UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF INDIANA
INDIANAPOLIS DIVISION

ELI LILLY AND COMPANY, AND LILLY USA, LLC,	)	
Plaintiff,	)	CAUSE NO. 1:21-cv-81-SEB-MJD
	)	Indianapolis, Indiana
-v-	)	**July 30th**, 2021
	)	12:00 p.m.
U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, et al,	)	
Defendants.	)	

Before the Honorable
SARAH EVANS BARKER, JUDGE

OFFICIAL REPORTER'S TRANSCRIPT OF
PRELIMINARY INJUNCTION AND CROSS-MOTIONS FOR SUMMARY JUDGMENT

Court Reporter: Laura Howie-Walters, FCRR/RPR/CSR
Official Court Reporter
United States District Court
Room 217
46 East Ohio Street
Indianapolis, Indiana 46204

PROCEEDINGS TAKEN BY MACHINE SHORTHAND
TRANSCRIPT PRODUCED BY ECLIPSE NT COMPUTER-AIDED TRANSCRIPTION

A P P E A R A N C E S

For Plaintiffs:

John C. O'Quinn, Esq.
Matthew S. Owen, Esq.
Andrea Butler, Esq.
KIRKLAND & ELLIS LLP
1301 Pennsylvania Avenue N.W.
Washington, DC 20004

and

Brian J. Paul
FAEGRE DRINKER BIDDLE & REATH LLP
300 North Meridian Street
Suite 2500
Indianapolis, IN 46204

For Defendants:

Kate Talmor, Esq.
Jody D. Lowenstein, Esq.
U.S. DEPARTMENT OF JUSTICE
1100 L Street NW
Washington, DC 20005

(Open court.)

THE COURT: Good morning again, although it's now afternoon, but greetings, all.

MS. TALMOR: Good afternoon.

MR. O'QUINN: Good afternoon, Your Honor.

Miss Harves, will you call the matter before the Court, please.

(Call to order of the Court)

All right. This matter's on the Court's calendar for oral argument on the parties' cross motions for summary judgment and the government's motion to dismiss.

We have had informal discussions this morning, and so it's my understanding that the parties have agreed to limit the scope of your arguments today. The issues that have been presented still are pending before the Court, but for purposes of today's hearing, the scope of your advocacy and remarks will be limited to the issues that you identified today.

So I'll try to catch the balls that you pitch to me as you're deciding which issues to raise. I'll hear -- they are cross motions obviously, so I'll here first from you, Miss Talmor, on behalf of the government, and then Mr. O'Quinn on behalf of Lilly, and then a rebuttal from you, Miss Talmor.

The way we'll allocate the time is 20 minutes to the government and 30 minutes to Lilly to handle the issues on the cross motions, and then ten minutes for rebuttal from the

government.

Do you want to move the admission of your co-counsel?

MS. TALMOR: Yes, Your Honor, I'd like to.

THE COURT: The appearance?

MS. TALMOR: Yes, Your Honor. I'd like to move for the appearance of my co-counsel, Jody Lowenstein.

THE COURT: All right. I'll grant your oral motion and you may participate now, Mr. Lowenstein, and welcome to our court.

MR. LOWENSTEIN: Thank you.

THE COURT: So, Miss Talmor, can you proceed by standing there? Is that good or shall we move the podium back? What would you like?

MS. TALMOR: Whatever Your Honor would prefer. I'm happy to stand here or stand at a podium, whichever.

THE COURT: Well, where is it easiest to use your notes? That's on castors, so we can move it.

MS. TALMOR: I don't want to rearrange Your Honor's courtroom.

THE COURT: Oh, no. It's a woman's prerogative, don't you know, and I'll exercise the prerogative to move it over.

MS. TALMOR: Thank you. We maintain better eye contact.

THE COURT: Thank you, Mr. O'Quinn. You'll see as we rearrange the furniture that we have the obligatory box of

Kleenex in there. That's usually for defendants in my criminal cases, but if something happens, Miss Talmor, that you need to use my Kleenex, feel free.

MS. TALMOR: Thank you.

THE COURT: Push it on over there. A little bit farther. A little bit farther. That's good.

Does that feel better?

MS. TALMOR: Yes, Your Honor. Much better.

Thank you, Your Honor. May it please the Court.

THE COURT: Miss Talmor, it's nice to have you in court today.

MS. TALMOR: Thank you. It's nice to be here in person.

THE COURT: Yes, indeed. I'd say so, too.

MS. TALMOR: I'd like to start with the big picture here. Last year, Eli Lilly led a handful of other global pharmaceutical companies --

COURT REPORTER: Please slow down.

THE COURT: And speak up now. The fact that we're sort of close together doesn't relieve you of the obligations of the arena.

MS. TALMOR: Thank you, Your Honor.

THE COURT: If you speak loudly, you'll speak more slowly, too, because you won't just read it.

MS. TALMOR: Thank you.

I'd like to start with the big picture here. Last year, Lilly led a handful of other global pharmaceutical companies in unilateral actions that upended the 30-year operation of the 340B program, which is a critical part of our nation's health care safety net.

Through this litigation, Lilly attempts death by a thousand cuts by challenging three separate agency actions on every conceivable ground in an attempt to avoid facing penalties for its unlawful overcharges to covered entities.

In its final brief, Lilly largely ignores the evidence gathered by HRSA demonstrating that Lilly is violating its statutory obligation, and instead continues to mischaracterize the nature of the transactions at issue here.

Rather than confront the government's position head on, Lilly's arguments obscure the fact that its statutory obligation is straight forward. The 340B statute requires Lilly to ensure that purchases by covered entities do not exceed the ceiling price and that its drugs are made available on the same terms as those they are made available in commercial sales.

HRSA correctly found that Lilly is overcharging covered entities, and its determination should be upheld by this Court so that enforcement can proceed against Lilly.

Now, before turning to the statutory interpretation question, I'd like to briefly begin with the factual basis that

HRSA gathered. Now, each time I've appeared before this Court virtually, I've discussed the fact that the portrayals in Lilly's brief are, in our view, inaccurate because it is not contract pharmacies who are participating in this program or purchasing drugs.

So now, instead of that being an abstract issue, we have actual evidence gathered by the agency to show that. While the administrative record is huge, I've brought a small sample of that with me here today, which I will not walk through all of it, but to emphasize the basis of HRSA's finding, we have here an invoice where a covered entity was charged 3,000 --

THE COURT: Do you intend to make these exhibits?

MS. TALMOR: They are all in the administrative record and so --

THE COURT: I'll have to have some identification or something so I'll know what you're referring to.

MS. TALMOR: Shall I individually move them or may I discuss them generally?

THE COURT: I don't know exactly what you've got, so go ahead and describe what you've got, and then we'll see how it needs to get into the record.

MS. TALMOR: These are several pages of the administrative record, and so perhaps I could just reference the page number because they are already in the record before

this Court.

THE COURT: That would be good. Do it that way.

MS. TALMOR: So this first one I have, they all begin with VLTR. So I'll just use the page number because that is the administrative record.

THE COURT: What did you say?

MS. TALMOR: VLTR, meaning violation letter.

THE COURT: Okay.

MS. TALMOR: So this is 1463. It shows a variety of overcharges, the largest being $3,603 for one unit of Lilly's drugs. This covered entity totaled up $126,000 in one month alone.

This is a different month. This is page 1468. This shows the same covered entity again paying $3,683 for Lilly medications.

This page, 5834, shows a different covered entity paying $3,597 for Lilly's drugs.

Page 5852 --

THE COURT: Wait, paying that amount too much?

MS. TALMOR: Paying $3,597 for one package of Lilly's drugs. Now, on all of these, the ceiling price is redacted because it's protected. In its complaint, Lilly pleaded that many of the insulin products are a penny each. I don't know that this particular drug is a penny. It could be more, but it's nowhere near $3,500 per package.

THE COURT: So you're saying that the amount that's been determined by HRSA in its examination is in the abstract and --

MS. TALMOR: No, Your Honor.

THE COURT: -- excessive?

How do I know it's too much? Because the charge is that it's an overcharge, right?

MS. TALMOR: Correct, Your Honor.

THE COURT: How I do know that?

MS. TALMOR: Because it's not in dispute. I do not believe that Lilly disputes that the ceiling price for these medications is below these amounts.

THE COURT: Okay.

MS. TALMOR: Now, I understand that Your Honor must decide the case on the record presented to the court. In compiling the administrative records, the ceiling prices are much lower than these prices here.

THE COURT: Okay.

MS. TALMOR: These prices represent wholesale acquisition cost or commercial pricing. Mr. O'Quinn can clarify, if I'm incorrect, but I do not believe there's a dispute that these prices are not 340B ceiling prices. They are much higher.

This page, 5852, again shows a charge of $3,500 for one package of drugs. This covered entity at page 3117 paid

$326.

