

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF INDIANA
INDIANAPOLIS DIVISION

ELI LILLY AND COMPANY, ET AL,)	
Plaintiffs,)	CAUSE NO.:
)	1:21-C-00081/SEB-MJD
)	Indianapolis, Indiana
-v-)	May 27th , 2021
)	3:00 p.m.
ROBERT P. CHARROW in his)	
official capacity as General)	
Counsel of Health & Human)	
Services, UNITED STATES)	
DEPARTMENT OF HEALTH AND HUMAN)	
SERVICES, HEALTH RESOURCES AND)	
SERVICES ADMINISTRATION, NORRIS)	
COCHRAN in his official capacity))	
as Acting Secretary of Health &)	
Human Services, DIANA ESPINOZA)	
in her official capacity as)	
Acting Administrator of the)	
Health Resources and Services)	
Administration,)	
Defendants.)	

**Before the Honorable
SARAH EVANS BARKER, JUDGE**

OFFICIAL REPORTER'S TRANSCRIPT OF
TEMPORARY RESTRAINING ORDER

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

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A P P E A R A N C E S

For Plaintiffs: John C. O'Quinn, Esq.
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For Defendants: Kate Talmor, Esq.
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1 (Open court.)

2 THE COURT: Good afternoon, all.

3 MR. PAUL: Good afternoon.

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

5 MS. TALMOR: Good afternoon, Your Honor.

6 THE COURT: Now, this says my volume is not on, but is
7 it?

8 COURT CLERK: You're speaking through the sound
9 system.

10 THE COURT: Can you hear me all right? Let's just
11 make sure we're clicking here.

12 Mr. Paul, can you hear me okay?

13 MR. PAUL: Yes, Your Honor.

14 THE COURT: And Mr. O'Quinn?

15 MR. O'QUINN: Yes, Your Honor. Can you hear me?

16 THE COURT: Yes, I can hear you.

17 And Ms. -- say your last name again.

18 MS. TALMOR: Talmor.

19 THE COURT: Talmor? Tal-a-more (phonetic)? I'm
20 looking at it, but it's not spelled the same, is it? Is your
21 first name Kate?

22 MS. TALMOR: Yes, Your Honor. I think it's coming up
23 strangely on Zoom, but it's Kate Talmor.

24 THE COURT: Yeah, Talamore, is it?

25 MS. TALMOR: Yes, Your Honor.

1 THE COURT: Okay. Well, I remember you from the prior
2 hearing, but I was thrown off by the little caption there.

3 Are you ready for us to take up the matters at hand
4 here? Everybody? Yes?

5 MR. O'QUINN: Yes for the plaintiff, Your Honor.

6 THE COURT: We have convened so that I can hear from
7 each of you with respect to the requested TRO that Lilly has
8 sought in its recent filings, but we find ourselves in sort of
9 a procedural thicket here.

10 So I want to try to clarify a little bit, if I can,
11 the procedural situation because it's quite convoluted and
12 we're overlapping now on deadlines and schedules and so forth.

13 The reason I'm feeling a need to address this is
14 because Lilly has filed -- sorry, the defendant, the
15 government, has filed an unopposed motion for an extension of
16 time to file a combined briefing. So I just want to talk about
17 the schedule for a minute.

18 The primary litigation, the initial lawsuit, based on
19 the December 30th, 2020 advisory opinion from -- that was
20 issued by the government was heard by the Court and I enjoined
21 the ADR process basically finding procedural APA kinds of
22 deficiencies.

23 That's the underlying lawsuit, and that has not been
24 finally resolved beyond just the injunctive relief. So the
25 government's brief in support of its motion to dismiss and

1 motion for summary judgment.

2 (Brief interruption)

3 I'm getting somebody else talking. We have a lot of
4 people listening, and you should all have your computers on
5 mute.

6 Okay. So the defendant's brief on its motion to
7 dismiss and motion for summary judgment, and Lilly's response
8 to those filings and the opening brief have already been filed.
9 Lilly -- the opening brief is a reference to Lilly's cross
10 motion for summary judgment. So those have been filed.

11 Defendant's reply on these issues and in response to
12 these briefs is due June 1, just a few days from today, but
13 that's the date that is the subject of the request for the
14 continuance to June 4th to allow the government to file a brief
15 in response to the preliminary injunction response.

16 Plaintiff's reply then is not due until June 14th. So
17 we're right in the middle of trying to get the initial lawsuit
18 teed up properly for the Court to resolve. And then I'll just
19 say it this way, although I don't mean it quite as negatively
20 as it sounds, out of left field comes a May 17th, 2021
21 enforcement letter to Lilly's issued by the compliance and
22 enforcement arm. What are the initials again?

23 MR. O'QUINN: H-R-S-A, Your Honor.

24 THE COURT: H-R, say it again.

25 MR. O'QUINN: Health Resources and Services

1 Administration, also referred to sometimes as HRSA.

2 THE COURT: Okay, good, thank you. I knew the agency
3 but I forgot the acronym.

4 HRSA issued a letter on May 17th, 2021, which was an
5 enforcement letter that Lilly's has interpreted as an effort to
6 basically do an end run around the primary litigation that is
7 pending. The government denies that that's what it is, but the
8 defendants are seeking through that letter to enforce the
9 December 30, 2020 advisory opinion against Lilly. That's
10 Lilly's take on it, and that's what has prompted the request
11 for the TRO.

12 Plaintiff's opening brief on that TRO and preliminary
13 injunction have been filed. The defense response to the TRO
14 request was due on June 4th, although I have briefing from the
15 government. I guess it's on the motion for preliminary
16 injunction, not the TRO that's due on June 4th. So we're
17 getting -- and then plaintiff's reply is due June 14th. And
18 there is supposed to be an in-person hearing on June 16th.

19 That's on Lilly's motion for preliminary injunction.
20 On Lilly's motion for TRO, it's basically the same request as
21 the relief for the preliminary injunction. And both sides
22 filed briefs on that today.

23 So we're tripping all over ourselves with respect to
24 the procedural posture of the case. And there are various
25 arguments by both sides, that one side says is at stake, the

1 other side says no, that's not true. So it's gotten pretty
2 confusing.

3 It's -- you're in a court of equity here when you're
4 seeking injunctive relief such as you have. And so the
5 fairness of this schedule and what's being asked for is part of
6 the Court's consideration. So the May 17th, 2021, letter, for
7 example, imposed a deadline of June 1 on Lilly's to respond to
8 that letter.

9 In the last paragraph, it says that "HRSA requests
10 that Lilly provide an update on its plan to restart selling
11 without restriction covered outpatient drugs at the 340B price
12 to covered entities that dispense medications through contract
13 pharmacy arrangements by June 1, 2021."

14 So that June date, coming as it does right after a
15 national holiday and without really much notice, has required
16 the heroics of the parties as well as the Court to try to
17 respond in accordance with your rights when a TRO is filed.

18 So it's not going to be enough for you simply to get
19 the matter briefed and argued because I have to rule on these
20 issues, and I think that it at least makes the June 1 date
21 unrealistic. I don't know -- that's not an order yet but it's
22 troublesome that the date would be so soon. It's also
23 troublesome that this arm of the department would issue the
24 May 17th letter without apparent regard to the litigation
25 schedule that is underway in the other lawsuit.

1 It does look punitive. It looks -- maybe the milder
2 way of saying that is incentive because the same lawyers are
3 trying to respond to all of it in the same court. The same
4 judge is trying to respond.

5 So I don't know if HRSA didn't check or they checked
6 and thought this would be another way for them to advance their
7 concerns and interests, but it looks a little like piling on by
8 the government with these deadlines. I'm only speaking of the
9 deadlines.

10 So you're leaving us in a tough spot in terms of just
11 trying to keep track of what is being filed, what needs to be
12 filed and what rulings are required both as we go along and
13 ultimately with respect to all the forms of relief that are
14 being sought.

15 So that said, I want to take up the issue of the TRO
16 today, only that, and see if we can determine whether with
17 respect to the May 17th letter, the enforcement letter, there
18 is a basis for some sort of injunctive relief that will answer
19 Lilly's concerns or dash them if they are unfounded concerns.

20 So it's your motion, Mr. O'Quinn. I've read the
21 submissions, but I'll hear you on that.

22 MR. O'QUINN: Thank you, Judge Barker. May it please
23 the Court. Again John O'Quinn, on behalf of plaintiff, Eli
24 Lilly, and we very much do appreciate the Court hearing this
25 matter on such short notice.

1 As the Court is aware, and as we've just been
2 discussing, the parties are in the midst of recent cross
3 motions for summary judgment in this action --

4 THE COURT: Hang on just a minute, Mr. O'Quinn. I can
5 barely hear this when it's coming through the system. Do you
6 have earphones? Do you have some way I can hear it?

7 (Off-the-record discussion.)

8 Speak again, Mr. O'Quinn. Let me see if I can hear
9 you any better.

10 MR. O'QUINN: Is that any better, Your Honor?

11 THE COURT: Not much, but I'll get in closer to the
12 computer. It's coming through our courtroom system here and so
13 the sound is going everywhere.

14 MR. O'QUINN: I can try to dial in from my phone, and
15 leave the video on and switch to the phone if you think that
16 would be better, Your Honor.

17 THE COURT: I don't know how to answer the question.
18 Go ahead and try it on your phone, would you, Mr. O'Quinn?

19 MR. O'QUINN: I'd be happy to.

20 THE COURT: Don't think I'm not impressed by your
21 savvy, Mr. O'Quinn.

22 MR. O'QUINN: I'm figuring out all of this technology
23 hopefully in time not to have to be able to use it.

24 (Off-the-record discussion.)

25 MR. O'QUINN: Your Honor, can you hear me any better?

1 THE COURT: Yes, that's better.

2 MR. O'QUINN: Okay. We'll proceed this way then.

3 Taking this from the top, again, Your Honor, we
4 appreciate you hearing this matter on such short notice. As
5 the Court is aware, the parties are currently in the midst of
6 briefing cross motions for summary judgment in this action,
7 both on the ADR Rule, which was the subject of the previous
8 preliminary injunction, and on the December 30th advisory
9 opinion decision, which announced that manufacturers such as
10 Lilly were obligated to sell their pharmaceuticals to contract
11 pharmacies at 340B discount prices.

12 Now among the core issues that are presented in this
13 case are number one, whether the government can, consistent
14 with the --

15 THE COURT: Sorry, hang on a minute. I just can't get
16 it. Let's try the headset.

17 Ms. Talmor, say something to me and let me see how I
18 hear you.

19 MS. TALMOR: Good afternoon, Your Honor.

20 THE COURT: That's better.

21 Have you got a microphone like that, Mr. O'Quinn?

22 MR. O'QUINN: I'll look, Your Honor.

23 THE COURT: Say something again, Ms. Talmor, because
24 we're checking the headsets.

25 MS. TALMOR: Yes, Your Honor. Testing. Can you hear

1 me?

2 THE COURT: I can actually hear you in the ambient
3 space here, but Mr. O'Quinn's microphone is too far away from
4 him.

5 MS. TALMOR: I think the headphones seem to make a
6 difference.

7 MR. O'QUINN: Let me try it one more time before I
8 plug it in. Any better, Your Honor? Can you hear me any
9 better this way, Your Honor?

