

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

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

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

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

1 putting aside its premature nature.

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

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

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

16 MS. TALMOR: Thank you, Your Honor.

17 THE COURT: Okay. Thank you.

18 So, Mr. Kedem, back to you.

19 MR. KEDEM: Thank you, Your Honor.

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

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

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

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

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

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

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

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

1 their representatives and agents that other provisions of
2 the Veterans Healthcare Act authorized contract purchases but
3 340B does not. And that Congress specifically considered but
4 rejected language that would have allowed contract purchases
5 for on-site sales.

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

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

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

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

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

1 topic.

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

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

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

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

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

25 And I want to be very clear about this. The

1 obligation under the 340B statute is to offer drugs to
2 covered entities. AstraZeneca's policy does that in
3 100 percent of cases. Any covered entity can purchase
4 AstraZeneca's products in whatever amount they want at
5 340B prices.

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

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

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

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

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

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

7 Turning to the 1996 guidance.

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

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

19 The government would have you believe, however,
20 that every manufacturer in the country between 1996 and
21 2010 was violating its obligations to provide discounts to
22 unlimited contract pharmacies and moreover that no covered
23 entity said anything.

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

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

6 Turning to the *Bostock* case very briefly.

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

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

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

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

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

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

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

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

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

1 separate.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

11 How does that fit into the analysis here?

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

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

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

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

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

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

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

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

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

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

1 enforcement contract; is that right?

2 MR. KEDEM: Yes, absolutely.

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

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

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

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

25 So again, we would never presume to tell you

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

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

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

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

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

25 In other words, there is no separate argument

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

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

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

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

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

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

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

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

3 And, you know, Ms. Talmor pointed to evidence of
4 overcharges from a covered entity called Erie. You know, on
5 7281, Erie is in communication with AstraZeneca regarding
6 designating one contract pharmacy. This process is not yet
7 finalized.

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

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

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

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

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

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

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

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

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

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

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

20 THE COURT: All right. Thank you.

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

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

1 address?

2 THE COURT: Not yet, but go ahead.

3 MS. TALMOR: Thank you, Your Honor.

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

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

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

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

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

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

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

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

23 Going back to the statute itself.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

18 THE COURT: Okay. Just a couple quick
19 questions.

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

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

25 Because the Supreme Court was explicit in saying

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

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

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

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

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

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

1 important aspects of the problem.

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

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

10 Mr. Kedem, anything you want to add?

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

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

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

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

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

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

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

9 MR. KEDEM: No, Your Honor.

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

12 MS. TALMOR: No, Your Honor.

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

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

17
18 I hereby certify the foregoing is a true and accurate
19 transcript from my stenographic notes in the proceeding.

20 /s/ Brian P. Gaffigan
21 Official Court Reporter
22 U.S. District Court
23
24
25

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