UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF INDIANA
INDIANAPOLIS DIVISION

ELI LILLY AND COMPANY, ET AL.,	
Plaintiff,	CAUSE NO.: 1:21-C-00081-SEB/MJD
-v-	Indianapolis, Indiana **February 26th**, 2021 10:15 a.m.
ALEX M. AZAR, II in his official capacity as Secretary of Health & Human Services, et al,	
Defendants.	

Before the Honorable
SARAH EVANS BARKER, JUDGE

OFFICIAL REPORTER'S TRANSCRIPT OF
MOTION FOR PRELIMINARY INJUNCTION

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

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(Open court.)

THE COURT: Good morning.

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

THE COURT: Isn't it a miracle that we're making this happen?

MR. O'QUINN: Yes, Your Honor.

THE COURT: I look out at the room and see you all doing what you're supposed to do, spread out, masked, all ready to go. And I know we've got people connected electronically. It's sort of a wonder. A year ago, we wouldn't have thought we could do this. So thank you for your cooperation and the logistics of this. And I think we'll test our system and make sure we're getting through to everybody.

We have a lot of people on the line. I'm not going to do a role call, but I want people to be able to tap in as they plan to do. So good morning again. You may be seated.

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

MS. PIERSON: Thank you.

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

(Call to order of the Court)

As I've been thinking about your lawsuit, I thought that probably the happiest person that has any connection with this lawsuit today, the happiest person, is Mr. Azar. He is probably very glad to have somebody else manage some of these

issues.

So I know, because I've been informed by my clerk, that, Mr. O'Quinn, you intend to be the spokesperson for the plaintiff's, right?

MR. O'QUINN: Yes, Your Honor.

THE COURT: I see my friend and colleague, Ms Pierson, over here. Good morning.

MS. PIERSON: Good morning, Judge.

THE COURT: I will recognize everybody who's at the tables, if you think I should. Otherwise we'll just count on recognizing you, Mr. O'Quinn. What do you think?

MR. O'QUINN: Yes, Your Honor, I think Miss Pierson was going to introduce who's here on behalf of Eli Lilly.

THE COURT: All right. That will be great.

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

THE COURT: Yes, Ms. Pierson?

MS. PIERSON: Thank you, Judge. Nice to see you again.

THE COURT: It's good to see you as well.

MS. PIERSON: Let me introduce you to my partner, Brian Paul. Brian is at Faegre Drinker as well. This is my colleague, Diana Watral. She's at Kirkland and Ellis with Mr. O'Quinn. And then along with us today is the general counsel of Eli Lilly, Anat Hakim.

THE COURT: Nice to see you this morning as well.

Representing the defendants is Miss Talmor from the Department of Justice. I see your face in my monitor, Miss Talmor. Good morning to you.

MS. TALMOR: Good morning, Your Honor. I am here on the line, and I must say, unfortunately I am having trouble hearing Your Honor.

THE COURT: That would be bad if you can't hear me. So let me see if that helps. Does that help at all?

MS. TALMOR: It does somewhat, Your Honor, and I certainly don't mean to imply that you take off your mask. I am not sure what setup is there, but it looks on my screen as though the link that you're on may be muted. Is that possible?

THE COURT: Might be muted? Let me see. Oh, you're pretty astute at that, but I have to see how to get -- no, we just leave it there? My instructions are "Don't touch the technology, Judge Barker." So we'll see if somebody else can fix it.

MS. TALMOR: I could be wrong. It looks like it may be picking up from a different mic because it shows --

THE COURT: See this microphone right here (indicating)?

MS. TALMOR: Yes, Your Honor.

THE COURT: That's the one that's picking me up rather than through the computer. But you're not hearing it very well, is that it?

MS. TALMOR: I can hear it better now, Your Honor.

THE COURT: Is that better if I just put it right there?

MS. TALMOR: Yes, Your Honor, although again, I didn't mean to imply that you need to do that for the entire hearing, but it is better.

THE COURT: Well, you'll be able to read the level of fatigue by how high I've held this microphone up during the hearing. That will be one of those nonverbal signals that all good trial lawyers should watch for. I'll keep my voice up and I'll try to keep this microphone nearby as well. But absolutely if you can't hear me, you need to say "Judge, please, a little louder" or something. I won't be offended, okay?

MS. TALMOR: Thank you, Your Honor.

THE COURT: How's everything in Washington?

MS. TALMOR: It's wonderful. We have sunny weather today.

THE COURT: Well, that's good. I didn't mean to get a Washington Post briefing. So the weather is fine.

MS. TALMOR: Yes, Your Honor.

THE COURT: All right. So I want you to know that I've read your filings of course. I understand that we're here for purposes of the Court's consideration of the issues related to a preliminary injunction on the ADR requirement that HHS is

imposing in the context of the 340B Drug Pricing Program.

The preliminary injunction is in some ways contextual on the rest of the claims. So I think I have a fairly good understanding of the lawsuit that has been filed that's given rise to the request for injunctive relief. But if you want to cover those things in a running start sort of way, that will be okay, to get the issues teed up that you want to raise.

I'll have some questions that I'll ask as we go along, but you go ahead and make your presentation and I'll try to sift in my questions as they're relevant to what you're talking about so that you're not thrown off your train of thought too much.

So it's your motion, Mr. O'Quinn, and I'll hear you first. Do you want to make an opening statement?

MR. O'QUINN: I do have a little bit of background that I wanted to begin with, Your Honor, and I wanted to ask just a couple procedural questions as we --

THE COURT: Fine. Let me just ask Miss Talmor. Do you want to make an opening statement, too?

MS. TALMOR: Your Honor, I would like to make an opening statement --

THE COURT: Wait, wait. First of all, you're talking way too fast, and we're getting a little feedback. So you're going to have to slow it down and speak at the pace I'm speaking at here, which is admittedly slow.

COURT REPORTER: She's not very loud either.

THE COURT: The court reporter says you need to increase the volume as well.

MS. TALMOR: Thank you, Your Honor. I do have an opening statement, but I'd also like to raise an objection if I may?

THE COURT: Okay. Is it -- excuse me, is it an objection to our proceeding today?

MS. TALMOR: No, Your Honor.

THE COURT: Okay. Well, what is your objection?

MS. TALMOR: Fifteen minutes before the hearing, Lilly's counsel e-mailed myself and I believe your courtroom deputy a set of 38 slides it would like to present. We have not had time to look at those in detail, but at a glance, they contain matters that are outside the briefing and irrelevant to the motion. And we object to Lilly's reliance on those slides that we just received.

THE COURT: Okay. What I'll do -- I'm not putting ideas in Lilly's head, they've got enough ideas, but I bet they think that springing things on opposing counsel is turn about and therefore fair play. That was part of their briefing, too, that they've been greeted with things that popped up overnight.

So we don't approve of that, of course. So I'll let Lilly's go forward with their slides, and you make a note of which ones you think are beyond the briefing, beyond the

evidence, and file your objection and I'll rule on that before I rule on the substance of the motion. Okay? Can you do it that way?

MS. TALMOR: Yes, Your Honor. Thank you.

THE COURT: All right. I'll hear your opening statement, Mr. O'Quinn, and then I'll hear Ms. Talmor's opening statement, and then back to you to present your oral argument.

MR. O'QUINN: Thank you, Judge Barker. With respect to the slides, we did email them to Miss Talmor and to your deputy about an hour and 15 minutes before the hearing was scheduled to begin. If I may, I have printed copies that I've brought. I e-mailed them to the government because they weren't going to be able to be here in person.

I don't intend to make a presentation and to walk through the slides methodically, but I may reference a few of them along the way, and I thought they would be helpful for Your Honor, because they do call --

COURT REPORTER: If you could slow down, please.

MR. O'QUINN: I understand. I apologize. We're all learning in the new environment.

THE COURT: That's right. We all have to adjust.

MR. O'QUINN: But with Your Honor's permission, may I approach and hand Your Honor a copy of the slides?

THE COURT: Yes, you may. Thank you, sir.

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

THE COURT: Miss Talmor --

MS. TALMOR: Thank you, Your Honor.

THE COURT: -- these are the slides I received.

MS. TALMOR: Thank you.

MR. O'QUINN: And, Your Honor, I'm happy to proceed however you prefer. If you would like me to keep my mask on, I will, of course, do so. If it's clearer for me to take it off, I will do that, but whatever Your Honor thinks is appropriate. I'm happy to proceed as we are.

THE COURT: If you would step this way a little bit and take off your mask, I think that would be a safe distance and we'll hear you better.

MR. O'QUINN: Sounds good.

Thank you, Judge Barker, and may it please the Court. John O'Quinn on behalf of Eli Lilly. Now while arising against the backdrop of the 340B program and questions over how that regime is supposed to operate, the issues presented in the motion before the Court today go to the heart of the checks and balances that are built into our constitutional system of government, first and foremost under the constitution itself, and then also under the Administrative Procedure Act.

As the Supreme Court has recognized, these structural safeguards fundamentally exist to protect liberty by ensuring that, on the one hand, there's political accountability, and on the other, there is judicial independence, as well as

transparent and reasoned agency decision making.

The administrative dispute resolution rule that was adopted by HHS on December 14th creates an adjudicatory regime that respectfully is the worst of both worlds. It is neither impartial nor is it accountable. Instead it is the product of hurried decision making that a sunsetting administration rushed out the door based on an earlier rule-making proceeding that had been abandoned years earlier.

In so doing, the agency issued a rule riddled with inconsistencies and those inconsistencies are exacerbated by the government's attempt to defend it from constitutional challenge here.

There are thus three independent but related reasons that Lilly is likely to succeed on the merits. First, the rule contravenes Article II by vesting powers reserved for principal-officers and functionaries who are merely appointed by the Secretary of Health and Human Services, not the President, with the advice and consent of the Senate.

THE COURT: Those are the panels?

MR. O'QUINN: Those are the panels, Your Honor, that's right.

Second, the rule runs afoul of Article III by permitting these HHS employees to adjudicate a private rights dispute between private parties determining monetary damages and equitable relief, the hallmarks of the judicial power of

the United States which is reserved to courts under Article III.

And so the rule violates the APA both in terms of how it was promulgated and what was promulgated. Given the constitutional issues as stake, irreparable harm follows, and the public interest likewise supports injunctive relief. And so as such, we respectfully submit that a preliminary injunction should be granted. And that completes my opening statement, Your Honor.

THE COURT: Thank you, sir.

MR. O'QUINN: Thank you.

THE COURT: Miss Talmor, I'll hear your opening statement.

MS. TALMOR: (Inaudible)

THE COURT: You're muted, Miss Talmor.

MS. TALMOR: My apologies. I'm sorry.

THE COURT: All right.

MS. TALMOR: Thank you.

Good morning, Your Honor.

THE COURT: Good morning.

MS. TALMOR: There's nothing unusual in the agency's dispute resolution process created in this rule; nor is there anything unforeseeable in Lilly being subjected to its decision since Congress mandated creation of the ADR process ten years ago.

Lilly and other pharmaceutical companies have wreaked havoc in critical segments of our nation's healthcare safety net in the midst of a pandemic. I have --

COURT REPORTER: Could you please speak louder, please?

THE COURT: Wait just a minute. You have to speak louder, please.

MS. TALMOR: Let me bring my device closer. I apologize.

THE COURT: That will work.

MS. TALMOR: Is that better? I also could get headphones but is this -- does that solve the problem?

COURT REPORTER: That helps.

THE COURT: The court reporter says yes, that helps. So I know that, and it's okay that you're reading something, but you look down when you're doing that and your voice goes down, too. So just hold your papers a little higher.

MS. TALMOR: Thank you, Your Honor, for alerting me to that.

Lilly and other pharmaceutical companies wreaked havoc in a critical segment of our nation's healthcare safety net in the midst of a pandemic by abruptly reversing course and refusing to follow HHS's decades-old guidance interpreting the 340B statute.

Now HHS, the agency charged with implementing and

enforcing 340B requirements, is poised to determine through the process called its directive whether Lilly's unilateral changes comply with the statutory obligation. But Lilly refuses to let that straightforward administrative process play out by challenging the 340B rule on nearly every conceivable ground and insisting that the claims now pending in the ADR process must instead be brought in Federal Court.

Lilly seeks to wrench from the agency the authority Congress granted it. This attempt should fail. The 340B statute is unambiguous that claims for 340B violation must be presented in the agency's ADR process. And the Supreme Court confirmed that principle explicitly in Astra versus Santa Clara County. Moreover, Lilly essentially is asking this Court to ignore long-settled administrative law with potentially disastrous consequences for other agencies since the ADR board created a new rule that mirrored other agency processes upheld by courts for the past century. The ADR Rule also complies with the APA's requirement. Lilly's emergency motion should be denied.

THE COURT: Thank you, Miss Talmor, and we got every word of that. Very good.

MS. TALMOR: Thank you.

THE COURT: Mr. O'Quinn, you may make your substantive argument.

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

With the Court's permission, before I dive into the constitutional issues themselves, I do think that it might be helpful to say just kind of a few words about the context in which this dispute arises, some of which responds to what Ms. Talmor had to say. Now I'm happy, of course, to proceed however Your Honor would like, and --

THE COURT: That would be an appropriate line of response because she has said things that warrant a reply from you.

MR. O'QUINN: Sure. And so -- and I think it's also helpful because, as Your Honor knows, there is more pending before the Court than just the motion today. There are other claims in the case. The motion today, of course, is focused on the ADR Rule itself and the constitutionality of that rule, but having some additional context I think is helpful.