10 THE COURT: Now I'm getting all the feedback from
11 this.

12 Go ahead, Mr. O'Quinn. I'm just going to try to
13 concentrate here.

14 MR. O'QUINN: I apologize. The phone that I have is
15 one that doesn't have an insert forehead buds, and so I think
16 I've reached the limits of my technological capabilities, but I
17 will do my best with this.

18 THE COURT: Maybe you better go back to where you were
19 before because this is not working.

20 MR. O'QUINN: I'll go back to the computer, Your
21 Honor.

22 THE COURT: Yes.

23 (Off-the-record discussion.)

24 THE COURT: Are you back in business, Mr. O'Quinn?

25 MR. O'QUINN: Is this any better, Your Honor?

1 THE COURT: Yes, that's better. You're up closer to
2 it. Can you still read your papers?

3 MR. O'QUINN: I can.

4 THE COURT: Okay. Now --

5 MR. O'QUINN: I'm glad we'll be in person for the next
6 one.

7 THE COURT: Yeah, me too.

8 MR. O'QUINN: So, Your Honor, what I was saying is
9 that the core issues that are presented in this case are:
10 Number one, whether the government can, consistent with the
11 340B statute and the constitution, require manufacturers such
12 as Lilly to provide the 340B discounts to contract pharmacies
13 as it purported to do in its December 30th decision; and number
14 two, even assuming that the agency has authority to issue such
15 a decision in the first place, whether the decision announced
16 in that December 30 advisory opinion is the kind of decision
17 that required the agency to go through reasoned notice and
18 comment rule-making.

19 Now as Your Honor noted, while those issues and others
20 were pending before the Court, set to be fully briefed and ripe
21 for decision in just a little over two weeks, the government
22 sent a letter to Lilly last week saying that it had now
23 determined that Lilly was in violation of its obligations and
24 threatening to issue penalties if Lilly did not comply
25 "immediately."

1 So (indecipherable) --

2 THE COURT: Wait, we missed it, Mr. O'Quinn. The
3 court reporter didn't get it.

4 MR. O'QUINN: I said the letter wasn't sent to
5 counsel. It doesn't acknowledge these proceedings or the fact
6 that these issues are pending before the Court. And it's an
7 extraordinary letter in that regard. It can only be explained
8 by political motivation and outcry, certainly not reasoned
9 administrative decision making, which is what we have been
10 concerned about in this case from the very beginning, Your
11 Honor.

12 The letter proves, as I said at the last hearing, that
13 the outcome of any ADR process would have been preordained with
14 no meaningful opportunity for a fair hearing and the Court was
15 right to enjoin that process.

16 Now the government demands to encroach upon the
17 decision-making process before this Court and force Lilly's
18 compliance with the government's position even before this
19 Court renders a decision.

20 THE COURT: Let me ask you a question, Mr. O'Quinn.

21 I don't read that to be what the May letter requires.
22 The May letter requires that by this June 1st date -- let me
23 find it again -- you're to provide a plan for restarting the
24 selling of the outpatient drugs.

25 So I don't understand this letter to be anything

1 beyond what's written in that last paragraph. The reference to
2 the possible sanctions, the penalties of up to \$5,000 for each
3 instance of overcharging is basically to get your attention but
4 they're not threatening to do that. This is -- as I understand
5 it, this is a notice of violation and the first step of the
6 agency in an enforcement action. So it's separate from the
7 issues that were raised in the prior complaint and request for
8 preliminary injunction where the Court enjoined the ADR
9 process.

10 So I don't see the threat to Lilly's from this letter
11 that would warrant a TRO based on what they have actually asked
12 you. They're not asking for any -- they've not made a
13 determination on the merits. They're not actually doing
14 anything other than saying they've done their audit and based
15 on their audit and their analysis, that Lilly's policy is not
16 consistent with the statute. And so I don't get what you think
17 is the threat here that warrants a TRO. What am I supposed to
18 restrain?

19 MR. O'QUINN: I appreciate the questions, Your Honor,
20 and there's two issues that are packed into that. One is what
21 is in this letter. And two is what are the issues before the
22 Court, and how do the issues that are before the Court
23 intersect with this letter.

24 And I agree it's not about the ADR process. It's not
25 about the ADR process that Your Honor has enjoined. It is

1 about the enforcement of the decision that the agency announced
2 in the advisory opinion on December 30th requiring that we sell
3 to or, if the government prefers, through contract pharmacies
4 as opposed to just selling to covered entities.

5 So if you look at the last page of the letter, Your
6 Honor, and the second paragraph from the top, it says -- the
7 sentence begins "For the reasons set forth above, Lilly must
8 immediately begin offering its covered outpatient drugs at the
9 340B ceiling price to covered entities through their contract
10 pharmacy arrangements."

11 That is the issue presented in Counts 1 through 4 of
12 the complaint pending before the Court. And this letter
13 doesn't just require that we give them a status update. Indeed
14 I reached out to the government to say "Can we have agreement
15 that there's not going to be adverse action taken pending the
16 outcome of this case?" And that wasn't something that they
17 could agree to.

18 And the reason that's significant, Your Honor, is
19 because the letter puts us to a Hobson's choice. It says you
20 either must immediately comply or you're going to face civil
21 monetary penalties as described in the final ruling.

22 And it specifically says that "Whether civil monetary
23 penalties are warranted, based on Lilly's willingness to
24 comply" and that is what we say in response on June 1st. It's
25 going to go with whether we face civil monetary penalties for

1 not agreeing to do the very thing that we have challenged in
2 this court, namely whether we have to sell 340B discounted
3 drugs to contract pharmacies.

4 THE COURT: Okay. Let me insert myself here.

5 If you view this letter as the first step in the
6 enforcement action as the government has described it, then all
7 that paragraph says on page 2, the first full paragraph, is
8 "This is what our audit has revealed. You're not in compliance
9 with the 340B ceiling price requirements. And as a result,
10 there are monies owed either by virtue of overcharges for which
11 there should be a credit or a refund to the covered entities."

12 So this is their position. This is what they are
13 saying. This is what their end goal is. But I don't read this
14 letter to be a threat to impose sanctions beyond the request
15 that's articulated there, and that is, "This is where we think
16 you're in violation, this is our position, and by June 1, you
17 need to start putting together a plan to restart selling that
18 complies with the law as we're telling you what it is in our
19 enforcement action."

20 So I don't read that paragraph to be an expression of
21 imminent threat or concern. In fact, when I read this letter,
22 this is sort of a lesser point, but it makes me think maybe the
23 right-hand at the department didn't know what the left hand was
24 doing because the unfairness of June 1 is apparent given all
25 the other deadlines in the case, and that there's nothing in

1 this letter that requires June 1. This letter could have said
2 July 1, except that they feel strongly about it in that there
3 are people who are supposed to be getting these beneficial
4 prices who are not getting them because of your policy.

5 So there is an exigency. There's just not a crisis.
6 And this letter could have been sent with a different time
7 frame that wouldn't create the confusion that I think this
8 letter has by virtue of importing a June 1st deadline into this
9 larger structure of briefing deadlines.

10 So I just don't read anything in this letter to create
11 the imminent threat that you attach to it, not if you agree
12 with Lilly's description of it that it's a violation letter and
13 this is the first step in their enforcement action --

14 MR. O'QUINN: Your Honor --

15 THE COURT: -- which is separate, they say; this is
16 separate because this is the agency enforcement action as
17 opposed to the general counsel's opinion which came out on
18 December 30th.

19 I think maybe this department likes to work on the
20 basis of the day before a holiday. The December 30th letter
21 comes down right before. It's like people cleaning off their
22 desks. I'll leave that one to you, Katie, to decide if that's
23 true.

24 MR. O'QUINN: Your Honor, I think several points.
25 First, I think this letter looks exactly like the type of

1 threatened enforcement action that the Supreme Court addressed
2 in the Sackett versus EPA case, as well as other cases, Your
3 Honor, to make the point that when a party is threatened with
4 imminent enforcement action unless it takes certain acts, then
5 that is itself something that is reviewable, it is
6 challengeable. And we can, if we need to, and we'd be happy to
7 do so and we could do it tonight, file a second amended
8 complaint that challenges this particular letter.

9 And the fact that the advisory opinion was general
10 guidance, a general position, and now you have a letter that
11 applies it specifically, doesn't make any difference in terms
12 of the issues that are before the Court.

13 The challenge to the advisory opinion is properly
14 before the Court because a "Litigant specific final decision is
15 not a requirement for APA suits as the Seventh Circuit recently
16 held in Builders Bank versus FDIC." It's a Seventh Circuit
17 opinion from 2017.

18 So what you have is you have an advisory opinion that
19 we have challenged. If we're right about our challenge, then
20 this more recent letter could have never issued. And the
21 threatened actions under that letter could never occur because
22 they involve the same question, which is what is our statutory
23 obligation under 340B in terms of selling to contract
24 pharmacies. And if the Court concludes, as we have raised
25 in -- specifically in Count 2 of our complaints, that the

1 statute does not require such sales, then that viciates this
2 May 17 letter.

3 THE COURT: Where do you find authority for your
4 argument that you're being -- or Lilly is being faced with the
5 requirement that Lilly sell discounted drugs to specific
6 pharmacies? I don't see that in the statute. That's not how I
7 read that. They have to give it to the covered entities and
8 that's the extent of the obligation, isn't it? That Lilly --

9 MR. O'QUINN: I agree.

10 THE COURT: That Lilly has to sell, at these reduced
11 prices, the drugs to covered entities but there's nothing in
12 the law that says how the covered entities distribute them or
13 sell them or dispose of them. Is there? Can you tell me what
14 you're relying on for that or are you just telling me that's
15 how it plays out in the real world?

16 MR. O'QUINN: I think it's a little bit of both, Your
17 Honor. So first, I agree that the statute did not require that
18 we sell to contract pharmacies. The statute only requires that
19 we sell to covered entities. And that is the heart of the
20 issue that is teed up in the summary judgment briefing that
21 we're about halfway through briefing in front of Your Honor.

22 THE COURT: So has Lilly continued to sell the 340B
23 drugs at the discounted price to covered entities?

24 MR. O'QUINN: We absolutely have, Your Honor. Lilly
25 is willing and does sell to covered entities. What it doesn't

1 do is sell to contract pharmacies who, after the fact, after
2 they have, as a retailer, sold a drug to a particular
3 patient --

4 THE COURT: Well, that's what I'm asking you,
5 Mr. O'Quinn. Where is that foreclosed? Where is that
6 prohibited?

7 MR. O'QUINN: Well, Your Honor, I think it's
8 foreclosed in three ways.

9 First, the statute specifically identifies who the
10 entities that we have to sell to are and who they are not. And
11 just to be clear, in the contract pharmacy transactions that
12 we're talking about, there's never a situation in which the
13 covered entity takes title to a drug, that it ever actually
14 purchases a drug or that even actually makes a decision about
15 dispensing a particular drug or where it is dispensed.

16 THE COURT: That's my question, Mr. O'Quinn. Those
17 aren't your concerns under the statute, are they? Because the
18 statute simply says you have to sell to covered entities, and
19 it identifies the entities. And there's been an opinion that
20 says if you don't have an in-house pharmacy, then it has to go
21 to the pharmacy that the covered entity designates.

