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IN THE UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT

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

(CONT'D ON NEXT PAGE)

1 Nos. 21-3167/21-3168/21-3379/22-1676/21-3380 (Cont'd)
 2 ASTRAZENECA PHARMACEUTICALS,) Case No. 22-1676
 LP)
 3)
 Appellant,)
 4)
 v.)
 5)
 SECRETARY UNITED STATES)
 6 DEPARTMENT OF HEALTH AND)
 HUMAN SERVICES; et al.,)
 7)
 Appellees.)

8
 9 NOVO NORDISK INC; NOVO NORDISK) Case No. 21-3380
 PHARMA INC,)
)
 10 Appellants,)
)
 11 v.)
)
 12 UNITED STATES DEPARTMENT)
 OF HEALTH AND HUMAN SERVICES,)
 13 et al.,)
)
 14 Appellees.)

15 ON APPEAL FROM THE
 16 UNITED STATES DISTRICT COURT
 FOR THE DISTRICT OF NEW JERSEY
 17 CASE NO. 3:21-cv-00634-FLW-LHG
 18 BEFORE APPELLATE PANEL:
 19 HON. THOMAS L. AMBRO, Circuit Judge
 HON. CHERYL A. KRAUSE, Circuit Judge
 20 HON. STEPHANOS BIBAS, Circuit Judge
 21 APPEARANCES (see next page)

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1 P R O C E E D I N G S

2 HON. AMBRO: We have one case this
3 morning. It's numbers 21-3176 -- 3167 -- excuse me --
4 3168, 21-3379 and 3380 and also 22-1676, Sanofi
5 Aventis, et al. v. the Secretary United States
6 Department of Health and Human Services.

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

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

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

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

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

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

6 HON. AMBRO: Yes, sir.

7 MR. FRANCISCO: Your Honors, Section
8 340(b) requires Sanofi to do one thing: offer its
9 drugs to covered entities at the ceiling price. It
10 clearly does that. They can purchase as much as they
11 want at the ceiling price and will deliver it to their
12 in-house pharmacy if they have one, to a contract
13 pharmacy if they don't and, in addition to that, to an
14 unlimited number of contract pharmacies if they
15 provide us with limited claims data. It takes them
16 five minutes every other week to comply with that last
17 part of our policy. That's plainly an actual
18 offering. Indeed, it's more generous than the
19 government itself required for the majority of the
20 operation of this program.

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

1 price.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

8 MR. FRANCISCO: Sure.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

25 HON. BIBAS: Okay.

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

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

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

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

1 HON. BIBAS: I understand that but --

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

4 MR. FRANCISCO: Excuse me, Your Honor?

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

7 MR. FRANCISCO: Exactly.

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

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

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

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

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

14 MR. FRANCISCO: Sure.

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

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

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

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

14 HON. AMBRO: But doesn't --

15 MR. FRANCISCO: -- you apply --

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

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

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

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

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

9 HON. AMBRO: Go ahead.

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

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

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

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

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

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

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

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

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

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

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

25 I would respectfully submit that

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

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

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

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

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

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

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

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

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

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

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

8 MR. FRANCISCO: Thank you, Your Honor.

9 HON. AMBRO: Mr. Parrish?

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

14 HON. AMBRO: Absolutely.

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

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

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

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

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

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

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

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

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

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

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

1 HON. AMBRO: Go ahead.

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

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

25 You take those three principles and

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

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

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

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

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

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

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

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

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

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

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

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

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

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

5 Your Honor, on the agency point, the
6 problem that the government has there is that in the
7 1996 guidance, the theory was that we could read into
8 the statute an agency relationship because one
9 contract pharmacy would be acting as equivalent to an
10 in-house. And at that time, you'll note that for 14
11 years, the statute operated that way. And we would
12 say, as a first point, is if the government is right
13 now then that meant that for 14 years the government
14 was interpreting the statute in a way it now says was
15 plainly wrong. That can't be the case.

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

25 HON. AMBRO: But let's say that

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

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

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

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

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

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

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

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

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

22 MR. PARRISH: Yeah.

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

1 least semi uniform?

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

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

1 who were local on site?

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

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

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

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

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

1 have with this program is that what's going on is, is
2 that the uninsured patients that would -- used to come
3 into the hospital and then the hospital would say I
4 have drugs that have been provided at a discount, I'll
5 give them to you, those patients aren't being treated
6 that way anymore. And both -- what's happening
7 instead, the patients that are getting are -- both the
8 insured and the uninsured are not being treated
9 differently unless they have that card which is the
10 1.4 percent that Mr. Francisco talked about. And so,
11 the problem is it's not helping the patients.