So I'll start with Congress's adoption of the 340B program in 1992. At a high level, that program mandates the drug manufacturers "must offer a ceiling price," which is a heavily discounted price off of market prices, sometimes discounted all the way down to one penny, and must offer that to 15 specific types of nonprofit healthcare providers as specifically identified by statute, and they're called covered entities under the statute. It's Section 256B, Subsection A1.

And the purpose of the 340B program is to help serve vulnerable, low-income, indigent patients of these entities,

reducing the price of outpatient pharmaceuticals for such patients among other things. And providing these heavily-discounted prices is a condition for drugs being eligible for reimbursement under certain aspects of Medicare and Medicaid, which are, of course, ubiquitous programs providing insurance to more than one-fifth of the nation's population.

This is thus, Your Honor, the rare government program where as a condition for participating, the government requires that one party directly subsidize another party rather than, for example, provide discounts for the government, for the government to then make a direct spending appropriation.

Given the massively-below market prices that the covered entities can demand for their purchases, Congress also enacted restrictions on reselling or transferring a covered outpatient drug to a person who is not a patient of that entity to prevent double discounts and other types of abuses.

And in 1996, HHS promulgated guidance, not a regulation, certainly not a statute, nothing with the force and effect of law, but guidance that explained how covered entities that did not have their own in-house pharmacy could work with one and only one outside pharmacy, a contract pharmacy, in order to purchase these types of drugs. And that, Your Honor, was the state of affairs for nearly 15 years. For nearly 15 years.

Then in 2010, HHS adopted new guidance. Again, not a rule. Certainly not a statute. Not anything with the force and effect of law in which it explained that covered entities could contract with an unlimited number of pharmacies. And the result was that the number of pharmacies proliferated exponentially with private for-profit nationwide pharmacy chains driving a massive expansion of what was a narrowly-tailored program designed to serve the most vulnerable and turning it into a for-profit enterprise in which patients often still pay full or near full price, but the contract pharmacies pocket most or all of the discount.

Now this exponential, and as our amended complaint points to, 1,400 percent increase --

THE COURT: Is there a requirement that the savings be passed on to the purchaser of the pharmaceutical?

MR. O'QUINN: So the statute doesn't require that the savings be passed on directly to the purchaser. Certainly the purpose of the statute was ultimately to benefit indigent, vulnerable patients. And what has happened is instead of them being benefited, these profits are being pocketed by contract pharmacies reaping hundreds of millions of dollars in profits, and at the same time --

THE COURT: Are those pharmacies limited to sales under those circumstance to patients of the covered entities?

MR. O'QUINN: Well, they are supposed to be, and that

is part of the concern, Your Honor, is that they are supposed to be limited in any scenario to sales to patients of covered entities. But what you have is practices where you don't just simply have local pharmacies supporting the covered entity. You have dozens, even hundreds of pharmacies far flung across the country, including -- I can give an example. There's an example in the slides at slide 18. There's an entity, a covered entity, here in Indianapolis that has a contract pharmacy in Hawaii. And it's very hard to see how that is benefiting the indigent and vulnerable population here in Indianapolis.

The proliferation of contract pharmacies brought with it the increased risk of abuse of improperly taking multiple discounts. And that's not just Lilly's view, Your Honor. That is something that has been documented in OIG reports, GAO reports, HRSA, the Health Resources Services Administration, audits. And that's laid out in our complaint at paragraphs 49 to 76.

THE COURT: Well, can you ballpark how many covered pharmacies there are? Contract pharmacies I mean?

MR. O'QUINN: There are thousands of them, Your Honor, and I don't recall off the top of my head exactly how many there are. I saw one statistic that's referenced in our slides that, if I may --

THE COURT: I assume there's been a proliferation of

covered entities as well.

MR. O'QUINN: There has not, Your Honor. There's been an expansion of covered entities, and that was part of the Affordable Care Act amendments of 2010. So there were increases in covered entities, but not the type of exponential growth that you've had in terms of contract pharmacies. And, you know, an example of the explosion of these arrangements is at -- I believe it's slide 9, Your Honor, which is referred to in paragraph 49 of our amended complaint.

And if you look also at paragraph 49 of the amended complaint, Your Honor, we point out that the number of contract pharmacies from 2019 to 2020 alone had doubled. And that was after having grown, you know, at a similar rate in earlier years. And the reason that I share all of this and I refer to these reports from OIG and from the GAO and so forth, is that this is the backdrop against which Lilly has put in place a program that is in no way materially different than the one that existed for nearly 15 years.

Lilly saw what was happening and recognized that it had to make some changes because despite pleas to the government to address these concerns, the government simply lacked the political will to take action.

THE COURT: When I was reading the materials you submitted, it did look to me like you went back to what was originally required of Lilly in the issuance that you

presented, let's say in July of 2020, right?

MR. O'QUINN: Your Honor, I would submit that what Lilly is doing is consistent with and indeed exactly what was the state of affairs in 19- -- from 1996 until the year 2010. And nothing about the statute changed in any material way in 2010 vis a vis the issue of contract pharmacies.

THE COURT: Okay. So let me ask you: If Lilly went back to the prior practice based on the July 2020 notice, I assume that you had not been resolving disputes even under that formulation through ADR; is that right?

MR. O'QUINN: Well, that's right, Your Honor. There was no ADR.

THE COURT: No disputes?

MR. O'QUINN: Well, there weren't any disputes that could be brought to ADR because there was no ADR.

THE COURT: My question was more generic. Were there disputes between you and the contract providers, the covered entities?

MR. O'QUINN: Your Honor, I can't speak to whether there was any, for lack of a better word, dissatisfaction between the covered entities and Eli Lilly prior to the summer of 2020.

THE COURT: I was just wondering how they got worked out.

MR. O'QUINN: It's a fair question, Your Honor. And I

do think that what Congress had in mind when it contemplated the existence of this ADR was something that was going to be very mechanistic, that is like literally doing the math on what the ceiling price should be or something along those lines as opposed to what has been promulgated here. And I'll get into that a little bit more when we address the Article III issues.

It is certainly possible that there were disputes or questions over what the prices were that were being charged. I'm just not personally aware of any that were of any significance. There were, as the government has alluded to, some covered entities that sought to pursue private right of action, not against Eli Lilly, but against some other manufacturers in the Astra case that she referred to. I'm not familiar with exactly what the genesis of that was, but I will note this: That in Astra, the Supreme Court decided a very simple and basic question, and that was: Were the covered entities third-party beneficiaries under these PPA agreements, which adopt the statute? That was all the Supreme Court was deciding. And yes, in the background, the Court noted there was the existence of an ADR proceeding, but it certainly didn't pass judgment on any of the issues about the permissibility of it, and certainly not this one, which didn't even exist because the agency took nearly ten years to promulgate regulations.

But I think the key point, Your Honor, in terms of responding to where the government started, you've heard from

the government that Lilly is the one who has somehow upset the apple cart, and that doing so puts patients at risk, but nothing could be further from the truth. As Your Honor noted, what Lilly has done is to go to a program like the one that existed for nearly 15 years. It still provides 340B discounts to all covered entities, and it will continue to do so. It still supports the use of a local contract pharmacy where the covered entities lack their own in-house pharmacy facilities. And above and beyond what existed under the 1996 guidance, Lilly makes insulin available to all contract pharmacies at fully-discounted prices so long as those pharmacies are willing to pass those discounts along to patients rather than pocketing them for themselves. But it is the abuses in the 340B program that gave rise to Lilly's implementation of these changes.

Lilly was transparent. Told the government what it was going to do before it did it. And the government didn't say that that would be a violation of the statute. It said it didn't like it, but it didn't say that it would be a violation of the statute. And what happened is a number of entities then sued the government to try to force its hand against Lilly, and ultimately they succeeded. And that is why we are here both in this motion and in this complaint more generally.

First, the government issued the December 30, 2020, advisory opinion about the contract pharmacy arrangements

purporting to find, for the first time, that manufacturers are obligated to sell to such entities. That is part of the case that we have filed, but it's not part of the motion before the Court today.

And second, after waiting over a decade, the government issued the ADR Rule citing a proposal that it had announced in 2016 but explicitly withdrawn in 2017, and it did so without any additional notice or comment. And that ADR Rule, of course, is at the center of today's dispute.

The statute behind the ADR Ruling -- and what I propose to do, Your Honor, is I'll say a word about the statute and the ADR Rule, and I'll go straight to the Article II issue unless there are other things that you have questions about at this pint.

THE COURT: Well, one of the reasons I asked the question I did about disputes that have arisen before the ADR regimen was imposed was because it reflects on what harm would result if the Court enjoined the ADR process. So it's one of the considerations that goes into the motion that's before the Court in balancing harms and to get a full picture of what the -- what chaos would arise, what bases would be left uncovered if I granted your request to basically enjoin the enforcement of the ADR procedures.

What does that mean in a practical sense because I need to know what was going on before the ADR was imposed and

what the ADR is intended to address. I mean, what kinds of disputes?

MR. O'QUINN: I appreciate the question, Your Honor. And in some ways, it's a little bit difficult to address in the abstract in the sense that because there was no ADR for nearly a decade, it wasn't like there was this mechanism that was being used.

THE COURT: Well, that's why I say I'm confident that -- I mean, I understand there was no ADR --

MR. O'QUINN: Right.

THE COURT: -- but I bet that there were disputes.

MR. O'QUINN: And, Your Honor --

THE COURT: What kinds of disputes is the ADR supposed to address here?

MR. O'QUINN: Well, let me try to answer it this way then. I mean, the ADR, I think, was intended to address disputes over things like determination of ceiling prices, had you done the math correctly essentially. And --

THE COURT: Had who done it?

MR. O'QUINN: I don't think there was any -- I don't think there are any disputes, at least related to today, vis a vis --

THE COURT: Wait, the manufacturer sets the ceiling price, right?

MR. O'QUINN: Well, Your Honor, the manufacturer sets

a number of prices from which a ceiling price is calculated. And to the extent that -- prior to the adoption of the ADR Rule, to the extent that a covered entity thought that it was being charged more than it should under the -- in terms of the ceiling price, what it would do would be to raise the issue with HHS, or to raise the issue with HRSA, and ask HRSA to essentially address it with the manufacturer.

And so that would have been the state of affairs prior to the adoption of the ADR Rule. The ADR Rule then provides a mechanism by which they can initiate a claim, but it's not just -- and this gets to both the Article III issues and some of our Administrative Procedure Act issues. It's not just a claim in which they show up and say to the government that there's been a miscalculation of the price, that we've been overcharged because they're using the wrong numbers, or anything to that effect.

Instead, what came out in the final rule is it puts these panels in the position of adjudicating a dispute between the parties in which the panel will decide, according to the rule itself, monetary damages --

THE COURT: When you say between the parties, who are the parties?

MR. O'QUINN: I'm sorry, Your Honor. The parties in the context of the ADR dispute would be covered entities or their representatives and manufacturers.

THE COURT: And contract pharmacies?

MR. O'QUINN: I don't think the contract pharmacies themselves would be parties to these types of dispute. They certainly have entities that are advocating on their behalf or advocating their interests, or whose interests are aligned with them, but the way that the statute and the regulation operate, it's for disputes between covered entities and manufacturers, not contract pharmacies.

THE COURT: That's how I read it, too, but I didn't know about all the pharmacies. If there's a proliferation of causes of actions under ADR because there's been a proliferation of contract pharmacies, that would be beyond the scope of what HHS's ADR could manage, wouldn't it?

MR. O'QUINN: Well, I think it would be, Your Honor. I think that the proliferation, of course, then ties to the question of, are manufacturers obligated to sell to contract pharmacies or through contract pharmacies if you prefer it the way that the Government tries to describe it, but I think that's a bit of a misnomer, as opposed to two covered entities themselves?

Now that's not part of the motion in front of Your Honor today, but does sort of set the background for both why the ADR Rule was promulgated when it was. It was promulgated in response to litigation that was brought by entities, including representatives of covered entities against the

government to force it to promulgate it, and who were also trying to force the government, separate and apart from the ADR Rule, to take action against Eli Lilly and other manufacturers directly.

And so if Your Honor were to enjoin the rule, and I'll come to the equitable factors in a bit in more detail, although I'm happy to turn to that now if that's what you would like to focus on. I think what it would mean is that the state of affairs would be, in terms of how disputes would get resolved in the meantime, what it was before the adoption of the ADR Rule. And certainly the covered entities and people advocating on their behalf have suggested that the agency itself can take action directly if it thinks that there's a violation of the statute.

THE COURT: Well, yes, that's why I'm interested because I have to know how big an ask this is by you, by Eli Lilly.

MR. O'QUINN: I respectfully submit that it is, in the grand scheme of things, Your Honor, a relatively modest ask. And the reason that I say that is that number one, of course, it is a preliminary injunction in the time in which Your Honor would be considering the resolution of, you know, the ultimate merits here, some of which will potentially be affected by the Supreme Court's decision in Arthrex. That court is hearing argument on Monday in the Arthrex case and would be expected to

issue a decision by June.

THE COURT: Tell me what issues they have in that case.

MR. O'QUINN: That is related to the Article II issue, Your Honor, and specifically the issue under the appointments clause.

THE COURT: All right.