I have more. I will not tick through them all, but we have here numerous instances of covered entities submitting invoices to HRSA showing that they paid for drugs, the wholesale commercial price, not the 340B price.

Similarly, I'd like to show an invoice that shows exactly how these transactions are effectuated. This is page 1842 --

THE COURT: Excuse me, on the six or so that you specifically identified starting with 1463, can you tell me who the covered entity is?

MS. TALMOR: I can. So with 1463, it's Beverly Hospital.

5834 is the University of Utah.

1837, this -- 1837 was the $326 charge. This also corresponds to the invoice I have here at 1842. I think this invoice is important for showing who it is that's making the purchases.

So this is an invoice where St. Joseph Medical Center, a covered entity, makes the purchase. They are listed as the "bill to."

Franciscan Pharmacy Tacoma is listed as the "ship to," the delivery location. And the covered entity, St. Joseph, actually paid $326 and $274 for packages of Lilly drugs. At least one of these drugs is -- one of the ones that was pleaded

in the complaint are penny priced; in other words, the ceiling -- 340B ceiling prices is a penny and the covered entity is paying this much.

So contrary to the portrayal in the brief, these are not purchases nominally made by covered entities. These are not purchases made by pharmacies. These are covered entities paying more than the celling price. This is the basis of HRSA's letter, and this is the basis of HRSA's threat to impose civil monetary penalties.

Now aside from instances where covered entities have actually paid the celling price, in other instances, covered entities have been denied the ability to make the purchase at all. So the administrative record contains significant proof of that, too.

And I brought more than I think I have time to discuss, but for instance, 3314 shows Lancaster Health Center documenting medications that it was unable to purchase through 340B because those purchases were going to be dispensed to its patients through an outside pharmacy.

One last one I will discuss is 1597. This is a covered entity documenting that when it goes to place an order of Lilly medications through a wholesale distributor, that the price it is shown for every medication is the wholesale price, not the 340B price.

So Lilly's finding is based on actual evidence that

covered entities are both being denied the discounted pricing or actually paying the wholesale pricing.

Lastly, as far as the factual basis, I would direct Your Honor to two of the sworn declarations in the administrative record. Importantly, 7261, which contains an explanation of how the covered entity purchasing and their replenishment dispensing operates.

Now Lilly has submitted a declaration purporting to explain how the covered entity purchases operate. That's the Asay declaration, and I apologize if I mispronounce Mr. Asay's last name. That's on the docket at 129-3. Now that declaration, we believe, is neither accurate nor admissible. Mr. Asay declares that he is the senior director of government strategy. I do not believe that as a senior director of government strategy that qualifies him to opine on how large commercial pharmacies obtain and receive medications or how covered entities operate. In other words, we dispute the factual basis for his opining on how completely other business entities operate.

Putting that aside, his depiction of how covered entities make purchases is just belied by evidence in the record. So I won't read this because of limited time, but at page 7261 of the record, we have a sworn declaration of a covered entity explaining how it purchases these drugs, how it maintains title, how it operates through the pharmacy.

THE COURT: And who's sworn declaration is that?

MS. TALMOR: This declaration comes from a Mr. Donald A. Simila, S-I-M-I-L-A, of the Upper Great Lakes Health Center. I think this entire declaration, which begins at 7260, contains several really important points for this discussion and for Your Honor's review.

This is a covered entity in the Upper Great Lakes in the Upper Peninsula of Michigan. This covered entity serves a 10000-square-mile service area with 11 different sites. So forcing all of its patients to obtain their medications from one site, whether that's the one in-house pharmacy or one contract pharmacy.

Either way, I think this declaration shows it's patently unreasonable. These individuals live many hours from -- you know, from one end of the service area to another, and with extreme weather concerns. So this declaration documents how impossible it is for this health center to serve its patients through one location as Lilly's policy requires.

One additional declaration, this begins at 7255, this is the declaration from the CEO of a covered entity in Georgia. This covered entity explains that while they do have an in-house pharmacy --

THE COURT: I'm sorry, would you give me the number again?

MS. TALMOR: 7255.

THE COURT: Okay. Got it.

MS. TALMOR: While this covered entity in Georgia does have an in-house pharmacy, it's only open eight to five, and it's only capable of serving about 40 percent of its 25,000 patients. This covered entity has 11 different sites in Georgia, five of which don't even have an in-house pharmacy. So this covered entity has patients that are significantly in poverty and rely on its contract pharmacy network to obtain their medications.

So while there is more I can say on the facts, if Your Honor doesn't have questions on that, I'd like to turn to the statutory interpretation question.

THE COURT: Go ahead. Turn to that.

MS. TALMOR: Your Honor, in response to our portrayal in the briefs of these facts, Lilly offers no cogent response to the evidence of overcharges and pricing denials. Instead, Lilly largely ignores this evidence, criticizes the covered entities for submitting two similar complaints, and blames the covered entities for not adhering to its policy.

Lilly also tries numerous tactics to cloud what is a remarkably clear statutory command. The question for this Court to resolve is not whether Section 340B contains any explicit delivery instructions, but whether Lilly is violating Congress's command to provide discounts to covered entities.

I'd like to explain why we believe Lilly's statutory

interpretation violates bedrock cannons of statutory interpretation. As Your Honor has noted in previous discussions, the 340B statute doesn't address delivery specifically, but the Supreme Court has repeatedly explained that courts must read a statute as a whole, and must interpret the relevant words not in a vacuum, but in reference to the contract's structure, history and purpose to determine Congressional intent.

Here, those factors each point in the direction that Congress created a comprehensive scheme to allow safety net providers to actually access discounted medications. The law does not permit a regulated entity to erect barriers that frustrate Congress's purpose just because they're not set forth explicitly in the text.

So since 1992, the statute has conditioned Medicaid access on Lilly honoring its PPA, or Pharmaceutical Pricing Agreement, under which the amount it requires covered entities to pay cannot exceed the ceiling price. So the core command of the statute is plainly --

THE COURT: Who sets the ceiling price?

MS. TALMOR: It's set through a statutory formula determined by HHS.

THE COURT: Is it HHS, is that -- is it also set by HRSA?

MS. TALMOR: I'm certain they have a role. As far as

how the ceiling price is set, I don't know the mechanics of that, but I understand it to be a complicated statutory process.

THE COURT: That's good. I don't have to decide that issue.

MS. TALMOR: I don't believe that is in dispute, Your Honor.

The core command of the statute plainly requires Lilly to sell discounted drugs to covered entities. So briefly, I'd like to explain why Lilly's focus on the absence of an explicit statutory command about delivery, why that runs afoul of the Supreme Court's recent explanation of statutory interpretation in Bostock versus Clayton County.

That was the case, Your Honor, where the Supreme Court held that it is clear that Title VII's prohibition of discrimination because of sex encompasses sexual orientation and transgender status, because even though the drafters of a bill may not have anticipated the --

THE COURT: I'm familiar with that case and that holding. So take it the next step. You don't have to tell me about the case.

MS. TALMOR: Thank you, Your Honor. I think its holding and its analysis is directly applicable because here, what Congress has done is establish a scheme that requires manufacturers to ensure that purchases by a covered entity do

not exceed the ceiling price. So whereas Congress didn't detail where the drugs must be delivered, that doesn't mean manufacturers can refuse to deliver them to a place that they actually can be used by patients.

Congress also didn't instruct Lilly what payment method to accept, but if Lilly required all covered entities to pay in pennies or unobscure foreign currency, that would clearly be unlawful, too. Congress is not required to detail the minutia of a legislative scheme for it to have effect. And that's why I invoke Bostock because Congress said that there is no such thing as a cannon of doughnut holes where the failure to speak directly to a specific case within a broad rule creates an exception, but when Congress chooses not to include exceptions, courts apply the broad rule. And I think that there are plenty of other statutes that are written in similarly-broad rules but have been interpreted over the years, such as the antitrust statutes which include -- have been interpreted to provide liability for different types of behavior besides just actual price fixing.

So I think that it is a common task for courts to interpret broad statutory language to determine whether actions contravene Congress's intent. And here, Lilly's restrictions where it will deliver drugs to just one location per covered entity, where covered entities are actually paying far above the ceiling price, where individuals are not being able to

access their medications, it clearly contravenes Congress's intent even without looking to the kind of outpouring of statements from Congress in the last six months confirming that point.

So on the interpretive point, there is no interpretive doctrine of which I'm aware where Congress is required to detail the minutiae of every aspect of a transaction. It's enough that Congress commanded that purchases don't exceed the ceiling price.

THE COURT: So let me ask you a question about the enforcement process. So the enforcement letter basically asserts HHS's and HRSA's view of the violation. So how does Lilly contest that if it chooses to disagree?

MS. TALMOR: Exactly as it has done, Your Honor. We have not moved to dismiss on the violation letter. We've only moved for summary judgment. So we're not arguing that it's not justiciable. So this process is playing out exactly as Congress intended.