22 But beyond selling the drugs at the discounted price
23 to the covered entities, that's what you're supposed to do in
24 exchange for your promise under the agreement you signed -- I
25 say you, but I always mean Lilly -- the agreement you signed to

1 get the benefit of the expanded sales. You just have to make
2 them available to the covered entities at this reduced price
3 but there's nothing about purchases or sales to pharmacies.

4 You do have a distribution requirement though, don't
5 you?

6 MR. O'QUINN: Your Honor, we have a requirement to
7 sell to covered entities. On that, we're in vigorous
8 agreement.

9 THE COURT: All right. And you're telling me that
10 Lilly's never stopped doing that?

11 MR. O'QUINN: Lilly has not stopped making sales to
12 covered entities. What Lilly has stopped doing is -- what
13 Lilly has done is gone back to the arrangement that existed in
14 1996 as opposed to what HRSA would like us to do today. And
15 under that arrangement, Lilly makes its drugs available to
16 covered entities that wish to purchase it. They can purchase
17 it directly and make it available -- if they do not have an
18 in-house pharmacy, it makes it available to them through a
19 single outside pharmacy.

20 What it does not do is make it available for
21 reimbursement demands that come from contract pharmacies that
22 purportedly have relationships with these covered entities. And
23 what you have is a situation where weeks, months after drugs
24 are dispensed, a contract pharmacy can make a demand for a
25 purchase that actually isn't for the benefit of a patient of a

1 covered entity in order to replenish the supply that it
2 allegedly disbursed on behalf of a patient of a covered entity.

3 And I think it's important to understand what's going
4 on here because the statute does not say that we must sell 340B
5 discounted drugs to patients of covered entities, nor does it
6 say that we must sell 340B discount drugs to retailers who are
7 selling to patients of covered entities, but only to covered
8 entities. And that is the heart of the issue that is presented
9 in the cross motions for summary judgment.

10 The government understands that the statute doesn't
11 require such direct sales. That is why the advisory opinion
12 engages in such gymnastics to come up with this purported
13 agency relationship to try to argue that these sales are okay
14 or are required because the contract pharmacy is acting as an
15 agency of the covered entities.

16 THE COURT: Mr. O'Quinn, let me ask you a question:
17 Is it Lilly's policy that a covered entity can be denied the
18 340B discounts when the covered entity directs the discounted
19 drugs to be shipped to an outside dispenser?

20 MR. O'QUINN: Well, the short answer, Your Honor, is
21 they can designate one and Lilly will honor that. What Lilly
22 doesn't do is honor requests from contract pharmacies in a
23 situation where the covered entity is not making the purchase,
24 is not taking title, is not controlling the dispensing of the
25 drug.

1 THE COURT: Okay. So explain to me, Mr. O'Quinn, in a
2 step-by-step way, how this happens. Lilly gets a request from
3 a covered entity to supply the discounted-priced drugs. So
4 that request comes from a covered entity, right?

5 MR. O'QUINN: Respectfully, Your Honor, it doesn't
6 work that way at all. And perhaps, you know, the single best
7 resource that I can point the Court to as you think about these
8 issues is the amicus brief that was filed just a week or two
9 ago by a 340B expert who then proceeds to describe exactly how
10 drugs are disbursed through this program. And he describes the
11 history in great detail.

12 In 1992, the 340B statute --

13 THE COURT: Wait, excuse me, I've not read the amicus
14 brief, and I'm asking you.

15 MR. O'QUINN: I understand.

16 THE COURT: You tell me, Mr. O'Quinn. I don't care if
17 you dumb it down for me. That will be all right. But tell me
18 how this works step by step and where you think your rights
19 arise.

20 MR. O'QUINN: Yes, so let me try to describe it. I'll
21 go back, and I think it would be helpful to talk a little bit
22 about the history, because I think --

23 THE COURT: No, I just want you to tell me the process
24 today, the process today.

25 MR. O'QUINN: So the process that happens today is

1 that if a patient goes to get a prescription filled, that
2 prescription --

3 THE COURT: No, I'm sorry, sir. Take it from Lilly's
4 perspective. Lilly gets an order --

5 MR. O'QUINN: I am, Your Honor.

6 THE COURT: Well, you're telling me --

7 MR. O'QUINN: There's --

8 THE COURT: Wait a minute. You're telling me about a
9 patient. I want to know about Lilly, the manufacturer.

10 MR. O'QUINN: Your Honor, we don't --

11 THE COURT: Go ahead.

12 MR. O'QUINN: Your Honor, in order to describe how an
13 order makes its way to Lilly, Lilly gets an order in the
14 context of a contract pharmacy. Lilly gets an order from a
15 contract pharmacy. Covered entities can send orders directly
16 to Lilly, too. And if a covered entity sends an order to Lilly
17 for stock, that is, I want X number of X drug, then Lilly sends
18 stock to the covered entity.

19 With respect to the contract pharmacies, what has been
20 the prevailing model over the last several years is that the
21 contract pharmacy just orders its stock from Lilly in general,
22 whether it's for 340B patients or whether it's for anybody
23 else. They just order it en masse. What happens is that a
24 patient comes in and the contract pharmacy dispenses the drug.
25 Call it a contract pharmacy, it's just a regular pharmacy. Any

1 patient comes in, they dispense the drug.

2 After the fact, using algorithms, that is, they go
3 back and decide was this person potentially the patient of a
4 covered entity. And using algorithms, they make a decision on
5 this. And if they do, they then go have their third-party
6 administrator basically ask for a credit from Lilly. That is
7 they will say "Well, when you sell us the next bottle, when you
8 sell us the next vial, we want it at the 340B price because we
9 think this person that we sold it to a few weeks or months ago
10 may have been a 340B patient." That is how it happens right
11 now.

12 So there is never a purchase under that so-called
13 replenishment model, and I'd be happy to walk through this in
14 more detail and was planning to in the context of our summary
15 judgment brief, or for that matter, the upcoming preliminary
16 injunction hearing, but that is the way the model works is that
17 the drugs purchased by a contract pharmacy are, in fact,
18 purchased by a contract pharmacy. They are not purchased by
19 covered entities. And then it is this entire accounting
20 exercise in which they say "Well, we think maybe this could
21 have been to a 340B patient. So we should get money back or we
22 should get the next one for a lower price," which is very
23 different than how the world existed and what Congress had in
24 mind when this all came into being where covered entities
25 themselves would go and make a purchase from Lilly.

1 So to this day, if a covered entity comes to us and
2 says "We'd like to make a purchase," Lilly will sell them what
3 they are asking for. What Lilly is not doing is engaging in,
4 you know, the receiving end of this arbitrage that's being done
5 by contract pharmacies on the theory that somebody may have
6 been a patient of a 340B entity, a covered entity.

7 THE COURT: So in this time since you changed your
8 policy, there have been no requests by covered entities that
9 you have refused to fill; is that true?

10 MR. O'QUINN: It is true that with respect to covered
11 entities themselves, we are willing to sell to covered
12 entities. I don't know whether there have been any disputes
13 with somebody about whether they are a covered entity or not,
14 but I know that we are willing to sell to covered entities.

15 And we are -- more than that, we are willing to sell
16 to a single contract pharmacy location for them if they do not
17 have their own in-house pharmacy, because we are committed to
18 providing drug access.

19 What we are not committed to, and what the statute
20 neither requires nor contemplates is for these for-profit
21 pharmacies to be able to engage in essentially the type of
22 arbitrage that they are engaged in at our expense and --

23 THE COURT: Hang on a minute, Mr. O'Quinn. So your
24 statement that Lilly has, during this period of time when you
25 changed your procedures from what the department has told you

1 you ought to be doing, has always made sales to covered
2 entities, but also to any and all of the contract pharmacies
3 attached to the covered entities or just one?

4 MR. O'QUINN: No, Your Honor, just to the covered
5 entities and to any contract pharmacy that they wholly own or
6 to a single contract pharmacy location if they do not have an
7 in-house pharmacy.

8 THE COURT: All right. But previously they weren't
9 limited to a single contract pharmacy, right?

10 MR. O'QUINN: Well, if the question is, was there a
11 time where Lilly had been permitting reimbursement along the
12 lines that I was describing earlier, yes, that is true. But
13 Lilly came to recognize that the situation was untenable, that
14 there was too much abuse and that it was not adhering to the
15 benefits of patients. So Lilly said it would -- from that
16 point, which was about a year ago that Lilly announced this,
17 Lilly made clear what its policy would be in terms of
18 absolutely being willing to sell to covered entities, but not
19 to reimburse through some unlimited number of contract pharmacy
20 arrangements, and the statute doesn't contemplate sales to
21 contract pharmacies at 340B discounts.

22 THE COURT: So getting back to the May 17 enforcement
23 letter, except for the June 1st, 2021 part, how does this
24 create a crisis for Lilly's that warrants the Court's
25 extraordinary powers here?

1 MR. O'QUINN: No, I appreciate that we are asking for
2 emergency, extraordinary relief, Your Honor. And I think it's
3 warranted here because what the letter does is it puts Lilly to
4 a Hobson's choice. The choice is, you can immediately begin
5 selling through these contract pharmacies, honoring these
6 so-called contract pharmacy contractual arrangements, or if you
7 are not willing to do that, if you are not willing to make
8 immediate reimbursements to third parties for whom you will
9 never be able to get the money back from, and giving discounts
10 immediately to third parties that you will not be able to get
11 the money back from, if you are not willing to do that, then
12 you will be subject to penalties, significant penalties. And
13 that is exactly --

14 THE COURT: But excuse me, Mr. O'Quinn, that's been
15 their policy all along. This is their --

16 MR. O'QUINN: Well, respectfully, Your Honor, it
17 hasn't --

18 THE COURT: Wait, Mr. O'Quinn. This has been their
19 policy all along that this is how they interpret the statute.
20 This is how they think the duty devolves on Lilly's and the
21 other manufacturers of pharmaceuticals. That -- so I don't
22 understand why this letter creates a crisis for Lilly's.

23 MR. O'QUINN: Respectfully, Your Honor, it has not
24 been their policy all along. It is not the policy that was in
25 the 1996 guidance, which only gave a safe harbor for covered

1 entities with respect to one contract pharmacy. It was not the
2 policy in the 2010 guidance, which did not contemplate this
3 replenishment model that we've been talking about. And the
4 first time that they articulated this position was in the
5 December 30th advisory opinion. And that is why I'm now here
6 asking for a TRO or a preliminary injunction relating to the
7 advisory opinion, because while the government explains it,
8 this May 17 letter is just simply the other shoe falling from
9 the December 30th advisory opinion decision.

10 THE COURT: So what do you want enjoined, Mr. O'Quinn?

11 MR. O'QUINN: I want the government to be enjoined
12 from requiring us to offer -- to use their words -- to offer
13 their covered outpatient drugs at 340B ceiling prices to
14 contract pharmacy arrangements pending this Court making a
15 decision on the merits on that issue.

16 THE COURT: That is not what that letter says. The
17 letter says "Here's how we see it. And by June 1st, you've got
18 to provide an update on your plan to restart selling without
19 restriction" and so forth. So you have to come up with a plan.

20 MR. O'QUINN: Well, the plan, I think --

21 THE COURT: And the plan -- let me just go on. The
22 plan would be the plan, I assume, that you would deploy if you
23 didn't prevail in the merits of your lawsuit.

