IN THE UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT

SANOFI AVENTIS US LLC, Appellant,	)	Case No. 21-3167
v.	)	10:00 a.m.
UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, et al., Appellees.	)	November 15, 2022
NOVO NORDISK INC; NOVO NORDISK PHARMA INC, Appellants,	)	Case No. 21-3168
v.	)	
UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, et al., Appellees.	)	
SANOFI AVENTIS US LLC, Appellant,	)	Case No. 21-3379
v.	)	
UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, et al., Appellees.	)	

(CONT'D ON NEXT PAGE)

Nos. 21-3167/21-3168/21-3379/22-1676/21-3380 (Cont'd)

ASTRAZENECA PHARMACEUTICALS, LP
Appellant,

v.

SECRETARY UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES; et al.,
Appellees.

Case No. 22-1676

NOVO NORDISK INC; NOVO NORDISK PHARMA INC,
Appellants,

v.

UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, et al.,
Appellees.

Case No. 21-3380

ON APPEAL FROM THE
UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY
CASE NO. 3:21-cv-00634-FLW-LHG

BEFORE APPELLATE PANEL:
HON. THOMAS L. AMBRO, Circuit Judge
HON. CHERYL A. KRAUSE, Circuit Judge
HON. STEPHANOS BIBAS, Circuit Judge

APPEARANCES (see next page)

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P R O C E E D I N G S

HON. AMBRO: We have one case this morning. It's numbers 21-3176 -- 3167 -- excuse me -- 3168, 21-3379 and 3380 and also 22-1676, Sanofi Aventis, et al. v. the Secretary United States Department of Health and Human Services.

We have given a significant amount of time for oral argument. And I'm not sure we're going to need it all but nonetheless, we set it out this way.

I would ask at the outset that once we're done today that a transcript be prepared of this oral argument and that it be split that side and that side, so split it in half.

And then also, if there were any issues that are duplicative of something that someone else has said, perhaps -- unless you have something new to add to that particular issue, if you would just hold off and, again, unless there was something that was not said earlier that you think you need to add.

Final point is on the mootness issue, I'm not sure that we have any questions on that particular issue. So if, again, unless you think there's something new to be added beyond what was stated in the briefs then you can let us know.

And with that, I invite Mr. Francisco to come on up and --

MR. FRANCISCO: Judge Ambro, may it please the Court. Noel Francisco for Sanofi Aventis. And if I could reserve five minutes for rebuttal?

HON. AMBRO: Yes, sir.

MR. FRANCISCO: Your Honors, Section 340(b) requires Sanofi to do one thing: offer its drugs to covered entities at the ceiling price. It clearly does that. They can purchase as much as they want at the ceiling price and will deliver it to their in-house pharmacy if they have one, to a contract pharmacy if they don't and, in addition to that, to an unlimited number of contract pharmacies if they provide us with limited claims data. It takes them five minutes every other week to comply with that last part of our policy. That's plainly an actual offering. Indeed, it's more generous than the government itself required for the majority of the operation of this program.

The government's only response is to say that manufacturers can't impose any condition on their offers no matter how reasonable. But there's no basis for that in the statutory text which requires just one thing: that we make an offer at the ceiling

price.

As a private entity, manufacturers like Sanofi generally are allowed to do what they want unless there's a statute or other law --

HON. AMBRO: One of the things that I would like perhaps to explore, the advisory opinion and the violation letters, do you consider them -- or is it a primary argument that you consider them arbitrary and capricious under the Administrative Procedure Act?

MR. FRANCISCO: Yes, we do, Your Honor. And the principal reason we think they're arbitrary and capricious is because they're contrary to law. They're contrary to the 340B statute. Again, as private entities, we're generally allowed to do what we want unless a statute prohibits our conduct.

HON. AMBRO: That would certainly get you there if that's how we come out. Are they also -- is there an argument that there's a change in direction from '96 to 2020 without any adequate explanation?

MR. FRANCISCO: Oh, absolutely. And I think Judge Stark's opinion on this is very persuasive on the various ways that it's arbitrary and capricious wholly apart from the violation of law language.

Here, we've seen a constantly evolving set of positions on the part of the government. It used to be that only one contract pharmacy was allowed. Now an unlimited number of contract pharmacies are required.

It used to be that covered entities had to maintain title to the drug until it fell into the pocket of their patients. That seems to have gone by the wayside and under the replenishment model. If you look at the advisory opinion, we only had to honor a contract pharmacy to the extent that they operated as the "agent" of the covered entity. That seems to have gone away under the violation letter as well. Judge Stark sets all of these changes out. But the government has never explained any of them.

So I do think that, wholly apart, from our contrary to law language, it is arbitrary and capricious. But again, we think it is also plainly contrary to law because there is simply nothing in the statute that prohibits Sanofi's program. We make an offer. They can buy as much as they want at the ceiling price. We'll deliver it right to their doorstep. We'll deliver it to a contract pharmacy if they don't have that proverbial doorstep because they're not set up.

HON. KRAUSE: But, counsel, is that because you interpret the term "offer" to mean at least that there is delivery to the covered entity?

MR. FRANCISCO: No, Your Honor. But it's that delivery obligation that makes this such a relatively straightforward case. I actually don't think offer encompasses delivery. They're separate. But here, we actually do agree to deliver it right to their doorstep, to another contract pharmacy if they don't have that doorstep, or, frankly, to an unlimited number of contract pharmacies if they provide us with seven data fields that they already collect and provide to all of the insurance companies in the government for other purposes.

HON. KRAUSE: And you're doing that just -- your clients are doing that simply as a charitable matter and not because it's required by the statute?

MR. FRANCISCO: Yes, Your Honor. And I think if you look at the underlying history of this program, it makes perfect sense. Remember, the 340B program was meant to restore a set of voluntary discounts that we were all providing the social safety net providers prior to 1990. We were doing that as good corporate citizens. In 1990, Congress passed a

statute called the Medicaid Rebate Act that had the unintended consequence of eliminating those voluntary discounts. Well, if you look at what those voluntary discounts were at the time, they weren't going to commercial pharmacies, to contract pharmacies. They didn't even exist at the time. They were going to social safety net providers who were buying drugs out of pocket for use at their facilities, to the poor and uninsured, that they were serving at their facilities. I think it shows how far we've come from the actual purpose of the program to now where the government is arguing for this massive multi-billion dollar cross-subsidy from one commercial for-profit industry, the manufacturers, to another for-profit industry, the commercial pharmacies. There's simply no basis for that conception of the 340B program.

HON. KRAUSE: Wasn't the key issue that they were then buying out of pocket -- I mean, your theory is that this was directed to them in bringing these pharmaceuticals in for their in-house pharmacy. So times have evolved. There's this massive use at this point of contract pharmacies. But if it is, in fact, the case that the covered entities are still doing the purchasing, why isn't it their out of pocket expense and they're still getting some funds back even

if there is a fee that's taken off by the contract pharmacy?

MR. FRANCISCO: Sure. And, Your Honor, frankly, we could have a very good and robust debate in this country about how best to subsidize covered entities. And I think that debate would include commercial pharmacies. It would include the manufacturers. It would include the insurance companies. It would include the covered entities and would probably include many others.

But one thing I'm quite certain of is that that debate is not resolved by the meaning of the word "offer" because that's all that this statute requires us to do is to make an offer. And our conception of "offer" makes perfect sense when you actually do look at the history of this program where the purpose of it was much more modest than what the government thinks that it has evolved into today where it's now this massive multi-billion dollar subsidy where billions of dollars are falling into the pockets of commercial pharmacies. I don't think there's any conception of this program that says it has to justify that level of a subsidy.

HON. KRAUSE: Didn't this purpose extend to the interest of individual patients

receiving drugs at a discount or sometimes for no cost at all? And if that's the case then to the extent at this point patients are using the contract pharmacies -- it's certainly more convenient for them but that's where the largest use is -- why shouldn't we interpret the statute to require that there be production of pharmaceuticals --

MR. FRANCISCO: Sure.

HON. KRAUSE: -- to those locations as well?

MR. FRANCISCO: Well, several responses, Your Honor. The first one is the text. But I'll put that to the side because I think you understand our textual argument.

The other point I would make is that very few -- very little of the discount is actually passed on to any customer at all. My understanding is that there's only 25 percent of hospitals that pass any of the discount on to their customers. And even then, it's only to a subset of the customers and only part of the discount. And there was one recent white paper that pegged the number of people who showed up at contract pharmacies with what's called a 340B discount card which is what entitles the person to get the discount. It was about one and a half percent

according to this white paper that showed up with that card.

The fact of the matter is that under the replenishment model, the commercial pharmacies don't distinguish between 340B drugs and other drugs. They don't distinguish between 340B patients and other patients. Basically, a patient walks in the door. They purchase the drug for generally whatever their insurance company is going to pay for it. And then the contract pharmacy and the commercial -- and the covered entity reverse engineer the discount and split the difference. It's basically this massive arbitrage opportunity where the vast majority of the difference is being shared not by the patients but by the commercial pharmacies and the covered entity. And I think it just underscores how far we've come from the actual purpose of this program.

I think that the best Supreme Court case to look at is the decision that the Court rendered in Christensen v. Harris County. Now that was a case involving the Fair Labor Standards Act where the FLSA basically said employees could use their comp time whenever they wanted to as long as it was reasonable to use that comp time. An employer then adopted an additional policy that said that in

addition to that, we're going to require you to use your comp time in certain circumstances so that we don't have to pay cash wages in lieu of unused comp time. And the Supreme Court held that that was squarely allowed precisely because there was nothing in the statute, the FLSA, that prohibited that additional policy.

Here, there is simply nothing in 340B that prohibits Sanofi's policy which, again, allows covered entities to buy as much as they want and we will deliver it right to their doorstep. And if they don't have that doorstep, we'll allow them to designate an alternative doorstep by virtue of designating a contract pharmacy. And then we even go substantially further to allow them to use an unlimited number of contract pharmacies making it far more generous than the agency itself allowed for the first 20 years of this program.

HON. KRAUSE: But you and your colleagues have asked us to go much further than that and to say as a blanket matter that there can be any conditions you wish and that there can't be, on the part of the government, this requirement.

MR. FRANCISCO: Yeah. Well, first, Your Honor, I don't think that we are asking you to

say that there can't be any conditions. What we're saying is that there has to be an actual offer. And there are certainly conditions that can be imposed that render the offer an illusory one. We don't dispute that at all.

The second point is we're not anywhere near whatever the outer boundaries of "offer" is because here, we'll deliver it -- all of us will deliver an unlimited amount to their doorstep and an unlimited amount to an alternative doorstep if they don't have a doorstep. And for Sanofi, we go substantially further. So whatever the outer bounds of that are, I don't think we're anywhere close to it in this case.

HON. BIBAS: Mr. Francisco, help us to think through how we would write an opinion and draw a line here because UCC says you don't even have to deliver things. But you appear to be agreeing, yes, delivery is one of those things that is commercially expected. So what body of law do we to to figure out what's a bona fide offer and what makes it illusory?

MR. FRANCISCO: Yeah. The first point I want to make, Your Honor, is that I don't agree that delivery is part of the offer obligation.

HON. BIBAS: Okay.

MR. FRANCISCO: But I think you don't have to get to it here. I'll put that to the side.

Here, we've got -- you know, it's not like the word "offer" is new to commercial law. The word "offer" is as old as the hills and courts applied essentially on a case by case basis. Have you made an actual offer?

In writing your opinion, assuming you write it favorably to us, I don't think you have to be the first Court ever that tried to come up with a comprehensive all-encompassing definition of what an actual offer is. I think it's enough to say that what the statute requires is an offer. That precludes the government's position taken in the violation letter which says that absolutely no condition can be imposed on that offer. So presumably, we couldn't limit our offers to delivery on the planet Earth because that would be an impermissible condition that we've imposed on the offer.

So you just need to say that it requires an offer. It doesn't impose any -- a flat out prohibition on all conditions. And that the conditions we have imposed clearly constitute an actual offer because we're willing to deliver an unlimited number of drugs right to their doorstep.

HON. BIBAS: I understand that but --

HON. AMBRO: Even if it was on the lunar surface?

MR. FRANCISCO: Excuse me, Your Honor?

HON. AMBRO: I'm sorry. Just teasing. Even if it's on the lunar surface?

MR. FRANCISCO: Exactly.

HON. BIBAS: It's not true of any of the three manufacturers here but there are other manufacturers out there who do not provide to any contract pharmacies. And so we have this issue when we write about a rule how should we think about that. Maybe we don't have to resolve that but how do we gesture it where the line is?

MR. FRANCISCO: Sure. I would look, first, to the plain meaning of "offer". Right? We look at dictionary definitions of the meaning of the word "offer". I think then we look at background common law principles, UCC principles, to determine what is encompassed by an offer. And I think one of those is that, in general, there's not a delivery obligation.