MR. O'QUINN: Then, of course, our complaint asks this Court to address the issue of whether or not, as a matter of law, a manufacturer in Lilly's position is obligated to sell not to covered entities, but to contract pharmacies. And that's not teed up as part of this motion, but I would respectfully submit that the legal answer to that question that is, in our position, properly before Your Honor, the government may or may not agree with that, but certainly our position is it's properly before Your Honor, resolution of that, I think in many ways would moot much of what the concern, vis a vis Lilly's program is, because if, as a matter of law, Lilly is not required to sell to contract pharmacies as opposed to covered entities, then there is no upsetting of the apple cart as the government suggests.

And, of course, our position is that that has to be the interpretation of the statute given it was the interpretation that existed for some 15 years, among other things. But again, that's not before the Court. That's just

to give you some background.

THE COURT: Would you touch lightly on the Article II argument? I don't find that as persuasive as the Article III argument, so just go ahead and give me sort of a distilled sense of it so I make sure I have it. But that one maybe we should leave to the Supreme Court to decide.

MR. O'QUINN: Well, I do think the Supreme Court --

THE COURT: They like it if we do that.

MR. O'QUINN: They certainly can provide guidance. Sometimes it's clearer than others.

So let me start with that, Your Honor. And let me start with the statute because I do think that that colors the entirety of the Article II argument. The 340B statute provides that the secretary can establish a decision-making body to review, "and finally resolve claims made by covered entities against manufacturers" and vice versa. And that the "administrative resolution of a claim or claims shall be final, a final agency decision and shall be binding upon the parties involved unless invalidated by order of a court of competent jurisdiction."

And that is again Section 256B, subsection D3 of the statute. And this language is important. It's been codified as part of the rule. And the -- and the reason that it's important, Your Honor, is because it goes directly to whether or not a decision is being made by somebody acting as a

principal-officer of the United States, but who was not appointed by the President and confirmed by the Senate.

The appointments clause, of course, requires the President's personal involvement in the Senate's confirmation in order to ensure accountability for decisions made under the Executive Branch. And here, because the statute and the regulations create a regime where officers who were not appointed by the President get the final unreviewable word on behalf of the Executive Branch, that is exactly what Justice Alito in the Association of American Railroads case said requires a principal-officer. And I understand that was just a concurrence. His position was then adopted by the D.C. Circuit on remand, and it follows from Justice Scalia's holding for the court in the Edmond case.

So let me start with Edmond because I think that that really does set the table for the appointments clause issue here. In Edmond, the court held that the Coast Guard judges that were at issue were inferior officers, not principal-officers. And the indispensable part of that holding was that they had superior officers who didn't just supervise their work generally, but who could actually review their decisions before they became the decisions of the Executive Branch.

I think it's very important if you look at Edmond, it was not enough that the Judge Advocate General exercised

administrative supervisory authority. It was not enough that the Judge Advocate General could remove these Coast Guard judges at will from a panel. That was still "not complete" control at page 664 of the Edmond decision.

But that was okay. They were still not principal-officers on the facts of that case because, "Supervision of the work of these Coast Guard judges was divided. Not just with the JAG, but with the Court of Appeals for the Armed Forces." And Justice Scalia went on to explain that the power to revise or reverse decisions of the Coast Guard was -- does reside in the Court of Appeals for the Armed Forces. And he proceeded to show that that court's ability to review those decisions made it so that they were not principal-officers. "What is significant is that the Coast Guard judges have no power to render a final decision on behalf of the United States unless permitted to do so by another executive officer."

And respectfully, Judge Barker, that is not the situation that we have here under the statute and the regulations. Once these panels are appointed, any decision that they make by statute is final. It is a final agency decision that is tantamount to something appearing in the Federal Register.

THE COURT: The final on the merits?

MR. O'QUINN: The final on the merits, that's right.

They are the last word --

THE COURT: Because the other agency, what's its acronym?

MR. O'QUINN: HRSA?

THE COURT: Yeah, has to enforce it, right?

MR. O'QUINN: Well, that's a little bit of a dispute between us and the government, but I don't think that it's ultimately relevant in the sense that the statute provides that whatever they decide is "a final agency decision" and that is "binding on the parties," which means it would have -- it has collateral effect.

Now, it is a truism that almost any order of any body has to ultimately be executed by somebody else, but I don't think that that changes anything here in terms of this regime because there will be a final decision that -- and this gets to the Article --

THE COURT: Properly drawn in your view would be some review process that goes up to the secretary who is appointed by the President --

MR. O'QUINN: That's right, Your Honor. If Congress had adopted a regime, and it is -- this is what is more common in agency decisions. This one stands out as being somewhat unique much like the interparty's review that is at issue in the Arthrex case. They're the administrative judges who do the IPRs, the inner-party's review of these patents.

Their decision is a final decision, and it can only be reviewed, in the words of Justice Scalia, "by the third branch." And that is exactly the same here.

THE COURT: Judges are pretty protective of that Article III power.

MR. O'QUINN: And rightly so, Your Honor, because it is an indispensable part of our constitutional design in order to protect everyone, whether they are politically popular or not, against that kind of unpopularity.

So it is -- there's an important -- here you have both an important Article III issue, which is, of course, as the Court's recognized, a personal right, but you also have an important Article II issue, which goes to having a proper decision maker who was properly appointed if you think that these can even be resolved by the Executive Branch as opposed to being something that should be resolved by the Judicial Branch.

And so my submission, Your Honor, is that when you look at Justice Scalia's reasoning in Edmond, and the fact that it was indispensable and a necessary part of the holding, that there was review of the decision by the -- by the -- in that case the Court of Appeals for the Armed Forces. In this case it would be the secretary except by statute, once they are -- and by rule, once they render a decision, it is final. There is no review of it. And that, as Justice Alito, I think, put

it very well in his concurrence in the Association of American Railroads case, he said, "As to that decision, who's the supervisor?" And the answer is there is none.

Now, the government's principal argument is to say "Well, the secretary can remove them at will, so that solves everything." And to be sure, the power to remove -- and Edmond says this quite clearly, I don't run away from this -- the power to remove is a powerful tool, but you have to look at context.

If there is no power to undue the decision, then the power to remove is limited. If you can undue the decision, then sure, the power to remove may be sufficient. And that's certainly the case in the D.C. Circuit's case in re: Grand Jury Investigation, which the government cites heavily in its opposition brief.

Obviously if you fire the prosecutor and replace them with a different prosecutor, they can dismiss the grand jury. They can take -- there's all sorts of actions that they can take to undue the things that the prosecutor has done up until that point. And the same was true, frankly, in Morrison versus Olson, and I think it was also true in the free enterprise case that was before the Supreme Court.

THE COURT: Removing the officer, removing the panelist, would in any event be an after the fact.

MR. O'QUINN: That is exactly my point, Judge Barker,

is that here if you remove the panelists after they have rendered a decision, it is too late to change the decision. And this goes to the point in Professor -- in Professor Gary Lawson's article that we cite in our -- I believe in our reply brief, that says, and he's talking about the IPRs and in the context of what's in the Supreme Court in Arthrex, but he makes the point, just because you can remove the administrative judge does not mean that you can undue their decision.

THE COURT: Wouldn't they have to remove all of the panelists?

MR. O'QUINN: Well, even if they remove --

THE COURT: There are three panelists under the ADR Rule, right?

MR. O'QUINN: So my understanding, I think that the secretary would appoint more than just three to the board at large, but then on a given panel, yes, there would be three who are appointed to --

THE COURT: Well, the board's supposed to be six, minimum six?

MR. O'QUINN: I believe that's right, Your Honor.

THE COURT: It's sort of a confusing rule frankly. At least it's written in a confusing way. I had to sit there and look at it and diagram it to see if I got it right.

MR. O'QUINN: Well, that is probably related to some of our APA challenges to the rule, Your Honor. But in terms of

the Article II issue, this is the key point. Even assuming the secretary can remove them at will, and I'll say a word about that in just a second, but let's just assume that the government is correct in its argument that the secretary can remove them at will, not for cause, but could remove them at will. That only works if you remove them before they make a decision, and that is true of the IPRs at issue in Arthrex.

Once they have made the decision, then under the regulation, and indeed I would submit by statute, that decision is final. It's a final agency action and it is binding. They have spoken. They've gotten the last word on behalf of the United States. And if there's anything that's clear from Article II and our constitutional structure, somebody who gets the last word on behalf of the United States, speaking for the Executive Branch, should be appointed by the President and confirmed by the Senate.

That is our modest argument here, Your Honor. And it is very similar to the one that is pending before the Supreme Court in Arthrex. Now I think --

THE COURT: Now talk to me about Article III.

MR. O'QUINN: Let me turn to Article III. Let me ask Your Honor if Your Honor has any questions about this removability issue. Because the government has argued -- before I turn to Article III. Because the government has argued that they are removable at will. If they weren't, that

is, of course, itself another reason --

THE COURT: Yes, I read the argument. I think I understand it.

MR. O'QUINN: And the only point that I would make on that, Your Honor, before turning to Article III is simply this: And that is that if the government here is now right in its read of the rule, that the secretary can remove these people at will, then what that means is that what's promulgated in the rule about for causal removal by the HRSA administrator once they are appointed to a panel is utterly illusory, because the HRSA administrator just turns to her boss or his boss, and says "I can't remove them except for cause. Could you just remove them at will?" And then she can -- the secretary can just remove them at will.

And, of course, for cause removal was discussed among other things as part of the justification for the fairness and impartiality of these panels despite the lack of using an administrative law judge. And so I think the government's arguments to say that they are removable at will -- which doesn't ultimately matter to our argument, we win either way under our argument, but that argument undercuts the arguments that they made in promulgating the ADR Rule, both about its fairness and about the reasons for not having an administrative law judge.

And ultimately, that would -- either way, that makes

the rule not defensible and a reason to grant the preliminary injunction. And with that, I'm happy to turn to Article III unless there were questions on that.

THE COURT: Please do.

MR. O'QUINN: So with respect to Article III, Your Honor, under the rules, an aggrieved party can file what the rule describes as "an action" for "monetary damages," or "equitable relief." That's 42 CFR 10.21.

Now, whether or not it is predicated on a right that was created by Congress, that is the stuff -- in the words of the Supreme Court, "The stuff of the traditional actions that common law tried by the courts at Westminster." That's the Supreme Court in Stern at page 484.

And just as whether a Seventh Amendment right attaches is determined by whether the action involves rights and remedies of the stuff that are typically enforced at common law, so too, whether or not it involves an exercise of the judicial power of the United States under Article III as the Supreme Court explained it in Granfinanciera.

The issue is not just whether the agency is using court-like procedures, although it certainly is because the rules require the use of the Rules of Federal Civil Procedure and the Rules of Federal Evidence, and a footnote by these three judge panels, two of whom I take to be not lawyers. So it sort of undermines the rationale for why they were picked in

the first place, but that's part of the APA challenge. But the question is not just whether the agency is using court-like procedures, but whether it is purporting to exercise court-like powers to decide a dispute between private parties.

And I think as Justice Thomas' opinion for the court in Oil States explained in discussing the IPR proceedings that were decided by these administrative patent judges, in finding that those were not a violation of Article III. He noted, "Although interparty's review involved some of the features of adversarial litigation, he does not make any binding determination regarding the liability of one party to another under the law as defined." That's at page 1378.

THE COURT: Is your Article III argument buttressed by the Article II argument, the finality of it?

MR. O'QUINN: Yes, yes, Your Honor, they are. In that sense, they are related in the sense that you have, by statute, and certainly under the rule, they have created a regime where under the rule, it is a final decision by these panels. And under the rule that they have specifically adopted, it's not just a final decision to go -- that the agency should take some action. It is a final decision that is in an action for "monetary damages or equitable relief."

And, you know, it doesn't just allow a party to claim that there's been a violation of the statute or the PPA, and it doesn't purport to adjudicate eligibility to participate in

Medicare or Medicaid. That might look more like the revocation of a patent. Instead it purports to decide whether or not there are monetary damages that are owed. And that would be like assigning to these IPRs in the Oil States case not a question of whether the public franchise of the patent was invalid, but instead whether or not the patent was infringed and money damages were owed.

THE COURT: The remedies in other words?

MR. O'QUINN: Both the deciding of liability and also the deciding of what the remedy should be whether they can enforce it or not. And that is, of course, what the Supreme Court in Oil States certainly was clear was not at issue under the IPRs. And even the government in its brief, both in opposing certiorari and at the merit stage, made clear that infringement and termination of liability and damages would be a different kettle of fish.

Now the government's principal argument here in response is to deny that the rule says what it actually says. An action for monetary damages is apparently not an action for monetary damages. And a decision by the panel that damages are owed is apparently neither final nor binding, even though the rule says the opposite, and for that matter, so does the statute.

And similarly, an action for equitable relief is apparently not an action for equitable relief. It is at most a

request for declaration. Now respectfully, that is not what the rule says. And if the rule doesn't mean what the rule says, then that is yet another reason to enjoin it from going forward. And the agency can go back and, we submit, properly seek comment, because these are issues in which they certainly departed significantly from what had been proposed back in 1996 and then withdrawn explicitly in 1997, but then promulgated into a final rule. They can seek comment on that, and they can try and fix it. That would be the appropriate remedy for the violation of Article III.

THE COURT: Let me ask you a question that's a little tangential, but it's been raised by the parties in any event. There was this delay between the promulgation of a procedure that was going to be used. The government came up with -- let me get my dates here. There was a notice of proposed rule making re: ADR in August of 2016. And then there was a little bit of activity, but the NPRM was withdrawn from the unified agenda in August of 2017 and everything sort of sat there.

As I understand it, the government is claiming that they gave sufficient notice, that that early notice has just basically been implemented now despite the delay in the apparent withdrawal of it, and so there's no need for further notice and comment and so forth.