The agency charged with enforcement has found a violation. It has issued the equivalent of a cease and desist letter, and Lilly can challenge it in this court. So this is as Congress designed, and it's directly analogous to other agency enforcement scenarios as well.

THE COURT: So the opposition to the quote, cease and desist order, end quote, is through judicial action?

MS. TALMOR: Yes, Your Honor.

THE COURT: Okay. So this would not be something -- we're not going to talk today about ADR too much, but it would not be something that would come within the ADR --

MS. TALMOR: No, Your Honor.

THE COURT: -- process?

MS. TALMOR: No, Your Honor. The ADR process allows covered entities and manufacturers to sue each other before the agency. It doesn't determine the agency's enforcement and it doesn't allow Lilly to challenge the agency's view.

THE COURT: Okay.

MS. TALMOR: So Lilly's counter argument that the statute requires it only to offer drugs is demonstrably wrong. So the Court cannot focus on a single phrase that manufacturers shall offer to the exclusion of necessary language in the same statutory subsection.

Now, we've explained in our briefs that the offer language Lilly relies on that manufacturers shall offer the drugs, that was added in 2010. It imposes a separate nondiscrimination requirement that manufacturers may not preference or prioritize commercial sales over 340B sales, say if there's a scarcity.

So we believe that Lilly also violates that provision because when a commercial purchaser buys Lilly's drugs, there are no restrictions on where those drugs are delivered, whether

it's a healthcare provider or a pharmacy chain. They can have the delivery location at any lawful site, but --

THE COURT: Presumably that gets worked into the price of the drug, doesn't it, with a non-340B purchaser?

MS. TALMOR: I'm sure that the price incorporates all of the terms of the sale.

THE COURT: Right. So let's say you have a non-340B purchaser in Alaska. And so in order to get the drugs delivered there, the cost of getting it there and delivering it in some remote part of Alaska has to be factored into the transaction, right?

MS. TALMOR: I'm sure it's factored in, but two responses, Your Honor. One is that Lilly is already delivering drugs to these contract pharmacies, whether they're 340B drugs or commercial prices. So Lilly isn't being asked to deliver to any new location by honoring its 340B requirements.

But more importantly, Congress specified the price for these drugs. So Lilly isn't allowed to impose additional obligations on top of that for covered entities.

The point being that when Congress instructed that -- the "shall offer" language, that is a separate requirement that did not abrogate Lilly's preexisting obligation to ensure the covered entities don't pay more than the sales price.

So these are two separate requirements in the same statutory subsection. And we think that Lilly's argument tries

to splice the statute into separate phrases and ask the Court to read them in a vacuum, which goes against the Supreme Court's admonitions.

THE COURT: Can you wrap up this part of the argument for sake of time?

MS. TALMOR: Yes.

Lilly's argument also violates the presumption against ineffectiveness. The Supreme Court has also made clear that courts will select an interpretation of a statute that furthers rather than obstructs Congress's purpose.

Here, Congress knew when it created the program in 1992 that only five of covered entities had an in-house pharmacy. The rest of the covered entities already relied on outside pharmacies when this program was created.

Congress would have to speak clearly if it wanted to exempt covered entities from the standard business practices of the day. So in reality, in order to be able to accept delivery of drugs and dispense them to patients, an entity has to have state licensing, a DEA registration, licensed pharmacists, controls, software, et cetera.

Most of these covered entities do not have the ability to accept Lilly's drugs in-house. And its response that it allows one contract pharmacy is no response because as the record shows, these covered entities often treat patients over hundreds or thousands of miles. They cannot all go to the same

location for medicines. So Lilly cannot fulfill its statutory obligation just by offering to sell drugs to one location.

One additional and I think critical canon of interpretation that I think Lilly's argument violates, the Supreme Court has forbidden courts from narrowing a provision's reach by inserting words that Congress chose to omit.

Now, this is one point that the court and Judge Stark in the Astra Zeneca case did get wrong, we think. That court wrote that Congress had considered particular statutory language in 2010. In reality, in 1992, when Congress created the 340B program, the initial draft of the bill that was considered in the Senate would have limited 340B sales to only drugs that are dispensed on site at a covered entity or -- sorry, in-house by the covered entity or on site.

Before the bill was enacted, Congress chose to remove that restriction from the bill. Congress wrote a statute that would largely mirror Lilly's view of it today. Then Congress removed those restrictions so that 340B can be accessed by covered entities who cannot dispense drugs in-house or on site.

Now, at 140 Supreme Court 1725, the Supreme Court forbids courts from narrowing a provision by inserting words. That is exactly what Lilly asks this Court to do.

Finally on the statutory analysis, Lilly charges that the government is providing a defense of the letter that's not found in its text. Your Honor, that is incorrect. Lilly is

pointing to the fact that in the violation letter, HRSA quoted the offer language, and Lilly construes that as only relying on the offer language.

On the contrary, the letter repeatedly discusses the requirement of the 340B statute as a whole. It invokes the Pharmaceutical Pricing Agreement, which is what Lilly signed back soon after, if not in 1992, to access the program. The letter lays out that HRSA believes that Lilly is overcharging covered entities and failing to offer them the same terms as commercial purchasers.

The letter fully discusses the statute's requirements. We're not offering any new justification here. And the fact that in our brief we discussed the evidence in the record and all of the different information that HRSA gathered, that's also not uncommon.

The APA doesn't require the agency to write a legal brief in the form of a violation finding. A violation finding issued by an agency will often be a brief recitation of statutory requirements, and then a finding that an entity is in violation of them. The entity will challenge it, and then the record on which that conclusion was based will be presented to a court. So this is common place and HRSA didn't need to write an analysis --

THE COURT: In the government's view, is Lilly justified in imposing any interpretations or restrictions or

conditions on the way in which it distributes the 340B drugs pursuant to that program? I mean, can it say -- when you say in the enforcement letter that they are in violation, they are not doing what the statute says, and your reason for saying that is because they've added some things like specific locations, and in something with respect to the non-340B purchasers having a preference, that sort of thing. So is Lilly permitted to do anything in order to fulfill its promise to make the 340B drugs available?

MS. TALMOR: I think that's a really important question, Your Honor. And the answer is that Lilly is required to treat 340B sales like commercial sales. So Lilly is not required to deliver drugs to the moon. That line in the advisory opinion perhaps was unfortunate and should not be taken literal.

Lilly is not required to do things for 340B purchasers that it does not do in the commercial context.

THE COURT: And is that because of the 2010?

MS. TALMOR: No.

THE COURT: The nondiscrimination?

MS. TALMOR: HRSA had issued guidance which clearly contains that requirement before 2010, and HRSA believed that manufacturers already had to treat covered entities on par. But in 2010, Congress codified that requirement. So we would take the position that the statute could fairly be read to

imply that before, but it's explicit now.

And so if Lilly -- I have here and I probably don't have time to read from it, but I have here and would point Your Honor to the 1994 and 1996 guidance. And that guidance issued early in the program's enactment explained, especially the 1994 guidance. It goes into detail that manufacturers, if they use wholesale distribution arrangements, they need to let 340B purchases go through them if they allow purchasing agents.

The terms that are allowed for commercial sales should be available for 340B sales, too. And the bottom line, the agency explained in 1994, is that if a manufacturer imposes a restriction that has the effect of limiting purchases or limiting access by a covered entity, that violates Congressional intent and is not permissible.

THE COURT: So the underlying fact of these sales, these 340B sales, is that the number of purchasers, not covered entities, but the ultimate consumers who are getting them through basically a network of pharmacies without restriction, so whoever it is that the covered entities decide can be their point of distribution can be a point of distribution, right?

MS. TALMOR: Not exactly, Your Honor.

THE COURT: Well, let me finish my question, and then you can fix it in all the ways it may need to be fixed.

So basically a covered entity has unfettered discretion as to how it distributes these drugs. And it's

chosen to you use a vast network of pharmacies and distributors and so forth. That means that the number of drugs sold by Lilly is going to also be much more expansive. So the distribution will have greatly increased over these years because of these interpretations. Can we agree on that?

MS. TALMOR: No, Your Honor.

THE COURT: No? Lilly's not having to distribute more drugs now than it did in 1990?

MS. TALMOR: I think that Lilly's portrayal is inaccurate. The program certainly has grown for various reasons, but partially because Congress has expanded the list of covered entities. But what's important here is who the purchaser is. The purchaser that's relevant here is the covered entity. And so the amount of 340B drugs that are purchased from any manufacturer is limited to the amount of drugs that are prescribed through covered entities to their patients.

This is the reason I brought in these pieces of the administrative record. The pharmacies are not purchasing these drugs. So the covered entities -- you know, our nation's healthcare safety net has grown. There are more patients who rely on safety net providers.