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

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

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

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

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

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

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

1 program without any growth in uninsured patients from
2 9 billion in 2010 to 38 billion in 2020. All of this
3 growth is explained not by helping indigent patients.
4 It's all explained by the arbitrage that's happened by
5 sending these drugs across the country in a way that
6 allows them to sell drugs to fully insured patients
7 and then pocket the difference.

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

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

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

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

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

1 practical question.

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

1 money.

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

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

10 HON. AMBRO: How --

11 MR. PARRISH: -- instead of that --

12 HON. AMBRO: How would it work out
13 practically?

14 MR. PARRISH: Well, Your Honor, so if
15 all -- I guess the point is, if the drug is usually
16 \$100 and then it's being sold at a penny, that 99.99
17 difference is what's making up that billion. And the
18 question is, is that appropriately -- can you read
19 "offer" so broadly that it means that we have this
20 obligation to deliver to the pharmacies. And our
21 submission is, is that's not in the statute. And the
22 background principal on that is that it shouldn't be
23 in the statute because Congress hasn't spoken to that.

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

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

3 MR. PARRISH: The full price, yeah.

4 HON. AMBRO: Oh. They're --

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

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

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

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

20 MR. PARRISH: Okay. Thank you.

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

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

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

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

23 HON. KRAUSE: So if I can just --

24 MR. PARRISH: Yeah.

25 HON. KRAUSE: Say that a covered entity

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

9 MR. PARRISH: Yeah. So they --

10 HON. KRAUSE: Is that right?

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

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

25 MR. PARRISH: Well, Your Honor, I think

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

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

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

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

23 MR. PARRISH: Thank you very much.

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

1 [Ka-deem]?

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

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

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

8 HON. AMBRO: That's fine.

9 MR. KEDEM: Perhaps a good place to
10 start would be with the two district court decisions
11 you have in front of you because although they reach
12 different results, I actually think there is a fair
13 amount of overlap on the central issue that we take to
14 be at the heart of this case. Both Judge Stark and
15 Chief Judge Wolfson took a look at Section 340B and
16 determined that there was no requirement to deliver
17 discounted drugs to third party contract pharmacies
18 contained in the statute. Where they differ is that
19 Chief Judge Wolfson then went on to say there's
20 nothing that affirmatively authorizes manufacturers to
21 restrict distribution and therefore they're forbidden
22 from doing so whereas Judge Stark looked at the May
23 17th violation letter and its accusation that
24 AstraZeneca had directly violated its obligations
25 under 340B and said that can't be right. If there's

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

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

1 offer provision.

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

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

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

25 HON. AMBRO: But I can say to you I

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

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

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

12 MR. KEDEM: Right.

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

15 MR. KEDEM: Right. But --

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

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

22 HON. AMBRO: At or below the ceiling --

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

25 HON. AMBRO: -- price, right?

1 MR. KEDEM: Pardon?

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

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

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

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

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

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

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

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

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

5 MR. KEDEM: So --

6 HON. KRAUSE: Right?

7 MR. KEDEM: Yeah.

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

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

1 well in 2010 when they opened things up. But even in
2 2010, they never said that this was imposed as a
3 statutory requirement. That's the key element, we
4 think, that the government has never even acknowledged
5 much less explained which is that it was only in
6 December 30th of 2020 that the government, in the form
7 of the advisory opinion, for the very first time said
8 that there was an actual statutory obligation that
9 manufacturers would violate if they failed to deliver
10 to third party contract pharmacies. That does not
11 appear at any previous point. And that is, by itself,
12 a sufficient basis to conclude that there's an APA
13 violation.

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

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

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

25 MR. KEDEM: So I think technically you

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

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

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

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

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

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

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

17 MR. KEDEM: Pardon?

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

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

25 And that's really just the final way of

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

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

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

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

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

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

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

18 MR. KEDEM: So I can take a look at
19 which GAO study I'm referring to and see where in the
20 briefs. It's not in the administrative record and I
21 think that's the key point because it doesn't matter
22 to the statutory question that's embedded in the May
23 17th violation letter. The agency, although they
24 include a lot of factual material in the
25 administrative record, they don't actually rely on it

1 in the May 17th letter because it's sort of irrelevant
2 to the statutory question that you have before you.
3 And so, I agree with you. This is all very useful
4 context and I think we all understand their important
5 policy concerns. But as Judge Stark put very
6 eloquently, those policy concerns are ones that
7 Congress can deal with. The only question that you
8 have before you is a question as to whether the May
9 17th letter was correct that the statute itself
10 imposes this third party distribution requirement on
11 manufacturers. If it doesn't, that is sufficient to
12 determine that the letter is invalid and set it aside
13 on that basis.