I actually don't think it's that high of a standard to make an actual offer. I also don't think you have to come anywhere close to what those

outer boundaries are in this case. I think it's enough to lay out what the plain text says, what the background principles are that go into interpreting that plain text, then apply it to the facts of this case under which I think every one of our policies easily meets the standard. And then you leave it to future courts to decide in that context whether programs different from ours likewise constitute an offer.

HON. BIBAS: We're going to be back here deciding a whole string of cases. If we think, no, we need to think a few steps ahead to the next few cases --

MR. FRANCISCO: Sure.

HON. BIBAS: -- what should we do in a case where we get no contract where they say we'll deliver it to you but you don't have a contract pharmacy, tough. Right? Go deliver -- develop an in-house pharmacy.

MR. FRANCISCO: Right. So two responses, Your Honor. First, if you made clear that our policies meet the offer requirement, as I very strongly believe that they all do, I actually don't think you're going to get a lot of other cases. I think that what you're going to have manufacturers do

is look at this and say, all right, we now have this -- we now at least have this safe harbor. And so we're going to adopt that safe harbor. So I doubt you're going to have that problem.

Secondly, I think it's very difficult, and I wouldn't urge you to try to resolve hypothetical future cases based on some general abstract all-encompassing definition of the word "offer". I don't think that's how courts have ever approached that kind of question because it's just impossible to figure out what the various future permutations are. I think you set out the plain text and the principles --

HON. AMBRO: But doesn't --

MR. FRANCISCO: -- you apply --

HON. AMBRO: Go ahead. Doesn't it become -- why don't you finish and I'll go.

MR. FRANCISCO: Well, and you apply it to this case. And then, yes, you leave it to future courts to apply those principles to future cases.

HON. AMBRO: Don't offer and -- I call it shipping or slash delivery merge in effect? If you say I offer you on the condition that I will ship to only one location of -- if you don't have an in-house pharmacy, only to one location of a contract pharmacy.

And let's say it's Walgreens and Walgreens has myriad locations in a rural area but they're miles and miles apart. So if you put that condition, I'll deliver it only to Omaha but I'm not going to deliver it to Lincoln and other places in Nebraska, you're saying that's okay?

MR. FRANCISCO: Yes, Your Honor. And I'd like to explain.

HON. AMBRO: Go ahead.

MR. FRANCISCO: But may I also reserve the balance of my time for rebuttal after?

HON. AMBRO: You're on our time. Go ahead.

MR. FRANCISCO: Okay. Thank you, Your Honor.

Yes. I don't think that -- frankly, I don't think that "offer" and "delivery" merge at all. I think that they are separate concepts.

Secondly, even if you do think that they merge to some extent, I think it is fully sufficient to say that it's okay that if we offer to deliver to their doorstep and also, if they aren't set up to accept delivery themselves, to designate one other place that essentially functions as their in-house pharmacy. I don't think there's any basis in

the text or the history of this to go any further and say that in addition, we have to honor this massive network of contract pharmacies the purpose of which is to exploit a gigantic arbitrage scheme where you end up transferring billions of dollars from one commercial entity, the manufacturers, to another commercial entity, the commercial pharmacies. There's just no basis for that. If you go back to the history of the program, for the first majority of the operation of the program, the first 20 years, they were only even allowed to use one contract pharmacy.

So even if you want to look at those kind of background principles, I think it's quite easy to say that, at the very least, they can't be required to deliver to more than just the doorstep or the alternative doorstep in the form of one contract pharmacy. That's how the government itself understood this program for the first 20 years.

I would submit then for my client, Sanofi, it's even much easier, because for Sanofi, we go beyond those two things and also allow delivery to an unlimited number of pharmacies as long as they provide us with those seven data fields that they're already providing to all the insurance companies and the government for other purposes.

HON. KRAUSE: We look at it as arbitrage but the government looks at it as accessibility to patients for it to be meaningful in terms of fulfilling the statutory purpose. If we were to go as far as saying if not an in-house pharmacy then at least one outside pharmacy, what is the principal -- what is it about the characteristics of your policy that provides some standard that could be applied more broadly?

MR. FRANCISCO: I mean, I think the characteristic -- to the extent that I understand the question -- and I hate to sound like I keep repeating myself -- it would go back to the meaning of the word "offer". Are we actually offering our drugs to them at the ceiling price?

To take a step back in terms of the policy, I get that their view of the policy is that we want to have this enormous subsidy to covered entities to provide services all across the country to the poor and uninsured and in rural areas and that they're willing to tolerate the fact that that means billions of dollars in arbitrage revenue going to commercial pharmacies, something that was never encompassed within this program at the outset.

I would respectfully submit that

there's no statute that pursues a single objective to the exclusion of all others. And I don't think it's reasonable to look at the history of the statute and say that that was its overall purpose. Rather, instead, if we want to have that kind of subsidization of health insurance for the poor, uninsured and rural areas, an extraordinarily important issue that this country does need to grapple with, that simply hasn't been resolved in this statute which imposes one obligation only, an offer. That's the type of debate that Congress should be undertaking in the future and it should bring all of the relevant stakeholders to the table. And those stakeholders extend far beyond the manufacturers, on the one hand, and commercial pharmacies on the other. That's a problem that Congress ought to be dealing comprehensively. But the one thing I know for sure is that they didn't resolve that debate in the meaning of the word "offer".

HON. AMBRO: Is there anything you wanted to note on your opening with respect to the ADR challenge that you've put in here?

MR. FRANCISCO: Ahh. You know, it's a very simple argument and I'm happy to rely on our briefs. But the basic point is that the ADR is a new rule. They withdrew the old rule. They put forward a

new rule and a new rule requires new notice and comment. The Supreme Court has repeatedly made clear that we've got to cut square corners with them. They've got to cut square corners with us. The sine qua non of the square corner under the APA is notice and comment ruling.

HON. AMBRO: Usually, the thing is -- the understanding is that there's a formal way of withdrawing a rule and that's in the Federal Register and that wasn't done here.

MR. FRANCISCO: Well, Your Honor, I don't think --

HON. AMBRO: And your response to that would be?

MR. FRANCISCO: Yeah. I don't think that there's a single formal way of doing it. But what I do know is that the principal way that you withdraw a rule is by saying that the rule is withdrawn. And that is precisely what they did here. They said it was withdrawn. They then issued a new rule under a new rule number reflecting the fact that the prior rule was withdrawn. And I presume that agencies speak English the way that the rest of us speak English and "withdrawn" for them means the same thing as it means for us.

HON. AMBRO: The problem that we're having, there's not a whole lot of case law.

MR. FRANCISCO: Yeah. The best case law I think you have on an issue like that is the dictionary.

HON. AMBRO: Thank you very much. We'll get you back on rebuttal.

MR. FRANCISCO: Thank you, Your Honor.

HON. AMBRO: Mr. Parrish?

MR. PARRISH: Thank you, Your Honors. May it please the Court. Ashley Parrish on behalf of Norvo Nordisk. I'd like to request five minutes for rebuttal.

HON. AMBRO: Absolutely.

MR. PARRISH: So what I thought I would do in light of your questions is three things. One is, I'd like to frame the question before the Court because I think it'll help, Your Honor, with your question about what the relief is.

Second, I'd like to remind the Court of three administrative law principles that, if you keep in mind, make this an even easier case than just looking at the text.

And third, I want to respond to just a few of the government's arguments that weren't

addressed in Mr. Francisco's argument in case that's helpful to the Court.

So the question before the Court, the precise question is: is the government's interpretation reflected in its May letter and in its December advisory opinion -- is that contrary to law or arbitrary and capricious? So the only thing that's before the Court is that the government has said that the 340B statute includes this extra delivery obligation not to covered entities but to third party contract pharmacies anywhere in the country. So the simple statutory question before the Court is: is that a legal interpretation of the statute. Does the statute include that additional delivery obligation to third parties?

The Court obviously will have to explain its reasoning as it gets there but in terms of the declaratory language that the Court needs to do, just like any administrative law case, Your Honor, is it just strikes down and vacates the government's actions as unlawful. That avoids a lot of the complexities in terms of what you're trying to do. We're not asking you to bless these policies in an abstract sense. What we're saying is that the government has taken a very specific position for the

very first time that the statute imposes a binding obligation for us to deliver to third parties at other locations. Our position is that that's not in the statute. All the Court has to do is say that we're right about that and it can vacate the government's position.

Your Honors, as I said, my next point was to lay out three administrative law principles because I do think it is helpful for the Court to keep this in mind in terms of thinking about what type of statute that you're interpreting and how you should approach it.

The first thing is to recognize is that the government can only address ambiguities in a statute or things that lack clarity or fill in gaps if it's been granted rulemaking authority and if it exercises that authority. So we know, here, that the government, first of all, says that it doesn't have rulemaking authority and, second, said --

HON. AMBRO: But they're basing the violation letters on the statute as opposed to their rulemaking authority.

MR. PARRISH: That is exactly right, Your Honor. I completely agree. That sort of takes me to my next point about --

HON. AMBRO: Go ahead.

MR. PARRISH: -- the private right baseline which is it's really important to recognize that these drugs belong to manufacturers. And I'm sure you noticed in the government's brief -- and this is what Mr. Francisco was talking about in terms of the Christensen case by the Supreme Court. The government just flips that. It's like as if these drugs do not belong to manufacturers. And the common law baseline -- and you can see this in any number of Supreme Court cases that we've cited, the Horne case, of course, talks about raisins and so forth, but any number of those cases. The right to exclude, the right to decide who gets your products, where you will deliver them to, that's all a matter of common law that exists unless it's displaced by a federal statute. So you have to look at the language of the statute to see if those common law rights are displaced.

And the third point that I would make about that is because the Supreme Court has been very clear that if Congress wants to displace those private law rights, it has to do so clearly what the Court has recently said in "exceedingly clear language".

You take those three principles and

what it means is the following is that if the statute is not clear in the government's favor, if you can't read the statute to say they clearly win, then they have to lose. If we're right in terms of applying everything, then --

HON. BIBAS: But why is that? I mean, if it's not rulemaking authority, we just parse the statute de novo ourselves. We don't have to -- there's not a clear statement requirement here.

MR. PARRISH: Well, there is, Your Honor, in the sense that there is a clear statement requirement for the Congress to replace the private rights. So what you would say is -- you're absolutely right. If you --

HON. BIBAS: What's your best authority for that proposition?

MR. PARRISH: Well, Your Honor, we cite in our briefs the Texas v. United States case. We cite the recent eviction case where the Court -- the Alabama case where the Court addresses that.

But, Your Honor, what I would say is that it depends on how you think about statutory interpretation. Some judges would say I apply traditional tools of statutory construction and I will get the best interpretation of the statute. We think

if you do that, we clearly win. But that's for you to do.

If you decide there's some residual ambiguity after that, you've applied traditional tools, my point is then we still win because that ambiguity would have to be resolved through rulemaking. It can't be -- that ambiguity can't be resolved in the ether. And the default is the common law rights which is they're our drugs and we can do what we want with them unless someone says something else.

HON. KRAUSE: But the default also includes agency law. And they're taking the perspective that these contract pharmacies are just being designated as agents. So if "offer" -- if we conclude "offer" does include some delivery obligation then what -- are we really arguing here about who pays for the mailing? Because if it needs to go to them and they say, okay, send it to our agent instead, is the objection that there's just too many agents so that's raising the cost?

MR. PARRISH: So I would say it's two things, Your Honor. One, let me give you an analogy so that -- which I think is helpful in terms of thinking about delivery. And second, let me address

the agency point because the government isn't relying on that anymore because it's never made a true agency showing.

But on the first point, Your Honor, the analogy we use in the brief is that if you were a supermarket and you had a 50 percent discount off of milk and it said you could get milk for 50 percent, you could have an argument as to whether the supermarket might deliver it to you or whether you're going to pick it up. But no one would think -- no one would think -- that that means that you can call up and say I'd like you deliver it to my grandmother in New York and my cousin in California and, you know, my friends in Indiana.

And that's the argument that the government has to rely on. And you'll notice that the government doesn't identify anything in the statutory text that supports that. Instead, the only way the government can have a textual argument is to flip Christensen on its head. So the only argument the government makes is to say, well, these drugs are not the manufacturers drugs but say that implicitly and therefore the manufacturers don't have any control over them. But the truth is, is that once you get rid of that, there's nothing they've identified in the

statute that's ambiguous. There's nothing about the word "offer" that's ambiguous that they rely on. You can read their brief. They just don't parse the language.

Your Honor, on the agency point, the problem that the government has there is that in the 1996 guidance, the theory was that we could read into the statute an agency relationship because one contract pharmacy would be acting as equivalent to an in-house. And at that time, you'll note that for 14 years, the statute operated that way. And we would say, as a first point, is if the government is right now then that meant that for 14 years the government was interpreting the statute in a way it now says was plainly wrong. That can't be the case.