24 MR. O'QUINN: Well, Your Honor, that is the rub,
25 right? In other words, if that's what the government was

1 asking for, if it was saying "Could you tell us what your plan
2 is if you lose this lawsuit?" That would be one thing.

3 Because obviously, you know, we will abide by the
4 decision in this case. And I assume that the government will
5 as well. And that's really the rub here is whether or not the
6 government can then say "Well, if you don't immediately begin
7 offering outpatient drugs, and if you do not demonstrate your
8 willingness to comply with what we say your obligations are,
9 and to demonstrate that immediately, then you will be subject
10 to penalties." That, I think, is what is untenable here
11 because that is what interferes with the very issues before the
12 Court.

13 If the Court decides the merits of the advisory -- of
14 the challenge to the advisory opinion, the December 30
15 decision, that will be dispositive of the things that are
16 presented in this May 17th letter. And I understand that the
17 government has a slightly different view on that, but I think
18 it's impossible that if this Court decides on the merits the
19 question of statutory interpretation and decides in our favor,
20 then that leaves no room for what the government is threatening
21 in the May 17th letter.

22 Likewise, if the Court says that the December 30
23 decision was procedurally improper, then it needed to go
24 through a notice and comment rule making, that you needed to
25 hear what the -- that the government needed to take into

1 account all sorts of significant considerations, the cost, the
2 benefits, whether they benefit, et cetera, et cetera. All of
3 that will require reasoned agency decision making, none of
4 which is reflected in the advisory opinion, which wasn't
5 subject to any type of notice and comment rule making. And the
6 May 17 letter, Your Honor, does nothing to cure that, does
7 nothing to make it better.

8 So our position is that these two rise and fall
9 together. And that is why if the Court were to enter a
10 preliminary injunction pending resolution of this case, which I
11 think would, be very, very soon, then that would protect us
12 from the actions that the government has threatened in this
13 letter, which as the Supreme Court said in Sackett versus EPA
14 and in U.S. Corps of Engineers versus Hawk, if you don't have
15 to be -- you don't have to already have the enforcement action
16 taken against you in order to be able to curtail the government
17 when it's threatened such actions, and that's exactly what we
18 have here. It's exactly the situation as was in Army Corps of
19 Engineers versus Hawks and in Sackett versus EPA.

20 And we -- again, if the Court thinks it would be
21 helpful and certainly if the Court thinks it's necessary, we
22 can file a second amended complaint about this May 17 letter.
23 We can do that forthwith. I just -- I didn't want to burden
24 the Court with additional papers because I think that this
25 letter and actions threatened in it rise and fall with the

1 decision that the Court has on the December 30th advisory
2 opinion on the contract pharmacy requirement.

3 And that was the first time that the government
4 articulated those requirements. The government argued "No, no,
5 that's always been our position." But as we laid out in our
6 complaint, Your Honor, paragraphs 90 to 94, and it's discussed
7 in our preliminary injunction brief, pages 12 to 13, it was
8 only last summer that the government was saying that it could
9 not take enforcement action based on its then existing
10 guidance. And that's what --

11 THE COURT: So wait, Mr. O'Quinn. Lilly's complaint
12 here, the heart of it is that the dispensing mechanism of these
13 drugs that have to be sold pursuant to the 340B program is what
14 causes basically the flood of product into the marketplace
15 beyond what the contemplation of the original statute was,
16 right? That it's the method of dispensing --

17 MR. O'QUINN: I think that's fair, Your Honor.

18 THE COURT: What?

19 MR. O'QUINN: I think that's fair, Your Honor. It's
20 not just dispensing. It is that the sales, the purchases, are
21 actually happening by the contract pharmacies, but I think
22 that's a fair shorthand way to describe it.

23 THE COURT: So the December 30th advisory opinion held
24 in part that to the extent the contract pharmacies were acting
25 as agents of the covered entities, then drug manufacturers,

1 such as Lilly's, who participate in the 340B program, were
2 obligated to deliver the outpatient -- the covered outpatient
3 drugs to those contract pharmacies and to charge the covered
4 entity no more than the 340B ceiling price for the drugs,
5 right? So you get drawn into the dispensing by virtue of this
6 obligation to deliver; is that right?

7 MR. O'QUINN: Well, I think that's the way that the
8 advisory opinion tries to describe it. I think one of the
9 procedural flaws with the advisory opinion is while it renders
10 some conclusions about hypothetical agency relationships, it
11 doesn't examine any facts, any real world facts about what
12 happens with the contract pharmacies and the covered entities,
13 and whether they are ever, in fact, acting as agents of the
14 covered entity, assuming that that would be enough under the
15 statute. It's not, but even if it were, that is not something
16 that the advisory opinion decision addresses.

17 So under Motor Vehicles versus State Farm, such an
18 important aspect of the decision, that the agency simply hasn't
19 considered, and part of why it didn't consider it is because it
20 didn't go through notice and comment. It didn't give anyone a
21 chance to -- it didn't give anyone a heads up, it didn't give
22 anyone a chance to comment on it and to explain what was
23 happening in the real world, and what this -- what the
24 implications of this would be.

25 That's another important factor that the December 30

1 advisory opinion decision simply doesn't consider. Where does
2 the money go? Because under their rationale, the contract
3 pharmacy could pocket it all. And that is decidedly not who
4 Congress intended to benefit under the 340B statute.

5 The 340B statute was ultimately intended to benefit
6 patients. And the fact is that through these contract pharmacy
7 relationships, very few patients are getting any type of
8 discount provided to them. And what monies flow in the form of
9 a discount to a patient is something that the agency didn't
10 consider. What money flows to the covered entities as opposed
11 to staying in the pocket of these big for-profit pharmacy
12 chains is something that the agency didn't consider.

13 THE COURT: So it sounds like, Mr. O'Quinn, the way
14 you describe the system is that the way things have evolved,
15 the covered entity and the single contract pharmacy arrangement
16 is a fiction. And that, in fact, the drugs go directly to the
17 pharmacy that dispenses to the patient, and then through some
18 algorithm tries to figure out what percentage of its
19 distribution of those drugs went to Medicare or
20 Medicaid-eligible customers. Is that right?

21 MR. O'QUINN: That is exactly right, Judge Barker.
22 And the upshot of that is that the statutory requirement for us
23 to sell does not apply, because the statutory requirement is
24 that we offer the covered entity the opportunity to make these
25 purchases, not these contract pharmacies that are making these

1 purchases and then doing accounting mechanisms after the fact.

2 They are not the ones that we're obligated to make a
3 sale to. It is the covered entities. And if we were, that
4 would raise -- as we explained in our complaint and our summary
5 judgment paper, that would raise some very serious
6 constitutional questions under the takings clause.

7 THE COURT: Okay. Since Lilly changed its policy and
8 you tell me you have been selling 340B drugs to the covered
9 entities in this interim time, how are you doing that? How are
10 you -- what are the mechanics, the nuts and bolts, of that?

11 MR. O'QUINN: Judge Barker, the short answer is that
12 when a covered entity -- for example, let me take the simplest
13 example. If a covered entity has its own in-house pharmacy and
14 they put in an order for a certain amount of stock because they
15 know that -- they anticipate that their patients are going to
16 need it, then we sell that to the covered entity at its -- at
17 the 340B ceiling price.

18 It is similar when they work with a single contract
19 pharmacy. There are different models one could use.
20 Historically what happened from 1996 until 2010 is that when
21 they work with a single contract pharmacy, that contract
22 pharmacy did what you might expect. It had a separate
23 inventory that it kept on behalf of the 340B ceiling --

24 THE COURT: I'm not asking about the history,
25 Mr. O'Quinn. I'm saying during this period since you changed

1 the policy, and you tell me that you have not ever failed to
2 give the discounted price to covered entities, how are you
3 doing that?

4 MR. O'QUINN: My understanding, Your Honor, and this
5 is where we reach the limits of what I know, but I certainly
6 will endeavor to know more before our next hearing, is simply
7 that they place an order and we send them the product.

8 How that works and in more granular detail, I'm not
9 aware. And how specifically it works with their -- in the case
10 of a single contract pharmacy, I think depends on the specific
11 arrangements. But I know it is something that is discussed by
12 and discussed with the covered entity and Eli Lilly.

13 THE COURT: Hang on just a minute.

14 (Off-the-record discussion.)

15 My clerk has a good question. She says if Lilly is
16 still dealing with the covered entities, but the covered
17 entities have multiple contract pharmacies that they deal with,
18 do you still supply the drugs to the multiple contract
19 pharmacies?

20 MR. O'QUINN: No. It's one contract pharmacy unless
21 it is a contract pharmacy that is owned by the covered entity
22 itself.

23 (Off-the-record discussion.)

24 THE COURT: Let me just clarify because we're a little
25 confused here. Lilly will sell to the covered entity --

1 MR. O'QUINN: Correct.

2 THE COURT: Period.

3 MR. O'QUINN: Period.

4 THE COURT: You'll also sell to a covered entity that
5 has a contract pharmacy if the covered entity doesn't have a
6 pharmacy in-house basically. Is that true?

7 MR. O'QUINN: Yes.

8 THE COURT: Will Lilly -- has Lilly been selling to
9 covered entities, whatever they ask for, even if the covered
10 entity deals with multiple contract pharmacies?

11 MR. O'QUINN: Yes. In other words, if the -- I think
12 what you're asking is if the covered entity has its own -- in
13 multiple contract pharmacy arrangements, are we still willing
14 to sell directly to the covered entity itself? Yes.

15 THE COURT: So if the contract entity is in that
16 category of whatever it was, 15 kinds of entities, and they
17 make an order, you fill it and what they do with it, you leave
18 to them to decide; is that true?

19 MR. O'QUINN: That is true, Judge Barker. In terms of
20 the sales that we make to the covered entity, the covered
21 entities then decide what to do with that pursuant to the
22 statute.

23 THE COURT: Okay. I've kept you from perhaps
24 attending to your outline there. So is there something else
25 you want to add because I want to turn to Miss Talmor?

1 MR. O'QUINN: I appreciate that, Your Honor. Just a
2 couple of points, and that's this: The Court plainly has
3 authority to enjoin enforcement of an agency decision if the
4 Court believes that we are reasonably likely to show that it is
5 invalid because it was promulgated the wrong way or because it
6 is contrary to substantive law, that is, for example,
7 inconsistent with the statute.

8 Respectfully, the December 30th contract pharmacy
9 opinion is such a decision. It articulates obligations. It
10 articulates requirements on manufacturers. And the May 17th
11 letter is simply an attempt by the agency to enforce that same
12 decision. And it makes no difference whether the government,
13 in the May 17th letter, fights the December 30 decision or not.
14 It doesn't change the substance of what the agency is doing.
15 It doesn't diminish this Court's authority to interpret the
16 340B statute, to enforce the APA, and to enjoin the government
17 from taking action that would be inconsistent with either of
18 those.

19 And as we cited in the short brief that we submitted
20 yesterday, the case called Habitat Education Center versus
21 Kimball's, the court there noted "Defendants cite no authority
22 and I have found none that would require plaintiff to file a
23 fresh lawsuit to challenge a final agency action, and the
24 action is no more than the latest iteration of an earlier
25 action that is the subject of a pending lawsuit."

1 That is exactly what we have here. If the
2 December 30th decision is substantively or procedurally
3 inadequate, then the May 17th letter is too. And we ask that
4 the Court enjoin enforcement of either pending a decision on
5 the pending cross motions for summary judgment that will be
6 fully briefed in just over two weeks. If the Court has any
7 other questions, I'd be happy to answer.