14 HON. AMBRO: Thank you.

15 MR. KEDEM: Thank you.

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

18 Mr. Aguilar?

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

21 So I think there are two --

22 HON. AMBRO: The third rodeo on this
23 one?

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

1 my colleague took it over which I --

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

4 MR. AGUILAR: -- greatly appreciated.

5 HON. AMBRO: -- for you.

6 MR. AGUILAR: Except for the sickness.

7 HON. AMBRO: That was a rough oral
8 argument.

9 MR. AGUILAR: To be fair, I'd rather be
10 talking with you all than cooped up with the flu. But
11 --

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

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

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

1 MR. AGUILAR: Sure.

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

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

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

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

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

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

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

15 HON. BIBAS: The "purchased by" phrase?

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

20 HON. BIBAS: A covered entity,
21 singular.

22 MR. AGUILAR: Yes.

23 HON. BIBAS: Okay.

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

1 the ceiling price.

2 HON. BIBAS: Okay.

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

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

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

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

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

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

18 MR. AGUILAR: No, Your Honor.

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

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

25 HON. BIBAS: And there's the Otsuka

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

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

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

18 MR. AGUILAR: So I know --

19 HON. AMBRO: What's wrong with that?

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

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

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

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

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

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

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

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

9 MR. AGUILAR: -- enforced.

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

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

15 HON. AMBRO: Correct.

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

21 HON. AMBRO: Let's say --

22 MR. AGUILAR: -- to the applicable --

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

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

5 MR. AGUILAR: Yes.

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

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

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

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

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

1 program?

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

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

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

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

11 MR. AGUILAR: -- and explain.

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

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

1 scheme --

2 HON. BIBAS: Okay.

3 MR. AGUILAR: -- for addressing those.

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

7 MR. AGUILAR: Yes, Your Honor.

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

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

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

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

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

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

23 MR. AGUILAR: Yes.

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

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

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

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

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

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

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

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

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

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

16 HON. BIBAS: Now looking back at the
17 1996 guidance, if these manufacturers, these very same
18 conditions back in 1996, we wouldn't be here. You
19 would not have been challenging their actions as
20 unlawful or violating any terms of the '96 guidance,
21 would you?

22 MR. AGUILAR: I think what we would say
23 is consistent with both the '96 guidance and the
24 '93-'94 guidance, is that it's -- the 340B statute
25 does not leave any room for the manufacturers to

1 restrict their delivery obligations at the outset.

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

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

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

1 serving people in local communities?

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

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

1 manufacturers about duplicate diversions -- duplicate
2 discounts or diversions. So we're going to study this
3 problem. And as our brief explains, for the next five
4 years, HHS conducted a number of audits and said we
5 aren't seeing many problems here, let's start a pilot
6 program to allow covered entities to use multiple
7 contract pharmacies. They continued that and then in
8 2007, it said we still aren't seeing any problems. We
9 think that we can advise people to use multiple
10 contract pharmacies so long as they're still retaining
11 title, still using these contract -- sort of guidance
12 contract forms to make sure that they are supervising
13 their --

14 HON. BIBAS: Evolution --

15 MR. AGUILAR: -- pharmacies.

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

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

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

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

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

3 HON. AMBRO: A question on the
4 consistency is there are, obviously, nuances as Judge
5 Krause has noted from '93-'94. But looking at it
6 maybe overly simplistically, it looks like there was a
7 nonbinding guidance, '96, that covered entities --
8 that they may use one contract pharmacy to nonbinding
9 guidance in 2010 that they may use more than one
10 contract pharmacy to binding enforceable guidance in
11 2020 that manufacturers have to deliver to multiple
12 contract pharmacies. And they backed that up by a
13 violation letter. So it looks to me, maybe
14 simplistically, as if the position has changed pretty
15 dramatically over the course of 24 years.