They're also -- it's well known that there's been consolidation in healthcare, both among safety net providers and non-safety net providers. So I gave the example of covered

entities that have ten or 11 sites over a very large geographic area. These covered entities may be writing more prescriptions and serving more patients than they did in 1990. And so the program has grown by volume because there are more patients getting their care through safety net providers.

THE COURT: Well, that's really my point, that the volume of the distribution has increased since the program was first formulated.

MS. TALMOR: The volume of prescriptions written by covered entities for their patients has certainly increased.

THE COURT: All right.

MS. TALMOR: But that doesn't mean that the program is operating in any way different than Congress intended.

THE COURT: No, no. You've conceded the point that I was trying to raise, and that is, Lilly's having to produce a lot more drugs now under this program and make them available to patients than they did when the program was first established and they agreed to these terms.

MS. TALMOR: Certainly. And in 2010, through the Affordable Care Act, one of the things that Congress did was expand the list of covered entities --

THE COURT: Right.

MS. TALMOR: -- but that just means there are more prescriptions, not --

THE COURT: Okay. Okay. So take that point, Lilly is

having to create more 340B drugs than it did initially. So for whatever reason, they're having to manufacture more drugs, and Lilly says that the economics of that are such that they're losing money, or at least they are not able to cover the costs of that because there are more controls in the 340B system, that it's gotten sort of out of control. It's like standing in front of a fire hydrant.

So how is Lilly supposed to respond when there's basically no limitation on the distribution?

MS. TALMOR: Your Honor, Mr. O'Quinn can correct me if I'm wrong, but I do not understand that to be Lilly's allegation. Lilly alleges in its complaint that it cannot give up access to medication and Medicare Part B, which it gets through its participation in 340B, because those government programs are provided with billions of dollars in annual revenue. Lilly takes in huge amounts of money through government health insurance programs. And it's a classic carrot and stick devise that Congress created. Lilly is able to obtain huge amounts of revenue through government programs in exchange for participating in this program that is a critical part of our safety net.

THE COURT: Right. So if it's all gravy for Lilly's, what's their complaint?

MS. TALMOR: Profit, Your Honor.

THE COURT: So they are not -- it's not enough gravy.

Is that what you believe their position to be?

MS. TALMOR: Your Honor, one of Lilly's most recent --

THE COURT: Is that true?

MS. TALMOR: Yes.

THE COURT: They're making a profit but not as much as they want to and they think they're entitled to. Is that how you interpret their position?

MS. TALMOR: Yes, Your Honor. Lilly in one of its most recent earnings reports to investors, investors credited 340B with having increased revenues -- 340B restrictions with increased revenues.

Now, I tried to print but could not get it large enough to be useful, but in the administrative record and cited in our brief, there are graphs that show what happened when Lilly's restrictions went into effect. And on a screen where it can be enlarged, I would encourage Your Honor to take a look at those graphs because they show that when Lilly's restrictions went into effect, its 340B sales fell off a cliff, and it's wholesale commercial price units ticked up.

And we have graphs in the record that demonstrate the huge loss to covered entities every month, and those coincided with Lilly reporting to investors that its earnings had increased as it restricted this program.

So Lilly can choose not to participate in Medicaid and Medicare Part B, and contrary to their portrayal, my

understanding is that not all manufacturers do participate in this 340B program. But Lilly is benefiting from government insurance programs and trying to cast off its obligations. And it's doing so by portraying these sales as being an accounting fiction for covered entities, and that's simply not true.

We have shown in the record that covered entities are being denied of these purchases. And while it is true, as Your Honor said, that the network of contract pharmacies has grown, these sales are still tied to prescriptions written for patients of covered entities. And that's why I say that the portrayal in the Asay declaration is not accurate and cannot be credited.

THE COURT: Okay. Now we've gone over your 20 minutes. So I'm going to ask you to step aside and let Mr. O'Quinn argue, and then you'll come back on rebuttal.

MS. TALMOR: Yes, Your Honor. May I ask if you would like me at that point to address the takings of APA claims I did not get to?

THE COURT: You decide how to use your rebuttal time.

MS. TALMOR: Thank you, Your Honor.

THE COURT: Mr. O'Quinn?

MR. O'QUINN: Thank you, Judge Barker.

I prepared a few demonstratives that refer to things in the briefs and that we've discussed at prior hearings, and I have copies with me. I don't intend to --

THE COURT: You may hand one up.

MR. O'QUINN: Thank you, Your Honor.

THE COURT: And give one to your distinguished opposing counsel.

MR. O'QUINN: And I don't intend to march through those, Your Honor, but I may reference some of them along the way.

THE COURT: All right.

MR. O'QUINN: Again, thank you, Judge Barker. May it please the Court, John O'Quinn --

THE COURT: Mr. O'Quinn.

MR. O'QUINN: -- on behalf of Eli Lilly.

The question before the Court today is Lilly's obligation. It's not a question of whether the statute permits Lilly to do various and sundry things. It's whether it affirmatively prohibits Lilly from doing them. And the question is whether or not Lilly is required to deliver to an unlimited number of contract pharmacies in a situation where contract pharmacies are indisputably making hundreds of millions of dollars off of the 340B program.

There's nothing comparable to this in the commercial transactions that Lilly engages in. There's nothing like this model that the covered entities and the contract pharmacies have entered into that resemble the commercial transactions that Lilly engages in. And this is certainly not what Congress

intended in 1992, and it is not required by the statute, nor is it consistent with the Constitution to put these burdens on the manufacturers of outpatient drug manufacturers alone.

So as Your Honor knows, the case has taken a number of procedural twists and turns, but we're here before you today on cross motions for judgment on the agency's May 17th determination letter that Lilly's distribution policy violates the 340B statute.

I think it's important to recognize what the May 17th letter addresses and what it does not. The May 17th letter was a determination that Lilly's policy violated the statute. And what is Lilly's policy? Lilly's policy is that it will distribute drugs that are purchased by covered entities to the covered entities, or if they don't have their own in-house pharmacy, to a single contract pharmacy.

Lilly's policy is that it will not distribute drugs to an unlimited number of contract pharmacies. And so much of what my friend from the Justice Department began her presentation with today is simply irrelevant to the question of what is Lilly's policy.

I could walk through and spend time, but I don't think it's particularly relevant to the issues before the Court, but the fact is that many of the things that she referred to are not overcharges that occurred at all. They are opportunities the covered entities say that they lost because they could not

purchase through the contract pharmacy, but the record is clear, and our reply brief spelled this out and attached a declaration from Ms --

THE COURT: Does the policy make the costs that were cited unsupportable?

MR. O'QUINN: Well, it makes it so that a covered entity should never be charged more than the ceiling price. What the covered entity cannot do is to facilitate a purchase that is in fact by a contract pharmacy for delivery to a contract pharmacy where it will then enter into -- and this is the words of the government's declaration -- the neutral inventory of the contract pharmacy, and then be dispensed to whoever happens to come along as part of a backward looking replenishment theory that did not exist at the time that Congress adopted this statute.

And that is part of the root of the problem here, Your Honor. This program has expanded massively, not just because Congress has increased the number of covered entities. And it has. It has ballooned over the last decade into the second largest federal drug program, second only to Medicaid Part D involving some 30 billion in discounted purchases a year constituting nearly 10 percent of overall drugs sales.

No one would have thought that in 1992, and frankly, I don't think they would have thought that in 2010. What has happened since then is the ballooning of these contract

pharmacy arrangements in which it's no longer covered entities and a contract pharmacy working hand in hand with inventory that's intended for 340B patients. Instead, and this is all laid out in the government's own declaration, this is the Pedley declaration, paragraph 10 that was attached to the government's reply brief. And what you see is that orders now are not placed by the covered entities. They're not delivered to the covered entities. And they're not dispensed to the covered entities patients, and there is no control by the covered entity when the drug arrives at its destination.

Instead, what happens, Judge Barker, is that allegedly, 340B patients are identified after the fact. They are not identified at the time of the transaction. They are identified after the fact.

THE COURT: So what difference does that make to Lilly's that the contract pharmacies are not the point of distribution anymore, that it's leaping over all of that and going directly to the consumer?

MR. O'QUINN: So, Judge Barker --

THE COURT: More market share for you, isn't it? It's more earnings?

MR. O'QUINN: Well, Judge Barker, when a ceiling price applies and you're required to in some cases give your drugs away for free, then there's no more market share. And, in fact, it's not even that drugs are given away for free. Lilly

then bears the cost of shipping them. So they're actually given away at a loss.

THE COURT: Ms. Talmor's assertion to the Court that Lilly is making a ton of money over these sales is not true?

MR. O'QUINN: Oh, I don't think that she was saying that Lilly's making money off of 340B sales. What she's saying is that the fact that Lilly can participate in the Medicare or the Medicaid program means there are other sales that Lilly can make that are ultimately reimbursed by government insurance, that it is the opportunity to participate in that that then comes with the obligation to give away this -- these drugs for free, or at celling price.