8 THE COURT: Thank you, Mr. O'Quinn. Not right now.
9 Miss Talmor?

10 MS. TALMOR: Thank you, Your Honor. HRSA, as the
11 government agency charged with oversight and enforcement of the
12 340B program, recently made a determination that Lilly, along
13 with five other manufacturers, are violating the statute
14 through their contract pharmacy restrictions.

15 This Court should deny Lilly's TRO for four reasons:
16 Because HRSA's violation letter is not yet before the Court;
17 because there is nothing improper in HRSA having made its
18 determination at this time; because Lilly is wrong on the
19 merits of the statutory dispute and is fundamentally
20 misportraying the facts of what is going on in these
21 transactions; and because the entry of an injunction will not
22 prevent irreparable harm. Indeed, it will have no practical
23 affect as this litigation proceeds.

24 Taking the first point I'd like to address quickly:
25 The violation letter is a new agency action that is not

1 predicated on the general counsel's advisory opinion from last
2 December. Lilly's argument that the violation letter rests on
3 and rises and falls with the advisory opinion are inaccurate.

4 In reality, this letter determined for the first time
5 that Lilly is noncompliant with its statutory violations. It
6 is the first step in an enforcement action. And it resulted
7 from a separate administrative process that was begun months
8 before the advisory opinion ever was authored, and is separate
9 from the advisory opinion. And just to be very plain here, it
10 is HRSA that is statutorily charged with enforcing the 340B
11 statute, not HHS's general counsel.

12 Now in two other --

13 THE COURT: Is this HRSA authority an authority that
14 can be exercised entirely in-house so you don't have the ADR
15 requirements that you had in the other opinion and the other
16 process that was laid out?

17 MS. TALMOR: Absolutely, Your Honor. Now a covered
18 entity can bring a claim in the ADR process, at least as to
19 other manufacturers while Your Honor's injunction is in place.
20 But that is a separate process from HRSA exercising its own
21 statutory authority.

22 And indeed, that is born out by the fact that HRSA
23 issued a letter to Lilly last August stating that it was
24 undergoing review of Lilly's policy. That is the process that
25 culminated in the violation letter. And as I noted, violation

1 letters that are similar went to five other manufacturers on
2 the same day.

3 Now the two other --

4 THE COURT: So the precursor to the May 17, 2021
5 letter was the August notice letter; is that right?

6 MS. TALMOR: Yes, Your Honor.

7 THE COURT: All right. And the August 2020 letter
8 that went out was independent of the December 30th advisory
9 opinion?

10 MS. TALMOR: Yes, Your Honor.

11 THE COURT: If there had been a notice in June of a
12 violation by Lilly, and then an advisory opinion on
13 December 30th, what's the connection between those two actions?

14 MS. TALMOR: They are not connected, Your Honor.

15 THE COURT: Are you saying there is no connection?
16 There's no legal connection?

17 MS. TALMOR: I am saying that HRSA's action does not
18 depend on the advisory opinion. It would have been taken in
19 the absence of the advisory opinion. And its authority for
20 taking an enforcement action is the statute and the regulations
21 that HRSA has promulgated. It is not the general counsel's
22 advice.

23 THE COURT: Does the HRSA acting administrator take
24 into account the general counsel's opinion?

25 MS. TALMOR: I believe that HRSA would take into

1 account an abundance of authorities, including looking at the
2 opinion of the general counsel. But HRSA is under no
3 obligation to agree. And, in fact, can disagree with the
4 opinion of the general counsel. But I believe that the opinion
5 of the general counsel would be relevant in the same way that
6 the opinion of covered entities that other material that would
7 be before the agency, including previous guidance, all of that
8 would be relevant material. But the action taken by HRSA
9 depends on the statute. It does not depend on the general
10 counsel's interpretation.

11 THE COURT: So what is the impact of the general
12 counsel's opinion then if it doesn't result in any enforcement
13 action?

14 MS. TALMOR: There is absolutely no impact of the
15 general counsel's advisory opinion, Your Honor. And that is
16 the reason that we demonstrated, we think persuasively in our
17 opening brief, that the advisory opinion is not final agency
18 action. It does not impose obligations on manufacturers --

19 THE COURT: So it's just an idle gesture by the
20 department? It has no effect? It's just how the general
21 counsel thinks about it on that particular day?

22 MS. TALMOR: I do not think it is idle, Your Honor. I
23 think on the contrary that it is common for agency counsel to
24 issue advisory opinions to regulated entities setting forth the
25 general counsel's view of a statute that the agency

1 administered. I think there are formal processes where a lot
2 of agencies do that. But that is not basis for an enforcement
3 action, particularly not in a statutory scheme like this where
4 enforcement is vested in a different agency component.

5 So the general counsel issued its advice, as we stated
6 in our brief, in response to a lot of public outcry about the
7 serious harm that Lilly's policy has been causing and still
8 causes. But that is not the basis for HRSA's enforcement
9 action.

10 And in fact, I would point out in two related cases
11 brought by two other manufacturers who also received violation
12 letters, the court has ordered those manufacturers to amend
13 their complaint adding claims to those violation letters, and
14 just this morning, those manufacturers have done so. And just
15 this morning, Defendant stipulated to a revised briefing
16 schedule so that HRSA can produce an administrative record
17 supporting the violation letter, and the parties can brief the
18 merits of it. And I would point out that the only authority
19 that Lilly supports to suggest that it need not do so fully
20 supports our position.

21 In Habitat Education Center versus Kimball, the
22 authority cited in their TRO brief, that court rejected an
23 argument by the government that a plaintiff needed an entirely
24 fresh lawsuit to challenge a new action. And the court said
25 that it is proper for a plaintiff to file supplemental

1 pleadings challenging new agency action when it relates to
2 existing claims. But we're not arguing that Lilly needs a new
3 lawsuit. We're arguing that Lilly needs to amend its complaint
4 and allow briefing on the violation letter --

5 THE COURT: So Mr. O'Quinn has said that Lilly's will
6 do that. They've offered to do it. They've offered to do it
7 quickly. So I don't think we need to delay too much more. Go
8 ahead and file your amended complaint, Mr. O'Quinn.

9 All right. So we mooted that issue. Now go to your
10 next one.

11 MR. O'QUINN: We'll do that, Your Honor.

12 MS. TALMOR: Thank you, Your Honor.

13 Next I'd just like to briefly touch on the reasons why
14 there is nothing improper in HRSA making its determination
15 during the litigation. Lilly is continuing to portray this as
16 though the declarations that it already seeks based on the
17 advisory opinion would moot out the HRSA violation. That is
18 incorrect.

19 Now I would like to, if I may in a moment, talk about
20 the factual inaccuracies in much of what Mr. O'Quinn said, but
21 for now, I would like to say that the agency at no time, either
22 the general counsel nor HRSA, has ever said that Lilly must
23 sell 340B drugs to contract pharmacies.

24 So the declarations that Lilly has asked HRSA to issue
25 would, if this Court were to issue them, would in no way stop

1 HRSA's enforcement because HRSA's enforcement does not order
2 that at all.

3 Now it is Lilly here who has tried to preempt HRSA's
4 enforcement action disclosed back last August when it filed
5 suit challenging the advisory opinion, which again wasn't final
6 agency action.

7 Now defendants are in no way trying to evade judicial
8 review as Lilly suggests. We believe that once Lilly does
9 amend its complaint, that the reasoning set forth in the
10 violation letter and the legality of that reasoning will be
11 before this Court, and this Court can properly decide it on the
12 merits. It is separate from the advisory opinion.

13 Now, as I mentioned, HRSA sent violation letters to
14 six manufacturers. Not all of those manufacturers are even
15 engaged in litigation right now with us, but several of them
16 are. And so we have, I believe it is five different actions
17 pending in district courts across the country with widely
18 varying briefing schedules, including one that is fully briefed
19 and has already had a merits hearing earlier today. And
20 another in which the matter won't be fully briefed for several
21 months to come.

22 So while HRSA is very respectful of the Court's
23 judicial process, I would submit that HRSA is under no
24 obligation to time its enforcement action against multiple
25 regulated entities to coincide with any one particular

1 litigation. And on the contrary, if every time a regulated
2 entity filed suit against the government challenging something
3 an agency was doing, if that obligated the agency to take into
4 account the litigation and even preclear things as Lilly
5 suggests, that would stop the working of government entities in
6 their tracks. That simply is not the law.

7 THE COURT: Did all the other recipients of the
8 enforcement letters have a June 1st response date?

9 MS. TALMOR: Yes, Your Honor, because that deadline
10 wasn't tied to anything in the litigation. That deadline was
11 the culmination of HRSA's determination that covered entities
12 are being wrongly denied access to statutorily discounted drugs
13 that they're entitled to purchase, and that those actions are
14 having such harmful consequences on patients and providers that
15 HRSA is seeking to have the manufacturers reverse their policy,
16 which is the role of the agency.

17 THE COURT: Are you telling me that the HRSA letter
18 says that covered entities have not been supplied the drugs
19 that they've requested? I'm just speaking of the covered
20 entities --

21 MS. TALMOR: Absolutely, Your Honor.

22 THE COURT: I'm not talking about the pharmacies. I'm
23 just talking about the covered entities.

24 MS. TALMOR: Absolutely, Your Honor. The thrust of
25 the letter is that covered entities are being denied access to

1 discounted drugs. And it is a fundamental misportrayal to say
2 that the agency is requiring any sales to contract pharmacies
3 or to pharmacies whatsoever.

4 So the letter that was issued to Lilly is akin to a
5 cease and desist letter, which is a common function of
6 administrative agencies just as the first step in an
7 enforcement proceeding, and --

8 THE COURT: I want to make sure you're not using
9 language that I'm misinterpreting.

10 So when you pull apart the system, the distribution
11 system, and you identify the components of the process as the
12 covered entity and a contract pharmacy, one, if the covered
13 entity doesn't have a pharmacy itself, just speaking about
14 those two parts of the distribution, is it HRSA's view, is it
15 the department's view, is it yours in this litigation, that
16 Lilly has not supplied drugs to those covered entities upon
17 request or upon ordering?

18 MS. TALMOR: Yes, Your Honor. It's stated as plainly
19 as I am able. HRSA has reviewed Lilly's policy and the
20 complaints of covered entities as referenced in the letter.
21 HRSA has determined that Lilly is denying purchases by covered
22 entities in absolute violation of its 340B statutory
23 obligation.

24 HRSA has determined that continued refusal to honor
25 purchases by covered entities may result in sanction and to

1 violate Lilly's PPA. So we stated on page 8 of our TRO
2 opposition this morning that "HRSA agrees with Lilly that the
3 statute does not obligate it to sell to contract pharmacies."

4 Well, I tried as well as I'm able to be mindful of the
5 precise words Mr. O'Quinn used this afternoon, and I believe he
6 said many times that it is Lilly's position that it not be
7 required to sell to contract pharmacies, or that HRSA or in its
8 view the administrator, AO, I'm sorry, is requiring Lilly to
9 sell to contract pharmacies or provide contract pharmacies with
10 discounted prices. None of those statements are true.