But on top of that, Your Honor, there's none of the things that are an agency relationship. An agency relationship would suggest that you have control -- the principal has control over the agent. There's no suggestion that these hospitals have controls over the CVSs and the Walgreens of the world. It would be a fiduciary relationship. There's nothing like that either. And also, there would be title that would be held by the covered --

HON. AMBRO: But let's say that

Walgreens is the contract pharmacy for a covered entity. And Walgreens has myriad locations, back to some extent my prior question. Are you saying that you will only deliver to Walgreens in one place even though it has 100 locations in a particular state, 200 locations?

MR. PARRISH: So what -- just to be clear, Your Honor, what we're saying is that if the covered -- we only will -- we'll only offer the drugs to the covered entity and give it to the covered entity. Under our policy, if the covered entity has an in-house contract pharmacy, we will deliver to that in-house pharmacy.

HON. AMBRO: Understood. But most of them don't.

MR. PARRISH: Most of them don't. So if they don't, what we will do under our policy, at the start of the case, we would deliver it to one contract pharmacy. We now agree to deliver it to two of their choosing. But it's not every Walgreens across the country.

HON. AMBRO: When I say contract pharmacy, let's say Walgreens was the contract pharmacy. Are you saying you'll only deliver to how many locations?

MR. PARRISH: Two locations. Not every location of -- that Walgreens might have.

HON. AMBRO: So that Walgreens would have to do the dispersing out from that particular location.

MR. PARRISH: For the covered entity, yeah. But there's nothing weird about that. If you think about the statute, what the purpose was is that these are disproportionate shared hospitals that are serving local communities that have people that walk in who are uninsured. Those are the patients they're supposed to benefit. What Mr. Francisco said is absolutely right. The problem about this expansion is that it's not helping the patients. There's lots of reports on that. What it's doing is it's creating extra money for the contract pharmacies who aren't even supposed to be part of the program.

HON. AMBRO: Isn't part of the problem from the government's perspective that you've got, in the DC circuit, the Seventh Circuit here, you've got five different manufacturers.

MR. PARRISH: Yeah.

HON. AMBRO: And they all seem to have different ways of addressing this perceived problem. How do you go about trying to get something that's at

least semi uniform?

MR. PARRISH: So what you do, Your Honor, is you say the statute imposed one thing. It imposed an offer obligation. The second thing you say is it did not displace any other common law rights that manufacturers have over their drugs just like if you were to make something yourself, unless a statute told that you couldn't do something with it, you would be free to sell it and to whomever, wherever you want. And you say those two principles stay in place. And therefore what you say is that you say Congress understood that this was a charitable program that manufacturers have always provided. It was for the benefit of those patients that visit the covered entities themselves not those patients -- not the Bill Gates that come in and then go off to a contract pharmacy a hundred miles away but the patients that come in to the covered entity itself. You say those three things and the case is over. And all you have to do, Your Honor, for in terms of your language as you say, the government's legal position that's taken the letter and the advisory opinion is contrary to law. It's also arbitrary and capricious.

HON. KRAUSE: But where do you get that restriction that this was focused just on the patients

who were local on site?

MR. PARRISH: Because when the statute was enacted, it -- first of all, it has all of these provisions. The first one is it's only to a covered entity. Then what it says, it says there shall be no diversion to anybody other than the patient.

HON. KRAUSE: These are patients, right? They're patients who were getting a prescription from the covered entity. It's just that they're going to fill it not at the pharmacy downstairs in the covered entity but at the Walgreens that's 40 miles away.

MR. PARRISH: Right. But the imposition -- so the key point that Mr. Francisco was making is that when they do that, the patient is no different off because what happens is the patient pays in the vast majority of the case, like 99 percent of the time, the patient pays the full price. And what's happening is, is that the contract pharmacy and the covered entities are pocketing the spread. What Congress intended originally --

HON. BIBAS: Even if the patient's uninsured?

MR. PARRISH: Even -- yes. That's -- I'm sorry, Your Honor. That's the frustration that we

have with this program is that what's going on is, is that the uninsured patients that would -- used to come into the hospital and then the hospital would say I have drugs that have been provided at a discount, I'll give them to you, those patients aren't being treated that way anymore. And both -- what's happening instead, the patients that are getting are -- both the insured and the uninsured are not being treated differently unless they have that card which is the 1.4 percent that Mr. Francisco talked about. And so, the problem is it's not helping the patients.

And if I can, you notice in our brief, there's a real takings problem that underlies this which is that as long as you are transferring to covered entities, it has a nexus to the program which is to help the patients.

HON. BIBAS: Those (indiscernible) take part in the program you take the conditions that come with it, it's not a taking.

MR. PARRISH: Your Honor, only if -- only if the statute is not read the way that we think it is. So if you want to make that argument, you have to say that the statute in the first place is clear. But the reason why you wouldn't interpret the statute adventurously is because --

HON. BIBAS: That anything. Either you're right on the statute or you're wrong on the statute.

MR. PARRISH: Well, Your Honor, what I would say, Your Honor, is it would be odd to read a statute that doesn't talk at all about delivery and then say that the point of it is to transfer for the private benefit of these contract pharmacies which is what is happening. The contract pharmacies are not part of the statute. But they're making a windfall in the profits from the sale of these drugs.

HON. KRAUSE: But why isn't that just incidental? Because these are covered entities that happened not to have an in-house pharmacy and there would be a lot of expense and burden that would go along with setting that up or running it, so there's a cost associated with that. It's a cost that is -- and the effort is being taken on by the contract pharmacy so they get a fee for the work that they're doing.

MR. PARRISH: So, Your Honor, you saw what was in the briefs which is that we're talking about, depending on the year, 3.6 billion that's being pocketed by the contract pharmacies which is not at all associated with the cost. It's entirely extra spread or revenues. And we've seen a growth in the

program without any growth in uninsured patients from 9 billion in 2010 to 38 billion in 2020. All of this growth is explained not by helping indigent patients. It's all explained by the arbitrage that's happened by sending these drugs across the country in a way that allows them to sell drugs to fully insured patients and then pocket the difference.

HON. KRAUSE: How is there any different benefit to patients who are going to get their drugs from their contract pharmacies than if it were an in-house pharmacy?

MR. PARRISH: Well -- I'm --

HON. KRAUSE: Well, you seem to be saying that these contract pharmacies aren't helping the patients. They were intended to help patients. They're not helping the patients. But how is the benefit any different when the patient goes downstairs to the in-house pharmacy? They still have their insurance, right? And --

MR. PARRISH: Your Honor, what we would say is this. As long as the program is interpreted as Congress intended, which is that the offer imposes just that obligation and you can't divert to third parties so only the covered entities --

HON. AMBRO: No. But she's asking a

practical question.

MR. PARRISH: Well, what I'm saying is if you do that, then the patient -- the patients that need the medications will go to the hospital and they will get the medications they need. The patients that are located at CVS a hundred miles away, they'll still get the medications they need. Their insurance will still pay for the medication. The only difference is, is that the pharmacy won't be able to then get the discount through the covered entity and then pocket it for themselves. So this is not impacting the patients. You're right. The patients see it the same. The difference is, is that all of these patients that are now going to these distance pharmacies are, as an accounting mechanism, being treated as if they're entitled to a discounted price. They're not getting it. But the discount is then going in the pockets of the pharmacies and the covered entities. That's why it's grown from 9 billion to 38 billion. And that's why it's not incidental because these contract pharmacies, like the CVS and Walgreens, they say this is material to their profits and the revenues because we're talking about three plus billion a year that doesn't have anything to do with the patients. It's just a question of pocketing the

money.

HON. AMBRO: But if we read the statute your way of that 3.6 billion that was going to the pharmacies, would all -- would any portion of that come back to you if it were not given -- if they didn't get the advantage of that particular amount of money?

MR. PARRISH: Well, presumably, it would, yes, because --

HON. AMBRO: How --

MR. PARRISH: -- instead of that --

HON. AMBRO: How would it work out practically?

MR. PARRISH: Well, Your Honor, so if all -- I guess the point is, if the drug is usually $100 and then it's being sold at a penny, that 99.99 difference is what's making up that billion. And the question is, is that appropriately -- can you read "offer" so broadly that it means that we have this obligation to deliver to the pharmacies. And our submission is, is that's not in the statute. And the background principal on that is that it shouldn't be in the statute because Congress hasn't spoken to that.

HON. AMBRO: But I thought what the pharmacies were doing for purposes -- if acting in

effect as the agent for the covered entity, they're charging some fee. Correct?

MR. PARRISH: The full price, yeah.

HON. AMBRO: Oh. They're --

MR. PARRISH: They're charging the customer the full price of the drug. And then what they're doing is they're going back to the covered entity and said there's somebody here that we think at one time was connected to you that we're going to call them a patient and therefore please replenish the drug at the discounted price. And then the spread, which is the difference between the regular price and the discounted price, that gets pocketed and shared between the covered entity and the contract pharmacy. And our point -- and this is why -- Judge, I don't mean to argue about the takings point. But the reason why it's important that the original program was confined to covered entities and to their patients and prohibited diversion was to stop others from benefiting from the program because there's a huge problem when you're trying to take money from one preferred group and give it to another. So they wanted it tied to benefiting the patients. And the problem is, is it's lost track of that because it's now just a matter of making money for the pharmacies.

HON. KRAUSE: But the primary focus seems to be the benefit of the covered entity and the patients not precluding others. I mean, there are -- there's the prime vendor. There are third parties that were contemplated are going to make some profit off the transactions. Right? So if we look at the -- if we're looking at the benefit to the covered entity, the covered entity from the contract pharmacies is still getting a benefit. Perhaps less because of what's shared with the contract pharmacy. But the covered entity is still getting some benefit and the patient is getting some benefit. So why doesn't it serve that very modest purpose that the original program did?

MR. PARRISH: Well, what I would say, Your Honor -- and I'm sorry. I notice my time's up but if I could save a little time for rebuttal. But let me answer this.

HON. AMBRO: No. We're not going to --

MR. PARRISH: Okay. Thank you.

HON. AMBRO: -- affect your time for rebuttal.

MR. PARRISH: All I would say is that that's sort of the Christensen problem in the sense that I realize that statutes have lots of purposes.

But it's a mistake to say just because it furthers one purpose. Congress made a tradeoff which is it said this is a little odd that we're going to force a charitable obligation to transfer essentially your property to somebody else. But we will do it within confines because it benefits the patients. And then we'll allow the covered entities within those confines of getting the drugs themselves to actually keep the spread rather than passing the discount on to the patient because we think they'll reinvest. And what's happened over the years is that they're not doing that anymore. It's not helping the patients.

And what we would say is that although that's all helpful background to the Court, the Court doesn't need to get there. All the Court needs to do is say does the obligation to offer at a price include the obligation to deliver to third parties at third party locations. There's no argument that it does. The government's only argument is to flip it and say that you don't have your common law rights. And Christensen says that's wrong. And then the Court can just rest there.

HON. KRAUSE: So if I can just --

MR. PARRISH: Yeah.

HON. KRAUSE: Say that a covered entity

has -- sets up a third party administrator. And it has these patients that are working contract pharmacies all over the country. You don't have any objection to the order being placed by the covered entity the full amount of the pharmaceutical drugs being delivered to them and for their third party administrator to then distribute it to all the pharmacies.

MR. PARRISH: Yeah. So they --

HON. KRAUSE: Is that right?

MR. PARRISH: They can't do that. So there have been cases in the past where this problem of diversion is where the covered entity has set itself up like a wholesaler where they're going to take the drugs and then sell them around the country. And the reason why they can't do that is the law is very clear that they don't have wholesale licensing rights. And that would be the type of diversion that the statute's supposed to prohibit.

HON. KRAUSE: But it's not diversion until it gets into the hands of the wrong patient. If it's going to their patient at a contract pharmacy, a prescription that was written by one of their providers, there's no diversion there. Right?

MR. PARRISH: Well, Your Honor, I think

there is in the sense that I think the correct reading of the diversion is particularly if that contract pharmacy was making any profit off of it beyond bona fide cost of providing the service.

But what I'm saying is there's not under the 340B program but there's other laws out there that limit when you can actually transfer like that which is why this program has developed. One of the things to recognize is that this does not exist in nature. These types of replenishment models, the idea that we would be -- we don't ship to any other pharmacies on the request of a customer like this. This is all just for the 340B program. It's been made up by consultants that realize that if you did it this way, contract pharmacies, and then in turn covered entities, could generate more money. But that's way beyond what the program was ever intended.

We don't need to convince the Court of all that. We just need to convince the Court that offering does not include delivering to third parties.

HON. AMBRO: Thank you. We'll get you back for rebuttal.

MR. PARRISH: Thank you very much.

HON. AMBRO: I don't want to mispronounce your name as Kedem [Keh-dem] or Kedem

[Ka-deem]?

MR. KEDEM: It's Kedem [Keh-dem].

HON. AMBRO: Kedem [Keh-dem]. Thank you, sir.

MR. KEDEM: Thank you, Your Honor. Allon Kedem on behalf of AstraZeneca Pharmaceuticals. If I could reserve five minutes for rebuttal.