So what I'd like to know is, is the current rule formulation that HHS has put forward identical to what they had

noticed previously when they did their proposed rule making?

MR. O'QUINN: No, it's not, Judge Barker.

THE COURT: Could you tell me the differences, please?

MR. O'QUINN: Let me focus on two. There are others but let me focus on two that I've talked about in our briefing that I think are particularly significant.

First, the rule that was proposed did not have the language about initiating an action for monetary damages or equitable relief. It did say that someone could complain if they had been overcharged, but it did not have anything in terms of the panel making a determination about what the monetary damages would be or the issuance of equitable relief.

The rule also did not incorporate by reference the Federal Rules of Civil Procedure, the Federal Rules of Evidence; and finally, and equally significantly for a number of reasons, the rule did not make the decisions of these panels precedential. The government says "Well, there's a difference -- there's no difference." If it's binding, it's precedential. No, no, no, of course not. There's a major difference between being binding between parties like res judicata versus being precedential. That's stare decisis. And it's especially important here because you have a federal district court in Washington, D.C. has that concluded that HRSA does not have substantive rule making authority with respect to this program. And so by making these rulings precedential,

what the agency is ultimately attempting to do is through the back door what it can't do through the front door because they will de facto become binding once they are made in the context of one of these ADR proceedings. And the government didn't get any comment on that because, number one, it didn't propose it, and then, number two, it expressly withdrew the rule. And it didn't just withdraw it from the unified agenda. Respectfully, Your Honor, if you look, for example, at slide 27, and it's referred to in our PI reply brief as well, what you see is that listed on the unified agenda is not just that the rule has been withdrawn, but it is designated as a completed action.

Well, that is -- that's a term that has significance to it. It's in the very document that describes the unified agenda that's cited in the government's opposition brief, and we talk about this in our reply brief. And it specifically says that a completed action means one of two things. It either means, number one, that it's been withdrawn, or number two, that they have, you know, promulgated a rule and completed the life cycle of the rule making. Well, we know that in 19- -- excuse me, in 2007 -- excuse me, in 2017, they had not done that.

So what does it say? What does it tell anyone in the public? It tells them that the rule's been withdrawn. And when you have withdrawn a rule, then you can promulgate a new rule. But what you have to do is you have to give the public

notice, and you have to give them the opportunity to comment on it. And respectfully, that is in some ways the narrowest way Your Honor could potentially decide the issues before you today. If they are required to put the rule -- if the rule's vacated and they are required to put it to notice and comment, then some of the issues that we are talking about, vis a vis the Article III issue, perhaps the Article II issue, you know, potentially could be addressed in the context of the rule making.

THE COURT: Thank you. I think I understand. Were the ADR procedures in the December 2020 published final rule similar to the ones that were noticed back in August of 2016?

MR. O'QUINN: Well, there's some very significant differences in them, Judge Barker. First and foremost is they are now going to be run under the Federal Rules of Civil Procedure, and with the application of the Federal Rules of Evidence.

Second, they had laid out a process in which panels would issue draft decisions that would be reviewed and commented on by the parties in the ADR. That was changed. And they flushed out more of the mechanics for how the ADR process would operate. But the chief differences are what the action is for, and I respectfully submit what it is that the panels ultimately determine.

The panels will make a final and binding decision as

to what -- whether there are monetary damages and what they are. And, you know, yes, there is another provision that allows somebody else to decide whether there should be sanctions or civil monetary penalties. It does include a reference to remedies.

I think the only sensible way to read the rules coherently is that what that means is that once there's been a determination by the panel, then the agency can potentially rely on that determination to determine if there's a broader set of remedies that should be -- that should be implemented, but I don't think there's any way to coherently read the rule as providing -- that it is an action in which you have to prove up and provide evidence of your monetary damages, and that there is then a finding that is made by the panel that is final and binding on the parties, and to say that the panels are not determining monetary damages among other things.

THE COURT: When Lilly went back to its prior position in July of 2020 --

MR. O'QUINN: Yes, Your Honor.

THE COURT: Is that what you're operating under now? Is that the procedure that Lilly is operating under now for the 340B?

MR. O'QUINN: So the procedures that -- separate and apart from the ADR, the procedures that Lilly is operating under in terms of making its drugs available at the ceiling

prices to covered entities, yes, it is the procedures that were promulgated in July with respect to a drug called Cialis, and then later in the summer with respect to other outpatient drugs; yes, those are the procedures in which it will sell directly to covered entities. For a covered entity that does not have a contract pharmacy, it will work with a contract pharmacy that they designate and then beyond that as I obviously --

THE COURT: Yeah, I just wanted to know if, having made that declaration, issuing that notice in July 2020, is that your SOP now?

MR. O'QUINN: Yes.

THE COURT: Okay.

MR. O'QUINN: Yes. I think there may be some tweaks in terms of how it has been implemented on the ground, but yes, as a general proposition, much like it was from 1996 until 2010.

THE COURT: And except for objections that some may have to your having done that, not -- apart from the government, I mean your covered entity cohorts, except for a general objection to your having done that, have there been disputes that have arisen that, for want of an ADR process, didn't get resolved? How did they get pursued? That's what I want to know.

MR. O'QUINN: Sure, Judge Barker. So as far as I

know, and let me be candid with the Court. I've not, like, inquired and undertaken research to see whether or not there are other disputes that have arisen. But as far as I know, the only disputes that have been raised are disputes related to Lilly's approach, vis a vis contract pharmacies. And that is the only actions that have, to date, been brought in the context of an ADR proceeding, is relating to the issue, vis a vis contract pharmacies, and the policy that Lilly implemented relating to that.

THE COURT: Talk to me a little bit about the public interest here because the government's argued, I expect it will argue it further, that the overall effect of their change in procedures to allow this rather expansive network through contract pharmacies serves the public interest because it allows more people who are indigent to participate in a discount drug procedure.

MR. O'QUINN: Yes. So let me start with that, Judge Barker, because to be sure, that is the government's theory. They've offered no evidence to support that. Our position is that what has happened with the proliferation of the contract pharmacies is that the pharmacies are profiting to the tune of hundreds of millions of dollars. And this is laid out starting around paragraph 49 of the amended complaint up through, I believe, about paragraph 76 of the amended complaint. In fact, you have contract pharmacies that are noting that what -- their

profits may turn on what happens, vis a vis, the 340B program and such.

So what's happening is that this program, which was intended to benefit indigent, vulnerable patients, no dispute, that's who it's intended to benefit, that what is happening is that in many cases, those patients are still being charged a full price, or the third party payor is being charged a full price, and the contract pharmacies are largely pocketing the difference.

Now they have some arrangement. We don't know, we don't have these contracts. They have some arrangement with the covered entities, and so I'm not saying that the covered entities don't get something out of this. And what you will hear is that the covered entities say "Well, we depend a lot on this."

But first of all, they operated very successfully for 15 years, or nearly 15 years under the regime that existed. And nothing changed in the statute in terms of the obligations, vis a vis contract pharmacies. And second of all, Your Honor, is, you know, what they do is they point to the patient's themselves and say "This is who is being hurt and who's being denied access to discounts." And it's simply not the case because, in fact, the opposite is true. The contract pharmacy arrangement is what is frequently resulting in discounts not being passed through. And that comes back to Lilly's point

about insulin. Being willing to provide it to all, to not -- through all contract pharmacies, not just the one, but to all as long as they will pass along the discount. And the covered entities say "Well, it's unreasonable to think that they wouldn't have to pay. They shouldn't be able to take a dispensing fee." Well, when our 340B drugs are purchased, some of them are purchased for a penny. We're not making anything off of that transaction when they're down to a penny. And so it's not unreasonable to say, you know, "Yeah, you should share in this, pass the discount on so that it's the vulnerable patient who's actually going to benefit from this program."

So I think the arguments about the public interest here are really, frankly, cut the other way. And certainly there is no evidence that anything that has happened to date or that would happen in the time while Your Honor decides the issues that are before you, which, you know, might tie in some ways to the Supreme Court --

THE COURT: Are these the kinds of abuses that Lilly was concerned about when it issued its July notice?

MR. O'QUINN: They are, Your Honor. They are. And the other thing I'll say that relates, of course, to the public interest -- and, you know, I recognize the concern and I think it's a fair one for us to talk about in terms of what are the practical real world effects of this. But again, no one is saying that the -- if the agency thinks that there's action

that it can take or should take, that the agency can't take it. The issue is about whether or not Lilly has to be subjected to these improperly constituted administrative dispute resolution panels. And that implicates the personal right to an Article III adjudicator. And yes, you know, some of these, the rights arise from structural constitutional provisions, frankly just like the dormant commerce clause issues arose from a structural constitutional provision in the North Main Street versus Cook case that Your Honor had a few months ago.

That doesn't mean that the presumption of irreparable harm doesn't follow from the violation of the Constitution. And indeed, the Supreme Court has put these -- some of these structural safeguards as being paramount to the protection of liberty. And so against this backdrop, when you have an agency that has sat on this rule for almost a decade, to then say that enjoining in a preliminary way the implementation of these ADR procedures with the serious constitutional questions they raise and the obvious violations of the Administrative Procedure Act we've talked a little bit about this morning that they implicate, I think just simply doesn't hold water.

THE COURT: Let me ask you a question about the December 30, 2020, advisory opinion that the defendants issued. I'm reading from that opinion. "It obligates each drug manufacturer in the 340B program to deliver its covered outpatient drugs to" -- this is not a precise quote, but this

is the information that I want you to talk to me about, "It obligates each drug manufacturer in the 340B program to deliver its covered outpatient drugs to contract pharmacies and to charge no more than the 340B ceiling price for those drugs whenever a contract pharmacy purports to act as a covered-entities common law agent." What does that mean, "purports to act as a covered-entities common law agent"?

MR. O'QUINN: Yeah, it's a bit of a puzzle to me as well, Your Honor, because it's not obvious to me that these contract pharmacies can even act in a -- as a common law agent as opposed to acting as independent contractors or other type things.

But what they are trying to do in the advisory opinion is they're trying to shoe horn the contract pharmacies into the statute. Even though the statute provides 15 specific types of covered entities, it was amended to add some of those, contract pharmacies aren't in there.

THE COURT: I see that, but I'm really perplexed about what a contract pharmacy would do in purporting to act as a covered-entities common law agent. How would that happen? What does that mean?

MR. O'QUINN: I think -- well, it's hard for me to explain it because number one, I don't think it's consistent with the statutory regime; and number two, I don't think it's consistent with the practices that are actually ultimately at

issue in terms of what contract pharmacies do.

What they're trying to do is to suggest that a contract pharmacy, you know, even when they have an exponential number of them associated with a given covered entity, can essentially act on behalf of the covered entity in providing the prescription to the covered-entities patients.

Now, the advisory opinion doesn't purport to define patient, and I think that's part of the rub here as well, your Honor, is that there is uncertainty and dispute about what that also means. But in all events that -- you do end up with this very far-reaching interpretation that puts manufacturers like Lilly basically at the mercy of contract pharmacies --

THE COURT: I assume that if there were notice and comment as to that view, that advisory opinion, that some of this would have been ferreted out.

MR. O'QUINN: You would think so, Your Honor, and that is part of the complaint here. Not part of the motion, of course, before Your Honor today, although it does factor into the background, but part of the complaint is that this advisory opinion was promulgated without the benefit of notice and comment. It certainly has -- serves as an interpretation of obligations under the statute, which under the Azar versus Alena case from the Supreme Court means it should have been subjected to notice and comment.

I think the government is going to take the position

that potentially, that the rule -- that the advisory opinion decision isn't even really a decision, that it doesn't decide anything.

I find that hard to believe because ultimately, you, I think, would concede that the ADR panels are supposed to apply the advisory opinion. To the extent that they're not, I'm not sure what they think that the ADR panels are supposed to do.

The Office of the General Counsel is, of course, a member of the ADR panels, among other things, but in all events, yes, it is a decision that was made in response -- as their own brief describes it, in response to public outcry. And that is why having an Article III court is so important in adjudicating the interests that are presented in this case so that everyone, whether you are politically favored or politically disfavored, will get a fair shake in front of a neutral arbiter, namely an Article III court.

THE COURT: Can you wrap up now so that I can hear from the government and then give you a little bit of time to respond?

MR. O'QUINN: Thank you, Your Honor. For these reasons, we respectfully submit that the ADR Rule should be enjoined in its application against Eli Lilly pending a decision on the merits of the case. Thank you, Your Honor.

THE COURT: Thank you.

Miss Talmor, would you like to start right up or do

you need a drink of water?

MS. TALMOR: Thank you, Your Honor. I have water here and I'll get started. Thank you.

THE COURT: All right.

MS. TALMOR: I'd like to focus my time on the legal issues that are before the Court as opposed to kind of the background facts about the 340B program; but first, I do believe there are a couple points about these background facts that counsel made that warrant a response. So I'll briefly touch on those if it's okay.

First off, the Congress was very clear when it passed the 340B statute and enacted the program in 1992 in stating that the statute benefits covered entities by allowing them to raise funds to further their provision of healthcare services, and in that way stretch scarce federal resources. And the way that covered entities can raise funds under the 340B program is by charging a price for medication that is higher than what they pay at the drug makers.

So a covered entity has the option and often will pass on the discounted price to a patient, but some patients can afford to pay more than the discounted prices, and some patients have insurance, including through Medicare or Medicaid. So it is entirely proper, in fact it's by Congressional design, that the discounts aren't always passed on to patients because again, Congress was very clear that

covered entities can use this program to raise money.