11 Lilly could refuse to sell drugs to contract
12 pharmacies if it chose, but Lilly cannot, without violating its
13 statutory obligation, deny purchases by covered entities,
14 including on the basis of the dispensing mechanism chosen by
15 the covered entities.

16 So I think there are two-points to address on that,
17 and there is the merits of the statutory dispute between the
18 parties, and then there are the factual inaccuracies that
19 Mr. O'Quinn discussed earlier today.

20 I'll start with the factual points. Mr. O'Quinn spent
21 a large amount of time discussing the, as he put it,
22 replenishment model of drugs going to contract pharmacies.
23 None of that material is before the Court. No evidence in the
24 record suggests that this replenishment model is an accurate
25 depiction of how covered entities purchase drugs.

1 There simply is no evidence before the Court, and it's
2 not this Court's role at this time to determine whether the
3 manner in which covered entities are purchasing drugs is the
4 best model. What is before the Court once Lilly amends is
5 whether Lilly's policy -- let me rephrase -- whether HRSA has
6 lawfully determined that Lilly's policy violates the statute.
7 And relatedly, when Mr. O'Quinn was discussing the so-called
8 replenishment model, he pointed to an amicus brief that I
9 understand Your Honor has not read. We will show in our
10 forthcoming brief that that amicus brief we contend should not
11 be considered by this Court. It was authored by a Mr. Aaron
12 Vanderveld who Mr. O'Quinn depicted as a 340B expert. In
13 reality, he is a (indecipherable).

14 THE COURT: I'm sorry, he's a what, Miss Talmor?

15 MS. TALMOR: I apologize. He is a consultant who has
16 been paid by Pharma, which is the pharmaceutical industry trade
17 organization, to produce a lengthy study undermining the 340B
18 program.

19 He also is currently accepting monies; in other words,
20 he currently is profiting off of another manufacturer,
21 (indecipherable) contract pharmacy restrictions.
22 Mr. van der Velde has developed the software that at least one,
23 if not other, manufacturers are using to restrict contract
24 pharmacy purchases.

25 So Mr. van der Velde, we believe, is not an expert,

1 but he is a consultant hired by the pharmaceutical industry to
2 undermine this program. So that is not material that this
3 Court should consider in deciding the merits of the statutory
4 question that actually is presented between the parties.

5 THE COURT: I have not permitted any amicus to
6 participate in this litigation, which is one reason I hadn't
7 read that. So I knew that the government opposed it. I'll
8 make a decision with respect to the amicus, but I don't -- I
9 guess I've already said, on this hearing, no. I can't think of
10 any other reason to include them.

11 MS. TALMOR: My broader point, Your Honor, is not just
12 about the brief, but it's that the -- all of the depictions
13 Mr. O'Quinn was giving about contract pharmacies buying the
14 drugs and replenishing their inventory, none of that's in the
15 record. None of that's before the Court --

16 THE COURT: Miss Talmor, you've got to slow down a
17 little bit.

18 MS. TALMOR: I apologize. At no time has the agency
19 required Lilly to sell discounted drugs to contract pharmacies.

20 THE COURT: So it sounds like to me -- let me just
21 say -- that the parties agree as to the specific requirements
22 of the 340B statute. And then after the language of the
23 statute is nailed down, that it's at that point that the
24 parties start to disagree as to what that means. Is that true,
25 Miss Talmor?

1 MS. TALMOR: I'm not sure, Your Honor. I don't think
2 so respectfully. I am not sure exactly the strategy, but I do
3 know that Mr. O'Quinn, both in his filing yesterday and his
4 presentation today, he continues to assert that the agency is
5 making Lilly make sales to contract pharmacies.

6 THE COURT: So let me stop you there. So if I issued
7 an order and said, "No, there's no requirement that sales be
8 made to contract pharmacies in the statute," that's consistent
9 with the government's view, right?

10 MS. TALMOR: Yes, Your Honor.

11 THE COURT: And that is also what Lilly wants. They
12 don't want to have to sell to contract pharmacies, true?

13 MS. TALMOR: Yes, Your Honor. I think the problem is
14 that if that order were issued, my understanding is that Lilly
15 would take it to mean that HRSA's violation letter could not
16 proceed through enforcement proceedings, and we would
17 absolutely take the position that it could. In other words, if
18 this Court rules that Lilly does not have to sell to contract
19 pharmacies, HRSA will proceed with its enforcement action
20 because we, HRSA, has determined that Lilly's policy is
21 wrongfully denying purchases by covered entities on the basis
22 of the dispensing mechanism selected by the covered entity.

23 THE COURT: Okay, I understand your position. Go
24 ahead and make your arguments.

25 MS. TALMOR: Thank you. I'd like to tick through,

1 briefly, the merits. We believe that once Lilly amends, that
2 its challenge to the violation letter will fail on the merits.

3 ,
4 Again, the arguments that the violation letter depends
5 on the advisory opinion is untrue. The determination made by
6 HRSA for the first time that Lilly is overcharging covered
7 entities is based on several factors that derive directly from
8 the statute and existing regulations.

9 So first, HRSA has determined that Lilly's policy is
10 denying sales to covered entities when those covered entities
11 distribute through neighborhood pharmacies. Before I hit a
12 couple other statutory points, I would just like to briefly
13 point out why that matters so much.

14 Some of the covered entities that we are referring to
15 serve particularly large geographic areas, meaning that there
16 could be patients that live hours away from the actual covered
17 entity. And for them to have to travel back to receive their
18 prescriptions directly from the covered entities in-house
19 pharmacy could prove impossible, even for those covered
20 entities that have an in-house pharmacy.

21 And regardless whether they do or not, we're talking
22 about particularly disadvantaged populations. We're talking
23 about people often below the poverty line, that are
24 underinsured and uninsured. And therefore, as we all know, may
25 have transportation barriers. To require all patients of a

1 covered entity to receive their drugs from one location,
2 whether it's in-house or one contract pharmacy, proves an
3 insurmountable barrier for many patients, and simply isn't
4 condoned by the statute.

5 Next, Lilly's continued assertion that it fulfills its
6 statutory obligation by offering discounted drugs to all
7 covered entities, they aren't talking about regular commodities
8 here. We're talking about controlled substances. Lilly doesn't
9 get to determine who does and does not have the lawful ability
10 to take delivery of controlled substances, store them and
11 dispense them, meaning that the vast majority of covered
12 entities do not have the licensing, a pharmacist on staff, the
13 ability to take delivery of Lilly's drugs; thus, they rely on
14 outside pharmacies.

15 And if they do have a small in-house pharmacy, that
16 in-house pharmacy often is not capable of serving all of their
17 patients. So for Lilly to say all covered entities can buy as
18 many drugs as they want is meaningless when the majority of
19 covered entities do not have the ability. They don't have a
20 DEA registration. They don't employ a pharmacist. So it
21 simply is meaningless in practice.

22 Lilly continues to insist that the agency's
23 interpretation has changed since 1996. That is false. We
24 showed in our opening brief and referenced in our brief this
25 morning that the agency has interpreted the statute

1 consistently since 1996 to prohibit manufacturers from denying
2 a sale to a covered entity on the basis of dispensing
3 mechanism.

4 THE COURT: On the basis of what?

5 MS. TALMOR: Dispensing mechanism. I apologize.
6 Dispensing mechanism. In other words, how the drugs are
7 received and given out to patients.

8 So the guidances that the agency has issued since '96
9 have flatly stated that the statute does not allow
10 manufacturers to deny purchases by covered entities.

11 The statutory obligation has never changed. Lilly
12 points to another provision that was added on to the statutory
13 obligation in 2010. This is the discussion and the party's
14 briefs about the language for purchase versus offer.

15 In truth, those words fall in the same statutory
16 command. They refer to the same obligation by Lilly to sell
17 its discounted drugs to covered entities. And the offer
18 language that was added to the statute, what it actually did
19 was it codified an additional requirement that says that Lilly
20 cannot discriminate against covered entities by offering
21 drugs to full price payors on more favorable terms than covered
22 entities.

23 So what that means is that full price payors are
24 allowed to buy Lilly's drugs through a variety of wholesale
25 distribution mechanisms. And HRSA's violation letter, one of

1 the rationales that it relied on, one of the things that it
2 stated is that Lilly is violating its requirements by denying
3 covered entities the ability to purchase on an equal footing
4 with full price payors.

5 The violation letter relies therefore on the plain
6 text of 42 USC 256BA1 to find that Lilly is violating its
7 obligation when it denies purchases by covered entities.

8 It also relies on the text of the purchasing
9 agreements Lilly entered into which require it to ensure that
10 that ceiling price is available to all covered entities. And
11 the violation letter explicitly does not require Lilly to
12 provide any discounts to a pharmacy.

13 It does state that existing regulations -- that's the
14 simple monetary penalty regulation that we cite in our brief --
15 explicitly state that an overcharge will occur when there is
16 any order that a covered entity results in paying more than the
17 ceiling price, which is exactly what happens when Lilly denies
18 purchases through multiple contract pharmacies.

19 As we mentioned in our brief this morning, the
20 statutory history shows that Congress considered, and then
21 removed from the statute, language that would have imposed a
22 restriction just like the one Lilly wants this Court to read
23 into the language. The original draft of the language that we
24 are debating here would have restricted discounted drug sales
25 to drugs that are dispensed by or -- dispensed by a covered

1 entity or through an onsite contract pharmacy.

2 Congress removed that language from the statute. So
3 essentially Lilly asks this Court to read into the statute
4 language that Congress explicitly removed.

5 Lilly's reading also violates the Supreme Court's
6 pronouncement on what the 340B statute requires. So again, the
7 statutory rationale set forth in the violation letter needs to
8 be judged on the four corners of that rationale set forth by
9 the agency, and it is wholly based on the statute and
10 consistent with it.

11 Moreover, Lilly has certainly not shown any
12 entitlement to equitable relief. First of all, it would be
13 improper to enjoin agency actions at large rather than -- I'm
14 sorry, to enjoin agency enforcement rather than a discreet
15 agency action, and that is what Lilly asks for.

16 The injunction they seek would seem impermissibly
17 broad. They aren't asking this Court to enjoin a June 1st
18 deadline to communicate to HRSA. They're asking this Court to
19 stop the agency from proceeding through its normal agency
20 enforcement, which would be improper.

21 THE COURT: Miss Talmor, what is supposed to happen by
22 June 1st?

23 MS. TALMOR: So, HRSA has instructed Lilly, as you
24 pointed out, Your Honor, to communicate to HRSA its plan to
25 come back into compliance with the statute. That presents

1 Lilly with a choice. Lilly can communicate to HRSA its plan
2 and Lilly could reverse its restrictions and resume offering
3 covered entities the ability to purchase discounted drugs no
4 matter how those drugs are dispensed. That is what HRSA
5 believes Lilly should do.

6 However, Lilly has the option of not doing so, and if
7 Lilly does so, what it is essentially doing is risking sanction
8 should its interpretation prove incorrect at the conclusion of
9 this litigation. Here's the critical point when analyzing
10 whether any kind of injunctive relief is warranted --

11 THE COURT: Hold the microphone up by your mouth
12 again.

13 MS. TALMOR: Thank you. Far from preventing an
14 irreparable harm, the injunction that Lilly seeks will not have
15 any practical effect at all. So let's walk through the options
16 if this Court were to -- well, regardless whether this Court
17 entered an injunction or not, if Lilly continues with its
18 policy while this litigation proceeds, then at the end of the
19 this litigation, should the government prevail, as we expect
20 to, Lilly will be subject to sanctions regardless whether there
21 was a TRO or a PI entered. In other words, if this Court were
22 to enjoin further agency action and the government prevails,
23 Lilly is open to sanctions for that entire time until it comes
24 back into statutory compliance.