HON. AMBRO: That's fine.

MR. KEDEM: Perhaps a good place to start would be with the two district court decisions you have in front of you because although they reach different results, I actually think there is a fair amount of overlap on the central issue that we take to be at the heart of this case. Both Judge Stark and Chief Judge Wolfson took a look at Section 340B and determined that there was no requirement to deliver discounted drugs to third party contract pharmacies contained in the statute. Where they differ is that Chief Judge Wolfson then went on to say there's nothing that affirmatively authorizes manufacturers to restrict distribution and therefore they're forbidden from doing so whereas Judge Stark looked at the May 17th violation letter and its accusation that AstraZeneca had directly violated its obligations under 340B and said that can't be right. If there's

no such requirement in the statute then there can't be a direct violation.

And we respectfully suggest that Judge Stark's way of looking at things is correct, both as a matter of administrative law in which agency action has to be judged on the grounds articulated by the agency itself, but also as a matter of constitutional principle under which private parties retain the right to structure their affairs as they see fit unless there's something in the law that says that they can't. But they don't need affirmative authorization to act the way that a federal agency would. And I think it's that APA overlay that actually makes this quite an easy case. And I agree with my friends from Sanofi and Novo that the only question before the Court is whether the May 17 violation letters and, to the extent that you're going to consider it, the advisory opinion as well, is correct that there is an obligation in the statute itself to deliver unlimited amounts of discounted drugs to third party contract pharmacies. And since we're so focused on the statute and the must-offer provision, I'd like to just put on the table, at the risk of being a little bit tedious, some additional textual arguments as to why there is no such third party delivery obligation in the must-

offer provision.

So we've talked about what the word "offer" means. The manufacturers provide some dictionary definitions. Perhaps our friend from the government, Mr. Aguilar, will tell you what the government thinks the word "offer" means, but there is no connotation of delivery included in the word "offer". But it's actually quite a bit stronger than that because it's not just a generic offer. The statute refers to an offer for purchase. And it's an offer for purchase at a particular price. So the combination --

HON. AMBRO: Again, maybe it's semantic games but isn't it -- aren't we dealing with offers with conditions from, in this case, three different manufacturers, then you add the other Novartis and Eli Lilly and you have five different manufacturers?

MR. KEDEM: So the conditions are placed on delivery. But I think there's a threshold question whether that's a condition on an offer. You have to figure out whether an offer includes any representation with respect to delivery in the first place. And we're simply submitting that when you're talking about an offer for purchase at a price --

HON. AMBRO: But I can say to you I

offer you X on the condition that I deliver it to you only at position A.

MR. KEDEM: Sure. And I think if there were those additional textual elements in the statute then I think we would then lead them back into what it means to be an offer. Since there is nothing of the sort in the statute, I think we can assume that offer just has its sort of generic definition.

HON. AMBRO: But my question is -- my hypothetical is there is an offer with a condition. And --

MR. KEDEM: Right.

HON. AMBRO: -- we see five different types of conditions here.

MR. KEDEM: Right. But --

HON. AMBRO: Why isn't that considered part of the offer?

MR. KEDEM: So I think the offer is to the covered entities for purchase at the ceiling price in unlimited amounts. And that is the element of the offer --

HON. AMBRO: At or below the ceiling --

MR. KEDEM: -- that the statute speaks to.

HON. AMBRO: -- price, right?

MR. KEDEM: Pardon?

HON. AMBRO: At or below the ceiling price, right?

MR. KEDEM: At or below the ceiling price, that's correct. And those are the elements that the statute speaks to. The only question is whether, in talking about an offer for purchase, the statute also includes some additional condition or requirement with respect to delivery. And based on the dictionary definition plus the combination of purchase and the price, we're suggesting that it does not.

But in addition, it's an offer to each covered entity, a term that Congress defined with incredible specificity going so far as to distinguish different parts of the same hospital, giving 340B treatment for one and not another. As Judge Stark pointed out, it is deeply implausible to think that the same Congress which defined covered entity with such exquisite specificity nevertheless implicitly included distribution requirements to unnamed third parties.

Third, there are other provisions in Section 340B that specifically deal with third party arrangements including distribution. For instance,

subsection (a)(8) is the prime vendor program. And it applies to prime vendors under which "covered entities may enter into contracts with prime vendors for the distribution of covered outpatient drugs". So exactly this sort of third party contract distribution language we don't have in subsection (a)(1). We also have (d)(2) which talks about distributors and (d)(3) which talks about representatives of covered entities.

And then we have the broader context of the Veterans Health Care Act which created the 340B program. We point you to section 603 which talks about discounted drugs purchased by a federal agency but "delivered through a commercial entity operating under a contract through such agency". So again, third party distribution contract language that we don't have. The reason 603 is so notable is because the immediately preceding section, section 602, is the one that created the 340B program.

So I think when you put all of those together, I think it thoroughly rebuts the idea that there's some sort of implicit delivery obligation.

HON. KRAUSE: Judge Stark accepted the argument that there was this about face and change in the agency's policy. But when you look back at what they were saying in '93, in '94, in '96, '97, 2001,

there is repeatedly this expression of -- or repeated rejection of the argument that you can't -- that there's not a requirement to give to the contract pharmacies.

MR. KEDEM: So --

HON. KRAUSE: Right?

MR. KEDEM: Yeah.

HON. KRAUSE: There's commentary saying we'd like the specificity that there's no requirement to give these drugs to anything other than the covered entity itself and the agency is rejecting that explicitly as early as '94.

MR. KEDEM: So I think that that's right but with a pretty significant caveat because what you'll see, for instance, looking at the 1994 guidance, what they said is that covered entities could use purchasing agents so long as the drugs were delivered to the covered entities themselves which is flatly inconsistent with the idea of contract pharmacy use. It was only in '96 that they endorsed the idea of contract pharmacy use. But again, they imposed all sorts of conditions which are no longer being met. For instance, that the covered entity had to retain title. And, for instance, they had to be the ones to set the price for the drugs. That was maintained as

well in 2010 when they opened things up. But even in 2010, they never said that this was imposed as a statutory requirement. That's the key element, we think, that the government has never even acknowledged much less explained which is that it was only in December 30th of 2020 that the government, in the form of the advisory opinion, for the very first time said that there was an actual statutory obligation that manufacturers would violate if they failed to deliver to third party contract pharmacies. That does not appear at any previous point. And that is, by itself, a sufficient basis to conclude that there's an APA violation.

But even if you don't believe our textual argument and you do think that maybe there is some sort of implicit connotation within the word "offer" that includes something about delivery, I want to give you a few different ways --

HON. AMBRO: Let me go back to what you just said that you believe there is an APA violation and your co-counsel believe that there is as well.

If there is an APA violation, do we need to go into the merits of the statutory construction arguments?

MR. KEDEM: So I think technically you

probably wouldn't. It would suffice just to point that out and send it back to the agency. Both sides, though, I think are urging you to at least start with the text to provide a little bit of clarity as to what it is that we're talking about. I think it would be appropriate to do so. And we've laid out what we think is a pretty good textual argument.

Let me give you a few additional ways to look at the must-offer requirement even if you don't buy our primary textual submission that there's just no distribution requirement contained in it.

One thing is, you could consider that it's the type of offer that the other side can accept. Now we don't think that that's textually what "offer" means. But even if you thought that, all the manufacturers that you have before you have made that type of offer because all of us allow distribution either to the covered entity itself through its own in-house pharmacy or through some contract pharmacy if they don't have one.

You might think it's the type of offer that's typical in the marketplace. Again, all of the manufacturers would satisfy that because no other commercial purchaser ever uses contract pharmacies of the sort that are used by covered entities. It is

unknown outside of the 340B program. And the only reason that it's used in the 340B program is because of this replenishment model arbitrage that we've been talking about.

You could also think that perhaps there is some sort of equal treatment or most favored nation principle inherent in the word "offer". It's the type of offer that's at least as good as the one made available. Again, we all satisfy that and more than satisfy that because covered entities, unlike any other purchaser, are allowed to designate at least one contract pharmacy -- to designate a contract pharmacy if they don't have their own in-house pharmacy. It's something no one else is offered.

HON. AMBRO: You want to take away the "at least"?

MR. KEDEM: Pardon?

HON. AMBRO: You want to just take away the "at least"?

MR. KEDEM: For us, it is just one. That is correct. I think for some of the other manufacturers, maybe they allow it if you provide claims data. You're correct, though. For AstraZeneca, it is just one designation.

And that's really just the final way of

looking at it is, it is an offer if it's the type of offer that the agency itself was endorsing for the majority of the program's lifespan. Obviously, the agency did not think that it was illusory to offer directly to the covered entity itself if it has an in-house pharmacy or to a -- to one contract pharmacy because that's the model that the agency itself was endorsing up through 2010.

So I think any of those ways would still lead you to the same conclusion if you just didn't want to base it solely on the dictionary definition.

Judge Krause, you had a question about patient access and why is it any different when you're providing drugs through your own in-house pharmacy versus externally. And there is, in fact, a pretty big difference and it's reflected in the statistics. If you are a patient of the covered entity and then you go downstairs to the pharmacy, they know that you're a patient of the covered entity. And so they're much more likely to be able to give you the discount from 340B at the point of sale.

If, however, you were just walking across the street to the CVS and the CVS has a contract arrangement with the covered entity and

they're using the replenishment model, the drugs have already been shipped to that CVS. They've been placed on the store shelves alongside all of the other drugs. There's no differentiation made. And the CVS is serving not just patients of the covered entity but anyone who walks in the door. And so they don't know at the point of sale whether you are a patient of the covered entity or someone else. And so they charge you full price or your insurer they charge full price. And then there is some retrospective process that goes on weeks, months, sometimes even as much as a year later where the contract pharmacy decides whether some number of the patients from the prior period were patients of the covered entity. Usually, they outsource this job to what's called a third party administrator which uses some sort of algorithm to basically give an educated guess. Often, what they'll say is, well, it seems as if this patient had an appointment with the covered entity in the prior month and therefore we're going to assume that that prior appointment was where they got the prescription that was filled at the CVS. Maybe that's true; maybe it's not. But by that time, the patient is long gone and so sees none of the benefit. And what the statistics show is that although covered entities who provide

services through their own in-house pharmacies often provide discounts directly to the patient, it is very, very rare for them to do so through third party contract pharmacies. It is only the instance that my friend, Mr. Francisco, talked about where they give them essentially a 340B card so that when they go to the CVS, they can present it at the point of sale and get the discount then. But it is roughly two percent of the time according to a recent industry study. And that's why -- what the Government Accountability Office and the agency itself have determined is that discounts are just not passed on to patients when the contract pharmacy model is used.

HON. KRAUSE: Where do we have in the record, in the GSA study or elsewhere the comparison of that benefit to the benefit to the patient from contract pharmacies versus in-house pharmacies?

MR. KEDEM: So I can take a look at which GAO study I'm referring to and see where in the briefs. It's not in the administrative record and I think that's the key point because it doesn't matter to the statutory question that's embedded in the May 17th violation letter. The agency, although they include a lot of factual material in the administrative record, they don't actually rely on it

in the May 17th letter because it's sort of irrelevant to the statutory question that you have before you. And so, I agree with you. This is all very useful context and I think we all understand their important policy concerns. But as Judge Stark put very eloquently, those policy concerns are ones that Congress can deal with. The only question that you have before you is a question as to whether the May 17th letter was correct that the statute itself imposes this third party distribution requirement on manufacturers. If it doesn't, that is sufficient to determine that the letter is invalid and set it aside on that basis.

HON. AMBRO: Thank you.

MR. KEDEM: Thank you.

HON. AMBRO: We'll get you back on rebuttal.

Mr. Aguilar?

MR. AGUILAR: May it please the Court. Daniel Aguilar for the federal defendants.

So I think there are two --

HON. AMBRO: The third rodeo on this one?

MR. AGUILAR: The second, Your Honor. Unfortunately, I was sick for the Seventh Circuit so

my colleague took it over which I --

HON. AMBRO: That was probably a good day --

MR. AGUILAR: -- greatly appreciated.

HON. AMBRO: -- for you.

MR. AGUILAR: Except for the sickness.

HON. AMBRO: That was a rough oral argument.

MR. AGUILAR: To be fair, I'd rather be talking with you all than cooped up with the flu. But --

So I think there have been two strands of discussion that have been going on today. One is the legal question that's before the Court, statutory construction, the text and structure of the statute, et cetera, and the agency's position in construing that over a number of years. And then additionally, a question about how the 340B program works as a whole, how it works with the manufacturers, the agency, the covered entities and their patients.

And so, I know the Court has thought a lot about this and we've heard a lot about this. I'm happy to answer your questions. But just for --

HON. AMBRO: Just as a factual question, how many --

MR. AGUILAR: Sure.

HON. AMBRO: -- contract pharmacies is each covered entity actually using right now. Do you know?