THE COURT: That's an important point. So is the bottom line impact of the 340B program on Lilly a loss? Do you run a tally as to just the 340B program?

MR. O'QUINN: So, Judge Barker, I don't know the answer to that question. I don't know off the top of my head. But certainly it is costing Lilly substantially, and what you have, and certainly a way that Congress could never have intended, you have the contract pharmacies who are profiting substantially off of this. And that's not money that -- that's not money going somewhere that Congress intended for it to go. And the idea that Lilly has to simply sit by and watch while this takes place when, number one, it's inconsistent with the text of the statute; number two, it's inconsistent with the

structure of the statute; and number three, it's inconsistent with the history of the statute simply doesn't follow.

And let me take each of those points in turn because the text of the statute simply provides two things: One, that Lilly shall offer the 340B-covered drugs to covered entities at ceiling prices, and that Lilly will provide the ceiling prices for drugs that are, quote, purchased by covered entities.

And we respectfully submit that under either one of those prongs, the statute does not permit these covered entities to require Lilly to distribute to or through what are really in effect, in a material way, purchases by contract pharmacies.

All Lilly's required to do is to make the offer. And Lilly makes the offer and it does the unremarkable thing. It just says "We'll sell you, a covered entity, as much as you want, but we're only going to deliver it to you as opposed to somebody else; or if you don't have the ability to receive it, we'll deliver it to a single contract pharmacy."

THE COURT: So you acknowledge Lilly has this obligation to offer the drugs to covered entities, right?

MR. O'QUINN: I agree.

THE COURT: That's the obligation?

MR. O'QUINN: I agree.

THE COURT: Okay. So the covered entity, once it receives it, can do what it wants to with it, right?

MR. O'QUINN: That is right in the sense that the statute imposes limitations on what the covered entity can do, and this is an important point. If you look at 42 U.S.C. 256b, subsection (a)(5)(B), it says "A covered entity shall not resell or otherwise transfer the 340B discounted drugs to any person who is 'not a person of the covered entity.'"

So part of that tells you that not just does the text of the statute only require that we offer, but the structure of the act as a whole does not contemplate these unlimited contract pharmacy arrangements because they essentially coerce Lilly into doing indirectly what the covered entity cannot do directly, which is to transfer the 340B drug to the contract pharmacy. And it is clear that at that point in time, the contract pharmacy, number one, takes title to the drug; and number two, no restrictions on what the contract pharmacy does with the drug; and number three, that it can dispense it to anybody who comes along. But this is all theoretically because it was replenishing.

THE COURT: But couldn't the covered entity do that, too?

MR. O'QUINN: While the covered entity potentially could, Your Honor, the statute prohibits that. And one of the concerns here has been that there is very, very limited oversight by HRSA, by HHS, with respect to the covered entities. In fact, it's part of why -- we think the statute --

THE COURT: Now wait, let me back you up. So you agree that under the statute, that Lilly's has elected to participate in, they came forward and made the offer to provide these drugs, that they could go to the covered entities. If they went to the covered entities, that's -- in Lilly's view, that's the end of it because the covered entities can do whatever they want to. They can set up a state fair booth and do whatever they want to with those.

MR. O'QUINN: They may be violating the statute, but Lilly's policy will send as much to a covered entity as the covered entity orders, or as much to a single pharmacy if the covered entity doesn't have --

THE COURT: Covered entity, theoretically, could greatly expand the distribution of these drugs so that it equals what it is now, right? Theoretically?

MR. O'QUINN: Judge Barker, I think theoretically, sure, that would be possible. But what would happen at that point is that you would have direct oversight with respect to what the covered entity is doing with the drugs, which doesn't exist now and goes to one of the flagrant inconsistencies in the government's position with how it's treating manufacturers versus how it's treating the covered entities.

And specifically, our position is that the statute is clear. It requires that we make an offer. We make the offer. It requires that we give the discounted price when the covered

entities purchase. And when the covered entities purchase, we provide the discount price.

We will not sell to them when they are trying to send it somewhere else. And to the extent that there was an errant example that Miss Talmor identified from September of 2020, it may be that a wholesaler charged something that it shouldn't have charged when the program was set up because the government had not allowed -- had not posted Lilly's notice. So there may have been some confusion in September, but that's not the basis for their violation letter. And it's really extraneous to what's -- to what Lilly's policy is all about.

Lilly's policy, we think, meets the statute unequivocally. But even if you think that the statute is susceptible to multiple readings, and I think Judge Stark's rationale for vacating the December 30th advisory opinion in the case in Delaware applies equally to the May 17th determination. And it would at least require vacature here, which would give the government the opportunity to go back to the drawing board and to talk with manufacturers and identify what some of the fundamental problems are here.

And I want to identify one of them to you in particular. The government's prior approach to the statute was to say that covered entities were not responsible for violations caused by contract pharmacies. Why? "Because the 340B statute does not address pharmacy use."

Now that's referenced at slide 7 in the materials that I handed up. It's referenced at page 39 of our reply brief.

THE COURT: Where did that come from?

MR. O'QUINN: What I'm quoting from, Your Honor, is from the GAO, and it's GAO circular report 21-107. And what this is, this is HRSA telling the GAO why it wasn't taking certain enforcement actions against covered entities. This came out in December of 2020, and we cited it in paragraph 78 of our amended complaint. But it's not in the administrative record because the government is just ignoring facts that are inconvenient to its position, and ignoring the inconsistencies in the positions that it has adopted over the years, which, as Judge Stark said in the context of the advisory opinion, but is no different than the context here, have materially shifted over time.

These inconsistencies, at a minimum, require the vacature of the May 17th determination as being unlawful agency action or being frankly the height of arbitrariness and capriciousness. Also illustrated by the fact that Lilly had no opportunity to respond to any of the things that Miss Talmor was talking about here at the podium at the beginning. They ran an entirely one-sided process. In fact, it's almost a little bit remarkable. They relied on the complaints that were submitted for the ADR procedure. Of course this is the ADR procedure that the Court has enjoined from applying to Eli

Lilly.

They relied on the complaints. They relied on submissions that were attached to those complaints. But they wouldn't even take a meeting with Eli Lilly. We attached several letters to our reply brief asking for meetings to address some of these issues. It did not happen.

So it is -- however you want to look at it, the May 17th determination, at a minimum, must be vacated because it is arbitrary. It is capricious. It's based on inconsistencies in how the government has treated the 340B program over the years. It's based on inconsistencies on how the government has treated manufacturers as opposed to covered entities. And it's based on the assumption that Judge Stark explicitly rejected just last month that the government's view of the statute is the only permissible one.

That is demonstrably not true. How do you know that that's not true? For almost 15 years, what Lilly does today is all that the government permitted. So the idea that Lilly is violating the statute as opposed to policy preferences that are being articulated by the government today, that can't possibly be right.

The statute can't possibly prohibit what Lilly is doing because -- at least categorically, because that is all that the government permitted for almost -- for over 14 years. And as Judge Stark noted, what the government allowed covered

entities to do, of course, affected what the obligations of contract pharmacies could be viewed as.

THE COURT: Where does the policy get its footing for limiting the points of distribution so that people who would otherwise benefit from this program, who are remote to the distribution point, can't get it?

MR. O'QUINN: Yeah, so -- and I want to -- there are a couple of points with respect to that. I mean, first of all, patients absolutely still can get 340B drugs. Now, whether or not the covered entities, or in the case of covered entities working with contract pharmacies, provide the discount to the patients is another issue. And in fact, one of Lilly's concerns has been not only are the contract pharmacies profiting to the tune of hundreds of millions of dollars at the expense of manufacturers, but they are also profiting at the expense of patients. And indeed as recounted in our brief, both the GAO and the Inspector General have documented that 340B patients are in many cases not getting any type of discount when they are getting their drugs through a contract -- through the contract pharmacy.

Again, whether the covered entity or not wants to provide it, I'm not saying that they have to, but of course part of the Congress's rationale in adopting this, it is not to create some massive lucrative revenue stream on the backs of a small subset of Medicare and Medicaid participants. That would

raise very serious takings concerns in the words of the Supreme Court in Armstrong versus United States, the courts have to be alert when you have a system that "forces some people alone to bear public burdens which in all fairness and justice should be born by the public as a whole."

It is not the responsibility of the manufacturers to provide some lucrative revenue stream. As opposed to discounting their costs, all that that meant was that if they were in the business of dispensing those drugs, that was a cost to them.

THE COURT: So answer my question.

MR. O'QUINN: So with respect to your question, it is -- the statutory language requires that the discounts be offered to the covered entities. They are. And with the unremarkable only condition being we will only provide the discount. We will only sell to you by delivery to you.

