UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF TEXAS
GALVESTON DIVISION

ROBERT L. APTER, ET AL	§	**3:22-CV-00184**
	§	
V.	§	**10:32 A.M. TO 11:39 A.M.**
	§	
DEPARTMENT OF HEALTH AND	§	
HUMAN SERVICES, ET AL	§	**NOVEMBER 1, 2022**

HEARING ON MOTION TO DISMISS
BEFORE THE HONORABLE JEFFREY V. BROWN
Volume 1 of 1 Volume

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PROCEEDINGS

(Call to order of the Court.)

THE COURT: All right. One case on the Court's docket this morning. It's in Cause Number 3:22-CV-184, Robert L. Apter v. United States Department of Health and Human Services and others -- Robert Apter and others v. Department of Health and Human Services and others.

Will the attorneys make their appearances, please. Plaintiff first.

MR. KELSON: Jared Kelson for plaintiffs, Your Honor.

THE COURT: Good morning.

MR. McCOTTER: Trent McCotter for plaintiffs, Your Honor.

THE COURT: Good morning. Welcome.

MR. BELFER: Good morning, Your Honor. Isaac Belfer for the government.

THE COURT: Great. Good to have you.

MR. McDONALD: Good morning. Oliver McDonald for the government.

THE COURT: Great. And I understand we have some folks on the phone who are listening in, and I think George has already asked for you to mute your phones a couple of times and there are people who have not muted their phones and we're going to cut the thing off if --

we're getting a lot of feedback here in the courtroom. Please mute your phones if you want to listen in.

All right. I have read the briefing in the case. I appreciate y'all coming down this morning. Sorry the 10:33:30 weather is not ideal. This is our first time back in our courtroom since -- in a few months. So it's nice to be back in our regular courtroom.

I have a series of questions I want to ask you all; but I would like to get kind of a general argument from 10:33:50 both sides first, recognizing that I am familiar with the case and the briefing. If there is anything that y'all want to add to the briefing you have already provided to the Court, this is your opportunity to do it; and then, we'll discuss some of the questions that I have for both 10:34:07 sides.

So it's the government's motion, if you would like to get us started.

MR. BELFER: Can I come up here?

THE COURT: You can argue from there or from 10:34:17 right here in front of the bench, whichever you prefer, as long as you are speaking into a microphone.

MR. BELFER: I'll try up there.

THE COURT: All right. Come on up. I'm sorry. Hold on a second.

10:34:37 George, can you just mute them so we don't get --

CASE MANAGER: Yes. I can do that.

THE COURT: Just so we don't -- or just turn the volume down so we don't hear them.

CASE MANAGER: Yeah. I lowered the volume.

10:34:47 THE COURT: I'm sorry. Go ahead.

MR. BELFER: After receiving multiple reports of patients requiring medical attention, including hospitalization, after self-medicating with ivermectin products intended for livestock, FDA made several public
10:35:02 statements on social media and on its website written in informal conversational language warning the public about certain risks of using ivermectin products to treat COVID-19.

These statements included non-binding recommendations
10:35:15 to consumers who could purchase animal-use ivermectin over the counter not to take ivermectin to treat COVID-19, but the statements did not say that doctors could not prescribe ivermectin to treat COVID-19 or that consumers could not take ivermectin for that purpose.

10:35:31 Instead, they said that, "If your healthcare provider writes you an ivermectin prescription, fill it through a legitimate source such as a pharmacy and take it exactly as prescribed."

Because the statements simply provided nonbinding
10:35:44 recommendations to consumers, they are not rules and,

thus, are not agency action as required for waiver of sovereign immunity. They did not bind the public or FDA, did not interpret any substantive rules, and did not set agency policy.

10:35:57 The statements are also not final agency action. They do not mark the consummation of FDA's decision-making process because they do not state FDA's final position on the use of ivermectin to treat COVID-19 but instead present FDA's tentative recommendations based on currently

10:36:14 available data.

They also do not have legal consequences for anyone but simply provide nonbinding recommendations to consumers.

Plaintiffs have also failed to meet their burden to

10:36:24 show standing. The amended complaint alleges five injuries to plaintiffs and three injuries to their patients.