MR. AGUILAR: That I don't know. I know there are several thousand covered entities currently in the program and several thousand contract pharmacies that work with them. There are 734 drug manufacturers who also participate in the 340B program. And so at least from the practical standpoint of how the program is administered, if each manufacturer is permitted to set conditions at the outset about whether and how you must comply before we will get your drugs to the pharmacy that will dispense them, then covered entities need to navigate a web of hundreds of potentially different policies with either radius of how far the contract pharmacy is to the covered entity, with whether or not the manufacturer deems it within their discretion to deliver it to that contract pharmacy, whether they need to update claims data to one particular third party server or another, et cetera. And that really goes to the question of whose program this is to administer. And what this --

HON. AMBRO: Actually, there's an easy response to that. It's just -- let's have a Court

tell us or Courts, if they're in unison, tell us exactly how the statute is to be interpreted.

MR. AGUILAR: And so just going to that statutory question, Your Honor, I think both the text of subsection (a) and the statutory structure as a whole support the government's reading which is why the District Court for New Jersey came up with that. And if you want to go into the merits of this as well, so subsection (a), which is at page 1 of our addendum, lays out an unqualified obligation.

HON. BIBAS: Which language in (a)(1) here supports your case?

MR. AGUILAR: So it's both the first sentence and the last sentence. And the relevant --

HON. BIBAS: The "purchased by" phrase?

MR. AGUILAR: "The Secretary shall enter into an agreement with each manufacturer...under which the amount...to be paid...for covered outpatient drugs...purchased by a covered entity" --

HON. BIBAS: A covered entity, singular.

MR. AGUILAR: Yes.

HON. BIBAS: Okay.

MR. AGUILAR: Because they're individually doing the purchasing -- does not exceed

the ceiling price.

HON. BIBAS: Okay.

MR. AGUILAR: And then at the end, it "shall require that the manufacturer offer each covered entity covered outpatient drugs for purchase at or below the applicable ceiling price".

HON. BIBAS: Okay. So what in these words are the three drug companies here violating?

MR. AGUILAR: They are not selling the drugs at the 340B price if --

HON. BIBAS: They are selling them -- offering them for sale.

MR. AGUILAR: -- if the covered entity does not comply with their conditions at the outset. So --

HON. BIBAS: Okay. So they're required to sell it on the moon or in low Earth orbit.

MR. AGUILAR: No, Your Honor.

HON. BIBAS: No. They're not. Why not?

MR. AGUILAR: Because drugs have to be dispensed pursuant to a prescription as set out in federal and state law which usually means dispensation in the doctor's office or at a pharmacy.

HON. BIBAS: And there's the Otsuka

brief which says that your current position conflicts with requirements that they have to supervise pharmacies dispensing these kidney medicine, JYNARQUE. And yet, your position suggests, no, they can't put any conditions on dispensing these medications.

MR. AGUILAR: So I think in terms of the dispensation requirement, one, that's why the pharmacies are in the business of being able to dispense drugs generally because as Congress knew when it enacted the 340 --

HON. AMBRO: Yeah. But on that point that Judge Bibas makes, you need specialized training for that particular drug. And are you saying to us that if you go to a particular location, they'll say, look, we don't have people with that specialized training. You can get this but you're going to have to go to this particular other place.

MR. AGUILAR: So I know --

HON. AMBRO: What's wrong with that?

MR. AGUILAR: For particular specialized drugs -- and this is reflected in the 2018 Government Accountability Office report. There are specialized pharmacies that deal with that that have people who have particular training and particular knowledge on how to dispense those and for particular

specialty drugs, as I understand it, that's how they're dispensed. Many of these drugs don't necessarily require that same sort of specialization, insulin, for example. But it is the kind of thing where people need it. And they need it on --

HON. AMBRO: But the manufacturer is saying, look, we're concerned about lives just as everybody else is. And we're telling you we are only going to offer this to the covered entity provided that it be distributed at a place that has specialized personnel. There's nothing wrong with that, is there?

MR. AGUILAR: So I think -- so, one, obviously, that's not this case. But, two, what the agency --

HON. AMBRO: Well, I mean, that's why it's a hypothetical.

MR. AGUILAR: I know. I was just flagging that because I think the dispute here really does turn on contract pharmacies and their history. But just going to your question, Your Honor, what the agency has consistently stated and what's been our consistent position since the 1993 guidance was where manufacturers said we want, as part of our contracts with the covered entities, to sell these drugs to require assurances that they're complying with the

statutory requirements of the 340B program. And what the agency said was that's not permissible at the outset. The covered entities do need to comply with those statutory obligations. And it is our responsibility -- it is the federal responsibility to ensure that those are --

HON. AMBRO: But my question to you is --

MR. AGUILAR: -- enforced.

HON. AMBRO: -- are they -- the example -- the hypothetical that I gave is the covered entity to the contract pharmacy complying or not complying?

MR. AGUILAR: By selling their particular drug that needs specialized care?

HON. AMBRO: Correct.

MR. AGUILAR: I think it would depend on the state law or the federal law that is requiring that particular dispensation. I don't know enough about the particular fact pattern but it would say you would need to look --

HON. AMBRO: Let's say --

MR. AGUILAR: -- to the applicable --

HON. AMBRO: Let's say that the state law or the federal law, whatever law applies, is saying that you can only dispense generic, for

example, at certain specialized -- certain locations where you have specialized personnel who are trained in how this drug is to be dispensed. My question to you is --

MR. AGUILAR: Yes.

HON. AMBRO: -- does HHS view that as a violation of the 340B program.

MR. AGUILAR: I don't think it would be a violation of the 340B program. I think it would potentially come into question of whether or not it's a violation of that applicable law regarding the dispensing of that particular medication.

HON. AMBRO: But let's assume for a moment it's not a violation of the applicable law under state law, for example. So now I'm asking you is it a violation of the 340B program.

MR. AGUILAR: So I'm going to repeat the question to make sure that I'm understanding it. There is dispensing of a particular medication that complies with state law?

HON. AMBRO: The manufacturer is saying that I will distribute generic -- I will offer it to you only if you distribute it to locations -- or a location that has specialized trained personnel. Does HHS view that condition as a violation of the 340B

program?

MR. AGUILAR: Yeah. That would be a unilateral requirement that the manufacturer is imposing at the outset about whether or not --

HON. AMBRO: Is it a violation? Yes or --

MR. AGUILAR: Yes. I was trying to say yes, Your Honor --

HON. BIBAS: Let's say the manufacturer --

MR. AGUILAR: -- and explain.

HON. BIBAS: -- has noticed a pattern of unusual kidney cysts that emerged from the use of this drug. But the FDA has not yet put a black box on it or limited it. You're saying the manufacturer has to continue to distribute it through all these different pharmacies when they might get sued in tort for not narrowing this down to the list of people who are getting the right kind of counseling and diagnosis through the pharmacy. You're saying 340B -- they're going to be liable under 340B.

MR. AGUILAR: I'm saying that 340B statute sets out a system by which when manufacturers or covered entities have complaints or concerns about how the program is operating, there is a reticulated

scheme --

HON. BIBAS: Okay.

MR. AGUILAR: -- for addressing those.

HON. BIBAS: A reticulated scheme that does not give your agency rulemaking authority. You agree. We're not in Chevron land here.

MR. AGUILAR: Yes, Your Honor.

HON. BIBAS: Well, then why is it that several pages later in the same statute, we have subsections that deal with distribution? We have subsections that deal with the depos in the next section, the Veterans Health Care Act. And yet, there's no mention of distribution networks in this one. Why should we read back to (a)(1) the distribution limitations that Congress spelled out later in the same section and also in the next section, Section 603?

MR. AGUILAR: So in 603, as I understand it, that's dealing with the program whereby the discounted price was applicable if it dealt with the particular depo and warehouse system. And we're saying if you're working outside of that system, the discount is not applicable. So it's setting up a closed system of distribution. There's no similar restriction here. And what happens is, is if a

patient has a prescription and tries to fill it outside of the covered entity or just at a pharmacy generally, similarly, they do not receive any statutory discount.

HON. BIBAS: Now that sounds like a reticulated scheme. I don't see that reticulation back in (a)(1).

MR. AGUILAR: So (a)(1) sets out the unqualified obligation that we're saying. I think the reticulated scheme is in those follow-on subsections and paragraphs. What it says is if a manufacturer is concerned that there are being duplicative discounts or diversions to nonpatients, it first must conduct an audit of the covered entity. And then after that audit, then the secretary, based on the findings or based on HHS' own audit, can bring an enforcement action. And the result of that enforcement action, if a violation is demonstrated, is that the covered entity has to pay back the discount to the manufacturer. And then additionally, later on --

HON. BIBAS: The covered entity in (a)(4) has 15 specific categories.

MR. AGUILAR: Yes.

HON. BIBAS: Contract pharmacies are not one of them. Yet, the contract pharmacy appears

to be taking title to the pills, at least under some of these distribution schemes, and then winding up with some rebate later. So isn't the -- if there's any violation, is the violation using the contract pharmacy when it's not listed in (a)(4)?

MR. AGUILAR: So HHS' consistent guidance has been that covered entities need to take title to the purchased drugs. They need to ensure that when they're at a contract pharmacy for dispensing to patients that all of the 340B statutory obligations (indiscernible) are still being carried out there. And I think that in terms of if we're talking about how the 340B accounting works, I think the 2018 GAO report is generally helpful on this. In addition, the 2020 goes along with this, too -- is that the contract pharmacy has the drugs on site. And then they need to match up the 340B drugs dispensed to the patients of 340B covered entities. Those need to match one to one. If there is a discrepancy or if they don't net out, then there is potential diversion. And then there is -- we conduct audits. And HHS conducts about 200 audits of covered entities a year in trying to make sure that we have a good understanding of what's happening out there in the real world.

HON. KRAUSE: How is the covered entity in that situation taking title?

MR. AGUILAR: So it's a bill to/ship to arrangement. So the title resides with the covered entity. That's why they're allowed to then dispense the drugs to the patients at the 340B price. But many covered entities, as Congress knew at the time that it enacted the 340B program, do not have onsite pharmacies. They're costly to construct. It needs people with specialized knowledge. And a lot of these covered entities operate on pretty thin margins.

So Congress knew at the time -- I think it was about five percent of covered entities had in-house pharmacies. The remainder, the vast majority, used outside pharmacies for dispensing these medications. And so what HHS has consistently said here is that's a real world scenario. And it was understood that these drugs were going to be dispensed at outside pharmacies. That's how they get to the patients.

HON. KRAUSE: But I'm asking about the replenishment model and how in that scenario there is title that is retained with the covered entity when we're talking about pharmaceuticals that are on the shelf in the contract pharmacy to begin with.

MR. AGUILAR: So I think the Community Health Clinics' brief is helpful on this as well as the 1996 guidance which explains that there's no requirement in the statute for separate inventory requirements. These drugs are essentially fungible. The pills are identical to each other. The bags are identical to each other. And so what we want to do is match this up at the backend to make sure that these discounted drugs are going to the covered entities and the covered entities' patients, the people that Congress intended for them to use. But having a separate inventory requirement saying we're going to shove off these particular medications here and these are only for 340B covered entities and separate them out, that raises practical problems. They might expire. You have to develop additional storage space for them, et cetera. And so, what HHS has consistently explained here as well, and I don't think that anybody seriously contested it since 1996, is that so long as the drugs are going to the patients and you're stretching scarce federal resources across a broader area, that's the point of the 340B program.

And so, to the extent that they're saying this is -- I've heard a lot of discussion of arbitrage to contract pharmacies. If you look to

pages 51 through 54 of 2019 GAO report, those are the administrative fees that the GAO analyzed for various contract pharmacies. They're $3 a pill, 20 percent of if it's covered by insurance or uninsured. And at pages 31 to 32 of that same report, they demonstrate that for a majority of the covered entities, both hospitals and clinics are passing on those savings to their patients. And as the State's brief outlines here and as the 1996 guidance does as well, if the covered entity is retaining some of those savings, they're reinvesting it. They're expanding services to the dental care, OB-GYNs, mobile clinics for rural populations or vaccine drives, et cetera, trying to expand those services to poor and medically underserved populations.

HON. BIBAS: Now looking back at the 1996 guidance, if these manufacturers, these very same conditions back in 1996, we wouldn't be here. You would not have been challenging their actions as unlawful or violating any terms of the '96 guidance, would you?

MR. AGUILAR: I think what we would say is consistent with both the '96 guidance and the '93-'94 guidance, is that it's -- the 340B statute does not leave any room for the manufacturers to

restrict their delivery obligations at the outset.

HON. BIBAS: But the '96 guidance did not require using contract pharmacies, let alone unlimited ones.

MR. AGUILAR: So you're correct. What the '96 guidance said, though, is that we're -- the contract pharmacy here is essentially almost (indiscernible) generous to the 340B program because it's the entity required to purchase it, take title to it and dispense it to its patients but they don't have the facility to do that. And so what the '96 guidance -- sorry -- at page 25110, said is that drug manufacturers often sell to intermediaries and wholesalers and contract pharmacies. And we expect that to continue. And we're rejecting your comment to say that you don't even have to make that delivery obligation at the outset.