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

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

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

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

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

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

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

23 HON. AMBRO: Yeah. Well --

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

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

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

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

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

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

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

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

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

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

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

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

4 MR. AGUILAR: But I think, Your Honor,
5 the beginning of your question there, I think,
6 demonstrates why Congress knew what the commercially
7 appropriate practice was at the time it enacted the
8 340B program. It knew that many of these covered
9 entities --

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

16 MR. AGUILAR: So let me explain that.
17 The contract pharmacy is solely to ensure that the
18 covered entity retains title of this so that it will
19 qualify for a discount when it's dispensed to a
20 patient through an outside pharmacy. Prior to the
21 340B program, many of these covered entities used
22 outside pharmacies. But there wasn't the same type.
23 You needed to retain title. That's why they had a
24 contractual relationship to both as a result of the
25 program to comply with its statutes. But they were

1 still using outside pharmacies.

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

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

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

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

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

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

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

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

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

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

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

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

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

15 MR. AGUILAR: I'm happy to --

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

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

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

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

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

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

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

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

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

17 MR. AGUILAR: I think they would need
18 to ask the agency on like is this going to happen
19 because, indeed, when Congress amended the statute, it
20 directed you that you need to pass a rulemaking here.
21 So what's going on and what the agency eventually did
22 --

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

25 MR. AGUILAR: The final rule was

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

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

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

11 HON. AMBRO: Oh, okay.

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

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

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

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

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

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

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

7 MR. AGUILAR: And with --

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

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

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

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

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

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

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

17 HON. AMBRO: And when you put it out in
18 2020, there is a different RIN.

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

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

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

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

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

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

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

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

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

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

18 HON. AMBRO: All right. Any further
19 questions?

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

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

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

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

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

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

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

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

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

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

13 And that's why the administrative
14 record, too, just within a couple of months of these
15 policies being enacted, the 340B sales dropped
16 precipitously by about 60 to 90 percent for each of
17 the plaintiffs here and that the number of savings
18 lost in just a couple of months was somewhere between
19 \$46 million and \$100 million which HHS projected to be
20 about \$3 billion over the course of a year. And those
21 are savings that largely are going to the covered
22 entities and their patients to provide these services.

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

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

3 MR. AGUILAR: Sure. So I think the
4 2018 GAO report and the state's amicus brief is
5 particular enlightening on this. The 2018 GAO report,
6 at page 51 to 54, lays out a lot of the administrative
7 fees that the contract pharmacies charge for this
8 which created six dollars -- I note in one case it's
9 particularly large for a brand name Hepatitis C drug.
10 For the generic version of that drug, it's zero
11 dollars. And a lot of times it'll even be no charge
12 if the patient's uninsured.

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

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

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

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

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

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

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

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

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

21 And I note that they say that they're
22 going to sell an unlimited amount to them. But it's
23 notable that the statute also doesn't talk about
24 quantity. It doesn't say that, you know, at 100 or
25 1000 pills a month is sufficient. But what HHS has

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

12 HON. AMBRO: Any further questions?

13 Thank you very much.

14 MR. AGUILAR: Thank you, Your Honors.

15 HON. AMBRO: Mr. Francisco?

16 MR. FRANCISCO: Thank you, Your Honor.

17 Just a few quick points.

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

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

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

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

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

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

6 HON. AMBRO: One question on the second
7 point.

8 MR. FRANCISCO: Yes.

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

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

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

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

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

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

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

10 MR. FRANCISCO: Yes.

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

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

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

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

1 if the agency tells you it was withdrawn.

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

10 I --

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

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

17 But the second point I'd make is that
18 our trade association, Pharma, actually did, in
19 November 2020, before the new final rule was issued,
20 submit a notice of -- a petition for a new rule in
21 which it explained at length why it didn't think --
22 why there were changes that occurred between 2016 and
23 2020 that needed to be taken into account.

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

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

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

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

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

9 HON. AMBRO: Thank you very much.

10 MR. FRANCISCO: Thank you, Your Honor.

11 HON. AMBRO: Mr. Parrish?

12 MR. PARRISH: Thank you, Your Honors.

13 I'd like to just make three points.

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

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

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

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

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

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

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

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

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

14 MR. PARRISH: I'm --

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

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

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

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

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

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

21 Okay. Thank you for your time.

22 HON. AMBRO: Thank you very much.

23 Mr. Kedem?

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

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

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

25 Judge Krause, you've been very focused

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

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

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

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

25 And the most remarkable thing about

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

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

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

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

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

11 Thank you.

12 HON. AMBRO: Thank you very much.

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

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

18 HON. AMBRO: Sure. You sure can.

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

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

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

5 HON. AMBRO: Okay. Thank you very
6 much.

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

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

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

12 (Proceedings end mid-sentence)

13 (End of oral argument)

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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

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