Second, counsel for Eli Lilly pointed to OIG reports and other documents that they say show that there is rampant abuse in the contract pharmacy program. What this does is really demonstrate that Lilly and other manufacturers are trying to change the settled operation of the program. And there are proper mechanisms for them to seek to effect change in the program if they truly believe there are problems with it, but not through kind of back door extra-statutory means. And so I'd like to point out that after the changes instituted by Lilly and its peers, there has been a bipartisan outcry with two different letters written by the Secretary of HHS for more than 200 members of both parties in Congress urging former Secretary Azar to take action.

There also was a letter written by a large group of bipartisan state Attorneys General across the country basically agreeing with the opinions set forth in the advisory opinion and also urging the former secretary to take action.

So the proper way --

THE COURT: Wait, wait, take what kind of action?

MS. TALMOR: I do not have those documents in front of me. I do believe that what they urged the secretary was to take action to reign in the changes by drugmakers. Both the letter from the lawmakers and from the State Attorneys General emphasize that covered entities have relied on these

arrangements for decades, and that the restrictions that Lilly and its peers are placing on covered entities' drug purchasers do not comport with the statutes. Both documents were very clear on that.

THE COURT: Well, maybe you should supplement the record because if you're going to invoke those communications as a source of influence and pressure on the department that resulted in these changes, I guess I need to know what they want. Lots of times those letters are just do something letters. They see a mess. They're getting letters from constituents and so forth. So I can't tell too much from what you've said about what the problem was that people were addressing, and what the secretary was attempting to do in formulating this particular procedure and these definitions. So they may not like Eli Lilly, but what do they think ought to happen other than just do something?

MS. TALMOR: Well, Your Honor, I would like to be clear that I'm not sure that the focus is on what lawmakers and State Attorneys General want to happen. I think the point is that both --

THE COURT: Well, Miss Talmor, you're the one who cited those references. So the fact that there may be clamor out there, without knowing what it is, I don't know that that's a very potent argument. Why don't you just go to the merits, okay?

MS. TALMOR: May I touch on the way that the contract pharmacy arrangements actually work? I think that's important --

THE COURT: Yes, yes.

MS. TALMOR: -- to answer your questions.

So contrary to what Lilly's counsel said, the advisory opinion does not say -- in fact, it does not even permit a manufacturer to sell discounted 340B drugs to a contract pharmacy. Contract pharmacies simply are not entitled to purchase 340B drugs, nor are they entitled to bring claims --

THE COURT: You're going way too fast. I can't even understand it, never mind -- I don't have to write it down but I can't understand it. So I'm sure the court reporter's having a challenge here. The technology is not your friend, so you have to work with it, and that means slow it down.

MS. TALMOR: I apologize to you both. I will.

The advisory opinion does not state or permit Lilly to sell covered drugs to contract pharmacies. What the advisory opinion confirms and what the statute requires is that Lilly sell covered drugs to covered entities. And the reference to a common law agent, what that means is that -- well, let me back up a bit. In the guidance that was first put out by HHS in 1996, the agency noted that only five percent of covered entities had an in-house pharmacy. Ninety-five percent did not have a pharmacy in-house.

It is obviously extremely burdensome to set up a pharmacy, including all the regulatory and licensing and costs that come along with that. So HHS has long taken the position and drug makers have followed the guidance that a covered entity is entitled to place an order to buy covered drugs, and that the covered entity can specify that those drugs be shipped to itself for dispensing, if it's lawfully able to do so, or that the drugs it purchases be shipped to a pharmacy who does have the lawful ability to dispense drugs to patients. And that that pharmacy will then take delivery of the drugs and, acting as the agent of the purchaser, will then dispense it.

All that means is that the arrangement is that the covered entity buys the drug and has it shipped to a pharmacy that holds it and dispenses it under their pharmacy license. So it's actually a straightforward mechanism.

THE COURT: How does that bring revenue to a covered entity?

MS. TALMOR: Because the pharmacy will sometimes pass along the discount to a patient, but oftentimes, especially if the patient is insured, the pharmacy will process the insurance for that drug. In other words, will bill insurance for that drug and the spread between the 340B discounted price and the price that is paid by the insurance or sometimes by the patient then is profit that can then be used by the covered entity to facilitate its healthcare service. That is what Congress

designed.

And so the fact that Lilly's portrayal of drugs being sold to contract pharmacies is false. Contract pharmacies cannot buy drugs. They also cannot bring a claim to the agency's ADR. They merely act as agents by receiving a purchase and then dispensing it under their license and with their registered pharmacist.

THE COURT: Can you tell me what this phrase means "whenever a contract pharmacy purports to act as a covered entity's common law agent"?

MS. TALMOR: Yes, Your Honor. What that means is that when a covered entity places an order for drugs, that a manufacturer is not permitted to deny that purchase on the grounds that the covered entity has instructed the manufacturer to ship the purchase to its agent, the contract pharmacy.

So that means that the manufacturers do not have statutory authority or any lawful authority to question whether the covered entity's instruction to ship to a pharmacist is proper. In other words, that the statute requires Lilly to sell its drug to a covered entity regardless of the dispensing mechanism that is selected by that covered entity.

THE COURT: Why would the original statute then have defined covered entities and limited it to 15 kinds of businesses?

MS. TALMOR: Your Honor, I think that is a critical

feature of how the statute is designed to work. There are numerous different types of healthcare providers in our society, of course. And there are only certain healthcare providers that Congress has decided should have access to this program.

So these are often healthcare providers serving the poorest, the most vulnerable people in particular categories that Congress has decided need access to subsidized healthcare. So Congress has very carefully delineated which covered entities can purchase these drugs, and HHS has not authorized any purchases by any entity that is not defined in the statute. That is a critical point.

HHS has made clear that when a covered entity purchases a drug, that the manufacturer must sell that drug and the manufacturer cannot place its own statutory restriction on the dispensing mechanism. In other words, health clinics located in extremely remote areas that may serve patients covering hundreds of miles away are not required to expend the traditional -- I'm sorry, the extraordinary resources that would be required to set up an in-house pharmacy, nor are they required to force their patients to drive potentially hundreds of miles to come and receive medications in-house.

A rural health clinic in somewhere that serves patients, you know, 150, 200 miles away, is able to contract with multiple pharmacies that allow the patients to go and pick

up their medication where it's convenient to them.

THE COURT: So when the phrase "contract pharmacy" is used, is the contract between the covered entity and the pharmacy? Is there a contract? Is that what the rule contemplates?

MS. TALMOR: Umm, I want to be clear on which rule you're referring to. What the guidance --

THE COURT: Well, I'm reading your advisory opinion, the one from December 30th, 2020.

MS. TALMOR: Thank you, Your Honor. What that guidance contemplates is that there is a contract between the covered entity and the pharmacies. And what that does is it lets the covered entity say to Eli Lilly "I would like to purchase this quantity of this drug, but I do not have an in-house pharmacy," or "It best serves my patients to allow them the flexibility to fill their medications in the neighborhood," whichever the case may be, and the covered entity is entitled under the statute to instruct Lilly to sell the drug but to ship it to a CVS or a Walgreens to be held and dispensed only to patients of the covered entity.

THE COURT: So really, the covered entity becomes a distributor. They're sort of the middleman in the process. The manufacturer provides the drug, sells it to the covered entity at the reduced price, and that covered entity can pretty much decide whoever it wants to distribute it on from there.

Is that right? Could it be a gas station, for example?

MS. TALMOR: No, Your Honor. No, Your Honor. I believe that there are two inconsistencies in that formulation. One, the gas station would never, as far as I'm aware, be entitled to dispense prescription medications in the first place, but aside from that, a covered entity is not like a distributor, because a covered entity is not a pass-through entity that is facilitating sales to a contract pharmacy.

The important distinction is that the contract pharmacy never owns the 340B discounted drugs. The covered entity is not ordering medication and then selling them to a contract pharmacy. Not at all. The covered entity is prescribing medication to its patient, but it is allowing its patient to go and pick up that drug each month from their neighborhood CVS. It's not at all like a distributor/retailer situation.

THE COURT: So what does the contract provide between the contract pharmacy and the covered entity?

MS. TALMOR: The contract will provide that the covered entity, place of purchases that the covered entity -- that the contract pharmacy would hold and store and dispense to their patients, and the contract pharmacy is performing valuable and necessary services under the scheme Congress designed because the contract pharmacy will dispense the medication to the patient and where applicable will bill

insurance for that, and then that spread, that profit, is what the covered entity is able to use to further its healthcare services.

THE COURT: Well, the covered entity basically has unfettered discretion in the number of contract pharmacies that it engages with, true?

MS. TALMOR: The covered entity is not limited because the contract pharmacy is never a purchaser or owner of the drug. That's the critical distinction.

The contract pharmacy never owns or has title to these drugs. The contract pharmacy is just letting John Smith go and pick up his monthly medication at the CVS in his neighborhood, but that medication is always owned by the covered entity.

THE COURT: So let me ask: Have disputes arisen before the ADR Rule was implemented?

MS. TALMOR: I think that's the critical point, Your Honor. Yes, and there's been no mechanism to deal with those disputes.

THE COURT: What kind of disputes?

MS. TALMOR: Disputes regarding overcharges and program violations. That was the thrust of the decision of the Supreme Court in Astra versus Santa Clara County. I think this is a critical point that dooms Lilly's argument here.

In its reply, Lilly excused (inaudible) the Astra versus Santa Clara County decision to its precise facts, but in

reality, what happened in Astra is that a group of covered entities wanted to sue drugmakers for not fulfilling their statutory obligation to sell covered drugs under the 340B statute. The covered entities looked at the statute and realized that they did not have a private right of action. They did not have a way to sue to bring their dispute about program violations in Federal Court. And so they used creative lawyering.

They tried to sue a third party beneficiary of the contract that Eli Lilly signed with HHS. And the Supreme Court's reasoning in that case answers Lilly's Article III challenge here because the Supreme Court said that in designing a 340B program, Congress chose to invest enforcement fully within HHS with no auxiliary role for covered entities to sue over program violations. And that when disputes began to arise and it became clear that there was no enforcement mechanism, no way for covered entities to bring these disputes before a court, the Supreme Court explicitly wrote on page 121 of the Astra decision that Congress amended the 340B program in 2010 to mandate the creation of an ADR dispute. And the Supreme Court said that Congress selected in its discretion to vest the resolution of disputes over 340B program violations within the agency before the agency charged with implementing the statute subject to review in Federal Court. In other words, the dispute that had arisen before the ADR was created and the

disputes that are now pending in the ADR as we speak are claims that cannot be brought in Federal Court under the Supreme Court's decision in Astra. That absolutely resolves the question whether there are private rights that can be adjudicated in Federal Court.

THE COURT: So the administrative process that was followed by HHS to basically bring us to where we are has been fraught with delays and fits and starts you might say. It came forward with its notice of proposed rule making in August of 2016, and there were some objections filed. And then the proposal was withdrawn, and then it sat there for a while. And then all of a sudden, a final rule was published on December 2020, and without any notice or opportunity for comment, with some new ADR procedures.

So how do you defend this process that you've undertaken to create a system now that Lilly and others have to comply with?

MS. TALMOR: Your Honor, the process that was used by the agency here fully comports with the APA. Lilly is asking this Court to impose a number of nonstatutory requirements on the agency's rule making, and there's no basis for them to do so. What the APA actually requires is that a comment period be open, notice be given, the comment period opened, that apprises interested parties of the general topis of rule making and allows them to consider and weigh in on that proposal. HHS

absolutely did that. As Your Honor noted --

THE COURT: But wait. Your published final rule didn't look like the one you first gave notice of, right? There were differences.

MS. TALMOR: No, Your Honor.

THE COURT: No? They are identical?

MS. TALMOR: No, Your Honor. They are not required to be identical, Your Honor. They are not identical, but they are --

THE COURT: What's the purpose of the notice and comment then?

MS. TALMOR: The Seventh Circuit has answered that, Your Honor, very clearly. The Seventh Circuit stated that if every aspect of a final rule were required to be included in the notice, in other words, if changes were not permitted between a notice and a final rule, that the rule making process would be seriously degraded because agencies would be loath to make any changes whatsoever in response to comments.

THE COURT: Well then, what do we make of the fact that the rule was withdrawn?

MS. TALMOR: The rule was not withdrawn, Your Honor. That is a critical point. The rule was not withdrawn. Lilly is reaching for bread crumbs to try to show that the rule was withdrawn, but they're ignoring the legal standards, the legally sufficient documents.

THE COURT: What does "completed action" mean then?

MS. TALMOR: I don't know precisely what "completed action" means because what Lilly is pointing to is the unified agenda, not the Federal Register, which is the legally-operative document. In other words, HHS allowed the comment period to fully stay open. The comment period elapsed. Interested parties were fully able to comment on the rule. After the comment period elapsed, the rule was withdrawn from the unified agenda because the new administration put a pause on it while considering rule making as it did across the federal bureaucracy. It was not withdrawn from the Federal Register. That is the legally-operative document. The Federal Register is a compendium created by statute that gives interested parties notice of rule making. Lilly is essentially claiming here that a reasonable observer would have concluded that the rule making ended. That is inaccurate.

It was not removed from the Federal Register. Moreover, the rule was mandated by statute, so no reasonable observer who was aware of the context would have concluded that HHS had abandoned any attempt to put forward the rule. But I'd like to really emphasize that Lilly's complaint that the rules differed from the notice absolutely fly in the face of settled administrative law. An agency is required to put out a notice that apprises interested parties of what it is considering. The agency, in fact, is required to solicit comments and then

consider those comments.