THE COURT: Yes, to a simple pharmacy, right?

MR. O'QUINN: Sure.

THE COURT: So --

MR. O'QUINN: Which --

THE COURT: Where does that come from?

MR. O'QUINN: Well, where that comes from -- I guess I'd flip it around. What prohibits that? That is the question. All the statute requires is that we offer them to them. We do offer it to them. And we will deliver it to them.

The statute doesn't require -- the statute doesn't say you must offer it to them for delivery to an unlimited number of contract pharmacies.

THE COURT: Are you doing that? Is Lilly doing that today?

MR. O'QUINN: Lilly is absolutely offering, and covered entities are absolutely purchasing. If you look at the declaration of Heather Dixson, which was attached to our reply brief, her declaration specifically lays out there were some 15 covered entities that the government identified in its reply brief.

We went through and looked at every single one of them. And Lilly is actively selling to at least ten of them today. And for ten of them, it is selling through direct purchases. For two of them, it is selling through a contract pharmacy because they designated a contract pharmacy. And for the other five, the only reason that Lilly's not selling to them is because they didn't designate a contract pharmacy or they didn't otherwise place an order directly.

That is the -- so the fact is that Lilly is selling to them. Lilly is distributing to them. But the statute doesn't require delivery to contract pharmacies. If Congress had wanted to require that, Your Honor, Congress knew exactly how to do that because Congress did do that in a different provision of the exact same act but for different

beneficiaries.

So the Veteran's Healthcare Act has a different provision. It's codified at 38 U.S.C. 126H3. And it made it clear that if a federal agency was purchasing drugs, that the drugs could be purchased by or delivered to "a commercial entity operating under contract with that federal agency."

They didn't provide that with respect to the 340B statute. Now my friend from the government says "Look at the legislative history. Look at some provision that wasn't adopted. It supports our interpretation." Well, of course Justice Scalia would tell you that you're already on pretty thin ice when you're looking at unadopted legislative history.

But respectively, to the extent that you're inclined to look at it, I think it supports us because what it shows is that Congress was unwilling to require outpatient drug manufacturers to sell or to deliver to even a single contract pharmacy that was located on site with the covered entity.

Congress wasn't even willing to require that and -- because that's what it would have required. It would have required sales and delivery to an on-site contract pharmacy. That didn't get adopted. So all Congress required is that the offer --

THE COURT: Is it Lilly's view that ever since the statute was first enacted back in 1990, whenever it was, that all the variations on the theme and all the actions taken by

HHS to implement and expand this program are improper? They are without force and effect? That Lilly doesn't have to pay attention to what HHS has said in implementing its statute?

MR. O'QUINN: Well, Judge Barker, I think, first of all, with respect to the 1996 guidance and the 2010 guidance, as Judge Stark articulated in his opinion about a month ago, those were guidance documents that were issued really principally to and for the benefit of covered entities as opposed to imposing obligations on manufacturers.

And indeed as Judge Stark observed, the December 30th advisory opinion, which the government has now withdrawn and Judge Stark's opinion has vacated, we submit it's still a live issue and it should be vacated here for the same reasons that the May 17th determination should be vacated.

But that was the first --

THE COURT: On that point in particular, why isn't their withdrawal sufficient?

MR. O'QUINN: Well, I think under Seventh Circuit precedent, it would only be moot if the government wasn't continuing to espouse the same view. And we know that the government is espousing the same view because it's articulating it in its defense of the May 17th determination.

In other words, it's relying on its same interpretation of the statute. They are a little bit different in the sense that at least the advisory opinion had articulated

an agency theory. Now I didn't fully ever understand what that agency theory was, but now the government has abandoned the idea that there even has to be an agency relationship in order for Lilly and other manufacturers to be obligated, which is just yet another inconsistency.

If you look at the government's opening brief, it says that the statute compelled this agency approach that was in the advisory opinion because that's what it was defending. And now, it doesn't say that the agency theory matters -- or it says the agency theory doesn't matter, even though in the opening brief, they said it was compelled by the statute. So it is an inconsistency and disconnect.

THE COURT: It does represent something of a change in the government's position to have withdrawn that advisory letter. I mean, it doesn't have any potency. It doesn't have an impact now as such.

The arguments may somehow filter through and need to be addressed again, but I think you can rely on the fact that they withdrew that letter from the general counsel for what it is. I mean, yeah, they withdrew it, which means they don't rely on it as such any longer.

MR. O'QUINN: Well, I hear --

THE COURT: I don't think you need to hang on to that point.

MR. O'QUINN: I understand, Your Honor. And to be

clear, I don't think there's any dispute that the main event here and now is the May 17th determination. And the only footnote that I would add to that is the fact that the advisory opinion is part of the administrative record.

It shows that the government is, you know, at least at some point was relying on it, considering it, doing something with it. I agree with you.

THE COURT: At some point, yes, but not today.

MR. O'QUINN: And perhaps it's not at this point, but the main point is that I think that all of the issues, vis a vis the advisory opinion, that they would rise or fall with the May 17th determination for the same reason --

THE COURT: Make your remaining points, if you would, sir, so that we can not stay here until the court reporter is chewing on her computer in lieu of lunch.

MR. O'QUINN: Thank you, Your Honor. I think just a few -- just a few additional points. As I said, with respect to the "shall offer" requirement, Lilly satisfies that because it offers the drug. And what the government is demanding, what the covered entities are demanding, is not something that Lilly does with, you know, anything remotely resembling this in the context of commercial relationships. And to the extent there's a dispute about that, there's nothing on that in the administrative record, which at a minimum would require vacature.

Second, these -- as I was explaining a little bit earlier, these are not drugs that are purchased by covered entities in any meaningful sense of the term. Not in economic terms. Not in legal terms. And I did want to point you to, as we attached to our reply brief, the example of a covered entity contract pharmacy contract that we were able to identify. It was from Dallas County 340B.

That's another -- just as a side note, that's another remarkable thing about this administrative record. There's not a single contract in it. Not a single contract between a contract pharmacy and a covered entity in it. And you would have thought under the Supreme Court's decision in State Farm and other cases, that in entering its interpretive decision, that it would have been important to the government to think about what the consequences of that interpretation are going to be. Where's the money going to go? What are the nature of these relationships? That sort of thing. There's none of that that's in the administrative record and certainly no rationale or articulation of that in the May 17th determination. But to close out the point --

THE COURT: So there are no contracts between covered entities and contract pharmacies?

MR. O'QUINN: In the administrative record.

THE COURT: Right.

MR. O'QUINN: Not a single one. Now we've attached

one that we were able to find. And what it shows you is that this idea that the covered entities take title, much less that they maintain title as the 2010 guidance expressly required, is pure fiction. It is pure kabuki. Because what that contract shows is that the only time that the covered entity ostensibly has title is between shipping out and delivering to the contract pharmacy, and never touches -- it never gets delivered to them. As I said, they are not the ones who placed the order. It doesn't get delivered to them. And then when it gets to the contract pharmacy, the contract pharmacy takes title and it puts it in with its general stock, and it gets dispensed to anybody.

That is not what this statute was ultimately all about. That was not something that could have been contemplated. And that is certainly not in any sort of plain English sense of the term what a purchase by a covered entity -- but you don't have to just take my word for that. You can look at the way the covered entities describe it and there's an example of this at slide 22 and at slide 23.

And the covered entity, what was its complaint with Lilly? It was that it was "refusing to give pricing to covered entities contract pharmacies." And that's at page 3117 of the administrative record, and there's a similar one at page 5834 of the administrative record.

So we think that the statute simply does not compel

what the government is requiring, and that requires vacating the May 17th determination. But even if the Court thinks that the statute is ambiguous on this point -- and silence is not ambiguity. They acknowledge in 1996 --

THE COURT: So would Lilly's obligation, and with this opportunity that Lilly's has, evaporate entirely if the covered entities dropped out of the equation? What if the contract pharmacies basically started performing as the covered entities?

MR. O'QUINN: So I think as a matter of federal law, they couldn't do that. And this was another point that I think Judge Stark noted in his opinion. Congress went through and specifically delineated 15 types of covered entities. And it didn't add a 16th by implication. But that is what is in effect happening here.

And you can say well, and the government does, that these are not really sales to the contract pharmacies, that these are sales to the covered entities, but it's only nominally so when you follow both where -- the way that the transactions work and you follow who is responsible for them, and where title gets taken.

Then the most galling part of it all, I think, and this is referenced in the administrative record, there's an Inspector General report that talks about how this replenishment model works. And it makes the point that because

these transactions are happening after the fact, part of what gets decided is very, very arbitrary, and we have no --

THE COURT: What does that mean, "These transaction are happening after the fact"?

MR. O'QUINN: I'm sorry. Let me be clearer.