HON. BIBAS: There's a number in the record -- forgive me for blanking on where it is, but I believe the average -- I don't know if this is mean or median distance between the patient and the pharmacy is somewhere upwards of 300 miles. What should we make of that? Does that just suggest that national chains like CVS and Walgreens are just making boatloads of money on this and it's not really about

serving people in local communities?

MR. AGUILAR: Well, I think what you can make from it that is in the administrative record is the affidavits and declarations that we have from the people who work at these covered entities who explain that we run a covered entity up in the Upper Peninsula of Michigan and we cover 10,000 square miles. Or I know there is an affidavit from -- I think it's North County Health Clinic in rural Arizona where they explained one of our patients is a diabetic. He lives very far away from our Flagstaff clinic where we have an onsite pharmacy so we need to use contract pharmacies to get him his insulin. If we're not allowed to use multiple contract pharmacies, he's very likely going to have to drive about 280 miles in order to get his insulin. Now it's true that he could try to purchase that somewhere that's not a contract pharmacy but then he's not going to get the discount for that because he's purchasing it not from the covered entity. Right?

And so, I think that that's why in building up (indiscernible) to -- and the '96 guidance said because the contract pharmacies are fairly new, we're going to -- as nonbinding guidance say covered entities use one. We've heard concerns from drug

manufacturers about duplicate diversions -- duplicate discounts or diversions. So we're going to study this problem. And as our brief explains, for the next five years, HHS conducted a number of audits and said we aren't seeing many problems here, let's start a pilot program to allow covered entities to use multiple contract pharmacies. They continued that and then in 2007, it said we still aren't seeing any problems. We think that we can advise people to use multiple contract pharmacies so long as they're still retaining title, still using these contract -- sort of guidance contract forms to make sure that they are supervising their --

HON. BIBAS: Evolution --

MR. AGUILAR: -- pharmacies.

HON. BIBAS: -- would make perfect sense in a world in which you had regulatory authority and we were in Chevron land. But you concede we're not. So why are we looking at the gradual evolution of these programs? We have to look at what the statute just means and means is the time that it passed.

MR. AGUILAR: So two things, Your Honor. One is, I think that this explanation of the agency's views and explanation for them goes to the

arbitrary and capriciousness discussion we were having earlier and particularly Judge Stark's opinion where he assumed that the agency had changed views over time without adequate explanation. So I'm explaining why that's incorrect.

But then also, it just goes to show that these sorts of objections were raised at the beginning of the program saying we ought not have to deliver to any contract pharmacy. So the agency said we think that's an incorrect interpretation of the statute. And nobody sued over that. I've heard a lot of talk from Plaintiff's counsel that this a new position from the government, that this has never happened before. But it is equally true that before the summer of 2020, no manufacturer had ever refused to sell these drugs at the statutory discounts based on the use of contract pharmacies. That was a new problem. They started with Eli Lilly and it spread to other manufacturers that developed in these policies. And the government, for a while, encouraged the manufacturers to relinquish these policies. It issued an advisory opinion and received letters from concerned covered entities and ultimately issued the violation letter saying we've had this consistent view of the statute for a long time. And we do think this

is a statutory violation to impose these unilateral -- sorry, Your Honor.

HON. AMBRO: A question on the consistency is there are, obviously, nuances as Judge Krause has noted from '93-'94. But looking at it maybe overly simplistically, it looks like there was a nonbinding guidance, '96, that covered entities -- that they may use one contract pharmacy to nonbinding guidance in 2010 that they may use more than one contract pharmacy to binding enforceable guidance in 2020 that manufacturers have to deliver to multiple contract pharmacies. And they backed that up by a violation letter. So it looks to me, maybe simplistically, as if the position has changed pretty dramatically over the course of 24 years.

MR. AGUILAR: I disagree, Your Honor. The nonbinding guidance that we've issued regarding contract pharmacies has always been advising covered entities how to use them and how to address concerns about duplicate discounts or diversion. What HHS has consistently said at the same time, and for even longer back to the '93 and '94 guidance, is that manufacturers cannot impose unilateral obligations even if they're entirely consistent with the statutory obligations that the covered entities already have.

And the reason for that, I think, which is instructive here, is the Supreme Court's decision in Astra USA v. Santa Clara County which addressed the 340B program. And there, covered entities were trying to sue to enforce the contracts between the manufacturers and the secretary saying we think there have been violations here, we're bringing a private suit. And the Supreme Court said the 340B statute doesn't leave room for you to try to pursue those private enforcement schemes. And the relative -- the important language here is on page 120 of the opinion: "Far from assisting HHS, suits [like 340B entities] would undermine the agency’s efforts to administer both Medicaid and 340B harmoniously and on a uniform, nationwide basis and they could spawn a multitude of dispersed and uncoordinated lawsuits." And I think that that central reasoning that this is a federal enforcement priority, it's supposed to be uniform, it's supposed to allow covered entities and manufacturers all to play by straightforward clear rules at the outset is exactly why the covered entities can't bring private suits and it's exactly why the manufacturers can't say --

HON. AMBRO: So basically, what you're saying is that -- I mean, what you answer does spawn a

number of questions, additional questions. But I come back to the question I had asked you before. So it's so blackline in terms of what the manufacturers can do by way of conditions that there can't be any conditions even if you said it would be a violation of a 340B program if JANARQUE, for example, were limited by a manufacturer to only those locations or contract pharmacies with locations having specialized personnel.

MR. AGUILAR: So I think, again -- I'm just focusing on the contract pharmacy issue here. But to answer your question, yes. They can't impose that kind of condition at the outset.

HON. AMBRO: Doesn't that seem like -- I mean, maybe technically that's right but in the real world, somebody could die by not getting specialized personnel advising them at the particular pharmacy that they go to.

MR. AGUILAR: And that's why there should be, practically speaking, good policy decisions being made here by everybody. Right? Covered entities should be --

HON. AMBRO: Yeah. Well --

MR. AGUILAR: -- making sure that they are giving patients --

HON. AMBRO: -- if that were to happen, if we'd all have a (indiscernible) would be happy holidays for all of us. Ain't going to happen.

MR. AGUILAR: I -- and, Your Honor, we're here today based on the meaning of the 340B statute. And what the --

HON. AMBRO: But it sounds like -- basically, what it sounds like is you're taking a position that's significantly out there on the spectrum, so it's either going to be a homerun or a strikeout. Is that where you really want to be?

MR. AGUILAR: I don't think so, Your Honor, because as I tried to say at the outset, I think we are focused here just on the contract pharmacy. That's where all the manufacturers' policies are. That's where our enforcement letter is. That's the question before the Court is whether or not these policies, these particular policies that they've enacted, are violations of the statute.

HON. AMBRO: But when you play out your interpretation of the statute, you seem to be digging a hole that says that, practically speaking, taking into account the consequences of our decision, that if we go your way, there's going to be a lot of chaos within the system and possibly tort suits brought, for

example, in connection with the question that was asked you by Judge Bibas and me.

MR. AGUILAR: I think, Your Honor, what the administrative record here demonstrates is the chaos that has already occurred because of these particular policies. If you look at pages JA900 through 901 --

HON. AMBRO: And I come back to there's an easy answer to that as I said before. Just say that there's either in-house and/or one contract pharmacy and that's it.

MR. AGUILAR: I think their view of the statute is broader than that. As I've heard, I think, from all three Plaintiffs' counsel today, their reliance on that word "offer" and focus on it doesn't with a delivery obligation. And so, I think the result of their position, similar to that of Eli Lilly, is that we don't have any obligation to deliver to you. We can make you come and pick it up from our corporate headquarters.

HON. BIBAS: We could disagree with that. We could say that what's commercially reasonable practice in the field of Pharma is to deliver by an ordinary commercial method that preserves the integrity of the drugs. But that's just

-- we're arguing about a borderline case about what the word "offer" means in this context. We don't then have to go to your position.

MR. AGUILAR: But I think, Your Honor, the beginning of your question there, I think, demonstrates why Congress knew what the commercially appropriate practice was at the time it enacted the 340B program. It knew that many of these covered entities --

HON. BIBAS: Except this runs the other way. If the contract pharmacies didn't exist until this program, how can you impute a requirement that there be contract pharmacies when it's this program's enactment that gives rise to the contract pharmacy phenomenon.

MR. AGUILAR: So let me explain that. The contract pharmacy is solely to ensure that the covered entity retains title of this so that it will qualify for a discount when it's dispensed to a patient through an outside pharmacy. Prior to the 340B program, many of these covered entities used outside pharmacies. But there wasn't the same type. You needed to retain title. That's why they had a contractual relationship to both as a result of the program to comply with its statutes. But they were

still using outside pharmacies.

HON. KRAUSE: So if we interpret the statute against the backdrop of what was going on before 1992, what do you say to the history that we've heard from your colleagues on the other side of the aisle that at that point, this was restoration of what had been the status quo in terms of the Medicaid floor that was set? And that there was provision of discounts to the covered entities but there was nothing about providing discounts to the outside pharmacies at that point. If that's the case, and we're looking at the statute as, in effect, restoring that status quo, why should we take it as this vast expansion to provide discounts to all of the contract pharmacies?

MR. AGUILAR: So again, I don't think it's providing any discounts to the contract pharmacies. Right? The contract pharmacies are not the one that get the discount. The covered entity is. Now in their contractual relationship, the contract pharmacy is doing a useful thing. They are dispensing the drugs in the way that they can to patients who need it.

HON. KRAUSE: I understand the different ways to frame that. But I'd ask you to

focus on what was going on before '92. And if we're looking at Congress' enactment as understanding that as the backdrop and there weren't at that point discounted pharmaceuticals going to the outside pharmacies, why should we think that they intended a different model with the statute here?

MR. AGUILAR: Because at the time that the 340B statute was enacted, Congress considered a different bill that would have restricted the 340B drugs and their savings to ones that were dispensed on site. And Congress chose not to enact that limitation. Instead, it just said these are for the covered entities knowing --

HON. BIBAS: (Indiscernible) to rely on unenacted bills. The inference could be that they thought it was already in there or that they consciously rejected it. But we avoid, and the Supreme Court generally avoids, resting on unenacted legislation.

MR. AGUILAR: I think that's true for legislative attempts that were made that postdate the actual statute. But where you have Congress actually considering between a menu of options and selecting one that does not have a restriction that appears in another, I think that is shedding some light here.

And more to the point, the statute, I think as everyone says, doesn't express --

HON. AMBRO: Maybe. But so little light we don't really know. I mean, they -- you know, a committee may be considering option A, option B, option C and ultimately goes -- and somebody drafts up a -- a staff person drafts up option A but they go with option B. It doesn't necessarily mean that they have made a firm decision on how they want to approach option A. They just think option B happens to be better in that circumstance. We just don't know.

MR. AGUILAR: What we do know is that Congress chose not to expressly address contract pharmacies at the initial out point even though many of these covered entities relied on outside pharmacies. And then as the program evolved over the course of the '90s and the 2000s, which Congress was well aware of as well because it was a major federal program, right, it then chose, in 2010, to further make amendments to the statute and impose no additional restrictions on the use of outside pharmacies or contract pharmacies. Or instead, what it did was further strengthen the particular reticulated enforcement scheme where it says you can bring these complaints in formally to HHS or you can

even use this administrative dispute resolution system which we have enacted. And if there is demonstrated to be a violation either on the part of the covered entities or the manufacturers, there is a remedy at the backend.

HON. BIBAS: Since you brought up ADR scheme -- I mean, my colleagues may want to stay on this longer, but I do want you at some point to address how we should understand the withdrawal with the effect of the notice of proposed rulemaking and the comments. So, you know, get there at some point.112826

HON. AMBRO: Yeah. We can do that now or you can do it later, whatever you'd like.

MR. AGUILAR: I'm happy to --

HON. AMBRO: We're going to hit it before you leave.

MR. AGUILAR: Sure. Let's go to it now. So I think there was a pause on a number of different regulatory initiatives across the government of the change of administration. And we cited a Tenth Circuit case where there was a similar pause based on this memoranda. The agency reconsidered it over a number of months and then eventually withdrew the rule as published in the Federal Register. And then there

was a challenge to that withdrawal which the Tenth Circuit ended up denying on the merits.

Here, there was a notice that we paused on this. We're not going to go further on it right now. There was no further notice on the Federal Register or anything else. And then the agency said, right, we're promulgating the final rule after this.

I think what Plaintiffs' theory rests on is both a passage of time and the fact that in the unified agenda, which is not binding on the agency, right? It's prospective looking forward giving advice --

HON. AMBRO: Yeah. It's looking forward 12 months. But you removed it from the unified agenda. It was listed as "withdrawn" and "completed action". An HRSA official said the agency was not -- wasn't going to act. And the final rule had a different RIN on the 2016 proposal.