And one of the important constraints in the APA is that the agency must consider those comments and where it considers them to be significant, where they raise sufficient arguments or comments warranting changing of rules. The agency is required to modify its rule making in response to significant comments in a way that cogently explains the choices that are made.

There is simply no constraint on an agency from being able to modify a rule from the notice. In fact --

THE COURT: Is there any record that the comments and input that you got in the notice and comment phase were considered?

MS. TALMOR: Absolutely, Your Honor. The documents that are -- the pages that are in front of -- the example of the rule itself contain the agency's response to comment.

THE COURT: Wait a minute. Say that again, please.

MS. TALMOR: The final rule contains -- the rule-making document before the Court contains both the agency's comments that it received and its responses to comments. And then it contains the rule itself, the 42 CFR provision at the very end.

The rule-making document before the Court contains the agency's consideration of various comments. It is before the Court. There also is an administrative record that would

contain more information, but the rule itself before the Court contains the agency's responses to comments.

THE COURT: So in the December 2020 published final rule, that's the effort by HHS to pull forward its decisions with respect to those comments that you received?

MS. TALMOR: Your Honor, as we noted in the background section of our brief, there weren't a lot of comments received, but the agency did respond to those comments. It's there in the rule. Comments came in both from covered entities and from manufacturers, and the agency responded to those comments. In fact, it made some changes in response to those comments.

We discussed in our brief how various entities, covered entities, asked the agency to include a specific enforcement mechanism that would allow panels to enforce their decision. And the agency explains that it elected not to do that because enforcement had been delegated through HRSA, and the agency wanted to grant HRSA flexibility to consider an appropriate remedy after the panels make a determination on whether a statutory violation has occurred.

THE COURT: Speak to me about the finality of the decision making by the panels, and the issues that the plaintiff has raised with respect to Article II of the Constitution.

MS. TALMOR: Thank you, Your Honor. Lilly's appointment cause challenge is really urging this Court to

apply a made-up standard that flies in the face of settled administrative law. There is no rule that the absence of direct review within an agency, in other words that the ability to issue final agency decisions renders an officer or principal. That simply is not the law.

In fact, the D.C. Circuit repudiated Lilly's invented standard this month. The D.C. Circuit explicitly rejected an argument that an inferior officer's decision must be subject to review by a principal-officer. That was in Fleming verses USDA.

Accepting Lilly's argument would really -- I'm sorry, accepting Lilly's arguments that an inferior officer's ability to have the last word on an issue or render a final decision violates Article II would truly upend modern administrative law. Throughout the federal bureaucracy, there are countless examples of inferior officers that have the last word by issuing final agency decisions through delegated authority.

So I'd like to give just a couple of examples.

THE COURT: Please do.

MS. TALMOR: The secretary of HHS has delegated to the CDC director on an inferior officer typically appointed by the secretary the authority to issue certain orders, and the CDC director has exercised that authority to issue rules published in the Federal Register.

My office recently defended a final rule issued by a

deputy under secretary at the Department of Agriculture. The deputy undersecretary is an appointee not needing Senate confirmation. And the Department of Agriculture, like other agencies, has regulations delegating the power to issue significant rule making to appointees below the principal-officer level.

One other: The Office of Foreign Assets Control is a component of the U.S. Department of Treasury. It's headed by an inferior officer who has delegated significant authority to impose fines, to freeze assets of private parties, and to bar entities from even operating in the United States.

Accepting Lilly's argument would require ignoring the practical realities of modern administrative law. The fact --

THE COURT: Has the authority that the panels would exercise under the 340B statute been specifically delegated by the secretary to the panels? Is that a delegated power? I mean, I understood your examples to be that there were specific delegations of authority down to the CDC and down to the deputy agriculture secretary, that sort of thing. But I'm wondering what's your trail here?

MS. TALMOR: Absolutely, Your Honor. 42 CFR 10.3, that is a provision in the rule that says that the board has authority expressly delegated from the secretary to issue a decision on only certain types of claims. So there are two important aspects of this.

One is that the board has no authority whatsoever, absent that delegation from the secretary. It is wholly a creature of the delegation. And two is that the claims that are presented to the ADR panel are only three types. They can be overcharging, diversion, or duplicate discounting.

THE COURT: Wait, wait, wait. You said it too fast. Diversion, overcharge, and what's the third one?

MS. TALMOR: Duplicate discounting. That means claiming a 340B discount and also claiming a Medicaid (inaudible) at the same time.

Now I think that's a very important point, the type of claims. It goes more to the Article III argument. So if it's okay, I'll shelve that for a moment and focus on the delegation of authority.

THE COURT: Fine.

MS. TALMOR: Eli Lilly's counsel focused significantly on the statute. What the statute does here is not unusual. The statute directs the secretary to create a process for either a covered entity or a manufacturer to bring a claim before the agency for a 340B violation. That's because Congress decided that claims of 340B violations should not be brought in Federal Court in the first instance. They should be presented to the agency.

Now two of the three types of claims that can be heard in the ADR panel would be brought by manufacturers. A claim

for a diversion of drugs means providing a drug to a patient who is not eligible, who's not a patient of a covered entity; and a claim for duplicate discounting would also be a claim against a covered entity.

So what Congress has done here in delegating authority to the secretary to create a dispute resolution process is the same thing Congress has done in many statutes, delegating the authority to create agency processes to determine compliance of a statute.

THE COURT: So wait, let me ask you this. So the effective date of the ADR Rule was January what, 13th, 2021 --

MS. TALMOR: Yes, Your Honor.

THE COURT: -- something like that?

MS. TALMOR: Yes, Your Honor.

THE COURT: And your agency issued through a web page the essence of the ADR Rule and invited stakeholders to begin submitting petitions. So has anybody submitted any petitions? Is there an ADR process that's up and running?

MS. TALMOR: There certainly is not the hundreds of petitions, the deluge of petitions that Lilly claims --

THE COURT: Wait, wait, wait. You said it too fast. I didn't catch it. Say it again.

MS. TALMOR: I promise to speak more slowly. I apologize.

There certainly has not been the deluge of complaints

that Lilly claims to anticipate. To my knowledge, there have been two or three complaints filed. And the petition -- I'm sorry, the process is still being implemented.

So a handful of claims have been filed, and there are internal agency processes going on to get the process up and running, including internal training and ethic checks. But the process is not -- the process is still in its early stages.

THE COURT: So is it true as Lilly's counsel has argued that once the ADR process works its way through to a decision and it's been declared to be binding and final and so forth, that, first of all, the decision can impose damages on the violating party, and/or impose injunctive relief, and that those are final decisions not otherwise subject to review on the merits --

MS. TALMOR: There are several --

THE COURT: On the merits?

MS. TALMOR: I apologize, Your Honor.

There are several problems with the way that Lilly has framed that. Now, to begin, the decisions are final in that they are final agency actions, subject to APA review. However, as I am emphasizing, that is not unusual. That is the way that modern administrative law works. Numerous bodies within agencies have exactly that power.

As far as the remedies --

THE COURT: Now wait. You have not included that

appeal right under the APA any place in your website or your formulation of the ADR Rules, right? Is that right?

MS. TALMOR: No, Your Honor.

THE COURT: You have? You have referenced that?

MS. TALMOR: Yes, Your Honor.

THE COURT: Appeals would be processed through the APA?

MS. TALMOR: Yes, Your Honor. Appeals would be processed through the APA.

THE COURT: Where does it say that?

MS. TALMOR: 42 U.S.C. 256(B)3(A), when it provides that the secretary shall establish a decision-making official or body that has the authority to issue final decisions, that does create a principal-officer as Lilly portrayed. That should be that the entity charged with reviewing 340B program violations is authorized to issue a final agency action reviewable under the APA. It's both in the statute and it's in the rule.

The rule also states that the decision will be final agency action reviewable under the APA. In fact, in its motion, I was a bit perplexed because Lilly complained that the rule only authorizes APA review. The statute authorizes APA review. The rule confirms that the statute authorizes APA review, and HHS could not authorize anything else. HHS can't authorize to do anything.

THE COURT: So if the panel decided to award damages to one of the parties in the ADR process, that decision could be pursued further through the Administrative Procedures Act steps?

MS. TALMOR: There are two pieces to the answer. A decision can absolutely be appealed under the Administrative Procedures Act, but I think that it is a misnomer to say the panel awards money damages. That's the remedy's point that Lilly is misportraying.

I'd like to talk about the claims presented to the ADR panel. I think that will clear this up. The ADR panel can --

THE COURT: Slow down. Slow down. Slow down.

MS. TALMOR: Thank you. A claim for overcharging, which is relevant here, or duplicate discounting or diversion. Those are the only claims the ADR can hear, and they have to be brought by a covered entity or a manufacturer. No contract pharmacies are involved.

Now, the claims that are pending before the ADR now, the claims that Lilly is seeking to thwart in this motion are claims by covered entities that Lilly is overcharging by unlawfully restricting their ability to buy discounted drugs.

What the panels are charged with doing is very similar, the same, as what other agencies do. They can determine statutory compliance. So while the agency has determined that covered entities have a right generally to use

contract pharmacy arrangements, the agency has not passed on the specifics of Lilly's new policy, because that belongs in the ADR.

So the panels are empowered to determine whether Lilly's policy comports with its obligations under the statute. That is all. And if the panel determines that Lilly's policy does not comply with the statute, it can refer its decision to HRSA for enforcement action. HRSA can consider whether to impose penalties, sanctions, to refer the decision to the OIG for civil monetary penalties.

Meanwhile, if Lilly is the subject of an adverse decision, it can seek APA review of the determination of statutory compliance. So the panel does not award, you know, money damages the way that Lilly portrays because the rule requires the panel to refer its decision to HRSA.

However, I think it is critical to note that there's nothing unusual in an agency imposing fines or restitution, any type of award like that. We provided a very small sample in our brief of other agency contacts where the agency orders coming out of an adjudication are much more sweeping than what's presented here.

So just to touch on those, the Federal Trade Commission issued cease and desist orders that very much resemble injunction. The Securities and Exchange Commission issued injunction, including exclusion orders which bar an

individual from practicing a certain business trade, et cetera. They touch on the natural rights to practice one's profession.

Citizenship and immigration services issues deportation orders, which are functionally equivalent to an injunction. The National Labor Relations Board will order an employer to reinstate an employee that's been wrongfully discharged. Certainly an injunction. And the Commodities Futures Trading Commission issues restitution orders that have a minimum of a hundred thousand dollars.

So the powers here are not only not what Lilly portrayed because enforcement is taken up by HRSA, not by the panel, but it also is not in any way unusual in modern administrative law.

THE COURT: What would the effect be if the Court were to grant the requested injunction and hold up the ADR process with respect to Lilly? What would the effect be in terms of HHS's operations?

MS. TALMOR: I think that would have a serious negative impact both on HHS's operation and on its ability to perform the functions that Congress entrusted to it, and an impact on the covered entities and their patients.

It is certainly true that Congress directed that the ADR process be created before 2020. And while I do not have an explanation for that delay, it is imperative that that process be up and running as soon as possible. Here, Lilly has not

presented any --

THE COURT: Well, as soon as possible seems to be defied by the facts, right? You got it up and running but it wasn't timely. I mean, you can't say that in light of when the direction came from Congress you acted in a timely prompt way. But I know it takes a while to get things -- to bring these things to fruition.

The problem with the schedule of events in this case is that it appears that HHS is springing things on manufacturers such as Lilly, because there's --

MS. TALMOR: No, Your Honor.

THE COURT: -- not an ample time for notice and comment. They're greeted by the rule, the website and so forth the day before the ADR Rule went into effect, et cetera. So there is running through this schedule some sense of unfairness to -- at least to Lilly, I'll just speak about Lilly's case because I don't know about others -- in the way these events unfolded.

MS. TALMOR: Respectfully, Your Honor, I disagree. As an initial matter, I don't think the facts that HHS was delayed in issuing this rule at all provides any grounds to further delay it or enjoin it, but as to surprise? There is no unfair surprise here to Lilly.

First of all, covered entities have relied on contract pharmacy arrangements for decades. Lilly unilaterally upended

those agreements by imposing its restrictions last summer. Other manufacturers have followed suit. The reason I reference the public outcry earlier is to reference the fact that there are real world implications here.

Now, Lilly brought up the fact that we have not put before the Court evidence of the impact of its changes. That's a function of the procedural posture of this case. This is a preliminary injunction motion. This is an emergency motion. We've not had the opportunity to put forward evidence. But also in this particular context, evidence that would be relevant, in other words, the evidence of how covered entities and their patients are being harmed every day is not within the possession of the agency at this point.

I will note that the cases that Lilly referenced and that we referenced in our brief that have been brought by covered entities against HHS, I handled those cases, too. And in those cases, the covered entities provided scores of pages of declaration of individuals being unable to fulfill their medications, about harms to covered entities.

THE COURT: Is that the injury to the patients that you're making reference to when you use that term, that they can't get the drugs or the pricing is not in keeping with the 340B statutory requirement?

MS. TALMOR: In the cases brought by covered entities, they provided a number of declarations that I cannot

individually verify the voracity of. They were declarations submitted by the plaintiffs in those case, but they purported to detail significant harms to both patients and covered entities being unable to fill their medications as they needed to or having to go to great lengths to fill them.