So a patient comes into a contract pharmacy and gets the drug dispensed to them. And in many times, they just pay full price. Sometimes they get a discount, but many times they pay full price, not because of anything that Lilly or the manufacturers do, but because of the policies and programs of the contract pharmacies and the covered entities.

Nonetheless, what will happen is that sometimes weeks or months after the fact, the contract pharmacies themselves or a so-called third party administrator -- and this is referenced in the government's own declaration, the Pedley declaration -- a third party administrator, many of which are affiliated with the contract pharmacy chains, that they will go back and decide "Well, you know what, I think that actually was a 340B eligible patient." And they will decide -- they'll decide that after the fact. And then they will -- either the third party administrator, or in some cases, the contract pharmacy as the Pedley declaration says -- will make a purchase, or put in an order nominally on behalf of the covered entity for a 340B discounted drug saying "Well, I want to replenish my drug."

And with respect to that patient who came in, the

parameters of deciding whether or not that patient was actually the patient of a 340B entity can vary widely. This Inspector General report identified that sometimes they'll look at whether or not the patient had been a patient of the covered entity within the last 60 days. Sometimes they'll look at whether it had been a patient of a covered entity almost 12 months after the fact.

And so what you have is, you know, these algorithms in which they'll tweak little knobs, and suddenly a lot more people will be considered to have been eligible purchasers, and then they'll go back after the fact and say okay, Eli Lilly, or wholesaler to Eli Lilly, send us drug on behalf -- at these decreased 340B prices.

That's nothing at all resembling the world in which Congress imagined that covered entities were going to get the benefit of a lower price in order to reduce their own costs.

THE COURT: Okay. Can you wrap up?

MR. O'QUINN: I'll end on that point, Your Honor. This is not what the statute requires. It is not what the statute contemplates. And we think that based on the statute alone, the Court should invalidate the May 17th determination, but even if the Court thinks that the statute is susceptible to multiple interpretations -- and silence would not be a reason why, silence is not a delegation of authority as the Supreme Court has held, silence doesn't give them the operating room

here when the text and the structure and the legislative history are all inconsistent. But even if the Court thinks that there were some ambiguity, because of the arbitrariness, the changes in positions and the arbitrariness of this whole policy -- excuse me, process in determining there is a violation, at a minimum, the May 17th determination should be vacated.

THE COURT: Thank you very much.

MR. O'QUINN: Thank you, Judge Barker.

THE COURT: Miss Talmor, what would you like to say on rebuttal?

MS. TALMOR: I will try to keep it to as little as possible.

THE COURT: Okay, good.

MS. TALMOR: Your Honor, Lilly is continuing to present a factually inaccurate view of what is going on here. The portrayal that Lilly is giving would suggest that individuals are going into pharmacies, obtaining controlled substances and other pharmaceutical drugs without the pharmacy having any idea where that prescription came from.

I don't know about you, but any time I've ever walked into a pharmacy, I had to present a valid prescription from a valid prescriber in order to obtain a prescription. In other words, when a pharmacy fills a prescription, they know who the prescriber is.

Now the pharmacist who hands the drug to the patient may not have to determine at that moment whether that particular prescriber is or is not a covered entity, but they will know who the prescriber is.

So these aren't algorithms that are tweaking variables and determining that suddenly there are more eligible patients. That's simply not accurate. And that's why we are objecting so strenuously to the portrayal in the Asay declaration, which is simply inaccurate.

The pharmacy is determining whether the patient who presented the prescription obtained that prescription from a covered entity, and where that prescription was obtained from a covered entity, the drug is eligible for 340B.

THE COURT: So a covered entity under that explanation can be a physician?

MS. TALMOR: The physician needs to work for a covered entity.

THE COURT: But if you don't recognize who the physician works for and you're the pharmacy, you wouldn't know, right?

MS. TALMOR: I don't want to attest to --

THE COURT: Your explanation makes it sound like the pharmacy knows at the time of the transaction whether the prescription came from a covered entity.

MS. TALMOR: I think that when -- I certainly don't

know what's in the mind of the individual pharmacist, but I think that a pharmacy hands out a prescription on the basis of -- that they are charged legally with verifying that that is a valid prescription.

THE COURT: Well, no, wait. That's not quite what I'm getting at here. So we'll just take an Indianapolis-centric example.

So my husband goes to the CVS to pick up a prescription that is a 340B covered drug from Lilly. And it was prescribed by his doctor, but not from Indiana University Health. It's just his doctor. And the pharmacy does not know to trace it back to a covered entity, which I assume Indiana University Health would be because it's in that category of 17 types of covered entities.

So I don't understand how you can say that the pharmacist would know in sort of a simplistic transaction like that to trace it back to a covered entity.

MS. TALMOR: Because it's not the retail pharmacist, Your Honor. It's that the pharmacy itself verifies that the number -- that the patient was seen by and prescribed by a covered entity.

So it doesn't have to be done at the point of sale. I think we're in agreement -- well, our position is that it doesn't have to be done at the point of sale. I think we're in agreement that it's not always done at the point of sale, but

our position is that the pharmacy verifies that the patient obtained the drug from a covered entity, and that's matched up.

So the point is that this is not being determined after the fact through algorithms that predict whether X number of 340B patients may have come through the doors in a given month. It's matched to prescriptions by a patient of a covered entity.

I also would very much like to take issue with Mr. O'Quinn's portrayal of the evidence I brought here. Now for time, I certainly didn't tick through every example, but we cited to a lot more of them in our brief. But this is not an errant example from September 2020.

This is evidence that covered entities are paying more than the ceiling price. I won't tick through them again, but I'll direct Your Honor to -- we have in our brief pages of evidence, and it's certainly not limited to December 2020.

In fact, one of the examples I have here is where a covered entity was subject to significant overcharges in one month months after Lilly's policy went into effect.

THE COURT: So what if the Court ordered, what if this Court ordered Lilly to continue to offer the drugs to covered entities at prices that were not above the celling price. That would be my order, let's say.

That would be compliant with the program, right? And if they did charge prices that were above the celling price, or

they refused to provide drugs to non-covered entities, there wouldn't be a -- the violation by Lilly's would be only with respect to covered entities and the celling. They would have permission to do whatever else they wanted to do, right?

MS. TALMOR: I don't think that reflects the nature of what the transactions -- how they actually work. So I'd like to turn back to this invoice, and I think it would help clarify.

This invoice shows that the drugs are shipped from and received by a pharmacy that both list a state pharmacy license number and a DEA registration number, because that's what you need to deal with pharmaceuticals.

But they also show that the drugs were ordered by, paid for by, billed to, everything. The purchaser is the covered entity. That's what's going on here.

So when Lilly keeps insisting --

THE COURT: So who's the purchaser?

MS. TALMOR: The purchaser is St. Joseph Medical Center.

THE COURT: So you know that to be a covered entity or is somehow otherwise established?

MS. TALMOR: It is known to be a covered entity. I do not believe that's in dispute, and it's in the administrative record.

THE COURT: Okay. So because it's generically that,

right? I mean, it's in the category of 17?

MS. TALMOR: They have to -- it is one of the 15 types of covered entities, yes.

THE COURT: Fifteen, yeah. Okay. So that's how you know it's a covered entity because it fits the definition of those -- that category of 15 --

MS. TALMOR: Yes, Your Honor.

THE COURT: -- providers?

MS. TALMOR: Yes, Your Honor.

THE COURT: So as long as Lilly's is providing the drugs to that provider, it's a covered entity, and it keeps it under the ceiling price that it's required to do, then Lilly has complied with the requirements, right?

So I understand that your auditors say that they have not done that, but if they did do that, they'd be in compliance; is that right?

MS. TALMOR: I think there are two sides of a coin. So they are required to not charge more than the ceiling price, but they also are forbidden from denying these sales. And so Lilly is largely ignoring this evidence.

So I think there are two types of evidence here. So there are covered entities that have overpaid, that we have the invoices that they have paid more. And then there are other covered entities that have been denied access to the pricing.

We think that's every bit as unlawful. So day by day,

every time a covered entity itself intends to purchase the drugs, and Lilly says "No, you've allocated this one pharmacy, we deny the sale because you want it shipped to a different one," that's a violation and that's subject to penalties.

So I'd like to go back to the example of the provider in the Upper Peninsula. I'm sure Your Honor is familiar with how rural that area is. So Lilly will ship its drugs to one location for this covered entity that serves 10,000 square miles. That is unlawful and unreasonable.

Lilly can't force patients across 10,000 square miles to visit the same pharmacy. And I think it strains credulity that one pharmacy could serve all those patients as well. Lilly violates the statute when it denies these sales every bit as much as when the covered entity actually effectuates the sale above the ceiling price. There are violations each way.

THE COURT: But if there were other covered entities up in the UP, then they'd have to supply them, right?

MS. TALMOR: If there were --

THE COURT: The problem is there's only that one pharmacy in the UP.