25 On the reverse --

1 THE COURT: Well, wait a minute. The sanctions turn
2 on a willfulness requirement, don't they?

3 MS. TALMOR: It has to be a knowing and intentional
4 violation.

5 THE COURT: Right. So I mean there's some room there
6 for something less than an automatic sanction, which you've
7 said they are subject to.

8 MS. TALMOR: I apologize, Your Honor, if it sounded as
9 though I meant it was automatic. It is far from automatic.
10 Let me clarify.

11 The agency has made no determination that sanctions
12 are warranted. And I believe the letter states that
13 explicitly. The letter does state that HHS will consider
14 whether sanctions are warranted (indecipherable).

15 THE COURT: Wait, wait, wait, you're going too fast.
16 Pretend like you're having to talk to a jury and slow it down a
17 little bit because we can't -- I can't even follow it, never
18 mind the court reporter getting it down, because you're just
19 going lickety split.

20 MS. TALMOR: I apologize. I will slow way down.

21 The agency has not determined that sanctions are
22 warranted at all and that, I believe, is explicit in the
23 letter. HHS will analyze whether sanctions are warranted based
24 on Lilly's entire course of conduct.

25 We cited in our TRO opposition this morning the

1 regulation that provides for the process of imposing sanctions.
2 There is nothing automatic and that determination would not be
3 made on June 1st. And even if the agency determined at some
4 later date that Lilly should be subject to monetary penalties,
5 that determination would be reviewable by a court, which would
6 provide Lilly the opportunity to argue that, even if it was
7 wrong, that it wasn't knowing and intentional. Lilly has all
8 of the procedural protections there if sanctions ever were --

9 THE COURT: So it sounds like from your explanation
10 that the June 1st date doesn't have any real effect. It's
11 just -- it was just where HRSA pegged a reply date. It could
12 have been July 1. It could have been August 1, right?

13 MS. TALMOR: Kind of, Your Honor. I would qualify
14 that. HRSA does take the position that Lilly is noncompliant,
15 that it's having real world harms, and that Lilly should stop
16 its policy.

17 HRSA does want Lilly to stop its policy. HRSA wants
18 the other manufacturers to cease their restrictions as well
19 because HRSA has made the determination that they are both
20 unlawful and harmful to access to discounted drugs for
21 underserved population.

22 So HRSA does want the manufacturers --

23 THE COURT: I know. I know they want that, but I'm
24 trying to decide does the June 1st date matter? I'm being
25 asked for emergency relief. I have to figure out what doom

1 will occur if June 1 comes and goes and Lilly doesn't respond
2 and I don't make them.

3 MS. TALMOR: Your Honor, I think that is one of the
4 strongest reasons why injunctive relief is not warranted is
5 because there will be no practical impact from actually issuing
6 an injunction. If the agency decides that Lilly is subject to
7 sanction, there is no reason that that determination would
8 necessarily be tied to June 1st. It will be an analysis of all
9 of Lilly's conduct.

10 THE COURT: So why wouldn't the agency change the date
11 sua sponte?

12 MS. TALMOR: I -- because the agency's interest is in
13 having Lilly come into compliance as quickly as possible. And
14 what Mr. O'Quinn --

15 THE COURT: Well, put that in there. Put that in
16 there, "as soon as possible."

17 MS. TALMOR: Your Honor, the manufacturers have shown
18 that they are unwilling to come back into compliance
19 voluntarily. This is the agency's -- this -- as I mentioned
20 earlier, the cease and desist letter, this is the agency
21 putting Lilly on notice that Lilly is violating the statute and
22 that the regulator has determined that Lilly should come into
23 compliance.

24 Now the reason that the June 1st date is depicted as a
25 date to communicate its plan is because HRSA realizes that the

1 manufacturer policies vary and that the real world distribution
2 channel, the wholesale distributors that manufacturers rely on,
3 are complicated. So it's not a matter of flipping a switch and
4 rescinding a policy. So HRSA has instructed manufacturers to
5 let it know by June 1st what steps it will take to come into
6 compliance. It's not a date for the imposition of sanctions.

7 And so we take the position -- certainly I have no
8 idea how long, you know, it will be before we receive Your
9 Honor's ruling. If Lilly decides to wait out the resolution of
10 this case and does not reverse its policy, then the agency may
11 take actions to impose sanctions if the agency prevails, but
12 the June 1st date isn't some magic date that needs to be
13 enjoined.

14 THE COURT: Okay. Well, if there's no magic to it, I
15 honestly don't understand why the agency couldn't take its own
16 steps to ameliorate any confusion or concern that that might
17 turn out to be a date that, while not problematic today,
18 becomes problematic in ways that the plaintiff didn't foresee
19 and we never probed; you didn't explain.

20 When there's a deadline that has to be met, most
21 lawyers will advise their clients not to ignore it.

22 MS. TALMOR: We certainly, for what it's worth, do not
23 think that Lilly should ignore it. Your Honor, we don't think
24 there's anything particularly onerous in ordering each of the
25 drug makers, not just Lilly, to communicate to the regulator a

1 plan to come into compliance within about two weeks, which is
2 what they did. We just -- we don't think there's anything
3 improper or unusual in that.

4 Lilly can choose to ignore the date, but we don't want
5 Lilly to ignore the date. And Mr. O'Quinn mentioned having
6 approached the government before filing his motion.

7 Mr. O'Quinn approached the government about suspending
8 operation of the letter, suspending operation of the date, and
9 the agency did decline to do that because the agency's interest
10 is in having manufacturers come back into compliance as soon as
11 possible.

12 The purpose of these letters is to put six
13 manufacturers on notice that the regulator has determined that
14 their policies violate the statute, and that by violating the
15 statute, they violate their PBAs, which are what entitle them
16 to access Medicare and Medicaid.

17 So the agency's interest is in having manufacturers
18 comply with the statute because, let me be clear, at this time,
19 Lilly's policy is denying purchases by covered entities. And
20 the harms that Lilly lays out in its motion simply could not
21 support injunctive relief.

22 As we've discussed, issuing a TRO or a PI at this
23 point will not prevent HRSA from pursuing civil monetary
24 penalties at the conclusion of this litigation if the
25 government prevails. Lilly points to reputational harm, but

1 that can't support relief because HRSA has already determined
2 that Lilly is violating the statute and HRSA's position will
3 not change if a TRO is entered.

4 Lilly's other claims can't justify relief --

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

6 MS. TALMOR: Lilly's counsel spoke about the
7 importance of notice and comment, but there is no cogent
8 argument that an agency is required to undergo notice and
9 comment before taking an enforcement action.

10 So the notice and comment claim just has no relevance
11 to the violation letter. And, you know, as far as the date
12 here, the public interest is served by Lilly and its peers
13 coming back into compliance with the statute as promptly as
14 possible.

15 So the public interest would not be served either by
16 this Court enjoining further agency proceedings, or by the
17 agency backing off its position that manufacturers should come
18 into compliance. You know, there certainly is no attempt to,
19 as Lilly put it, usurp the litigation here, but HRSA's interest
20 is in having Lilly resume honoring purchases by covered
21 entities, and we feel there is real exigency in that happening.

22 THE COURT: Okay. Is that all?

23 MS. TALMOR: If Your Honor has any further questions,
24 especially related to the merits, I would be happy to answer
25 them.

1 THE COURT: I don't have any more questions. Of
2 course I've read what you've submitted, and I'm alert to the
3 fact that I've got to decide something quickly, so I'm eager to
4 finish up the oral arguments here and do my work.

5 MS. TALMOR: Is there any matter I should address as
6 far as the reason that we asked for combined briefing and the
7 short extension on the remaining brief?

8 THE COURT: You want an extension of time and you
9 won't give me one? Is that what I'm hearing you say?

10 MS. TALMOR: That is not my intention to say.
11 Certainly not. Your Honor, with the unexpected hearing here,
12 my team, which is just three attorneys, we had another hearing
13 just before this one, and we've had four emergency motions that
14 has not allowed us to continue with our reply briefing.

15 THE COURT: Well, I'm just giving you a little bit of
16 a hard time here because if you think you've been busy, so has
17 the Court. I bet Mr. O'Quinn has been, too. That's the nature
18 of what we do for a living. So we're all facing deadlines, but
19 I tried to get you to say "Oh, we'll overlook the June 6th.
20 We'll put it off for 30 days or something." And I couldn't get
21 you to do that. So I'm of two minds about giving you -- you
22 didn't come into court in due equity yourself, Ms. Talmor.

23 MS. TALMOR: Well, Your Honor, respectfully, I don't
24 think there's any real relationship between HRSA asking Lilly
25 to communicate about its plan to come into statutory compliance

1 and counsel's reply brief. I do apologize for this matter
2 being teed up so quickly before the Court, but I don't think
3 those matters are really related, and I would note that Lilly
4 did not oppose our request for a few extra days. And we also
5 believe that it would seriously cut down on the reading
6 material before this Court for us to combine our briefs into
7 one.

8 THE COURT: I get that. I get that it's apples and
9 oranges. I just wanted you to be a little uncomfortable.

10 MS. TALMOR: I am, Your Honor.

11 THE COURT: Okay, very good. I've accomplished what I
12 intended to. I'll grant your motion for the extension of time.

13 MS. TALMOR: Thank you.

14 THE COURT: All right.

15 Mr. O'Quinn, is there anything further that you need
16 to add to the day's record here?

17 MR. O'QUINN: Respectfully, Your Honor, there's quite
18 a bit that I need to respond. I will try to do it very
19 briefly.

20 THE COURT: All right. Get as close to your
21 microphone as you can.

22 MR. O'QUINN: Yes, Your Honor.

23 So first, I think it's important to recognize that
24 with respect to the May 17 letter, government's counsel just
25 told you that Lilly is risking sanctions if it does not comply

1 immediately. That is what you heard. And that is exactly the
2 type of thing that the U.S. Supreme Court in Sackett versus EPA
3 and Corps of Engineers versus Hawks said that a court
4 absolutely can step in and review.

5 And if the Court can step in and review it ultimately,
6 then the Court can step in and review it preliminarily, and can
7 grant emergency relief. It sounds like the government is
8 saying that any number of choices that Lilly has made,
9 including the choice to pursue this lawsuit, could be used
10 against Lilly in terms of sanctions.

11 They keep saying that they want Lilly to come into
12 compliance. You heard her say "come into compliance" multiple
13 times. Well, that is coming into compliance with their view.
14 And the last time I checked, they don't get to decide what the
15 law is. You do. And that is the issue that we have presented
16 in our complaint, and that is the issue that will be presented
17 in the amended complaint, which will raise the exact same
18 issues. And that -- the veiled threats against Lilly, both
19 with respect to sanctions and the threat of potential
20 revocation of PPO, is exactly why this Court ultimately needs
21 to render a substantive decision.

22 Lilly, of course, will abide by a judicial
23 interpretation of the statute. An open and judicial
24 interpretation of the statute is exactly what we're seeking.