I am representing that while the agency does not know the voracity of all of these claims, Congress designed a system to allow the agency to gather that evidence, to consider that evidence, and to decide how the 340B statute should be implemented.

So it is firmly in the public interest to let HHS play out that process and determine how the statute should be implemented.

THE COURT: So extending your argument, so having more pharmacies be able to use the drugs that are coming to them through the covered entity procedure is the point of the statute and the point of the regulations; is that right?

MS. TALMOR: No, Your Honor. I don't believe that the contract pharmacies are using the 340B program or the discounts. That's the fundamental point here.

The contract pharmacies are not purchasing drugs. They're not receiving discounts. The covered entities are buying drugs. They choose to dispense those drugs through pharmacies. Many of them do not have an in-house pharmacy, and some of those who do serve patients for whom it would be very

onerous and burdensome.

THE COURT: Right, I get all of that, Miss Talmor. But what Lilly is saying is that the proliferation of contract pharmacies as recipients of the drugs from the covered entities is creating a problem of diversion and lack of control and so forth. So it's the -- that's why I understand, I mean I'm just responding to the argument that they've raised, I'm not making a finding, but that's why Lilly says it went back to what was the procedure before when it implemented its July procedures.

MS. TALMOR: Your Honor, first of all, although this is something, a matter for resolution at a later stage, we would absolutely dispute that all Lilly has done is revert to its pre-1996 procedures. We do not agree that that's all that has happened.

But even putting that aside, what is important here -- well, first of all, Your Honor mentioned diversion. Diversion is absolutely one of the types of claims that can be presented in the ADR. That is not what I understand Lilly to be arguing here.

Diversion means that a covered entity has purchased the drug and given the drugs to an entity that is not entitled to have them. I do not understand that to be Lilly's complaint about contract pharmacies.

Lilly instead complains that there are too many contract pharmacies and that they make too much money. Lilly

is not entitled to make that determination. That is for Congress to decide and it's delegated to HHS authority to implement the statute.

But more importantly, if I am wrong and Lilly does want to allege that drugs are being unlawfully diverted, then Congress told Lilly how to do that, and that is through bringing a claim in the agency ADR process. Congress set up a process for this, and Lilly cannot get out of its obligation to submit to that process.

THE COURT: Would you be able to wrap up in about five minutes so that I can have a little time for rebuttal? We've gone an hour with each side.

MS. TALMOR: Yes, Your Honor. If it's okay, there are a couple of key points that I'd like to hit on.

THE COURT: Yes, please do.

MS. TALMOR: I'd like to briefly turn back to the Article II argument, although I recognize that Your Honor said you're more interested in the Article III argument, but I'd just like to touch on the fact that what Lilly is doing is urging this Court to apply a standard that Lilly wholly invented.

Lilly charged in its reply that the government had no cases showing that the absence of direct review does not render a principal-officer -- sorry, an inferior officer principal. That is false. We cited plenty of authorities. To touch on a

couple, the D.C. Circuit's opinion in Intercollegiate Broadcasting is directly on point. That case showed that there is no Article II problem here.

The copyright judges at issue in Intercollegiate Broadcasting, and this is a quote, "Issue decisions that are final for the Executive Branch subject to reversal or change only when challenged in an Article III court." That is exactly like here. In that case, the judges at issue had a for-cause removal provision. The D.C. Circuit struck that provision, and then said it was unfettered removal power. There was no Article II problem.

Lilly misportrays that case in its reply. Lilly argues that there was the power to reverse the judge's determination. That is incorrect. At page 1339 of the D.C. Circuit's opinions, it wrote that "The register's control over the most significant aspect of the determination for rates is quite faint, and that the decisions could not be reversed or modified or altered once they were issued." That is exactly the case here.

I won't go deep into the details, but I will also say that the Federal Circuit's decision in Arthrex is also directly on point. The Court in Arthrex also struck a for-cause removal provision, which again is not present here. And after doing so, the Arthrex court found that there was no Article II problem, even though the judges at issue there could issue

final decisions reviewable only in the federal circuits, and that the supervising officer lacked any statutory authority to review or nullify those decisions.

THE COURT: Why did they strike the for-cause removal provision?

MS. TALMOR: Yes, Your Honor. They struck the for-cause removal provision because the Supreme Court has made clear that the power to remove is a powerful tool for control. The Supreme Court in Edmond did not, as Lilly portrays, hold that there must be review of the individual decisions of an officer within the agency. Not at all.

Edmond emphasized that there were numerous indications of control, one of them being removal, and there one of them being review. And both the D.C. Circuit and the Federal Circuit concluded that if a statutory restriction on removal were struck, that the judges at issue were inferior officers, just like here.

I'd also like to draw Your Honor's attention to one additional case because again, Lilly stated in its reply that we lacked authority. There's a case called Commonwealth of Pennsylvania versus HHS. It's 80 F.3d 796 from the Third Circuit in 1996. That decision could not be more on point.

It concerns an appeal board within HHS that had been created by the secretary through regulation. The appeal board still exists, although I'm not sure whether its power has

changed since 1996. But there, the Commonwealth of Pennsylvania was challenging a decision by the appeals board reviewing an order from the secretary of HHS. And the Third Circuit said that it was difficult to imagine how the appeals board could be inferior officers under Supreme Court precedent because they still were supervised and directed by the secretary.

I would like to briefly touch on Lilly's arguments about removal. Your Honor, all that matters is that there is no statutory constraint on the secretary's power to remove board members. None whatsoever. Lilly is engaging in subterfuge.

What they do is they focus in the rules on a partial delegation of authority to allow the HRSA administrator to share in the supervision of the panel members. What that means is that the statute does not restrict the secretary in any way from removing board members or panel members. And the secretary did not even purport to bind himself from doing that in the rule.

However, the secretary has many responsibilities and has delegated in the rules to the HRSA administrator the ability to partially supervise the panel by removing a member for cause. The constitutional question, however, is only whether an appointment can be revoked at will, not whether an assignment can be revoked at will.

So not only is the partial delegation to remove a panel member for cause entirely sensible because it allows the HRSA administrator to help supervise the board, but it has no constitutional significance because the Supreme Court stated very clearly in Free Enterprise Fund that the power of removal is incident to the power of appointment. So absent a statutory restriction, any appointing official has unfettered ability to remove their inferiors.

And one last point on this, Lilly has made much of the fact that there is no internal appeals process within HHS under the rule. There are two reasons that that argument failed.

One is because there is no standard that there needs to be an internal agency review process. As we've talked about, that is common throughout the administrative agencies. But even aside from that, the secretary still has the reserved power to reverse or nullify a decision if some panel decision went completely off the rails.

So the Tenth Circuit held that as a general proposition of administrative law, the head of an administrative agency has the power to review and revise the acts of a subordinate where the powers in question are vested in the subordinates under the supervision of the superior. That's Morrow versus Clayton, 326 F2d 36.

The secretary delegated every bit of power that the board had to that board. The secretary can rescind that

delegation, but the secretary does not have to rescind the rule or through another notice and comments to do so, because under that decision and another Fifth Circuit that I will not read out unless Your Honor would like, it is axiomatic that when a principal-officer delegates authority, that absent some statutory restriction, a principal-officer can always reverse an errant decision that he has delegated. And that is why the examples I gave earlier today of other agencies where authorities had been delegated to issue final decisions, the reason that comports with the Constitution in the APA is because the officials are only exercising delegated authority, and implicit in that is the ability of the principal to reverse the decision if they go too far awry.

THE COURT: Okay, let's wrap it up here.

MS. TALMOR: Okay. I'd like to touch on the Article III argument if I may?

THE COURT: Very quickly.

MS. TALMOR: Lilly's Article III challenge really urges the Court to make a radical departure from modern administrative law. The ADR process again is indistinguishable from other schemes because these are only public rights that are at issue.

Now Lilly tries to distract from this by talking about the property rights. That totally fails. The proper formulation of public rights are those that derive from the

federal regulatory scheme where the resolution by an expert agency is deemed essential. That's from Stern versus Marshal.

So what it means is that it's not whether a property is determined. I have provided to Your Honor several examples of other agencies that determine statutory compliance in ways that impact property rights. That's fully common. What matters is the claim. And so we've talked about how here, the ADR panels can only determine overcharging, diversion and duplicate discounting.

The critical point here is that there was no preexisting common law cause of action tried by the courts at Westminster in 1789 for overcharging, duplicate discounting or diverting medication. The proper inquiry isn't whether Lilly's property is affected. It's the nature of the claim.

So here, Lilly does not have any right to set the price for a drug sold to a covered entity. It gave up its right to do so when it accepted Congress' bargain and entered the 340B program. The board is not determining Lilly's right to set its price because the statute already does that.

Lilly admits in its brief that a covered entity's entitlement to 340B discount arises from a public right given that exists as a matter of statute. That is a dispositive concession because the ADR claim Lilly is seeking to thwart is simply a question whether it is violating a statutory obligation to make certain sales to covered entities.

THE COURT: I understand that argument, so you don't need to dwell on that one further.

MS. TALMOR: The public rights arguments?

THE COURT: Right.

MS. TALMOR: Thank you, Your Honor.

Lilly also asserts that most other administrative review schemes require a litigant to apply to Federal Court for enforcement. That is incorrect. It points -- Lilly points to statutes that allow a private party that has prevailed before an agency to then go to Federal Court to enforce the favorable decision. That has no bearing on whether an agency can enforce its own decision. And as we've talked about, agencies very often can enforce their own decisions.

And finally, I'd like to emphasize that HHS fully complied with the APA in promulgating this rule. Lilly is basically asserting that the NPRN issued in 2016 somehow expired or they actually used the word --

THE COURT: Okay, hold on. We're missing it.

Let's see. You'd like to emphasize that HHS fully -- repeat that part. We're having trouble getting it.

MS. TALMOR: Thank you, Your Honor.

I'd like to emphasize that HHS fully complied with the APA in promulgating the rule. Lilly claims --

THE COURT: Wait, complied with the APA in promulgating the rule, right?

MS. TALMOR: Yes, Your Honor.

THE COURT: Okay.

MS. TALMOR: In its brief, Lilly actually used the word "scale." It is asserting that the 2016 NPRN is no longer valid, but the Supreme Court has emphasized that courts are not allowed to impose extra statutory or extra requirements on agencies across the APA. That is what Lilly urges here.

As we briefly talked about, the operative notice to the public on whether rule making is ongoing or has concluded is the Federal Register. Simply because HHS never withdrew this rule from the Federal Register, the public was not notified that the rule was off the table, nor could HHS lawfully abandon any -- its obligation to promulgate this rule because it's mandated by statute. So --

THE COURT: How would you have withdrawn it if that was your intention?

MS. TALMOR: That certainly happens, Your Honor. A withdrawal notice is published in the Federal Register. In fact, some of the cases that we cited in our brief were cases where entities challenged the withdrawal of a notice in the Federal Register. In other words, the operative way to cancel a rule making is to publish a withdrawal in the Federal Register. That in itself is final agency action.

In other words, if an agency puts out an NPRN and then cancels it, withdraws it from the Federal Register, that itself

may be a final agency action that could be challenged by an entity. That didn't happen here. That is the point.

Moreover, the NPRN is very close to the final rule, but all that is required under the APA under controlling Supreme Court and Seventh Circuit precedent, is that the topics under consideration be noticed. There is -- there is no requirement at all that the final rule mirror the notice. That would defy the purpose of the notice to allow entities with an interest in the action to put before the agency things that it should consider.

THE COURT: Okay, we need to wrap up.

MS. TALMOR: I will ask if Your Honor has any additional questions?

THE COURT: Say that again.

MS. TALMOR: I'm happy to answer any additional questions. If not, then I will ask that you deny the motion.

THE COURT: All right. Thank you for that. I don't have any additional questions right now, and I appreciate very much your thorough advocacy, and especially since we had to do it through Zoom. You did well.

MS. TALMOR: Thank you for permitting me to do it by Zoom.

THE COURT: All right.

Okay, Mr. O'Quinn, do you want ten minutes here to rebut?

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

We've covered a lot of ground, and I'm going to try to respond as concisely as I can to as many points as have been raised.

I want to start with the issue vis a vis the relationship between covered entities and the contract pharmacies. Again, I don't think anything in the decision today, that's before Your Honor today, turns on that. But I do want to respond to a couple of the points that counsel for the government made.

First, I think it's noteworthy that the statute doesn't address covered entities at all. And certainly Congress didn't intend to have a regime in which contract pharmacies would be profiting at the expense of not only manufacturers, but also of patients, but that's exactly what's going on here.

The idea that's advocated by the government that these are really purchases by covered entities and not essentially through -- by the contract pharmacy, we address that, I think, at some length in paragraph 118 of the amended complaint. And I'm not going to repeat that here today. I just would refer Your Honor to it.

The practices that these entities are engaged with, the idea that they are simply acting somehow as an agent for the covered entities, and it's the covered entity that's making

the purchase is pure legal fiction. And it's not consistent with what's actually happening on the ground in terms of the way that these things are operating.

The statute is designed to prevent arbitrage. It prevents diversion. It prevents transfer to a person who's not a patient. And paragraph 118 of the amended complaint addresses the concerns that have multiplied with the explosion of contract pharmacies relating to that issue.

Now having said that by way of background, I want to turn to a couple of the points that counsel for the government made related to both the APA issue and the Article III issue, and particularly part of where she just left off in asserting that there are no private rights at issue.