MR. AGUILAR: And so I think that that's -- their argument there is relying on particular indicia that are unique to the Office of Management and Budgets Control System and OIRA. But what the district court noted and what's also perfectly clear is that the APA sets forth the maximum requirements that the agency has to comply with. I

think their best case for their argument is the D.C. Circuit's decision in Mobile Oil where it dealt with a particular rule that had been vacated by the D.C. Circuit that was then repromulgated by the agency without any notice and comment. And what the D.C. Circuit said was, no, we vacated that rule. It's gone. You need to start over again from the very beginning of 5 U.S.C 553 and go through notice and comments.

HON. AMBRO: But what is the average person supposed to do when somebody says that it's not in the unified agenda? It's withdrawn. It's out of here. We're not going to rely on it. And when we do some type of proposal, we have a different -- completely different number that relates to it. What is that person supposed to do?

MR. AGUILAR: I think they would need to ask the agency on like is this going to happen because, indeed, when Congress amended the statute, it directed you that you need to pass a rulemaking here. So what's going on and what the agency eventually did --

HON. AMBRO: But that was in 2010. I mean, nothing's happened yet, has it?

MR. AGUILAR: The final rule was

published in 2020. And that's why they've challenged it as a final agency action that didn't comply with notice and comment. And I'd also note that the agency right now is in the process of issuing another notice of proposed rulemaking to further refine the ADR process.

HON. AMBRO: But the rule in 2020 is based on a statutory interpretation, correct?

MR. AGUILAR: The final rule in 2020 is setting forth the ADR process.

HON. AMBRO: Oh, okay.

MR. AGUILAR: Yes. And so that's -- it's saying that this is how we have hearings and evidence and come to a decision and issue the ADR panel's decision. And then you can challenge that in court. And it's just laying the regulatory mechanisms for having that happen. And in their opening brief, Sanofi says a lot of things that we don't think this complies with notice and comment. I think that's based on, again, the unified agenda theory and the passage of time which I know that we've discussed --

HON. AMBRO: But because there's so little case law here, to rule in your favor here seems to me the consequence is we're going to set a precedent that undermines the notice requirement.

MR. AGUILAR: I disagree, Your Honor. I don't think that this particular fact pattern is going to happen very often. But what I do worry about is a rule that particular statements made outside of the federal register in the unified agenda, which I don't know who's necessarily issuing them or making them, bind the agency and result in final agency action that can be challenged in court even if the agency, as here, was further contemplating possible modifications to the rule, responding to comments and then indeed did issue a final rule that responded to all of the comments that it had received during the notice of proposed rulemaking. I don't think that that's -- I don't see anything in the text of the APA that says that the agency violated any of this. It responded to the comments. And as I was saying, I think it's notable that in Sanofi's opening brief, they don't identify any particular substance. And indeed, they haven't challenged any other substance of the rule that they say they were prejudiced by this.

HON. KRAUSE: Is there some period of time where it's presumptively withdrawn? We've had four years here of an action.

MR. AGUILAR: So as we noted, sometimes agencies do take time with particularly -- with

particular rules. We noted some instances in our brief. But the mere passage of time, I don't think by itself stands for a proposition. I do know of cases where after --

HON. AMBRO: But there's a plus factor here. It's withdrawn. It's completed action.

MR. AGUILAR: And with --

HON. AMBRO: We ain't coming back, as someone says, in effect.

MR. AGUILAR: So I think if that happens in the Federal Register, which is how the government usually operates in this area, I would take that at face value. But again, I don't know who's operating the particular buttons or whatever they are on unified agendas that exist on the internet. But what I do know is that there are cases where if the agency hasn't acted in a period of time, we do get petitioners who seek review and the courts of appeal saying we want to compel unlawfully withheld agency action. We want the agency to go ahead and issue this rule. And usually, what the D.C. Circuit has said is in that time, usually we don't think of that as necessarily ripe for review if there is indicia that the agency is considering on. But those could be challenges. But they don't think the mere passage of

time by itself stands for it. And I don't know of any precedent standing for the proposition that comments and unified agenda are binding on the agency or the secretary of HHS who can promulgate the rule.

HON. AMBRO: But as I just said, one could make an argument that there -- a good or plausible argument it's not just passage of time but the passage of time plus, plus, plus, plus.

MR. AGUILAR: I think the only other plus that they have identified is the unified agenda. I don't think that we --

HON. AMBRO: No. They've said that people -- statements have been made that it's withdrawn.

MR. AGUILAR: I -- and if I'm remembering correctly --

HON. AMBRO: And when you put it out in 2020, there is a different RIN.

MR. AGUILAR: I don't know of any precedent saying that different RINs result in different substantive rules, that issuing an RIN means that we're not responding to the comments that we received before. And as I said, again, I don't see that they've actually been prejudiced by this. Their opening brief doesn't identify anything that they

think ought to have changed other than the number of contract pharmacies which the agency had been aware of.

HON. AMBRO: Again, my point is, it may not be necessarily this case. There may not be a whole lot of surprise. But the question is how is this case going to be interpreted for the next case.

MR. AGUILAR: So I think what you can say is that there is no precedent setting forth that this results in a withdrawal of a rule and whereas Plaintiff -- the only plaintiff in the case who's challenging the notice and comment requirements has not demonstrated any prejudice which the Administrative Procedure Act says the Court needs to take into account of --

HON. AMBRO: Well, clearly, there's no precedent.

MR. AGUILAR: -- that there is not reversible error.

HON. AMBRO: But after we decide it, that will be a precedent.

MR. AGUILAR: Yes, Your Honor. And we're asking you to decide it in that way because we think that that's the correct way to adjudicate that case.

HON. AMBRO: And I'm saying to you what are the consequences and you're saying, don't worry, it won't appear again.

MR. AGUILAR: No. I don't think that this fact pattern usually happens. Usually, either the agency is going to be able to respond faster after a regulatory pause or it's going to officially withdraw the rule as it did in the Tenth Circuit case which we cited. And I think there, when the rule has been withdrawn, then you actually get a legal challenge to it as the Tenth Circuit adjudicated. And I think that that's the usual course that the government operates in. We want to be able to take definitive action when we have decided to withdraw a rule. But where we haven't taken that step, it usually means it's still under consideration at the agency as was the case here.

HON. AMBRO: All right. Any further questions?

HON. KRAUSE: I'd like to just go back for a second and make sure we understand your position on what the status quo was before '92.

MR. AGUILAR: So as I understand the status quo before '92 was that there were some programs by which there were discounted prices given

out to drugs -- for drugs sold to covered entities and that the covered entities many times -- or I think in an overwhelming majority of them, did not have in-house pharmacies and had to rely on --

HON. AMBRO: Well, 95 percent of them didn't.

MR. AGUILAR: I'm sorry, Your Honor?

HON. AMBRO: Ninety-five percent of them did not.

MR. AGUILAR: Yes, Your Honor. 500 out of 11,500. And so, there, they needed outside pharmacies to be able to dispense those drugs. And that was the real world circumstance that Congress was mapping on to. It was taking --

HON. KRAUSE: And were manufacturers providing those same discounts to the outside pharmacies at that time?

MR. AGUILAR: I don't know the factual answer to that, Your Honor. But I think that -- again, the discount here really is going to the covered entity. You can see that in the affidavits that were received where the covered entities are saying -- I think it's at page 1179 of the Sanofi joint appendix. Federal grants only make up about 28 percent of our revenue. We rely on the 340B savings

to make up 41 percent of our operating expenses. And if we can't get those discounts because we rely on outside pharmacies and we rely on multiple ones of them to get to our patients, we're going to lose operating revenue. And that's why in the administrative record, time and again, and many of the affidavits that are cited by the Community Health Clinics' brief, people are explaining that we might need to cut services. We might need to not be able to cover our patients' copays. We might not be able to pass on all the discount that we are currently doing, et cetera. This is going to cause real world harm.

And that's why the administrative record, too, just within a couple of months of these policies being enacted, the 340B sales dropped precipitously by about 60 to 90 percent for each of the plaintiffs here and that the number of savings lost in just a couple of months was somewhere between $46 million and $100 million which HHS projected to be about $3 billion over the course of a year. And those are savings that largely are going to the covered entities and their patients to provide these services.

HON. BIBAS: But how do we know that? I mean, we hear from the other side that a lot of this is being pocketed by CVS and Walgreens and Rite-Aid

and Walmart. So how do we know that, in fact, this is all going the way you say it's supposed to go?

MR. AGUILAR: Sure. So I think the 2018 GAO report and the state's amicus brief is particular enlightening on this. The 2018 GAO report, at page 51 to 54, lays out a lot of the administrative fees that the contract pharmacies charge for this which created six dollars -- I note in one case it's particularly large for a brand name Hepatitis C drug. For the generic version of that drug, it's zero dollars. And a lot of times it'll even be no charge if the patient's uninsured.

And then, again, you can look at the GAO report where it's talking about this. It identifies problems potentially with covered entities being able to truly monitor everything and HHS needs to take additional action on that. But there is no speculation here that the covered entities are being coerced to pay an inordinate amount to the contract pharmacies or the third party administrators. It's explained that this is a system that works for that point. And then you have all of the affidavits and declarations in the administrative record to demonstrate we are using this money to either pass it on directly to our patients or to provide additional

services to more people, like OB-GYN or dental services or vaccine drives or mobile clinics or translation services.

And so, for these -- and they further note -- the outside pharmacies are a real world necessity. A lot of times their populations are either rural and can't get to the clinic. They work 9 to 5 jobs when any on site pharmacy might be open. Or the people they're serving are homeless and don't necessarily have said addresses or clear ways that they can get back to the clinic if they need to. But going to a contract pharmacy certainly helps.

And those are real world circumstances that Congress was aware of both when it enacted the statute and when it amended it. And there's nothing to say that it sought to disrupt the way that that was working.

HON. KRAUSE: But if Congress had anticipated that there would be this level of involvement of outside pharmacies, wouldn't you expect to see something in the statute that also regulated their ability to charge the fees that they do?

MR. AGUILAR: So if that's a measure for concern, that's a measure for concern that Congress probably should act on saying we want to add

additional authority here in the statute for controlling what we think are reasonable fees either for contract pharmacies or third party administrators or something. That is something that Congress could address.

HON. KRAUSE: Hasn't Congress done that elsewhere?

MR. AGUILAR: I'm not certain about that, Your Honor, potentially. But I think that is something where that's really in Congress' wheelhouse. If you want to add further regulation on here to further refine the program and direct it in the way you want, you certainly can. But there's nothing to say that that rule which Congress can weigh the competing interest of the covered entities and the patients and the manufacturers and everybody else involved, that those kind of decisions should instead be being made by private drug companies who then determine whether or not they'll sell this to the covered entities.

And I note that they say that they're going to sell an unlimited amount to them. But it's notable that the statute also doesn't talk about quantity. It doesn't say that, you know, at 100 or 1000 pills a month is sufficient. But what HHS has

said since the '93-'94 guidance is, obviously, just reading the statute on its face, you can't say that a covered entity needs to make a minimum quantity purchase in order to be eligible for the statutory discount. There's nothing in the statute that expressly prohibits it. But it's understood from the unqualified obligation in section (a) and the reticulated scheme as a whole that that's how the statute does operate. And it doesn't leave room for the manufacturers to impose those unilateral conditions.

HON. AMBRO: Any further questions? Thank you very much.

MR. AGUILAR: Thank you, Your Honors.

HON. AMBRO: Mr. Francisco?

MR. FRANCISCO: Thank you, Your Honor. Just a few quick points.

On my friend's very last point, the statute does actually answer the minimum requirement. It's just not in the "offer" language. It's in the very last phrase of the provision that says that we have to offer each covered entity the drug at the ceiling price if such drug is made available to any other purchaser at any price. If we sell 500 pills to somebody else at any other price, we got to sell 500

pills to covered entities, too. So I'll put that to the side.

My first major point, Judge Ambro, is on your line of questioning about specialty pharmaceuticals, I would direct you to the amicus brief filed by Otsuka America in connection with the AstraZeneca case. I think they did a very nice job of explaining how it is essential for the safety of their drugs to go to specialty pharmacists who know how to handle them and advise patients. They also explain how they received a letter from the government asking them to justify how that complies with 340B. I think we've just heard the answer from the government, that it doesn't comply with 340B. And that's fairly absurd, and it's not a word I use lightly.

Point number 2. And again, Judge Ambro, we understand that there are a lot of covered entities that don't have in-house pharmacies. And that's why every one of our programs solves that problem by allowing them to use a contract pharmacy that serves as a stand-in for an in-house pharmacy. So if you're not set up to do it yourself, you get at least one to stand in for your in-house pharmacy. And for Sanofi, at least, you get a lot more than that. You get an unlimited number of contract pharmacies if

you provide us with this minimal amount of claims data. So I think that there's no world in which that is not an offer within the meaning of the statute.

Third point, having to do with the notice and comment --

HON. AMBRO: One question on the second point.