25 Now on the issue of interpretation, I think the

1 government's counsel respectfully is playing word games,
2 semantics. And I don't want the Court to be misled about some
3 key points. I don't think there is any dispute about whether
4 or not Lilly is willing to sell to covered entities at ceiling
5 prices when the covered entities are who are making the
6 purchase. The covered entity never pays more than the ceiling
7 price when the covered entity is making the purchase.

8 The word games that you're hearing is over what it
9 means to sell to a contract pharmacy, and the fact is, that
10 query to the contract pharmacy relationships, the covered
11 entities never take title. They never actually make the
12 purchase. Contract pharmacies are what are making the
13 purchase, and the contract pharmacies are not entitled to the
14 340B discounts.

15 Now whether you want to think of that as sales,
16 whether you want to think of that as distribution, however you
17 want to describe it, the statute does not impose an obligation
18 for us to provide discounts to contract pharmacies as opposed
19 to the covered entities. And what we are seeking is relief
20 against the very first thing that the government identified in
21 its letter on May 17th where it says that Eli Lilly's policy
22 places restrictions on 340B pricing to covered entities that
23 dispense medications through pharmacies under contract.

24 That's what we're all talking about here. That is
25 what we contend is not required by the statute. And that is

1 inconsistent with the structure of the statute, and that is
2 what we are seeking relief against, both in terms of our
3 challenge to the administrative order -- excuse me, to the
4 advisory opinion that was issued on December 30th, and with
5 respect to what the government has currently threatened.

6 Now the government's counsel comes back and says that
7 I referred to a bunch of things that are not in the record in
8 terms of the replenishment model and how things actually work
9 in the real world when it comes to contract pharmacies and
10 covered entities. And my simple response is this: If it's not
11 in the administrative record, then that is the government's
12 problem. And that is a reason why the government's
13 December 30th decision should absolutely be vacated at a
14 minimum, because under *Motor Vehicle Association versus State*
15 *Farm*, the agency's absolutely required to consider all
16 important aspects of an issue when it is making a decision.

17 And so if it doesn't have the facts, and if the facts
18 are in the record with respect to how its contract pharmacies
19 actually work, and whether covered entities ever take title,
20 whether they ever have possessions, whether they actually are
21 involved in the dispensing decisions as opposed to an all being
22 an after-the-fact algorithm, well, that is the government's
23 problem and that is reason enough to require vacatur of the
24 advisory opinion and everything that the government is trying
25 to do consistent with that opinion.

1 THE COURT: What is the effect of the general
2 counsel's advisory opinion from December 30, 2020? Miss Talmor
3 says not much.

4 MR. O'QUINN: Yeah, I appreciate that question because
5 that's exactly what I wanted to address next because it is
6 clear on the face that that decision announces obligations, it
7 identifies requirements. It says, and it says it for the first
8 time, interpreting the statutory language at issue, that
9 manufacturers are obligated to make sales through these
10 contract pharmacy arrangements. And that has legal
11 consequences.

12 And again, I think if there was any doubt, the
13 May 17th decision reflects that. Now they say "Oh, well, this
14 has all been a question of some sort of investigation." What
15 investigation? They issued the same letter to a number of
16 manufacturers on the same day in which they just disagree with
17 our interpretation of the statute. There's not anything --
18 there's no investigation here. This is a dispute about what
19 the statute means and what the statute requires.

20 THE COURT: Well, you haven't quite answered my
21 question. You told me what's in the general counsel's advisory
22 opinion, which I can read and have read and thought about and
23 studied, but what difference does it make?

24 That's what Miss Talmor said, that in terms of the
25 enforcement effort that's underway now through HRSA, that it

1 doesn't have any effect.

2 MR. O'QUINN: The advisory opinion, Your Honor, is,
3 respectfully, it's a disguised legislative rule. It is a rule.
4 It didn't go through notice and comment rule making, which it
5 should have, but it is a rule. And part of how you know it's a
6 rule is because it is the first place and the first time when
7 the government imposes the requirement to sell to all contract
8 pharmacies based on this statutory language regardless of what
9 their dispensing model looks like. That's the first time that
10 you see this.

11 And the government spent last year essentially taking
12 the opposite position. This is documented in paragraphs 90 to
13 94 of our complaint. It's at pages 12 to 13 of our preliminary
14 injunction brief. And the government was representing to Lilly
15 that there was no binding obligation in terms of the
16 requirement to sell to or through, or whatever semantics
17 government wants to use, contract pharmacies.

18 That is what they represented to the covered entities
19 themselves in other litigations in part to get that litigation
20 dismissed. That is what they represented to the public. This
21 is laid out, I believe it's in paragraph 96 of our amended
22 complaint about things they said to the public, that there was
23 no requirement that the government -- that -- excuse me, I
24 think it's paragraph 94 of our amended complaint references an
25 article that is reporting on what HRSA represented to it and to

1 the public, that the 340B contract pharmacy guidance that then
2 existed was not legally enforceable. And that contract
3 pharmacy guidance that then existed was guidance that involved
4 a different statutory provision because the statutory language
5 in both the advisory opinion from December and the May 17th
6 letter is --

7 THE COURT: Well, isn't the more likely explanation
8 here, Mr. O'Quinn, that the enforcement action by HRSA that's
9 running down this parallel track either will or will not
10 embrace the general counsel's view and standards, and you don't
11 know yet basically whether that general counsel's advisory
12 opinion will influence the kinds of allegations and findings
13 that HRSA will make if they find that Lilly isn't in
14 compliance.

15 I mean, you don't really know yet how the enforcement
16 arm of the department, the agency, will use the advisory
17 opinion; isn't that true?

18 MR. O'QUINN: Well, Judge Barker, I know one of two
19 things is true. Either it will, which proves my point about
20 the advisory opinion, or it will not, which proves my point
21 about it all being arbitrary and capricious with the government
22 zigzagging on what its rationale is and why it thinks that we
23 have some kind of obligation to sell to or through these
24 contract pharmacies as opposed to all the statute says, which
25 is that we have to make -- we have to honor purchases by

1 covered entities themselves that are no more than the ceiling
2 price.

3 So they either will follow the advisory opinion, which
4 proves my point that it was a legislative rule, or they will
5 abandon it, which will prove my point that this is all
6 arbitrary and capricious. And that is really, I think, where
7 this all ultimately ends, Your Honor, is that there are two
8 issues before the Court, either of which -- and frankly,
9 probably more than this -- will be decisive as to what the
10 government can do here. And that is true now, and it will be
11 true after we amend our complaint to specifically make
12 reference to the May 17th letter. But issue number one is what
13 does the statute require? And if the Court agrees with us,
14 that the statute does not require honoring these accounting
15 arrangements as opposed to sales to the covered entities, then
16 that will be dispositive of the advisory opinion, and that will
17 be dispositive of the May 17th letter and the not veiled
18 threat, the open threats that are being made about it.

19 And number two, if the Court finds that the advisory
20 opinion from December 30th was -- you know, should have been
21 subject to notice and comment but was not, well, that means
22 that they can't be doing what they are trying to do through the
23 May 17th letter either because if it announced a new rule and
24 it did so without notice and comment, then the May 17th letter
25 necessarily falls for the same reasons.

1 So that is why we respectfully submit that these rise
2 and fall together. Again, I'm happy to amend the complaint. I
3 don't think that that makes a substantive difference here, but
4 the fact that we're talking about facts that the government
5 submits are not part of the administrative record just goes to
6 show that the government has not approached its problem
7 solving, its decision making in a way that it's required to
8 under the APA. And in terms of the ultimate question of
9 statutory interpretation, that is a question for the Court and
10 the Court's answer to that question is what should be
11 dispositive of all of these issues.

12 So for these reasons, for the same reasons that the
13 Supreme Court decided Sackett versus EPA, we ask that the Court
14 grant relief in order to protect Lilly from the Hobson's choice
15 that the government has admitted that it has put Lilly to,
16 which is it must either come into compliance or risk severe
17 sanctions.

18 THE COURT: Okay. Thank you very much. Hold on now.
19 Just a minute. Can you turn off the sound now?

20 Can you hear me now?

21 MR. O'QUINN: (Nodded.)

22 THE COURT: Yes, they can.

23 Okay, I'm going to step down from the bench. You just
24 stay there for a minute because I'll step away, and that will
25 be like turning off the technology if we knew how to do that.

1 So just hang on a minute.

2 (Off-the-record discussion.)

3 All right. I wanted to discuss a couple of things
4 with my clerk to make sure I had clarity about my intended
5 course of action here. I will not enter a temporary
6 restraining order against HRSA or the defendant, the Department
7 of Health and Human Services, based on the May 17, 2021
8 enforcement letter. There's no irreparable harm that's
9 threatened to Lilly by virtue of that enforcement letter.

10 There's no likelihood of prevailing on the merits of
11 that enforcement letter as it's been instigated here in the
12 first step of the enforcement proceedings in the form of a
13 violation letter, which is how I interpret that. So I will not
14 grant the requested relief, and the petition for a temporary
15 restraining order is denied.

16 That said, the June 1 date is inequitable. It's
17 unfair. It's the day right after the holiday, and it is
18 insensitive to the way lawyers and their clients like to take
19 advantage of opportunities like Memorial day.

20 And so since this is a court of equity as I am
21 presiding now, I will ameliorate the effect of the June 1st
22 deadline by making it ten days from June 1st, which would be
23 June 10th as the date on which Lilly must submit to HRSA the
24 plan that's referenced in the last paragraph of the May 17th
25 letter.

1 That plan does not need to be expressed in a way that
2 requires Lilly to give up any of its claims in the pending
3 litigation. It can do so without prejudice to its litigation
4 positions and strategies in the primary litigation. That's a
5 usual technique to say without admitting liability, without
6 acceding to the interpretations of HRSA or the explanations,
7 the predicates, that are laid out in that May 17th letter, the
8 Lilly plan for compliance would be to "do what we've said we're
9 required to do." I assume that's what you'll say, that is your
10 position. And if HRSA takes a different view about your
11 interpretation of the plan, then they'll have to prove up
12 through their enforcement mechanism whatever it is they intend
13 to do.

14 So I think that that's the extent of the relief that I
15 can offer today under the usual paradigms of injunctive relief.
16 The other schedules, I granted the government's request for a
17 brief extension to make the filings that were referenced in
18 that motion. And I have directed counsel for Lilly's to go
19 ahead and amend their complaint, which could be done pretty
20 quickly, and get that on file so that everything's incorporated
21 in the litigation that I'm going to have to sort through and
22 resolve. And then we'll hold the in-person hearing on
23 June 16th, 2021 to determine what action to take on Lilly's
24 motion for preliminary injunction.

25 So that's the action that flows from the Court today.

1 Is there anything else I need to address, Mr. O'Quinn?

2 MR. O'QUINN: Not for the plaintiffs, Your Honor,
3 thank you.

4 THE COURT: Anything from you, Miss Talmor?

5 MS. TALMOR: No, Your Honor, thank you.

6 THE COURT: All right. Have a good holiday weekend
7 and I'll be in touch, and we'll see you in mid June.

8 MR. O'QUINN: Thank you, Your Honor. You too.

9 MS. TALMOR: Thank you, Your Honor.

10 (Court adjourned at 5:25 p.m.)

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13 CERTIFICATE OF COURT REPORTER

14

15

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

19

20

21 /S/LAURA HOWIE-WALTERS May 31st, 2021

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