I think it's important to recognize that just because the covered entity doesn't have a private right of action doesn't mean that Lilly's private rights are not implicated, and it doesn't mean that they can subject Lilly to these types of administrative proceedings. And we cited Professor Caleb Nelson's article in our briefing on the intersection of public and private rights, and how traditionally when those intersect, the fact that a private right is implicated -- in this case it is the private right to sell at the -- to who we want at the price that we want. And the thing that is -- if these panels adjudicate the issue and adjudicate it incorrectly, it is that private right that is going to be impaired. And traditionally

that was a question for a court as explained by -- in Professor Nelson's article.

THE COURT: Wait, the defendant's response to that is that by entering into this statutory regime that gives benefits to Lilly in terms of the manufacture and distribution of pharmaceuticals, that you have transferred your private right into a public right because you've chosen to participate in the public program.

MR. O'QUINN: And, Your Honor, if all that we were dealing with was, for example, a dispute with a covered entity, vis a vis whether or not we properly offered the ceiling price, whether the price was calculated, then that might very well fit within the description of what you just articulated.

But what we're dealing with here is a type of threshold issue. And indeed it's the type of threshold issue that even Crow versus Benson recognized was for a court to decide de novo. There, of course, you have the issue of worker's compensation having replaced the liability regime that exists, but whether somebody was an employee or not in the first place was a question for the court at trial de novo.

And the idea here that there is some APA review available on the back end does not solve the Article III problem for the same reason that appellate review of a bankruptcy court decision by a district court did not solve the Article III problem at issue in Stern versus Marshall because

it wasn't for the Article III court to decide the issues for itself.

If the Government were saying --

THE COURT: Ms. Talmor emphasizes that there are only three kinds of cases that can go before the ADR panels, and after you get outside that system, those three causes of action, basically those three ADR cognizable complaints, that Lilly's interests aren't otherwise restricted in this way. So you can bring whatever judicial actions you want to beyond these that have to do with overcharging, diversion and duplicate discounting.

MR. O'QUINN: Well, and I think that what's very interesting about that, Judge Barker, is that what she is putting within the ambit of overcharging is what the rule refers to as an action for monetary damages and equitable relief, and it includes within it under the ADR Rule itself for the panelists to decide whether or not somebody's a patient, whether or not a contract pharmacy is acting on behalf of a covered entity or not, and that reaches far beyond what I think either Congress or even the Supreme Court in its passing reference to this in Astra, which was not a case that involved Eli Lilly, had in mind in referring to that regime.

THE COURT: So do you think if Lilly had a complaint, I don't mean that with a capital C, just a dispute, Lilly had a dispute with a contract pharmacy -- and you can choose your

theory -- that the only way Lilly could proceed against a contract pharmacy is through this ADR regimen; is that your view?

MR. O'QUINN: Well, Judge Barker, I guess I'd put it this way: I think that the government's theory of -- if Lilly has a dispute about what a contract pharmacy is doing, vis a vis the 340B program, then they're going to say that that would have to be a claim brought against a covered entity in the context of the 340B program because they're going to say that that's really what Lilly's dispute is actually about.

So I think that their theory --

THE COURT: Yes, but let's say that they're wrong about that, that your dispute really is with the contract pharmacy. They're saying that that's not cognizable under the ADR process, that you would retain an Article III process, access to the courts to bring that claim.

MR. O'QUINN: Well, that -- I guess I'll answer it this way. To the extent that the claim is that what the contract pharmacy is doing ties to or turns on whether or not it is operating within the ambit of the 340B program, then I think they would say that that is necessarily funneled into the ADR process. And ultimately, that is -- I'm sorry, Your Honor, go ahead.

THE COURT: Well, they'd have to tie it to the covered entity, wouldn't they? Because they are saying this applies

only to covered entities.

MR. O'QUINN: Yes, they would. And that is the theory that they have articulated, in among other things, the advisory opinion.

THE COURT: Yes, but if they don't tie it to the covered entity, you still have a cause of action, don't you? You're at least entitled to go to court as opposed to the ADR?

MR. O'QUINN: Whether or not we have a cause of action, which I think is a different question, then I don't take the government's position to be that that would be something that is in the context of the 340B program. But I don't -- but given the nature of the issue here, I don't think that there's any daylight in terms of what they've articulated in the content of the advisory opinion.

THE COURT: Okay, go ahead. I didn't mean to get you off track.

MR. O'QUINN: No, no, not at all, Your Honor. While we're on this, let me just say a few more words about the APA issues, just to be clear. We're not saying that the rule had to be identical to what was in the notice of proposed rule making.

What we've identified in our briefing is a number of serious changes that are seriously problematic in which there was no opportunity to comment. That includes the importation of the monetary damages, equitable relief, the making of these

opinions precedential, a very, very significant issue that is not a logical outgrowth of what was proposed.

Now, I'm not aware of a single court actually holding that a withdrawal has to be published in the Federal Register. I've looked at the cases that they cited in their opposition brief and they are all cases in which there was a withdrawal that was published in the Federal Register and the court referred to that fact. But the cases that they cite don't say that a withdrawal has to be published in the Federal Register. And in this case, not only do actions speak louder than words, but words speak loudly. HHS explained what it was doing back in March of 2020, and a HRSA official said, "It would be challenging to put forth rule making on a dispute resolution process when many of the issues that would arise for dispute are only outlined in guidance." And defendants understood that would be legally unenforceable.

The reason that they withdrew, and the reason that they didn't promulgate something else is because you had a federal district court in Washington saying that you couldn't do substantive rule making. And to the extent that what they were trying to do was use ADR as a back door way of engaging in substantive rule making, well, that's what a court said that you couldn't do. That is what as a consequence of the rule -- of the rule in which it makes the panel decisions precedential, and that was something that again, no opportunity to comment.

So whether you think it was withdrawn or not, ultimately the fact that the rule is not the "logical outgrowth" of what had been articulated in 2016 in a number of material ways means that we are likely to succeed on our APA challenge --

THE COURT: Where did your quote come from that was the one in, I think, March 2020?

MR. O'QUINN: Yeah, it is -- you can find it in paragraph 134 of our amended complaint. It is from a news outlet that is reporting on the statement of a HRSA official on the status of ADR Rule making, and it's referenced at paragraph 134 of our amended complaint.

THE COURT: Thank you.

MR. O'QUINN: Now, I'd like to turn briefly to Article II. I'll come back to Article III and then I'll close.

The -- they argue that the absence of direct review of a decision doesn't make somebody a principal-officer. And I think that there's a little bit of sleight of hand going on here.

No one is saying that a principal-officer necessarily has to review the work of the inferior officer. The argument is that they have to be able to review the work of the inferior officer. And here, what you have is not an issue of delegation. You have a statute that tells the secretary that he is to create this body, and that the decisions that this

body makes by statute will be a final agency decision and will be binding on the parties. And so this is a very rare statutory regime. It is analogous --

THE COURT: Why isn't it subject to the APA general processes of appealing even a final decision at the agency level, at the ADR level?

MR. O'QUINN: Just to be clear so that we're not misunderstanding each other: A party that's unhappy with that final agency action can file a complaint in court under the APA to challenge that decision, but that gets back to Justice Scalia's point in Edmond where he said that it was -- that part of what differentiated the Coast Guard judges that were at issue there versus the tax court judges that had been at issue in an earlier case, is that the Coast Guard judge's decisions were reviewable within the Executive Branch by the Court of Appeals for the Armed Forces.

The tax court judges, their work was only reviewable by the "third branch," the courts. And the argument is simply this, that what Edmond, as part of the necessary holding of Edmond, an issue that is currently in the Supreme Court in Arthrex is that if there is a final decision that is final on behalf of the Executive Branch, and the only other review of that decision lies in the Judicial Branch, well, that final decision on behalf of the Executive Branch has to be made by a principal-officer, or it has to be a decision that a

principal-officer could have reviewed.

The statutory regime here is such that the principal-officer can't review the decision. When the decision is made, it is final agency action and it is binding. And that is true regardless of whether or not these individuals are removable at will because that doesn't do anything after they've made the decision.

THE COURT: All right.

MR. O'QUINN: And with respect to the cases that they cite from the D.C. Circuit, I think Fleming supports us. This was the case from last week. They specifically noted that the secretary did have the ability to step in and review the decision. And in Intercollegiate, there was some availability of review. Now it wasn't de novo review, but there was some availability of review for the register of copyrights. And in Edmond, Justice Scalia said it wasn't dispositive that the Court of Appeals for the Armed Forces didn't have de novo review. It was enough that they had the ability to review before there was a final decision on the Executive Branch.

If the Court has other questions on Article II, I'm happy to address those. Otherwise I'll turn to Article III and I'll close.

THE COURT: Do Article III and then wrap it up, please.

MR. O'QUINN: So, Your Honor, with respect to Article

III, as I said before, this is not some sort of -- to the extent that APA review follows, it's not de novo review. And that is, of course, what was at issue at Stern. At least it's not de novo as to everything. There may be some aspects that would be.

And ultimately, at the end of the day, whether or not other agencies have the power to issue injunctions and orders and so forth, if those are about, you know, issues between the agency and a private party, well, those are implicating public rights as opposed to what's implicated here, which is Lilly's preexisting private rights. And the forbearer to Lilly's rights here and the rights that are at issue are the common law right to sell to whom you choose, and to sell at the price at which you choose. And that right, that preexisting common law right, is going to be necessarily decided in the context of these ADR proceedings. And the agency has essentially already told you that it knows what the answer's going to be because it has issued its --

THE COURT: Does Lilly have the prerogative to drop out of this program? Do you have to be part of the 340B program?

MR. O'QUINN: Well, I'll answer it this way, Your Honor, in the sense that being part of the 340B program is a condition for being -- having your drug eligible for reimbursement under Medicare and Medicaid, which, of course,

serve like one fifth --

THE COURT: You've got reasons to participate, but you don't have to participate.

MR. O'QUINN: That is -- I would submit --

THE COURT: Isn't that your private right?

MR. O'QUINN: Certainly you are absolutely right to say, Your Honor, that Lilly would have the right not to participate in Medicare and Medicaid. As a practical matter, I think that is akin to the sort of economic dragooning the Chief Justice has talked about in other contexts. And I think what's going on here is, you know, as a practical matter, analogous to unconstitutional conditions that Congress will impose on other exercises of rights. That is, its voluntary, but in the sense that if you're making drugs for the elderly, all of whom are in these programs, as a practical matter, it's very difficult to say that there's actually a meaningful choice, just like the objector --

THE COURT: Right, they've got coercive powers.

MR. O'QUINN: And the Supreme Court has been very clear that there are limits to how far the Government can go with the use of such coercive powers. You can't say "I will grant you a permit to build your house on the beach if you grant the public access a right of way," sort of the Nollan and Dolan line of cases.

So ultimately, I think what you have here still are

private rights even if they are limitations or impairment on these private rights. In the same way that if you have a preexisting state law right and then there is preemption that takes place, it may impair it, but ultimately the question is, who should be deciding that? And the answer is an Article III judge. And that brings me to where I wanted to conclude unless Your Honor has --

THE COURT: No, that's good. Bring it home now.

MR. O'QUINN: -- other questions. Thank you, Your Honor.

And that's this: You heard this from the government's counsel earlier today. It was cited in their brief. They talk about public outcry, about what Eli Lilly has done here. And they talk about, you know, letters from hundreds of members of Congress who were dissatisfied with Lilly's decision.

That is exactly why the framers created the three-part system of justice that they did, to ensure that a neutral arbiter would be available for deciding cases, you know, not just for the politically favored of the moment, but the politically unfavored at the moment.

And our basic submission here is that the violations of both Article II for purposes of accountability, of Article III in terms of impartiality, and of the Administrative Procedure Act in terms of putting the public on notice, and then following through with a rule that has actually been

commented on and been able to address the types of concerns that we've articulated, that those failures here result in a fundamentally-unfair process that is neither impartial nor accountable, and it should be enjoined while Your Honor considers these questions and others in Lilly's complaint.

We thank the Court for its time.

THE COURT: Thank you very much, Mr. O'Quinn. Thank you, Miss Talmor, too.

We'll try to hand down a ruling promptly given the fact that you're seeking injunctive relief, which allows you to elbow to the front of the queue, and so we'll try to honor that. I do want to look at some of the cases that you've raised today and make sure I have those well in mind before we issue a ruling, but we'll turn to this promptly.

I don't think that there's anything else you need to supply by way of filings for me to do the work at hand. So we'll just let the record stand as it is. You may interpose whatever objections you wanted to, Miss Talmor, to the slides that were presented if you just want to send me a brief reference to those page numbers.

Now hang on just a minute. My law clerk came over here and I've got to find out if I just made a mistake.

(Off-the-record discussion.)

The Clerk raises a good question, and that is with respect to the substitution of parties to replace the secretary

of HHS's name. So do you want me to do that? Do you want me to do that, Miss Talmor?

MS. TALMOR: Yes, please. Thank you, Your Honor.

THE COURT: All right.

MR. O'QUINN: No objection on behalf of Lilly, Your Honor.

THE COURT: It's usually a pretty minor procedural shift, but we'll do that.

Okay, thank you again very much. We all owe a debt of thanks to our court reporter who managed through all of this for three hours. So that's pretty good. Thank you all. It's good to see you today.

COURT CLERK: All rise.

THE COURT: Stay safe all of you.

MS. TALMOR: Thank you.

MR. O'QUINN: Thank you, Your Honor. Good to be back in court.

THE COURT: You'll carry only good germs back to Chicago.

(Court adjourned at 1:05 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 March 5th, 2021

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