MR. FRANCISCO: Yes.

HON. AMBRO: To what extent -- I mean, there are audit requirements, et cetera. To what extent do the manufacturers or, in this case, Sanofi, do you think you need to go beyond that in order to find out if there's been duplication or some type of diversion? What makes you think that has to be done by the manufacturers as a condition at times?

MR. FRANCISCO: I'm not a hundred percent sure I'm following.

HON. AMBRO: In other words, there are -- when you have this program, there are some that may wish to take advantage of the program in a way that both the government and the manufacturer thinks, nope, that's not (indiscernible). And the government does have certain audit requirements that the GAO does. Why do the manufacturers think they need to do more than that?

MR. FRANCISCO: Oh. For a few reasons, Your Honor. So one is that we also have the ability to do an audit and to trigger the ADR process. But under the regulations that HHS has put out under the guidance documents that they've put out, we're not even allowed to trigger that audit process unless we have evidence that there's a problem going on. This is at 61 Federal Register 65,410. And what it says is that in order to initiate an audit, first we have to submit a work plan that "sets forth a clear description of why we have reasonable cause to believe that a violation has occurred along with sufficient facts and evidence." And then in addition, it says, we have to submit "copies of any documents supporting our claim". So we can't even trigger that process unless we have evidence of wrongdoing. That's one of the purposes of Sanofi's collection of the claims data is to decide whether or not to trigger the audit process.

But the other thing I'd emphasize is -- and this is in response to my friend's suggestion that Astra somehow has anything to do with this case when it doesn't. Sanofi's program is not an enforcement policy. If you provide us -- if they -- if the covered entity provides us with the claims data, they

can purchase an unlimited amount of drugs and we'll send it to an unlimited number of contract pharmacies even if that data shows rampant diversion and rampant duplicate of discounts. It's not a mechanism for enforcing the statute. It's simply a mechanism for identifying whether there's a problem in the first place so we can prevent it from happening.

HON. BIBAS: I did want to ask you to get to the notice of proposed rulemaking.

MR. FRANCISCO: Yes.

HON. BIBAS: You can finish your other substantive point but make sure to get there.

MR. FRANCISCO: I'm going -- that's exactly where I was going, Your Honor.

HON. BIBAS: Okay. So why shouldn't we have a formal bright line rule that says, look, if there's a withdrawal of the Federal Register, it's off the table; otherwise it's on. It seems like a clear neat rule. Instead, we're supposed to be like gauging other statements that people make or things on the website. How are we to know how withdrawn is withdrawn enough?

MR. FRANCISCO: I think that -- you're exactly right. And the only way to know or at least the easiest way to know if something is withdrawn is

if the agency tells you it was withdrawn.

Now my friend suggested that there's no prejudice. Well, of course there's prejudice. We were deprived of our ability to comment on the rule. The very substantive thing that the APA give us, the most important substantive thing, is the ability to comment on a new rule. And we were completely deprived of the ability to comment on this new rule. So that's the prejudice.

I --

HON. KRAUSE: What additional comments would you have made beyond those that were submitted?

MR. FRANCISCO: Sure, Your Honor. Well, the first thing I'll say is that, you know, I don't know the full range of them because we were never given the opportunity.

But the second point I'd make is that our trade association, Pharma, actually did, in November 2020, before the new final rule was issued, submit a notice of -- a petition for a new rule in which it explained at length why it didn't think -- why there were changes that occurred between 2016 and 2020 that needed to be taken into account.

Just to give you a couple of examples, one was didn't think that the old proposed withdrawn

rule sufficiently took into account the growth of the use of the use of contract pharmacies in that four-year period.

Secondly -- and this goes to one of your other lines of questions, Judge Bibas, as to, you know, how you have a patient 300 miles away from the covered entities. Because of the regulatory definition of the word "patient". A patient of a covered entity only has to be very quite loosely affiliated with the covered entity. And that's why you could have somebody that's a patient 300 miles away that really isn't in any meaningful way being served by the covered entity. So we also -- the Pharma comments also said that you ought to address the problematic definition of the word "patient". So I think that there's clear prejudice there.

My final point just goes to what the overall purpose of 340B is, wholly apart from the text. And, look, I would agree that one purpose of the statute is to provide a subsidy to covered entities of some level in the form of discounted drugs. But as the Supreme Court has repeatedly made clear, no statute pursues a single purpose to the objective of all others. And there's no way that you can get out of this language an attempt to address a

very important social question as to how you address health care for poor uninsured in the rural areas. There's no way you can say that the word "offer" was meant to resolve that very important social question. Rather, the offer simply requires one thing about clients and that is to make an offer of the drugs at the ceiling price. Every single one of them does that.

HON. AMBRO: Thank you very much.

MR. FRANCISCO: Thank you, Your Honor.

HON. AMBRO: Mr. Parrish?

MR. PARRISH: Thank you, Your Honors. I'd like to just make three points.

One, I do want to underscore the 1996 guidance point, Judge Bibas. If they're right about that, the government extinguished a right that they say that the covered entities always had which was to demand delivery to unlimited contract pharmacies. That just doesn't make any sense that for 14 years no one noticed that.

Judge Krause, related to that, I won't go into detail but your questions are in the right direction of 1992. It's been a world change since then. But even today, you should know that the majority of covered entities don't use contract

pharmacies. This is abuse by a very small group. So a third of covered entities have contract pharmacies. Of that third, 75 percent only have five or less contract pharmacies. So what we're talking about is a few covered entities that are causing all the problems in this program. And you can take a look at JA585 and JA534. One's the GAO report and one's a private report.

My two other points -- this is clearly arbitrary and capricious. My opposing counsel keeps referring to the administrative record. I'm sorry. He doesn't get to do that. He only can rely on what statements are made in the May letter. And if he wants to say it's not moot, the advisory opinion, he hasn't done that. So at a minimum, it's unreasoned and it's unexplained. It hasn't responded to objections.

But, Your Honors, we urge you to get to the statutory question because all of the arbitrary and capricious errors here stem from that misunderstanding of the statute. Judge Bibas, he was unable to identify any statutory language that actually supports his position. And remember, his position is that it's unambiguously clear that he's right not that it's ambiguous. That causes a lot of

problems because we're not in Chevron land. This is not a case where they're engaged in rulemaking. So you don't look at legislative history. You don't look at purposes. You just look at the text.

He keeps saying it's an unqualified obligation. I guess the idea is that everything is prohibited unless it's permitted. That's not right. We know that's not right. Christensen is so clear on that. He has no answer to the Supreme Court case.

And then I would just say this, is that all the issue before the Court is, is the May 17th --

HON. AMBRO: So what you're doing is you're flipping it around.

MR. PARRISH: I'm --

HON. AMBRO: If there's silence, everything's permitted.

MR. PARRISH: I'm sorry, Your Honor?

HON. AMBRO: Isn't what you're saying the inverse of that?

MR. PARRISH: What I'm saying is, is that your common law rights over your own property exist until Congress takes it away and that it takes it away to the extent that it does which is, here, there's an offer. There is no idea which he's trying to suggest that because it's an offer that we then say

anything else that you might do is prohibited. It's not true. You have to read into the offer. Is there an obligation to deliver to third parties at third party locations? That doesn't exist. And therefore, the private right baseline remains. It hasn't been taken away.

And then I would just say that in terms of answering Your Honors' key questions, what does this Court need to do, all the Court needs to do is say that the May 17th letter has interpreted the offer requirement and the purchased-by language in the statute to impose an obligation on manufacturers that they must deliver to contract pharmacies wherever covered entities want. That is wrong as a matter of law. And you should strike that down and vacate the letter. And we also think you should do the same for the advisory opinion but I won't get into mootness. But that's all the Court needs to do in order to set this program back on the pace where Congress wanted it.

Okay. Thank you for your time.

HON. AMBRO: Thank you very much.

Mr. Kedem?

MR. KEDEM: Thank you, Your Honor. A few quick points.

Judge Krause, you had asked me where in the record you could see the fact that most patients are paying full price when they use contract pharmacies. I point you to footnote 8 of our brief. One of the sources cited there is in the administrative record. It's an agency report. The other is from the Government Accountability Office. And you'll see that they validate the representation.

My friend from the government makes a different representation that there's been up to a 90 percent decrease in 340B sales as a result of these policies. That is just deeply misleading, at best. The data which the government has never shown us actually comes from a company called Apexus whose parent, Vizient, profits directly from contract pharmacy sales. They cherrypick four months immediately after AstraZeneca's policy went into effect by which time a number of covered entities hadn't designated a contract pharmacy even though they were eligible to do so. It doesn't take account of the fact that 340B sales are seasonal. The bottom line is I can represent to you that 340B sales for AstraZeneca are now higher than they were before this policy was implemented.

Judge Krause, you've been very focused

on what this policy was originally for. There were a small minority of covered entities who were providing drugs for free or at a discount to their uninsured or indigent patients. Those were the covered entities that Congress was concerned about and wanted to make sure that they didn't have to go to the market and be out of pocket a lot of money. You asked exactly the right question when my friend pointed out that 95 percent of those covered entities didn't have their own in-house pharmacy. You asked, well, when people went to the neighborhood CVS, were the 340B -- were discounts being provided there. To my knowledge, the answer was no. They were outside of Congress' concern. Yes, it was a small minority relatively speaking who -- but those were the exact minority that Congress was concerned about.

My friend brought up a number of times the questions of diversion or agency action. We don't have the contracts between the covered entities and the contract pharmacies. They're not in the record. They're not public. But every once in a while, some of them do become public. Usually because the covered entity is a governmental entity that has to post these sorts of things. And what we see, and this is cited in briefs that AstraZeneca filed in the district

court, is that they actually don't maintain title and it's not an agency relationship. It's a contractual relationship which is exactly as you would expect. And it's validated by evidence that the government itself submitted in the Sanofi case which we cite on page 13 of our appellate brief. What you see is there's a declaration from Rear Admiral Pedley, who is the Office of Pharmacy Affairs director, and what she says is that the drugs are taken and assimilated into the contract pharmacies' own stock and treated just like its own property. And so title is taken by the contract pharmacy itself.

My friend liked to talk a lot about how this is a reticulated scheme. But this is just a form -- and that there's no room for manufacturers to restrict their offers or restrict their sales. But again, this is just a form of verbal Jiu Jitsu. He is assuming his own conclusion or what some people refer to as begging the question. The question is, is there an obligation there in the first place. If there's no such obligation, then yes. It would be improper self-help. But if there's no such obligation then all it is, is manufacturers structuring their affairs as they have a right to do.

And the most remarkable thing about

this case is after four briefs and 60 minutes of argument, the government has yet to tell the Court what an offer is and what it thinks that offer -- the word "offer" means. Instead, we hear about unenacted legislative history. Judge Stark had a great answer to this. In footnote 9 of his second summary judgment opinion, you can look at it there. But the point is, unenacted legislative history essentially tells us nothing.

Finally, there have been a lot of difficult hypotheticals in this case to both sides. And as much as we litigants fear them, they are an appropriate way to sort of suss out the limits of a litigant's position. But all of the hypotheticals on our side are just hypotheticals. No manufacturer has ever restricted 340B sales to covered entities in a way that they don't at least provide to the marketplace generally. In fact, they all go well beyond the offer that's made to anyone else in the marketplace.

But the difficult hypotheticals on the government's side aren't hypotheticals at all. They are this case. Although most covered entities don't use contract pharmacies, there is a very small minority that are using hundreds of them scattered

around the country which is why, as, Judge Bibas, you pointed out sometimes the distance that you have to travel to get to one of those contract pharmacies is as much as or more than 300 miles.

The basic point here is the only thing that you have to decide, was the May 17th violation letter correct when it said that our policies were in direct violation of some requirement contained in the statute. Because there is no such requirement, those letters were incorrect and should be set aside.

Thank you.

HON. AMBRO: Thank you very much.

Thank you to all counsel for very well presented briefs and also well presented arguments. We'll take the matter under advisement and --

MR. AGUILAR: Your Honor, could I correct a misstatement that I made?

HON. AMBRO: Sure. You sure can.

MR. AGUILAR: I'm sorry. This was -- I'm sorry, Your Honor. This was a misstatement that I made in my argument. And I realize I didn't understand the question until Mr. Francisco raised it back and then I understood.

If there's a generally applicable requirement for all manufacturers on how to distribute

a particular drug that's not unique to the 340B program, the 340B program doesn't grab it in. And I misstated our position that that would be a violation. If it's generally applicable then that's not.

HON. AMBRO: Okay. Thank you very much.

MR. AGUILAR: I'm sorry, Your Honor.

HON. AMBRO: Thank you very much for that clarification.

Again, thank you to all counsel and appreciate you being here today. We'll take --

(Proceedings end mid-sentence)

(End of oral argument)

I N D E X

A R G U M E N T

C E R T I F I C A T I O N

I, Lisa Beck, certify that the foregoing transcript is a true and accurate record of the proceedings.

Lisa Beck

Date: November 20, 2022