MS. TALMOR: There are many pharmacies, Your Honor, and up until last --

THE COURT: Well, covered entity I should say.

MS. TALMOR: The one covered entity serves many patients.

THE COURT: Right. So hear me. If there were more covered entities in the UP, then Lilly would be required to supply them, right?

MS. TALMOR: Sure. Yes, Your Honor.

THE COURT: So the problem is that there's only this one covered entity that is using all the pharmacies up there to distribute the drugs, right?

MS. TALMOR: I don't think it's a problem, but I think that's an accurate statement.

THE COURT: Well, I mean that's why people would otherwise be underserved if you didn't have that distribution network, right? That's a problem. That's what you told me was the problem.

MS. TALMOR: Yes, Your Honor.

THE COURT: That 20,000 people have to use one pharmacy.

MS. TALMOR: Yes, Your Honor.

THE COURT: They probably have to come in on dogsleds or somethings in the UP. So is Lilly responsible for the fact that there are no other covered entities up there?

MS. TALMOR: Lilly is responsible for denying sales to that covered entity. That covered entity has many locations -- not many. I forget the exact number. I have that here. That covered entity has multiple locations. Lilly is responsible for not denying sales to that covered entity that has many

locations.

THE COURT: So you're saying that Lilly's refusal to deal with the network, which is actually pharmacies, not the covered entity, not in the group of 15, but in its distribution network through pharmacies, right?

MS. TALMOR: I think that is Lilly's portrayal, and I think that is inaccurate.

THE COURT: Okay, so clarify that.

MS. TALMOR: HRSA does not require Lilly to deal with pharmacies in the way that Lilly portrays. HRSA requires Lilly to honor a purchase when a covered entity requests to make a purchase. When the covered entity buys Lilly's drugs, Lilly is required to sell the drugs.

I think it may help. Let me turn to this. Mr. O'Quinn said that no one would have anticipated that the program would work this way when it was passed in the '90s or even in 2010. That is inaccurate.

We can show that because this is guidance that the agency issued in 1996 that explains how the program should operate. It largely mirrors its current operation with one distinction. So in this guidance, which is published in the Federal Register in 1996, HRSA explains that the use of contract pharmacies is not allowing pharmacies to access the program. It's only providing those covered entities a process for accessing the pricing.

THE COURT: Read that last part. It's only what?

MS. TALMOR: Providing a process for those covered entities, which would otherwise be unable to participate, a process for accessing 340B pricing. It does not in any way extend this pricing to entities which do not meet program eligibility.

And equally importantly, it --

THE COURT: What were you reading from there?

MS. TALMOR: This is the 1996 guidance, which is found at 61 Fed. Reg. 43549.

THE COURT: Okay.

MS. TALMOR: It also mirrors several of the program's current operations -- several of the factors that Lilly now attacks.

So Lilly portrays it as though in the past, pharmacists had different shelves with 340B drugs and non-340B drugs and never did the two mix.

The 1996 guidance explains that that's not true. It says that the pharmacy and the covered entity maintain separate dispensing records so that they can keep track of which medications go to patients of covered entities. But it says that maintaining separate inventories would be needless and a waste of space and inefficient. That's in 1996.

Now, the guidance did instruct at that time, and it made very plain that it was a recommendation, it contained

model provisions for covered entities to establish contract pharmacy arrangements in a way that would not violate the statute. And the guidance says in multiple places that the guidance is optional for covered entities. It's recommended provisions. And one of those recommended provisions is that the covered entity contracts with only one contract pharmacy.

It also stated in 1996 that they were studying methods that would allow covered entities to use multiple contract pharmacies and would look into that later, which they did.

But putting that aside, all the way back in 1996, they instructed that separate inventories don't have to be maintained. It's the dispensing records that have to be kept so that they can tie the 340B drugs to eligible patients of a covered entity.

The program has grown over time for the reasons we've previously discussed, but that doesn't mean that the transactions work differently. That doesn't mean covered entities don't purchase the drugs. They certainly aren't nominal purchasers. They are actual purchasers, and they rely on this program to serve their patients.

So I'm from Georgia. Maybe that's why I selected the other declaration of the covered entity from Georgia, but this is a covered entity --

THE COURT: It doesn't explain why you talk so fast.

MS. TALMOR: I've heard that before. I apologize.

This covered entity is in an area, part of which is urban and part of which is suburb, and there certainly are other healthcare providers. But this covered entity serves disproportionally the lower income, the individuals who are below the poverty line across a wide geographic swathe. And I think they do a very good job of explaining why their patients have significant transportation barriers and other barriers that do not allow them to come into the one in-house pharmacy that's open from eight to five.

What Lilly's doing is making the program inaccessible in practice. That's why it's unlawful. Lilly insists that it fulfills its statutory obligation by making an offer to sell drugs. Respectively, Your Honor, we just think that portrayal is disingenuous because this offer is coming with strings that make it inaccessible. And that's why I keep pointing out that there are a web of requirements to be able to dispense drugs, and it isn't reasonable and it isn't practical to limit it so that these large covered entities with tens of thousands of patients for one provider have to funnel them all through one location.

So that simply is not workable in practice, but it also ignores the fact that this offer language Lilly keeps hanging its hat on wasn't in the statute till 2010. Lilly signed it's PPA sometime shortly after the program was created in 1992 obligating it to insure that covered entities do not

pay more than the celling price.

And while we are -- I acknowledge that the facts here are -- there's a lot to it, but I'd like to emphasize that this is not a case where we're here on an evidentiary hearing. This is an administrative record review case where the agency is charged with making its determination. And this Court sits as an appellate tribunal to determine whether they got it wrong, not whether they got the best answer possible, but whether the agency legally erred.

So, Your Honor, this case has to be decided on the basis of this record which contains thousands of pages that support the agency's decision. And respectfully, Your Honor, Mr. O'Quinn's insistence that the letter can be vacated if the Court finds that the statute is ambiguous or has some doubt as to the statute's meaning, that's incorrect.

This is an APA case. Your Honor, the agency didn't look at a variety of policy concerns and write a new rule on a blank slate. This is a finding that a regulated entity is violating the statute.

Your Honor is charged with looking at the evidence, determining whether the agency made a decision that's supported by the record. And that decision must be upheld unless the Court finds that the agency legally erred.

So the agency wasn't required to go out and look and see whether there are any compliance problems anywhere in the

contract pharmacy model. It wasn't required to do all of these things Lilly was requiring it to do, because the agency audits covered entities, audits contract pharmacies. That is a separate arm of the agency enforcement.

In this action that we're before the Court on, the agency determined that Lilly is violating the statute and that's what's before the Court.

THE COURT: All right. Let's wrap it up there.

MS. TALMOR: I'd like to make two last quick points if I could?

THE COURT: Thirty seconds each.

MS. TALMOR: Lilly complains about this being a one-sided process. That's actually not a legal error. There's no requirement in the APA or the 340B statute for Lilly to have engaged in -- sorry, HRSA to have engaged in an adjudicatory process.

HRSA was entitled to make its own determination, and then it can be presented to this Court for review. So there's no error there.

Lilly also makes much about patient cost, but the statute doesn't dictate the price covered entities charge their patients. The statute dictates the price that Lilly charges covered entities, so there's nothing wrong with patients sometimes paying more than what the covered entity pays. That's by Congressional design.

THE COURT: Very good.

Okay. Thank you, lawyers, for honing your presentations and basically advancing these two really urgent issues for expedited priority consideration by the Court, and thereby allowing the other issues that you've raised to remain pending and not requiring the Court to specifically address the ADR and the constitutional issues in particular.

So I will play the cards that are laid and try to resolve these immediate issues on an expedited basis. Now "expedited" is in the eyes of the beholder. And from your point of view, I know you'd like me to rule from the bench, but not really. You don't really want me to rule from the bench because I have to march through it in a more cautious and deliberative way.

But I do give you my word that I'll try to get that done, and give you some guidance on these issues while reserving the other issues to see if we need to reconvene to address those.

So thank you for positioning the case in a way that's more manageable. And hopefully, based on these rulings, you'll get some indication of what level of controversy remains and also the relative importance of those issues to decide if, as we say around here, a full church wedding is necessary.

It's awfully nice to have you in court. I hope you have a good rest of your summer. Take your vaccines. Make

sure everybody you know takes their vaccines. And stay safe. Good day.

MR. O'QUINN: Thank you, Your Honor.

COURT CLERK: All rise.

Court is adjourned.

(Court adjourned at 1:50 p.m.)

****

CERTIFICATE OF COURT REPORTER

I, Laura Howie-Walters, hereby certify that the foregoing is a true and correct transcript from reported proceedings in the above-entitled matter.

/S/LAURA HOWIE-WALTERS August 4th, 2021

LAURA HOWIE-WALTERS, FCRR, RPR, CSR
Official Court Reporter
Southern District of Indiana
Indianapolis Division