Regarding injuries to the plaintiffs, the amended complaint alleges: First, that there was interference

10:36:36 with their ability to practice medicine; second, that they were referred to state medical boards; third, that they were forced to resign from their jobs; fourth, they were subjected to public ridicule; and fifth, that patients delayed seeking treatment from plaintiffs.

10:36:51 And then with regard to injuries to their patients,

the amended complaint alleges three injuries: First, that pharmacists refused to fill patients' ivermectin prescriptions; second, that insurance companies refused to pay for those prescriptions; and third, that patients
10:37:06 delayed seeking treatment from plaintiffs or delayed taking ivermectin.

As discussed in our briefs, many of those injuries are not an adequate injury in fact. Plaintiffs have also not shown that any of their claimed injuries are fairly
10:37:22 traceable to defendants' statements because their injuries were caused by independent third-party conduct that was not a predictable response to those statements.

For example, it was not predictable that plaintiffs' employers would punish them for prescribing ivermectin to
10:37:33 treat COVID-19 when the statements themselves acknowledged doctors' discretion to do just that.

Furthermore, plaintiffs have not shown that the requested relief would likely redress their claimed injuries. Many organizations, in addition to FDA, have
10:37:46 recommended against taking ivermectin to treat COVID-19; and plaintiffs have not shown that removing just the cited FDA statements would likely cause the third parties that allegedly injured them to reverse their past decisions.

Finally, plaintiffs have failed to state a claim
10:38:01 because they did not present their issues in the amended

complaint to FDA. They thereby deprived the agency of the opportunity to consider their issues in the first instance and prevented the agency from creating an administrative record that addressed those issues.

10:38:15 So I would be happy to talk about any further issues but I think that's a good summary and I'll answer any questions the Court has.

THE COURT: Okay. All right. First of all, just a couple of things on -- well, the -- you mentioned the

10:38:32 informational conversational tone of the social media statements. To me, that seems like part of the problem in that those statements don't include the qualifier statements that the article has that was referred to; and I think those -- I think as far as reputational harm goes,

10:39:04 it's the social media statements are what bother me the most. And I don't even know where I'm going with the question here.

But can you understand my concern with that? I mean, it's like was the purpose of those statements really to

10:39:20 advise patients not to self-medicate with ivermectin? The social media -- the social media comments in particular.

MR. BELFER: Right. So I don't think the record shows the FDA's motivation for those statements in particular. We do know that the article was motivated by

10:39:43 people self-medicating with animal-use ivermectin and

requiring hospitalization. So we do know that that was part of FDA's motivation.

And so I think with regards to the social media posts, which are two tweets and an Instagram post, those statements were clearly aimed at consumers. As we discussed, they used this conversational language, you know, "Hold your horses. You are not a horse. You are not a cow." Information like that.

So clearly this was aimed at consumers. It was not aimed at medical professionals or hospitals; and it was not predictable that hospitals or insurance companies or pharmacies would act based on these statements, let alone it was not predictable that they would respond to these statements by firing plaintiffs.

And indeed, the tweets linked to the article. And so if you look at the tweets, they include the link to the article. And so it was predictable that if you include the link to the article, people, you know, will click on the link and will see the full article, which includes that disclaimer that if your doctor writes you a prescription, you should fill it exactly as prescribed.

So in terms of the standing analysis when you are asking was it predictable that third parties would take the actions that they took based on the cited statements, you know -- and it's plaintiffs' burden to show that; and

plaintiffs have not met that burden because, first of all, the tweets included links to the article and those statements were clearly -- they were aimed at consumers, and they were not the sort of statements FDA would make to
10:41:20 influence, for instance, hospitals or, you know, pharmacies or insurance companies. Right.

So I think for those reasons plaintiffs have not shown -- certainly have not shown traceability regarding those statements.

10:41:33 And also, they have not shown redressability regarding those statements because, as we discussed in our brief, many organizations, in addition to FDA, have made public statements advising against the use of ivermectin to treat COVID-19.

10:41:45 So, you know, even if FDA's tweets and other statements were taken down, there would still be many statements by other organizations, like the World Health Organization and Merck, which makes one of these drugs, and CDC and NIH, all advising against the use of
10:41:58 ivermectin to treat COVID-19.

And so it would not -- plaintiffs have not shown that they would -- that the third parties would likely undo their actions, reverse their past decisions, given that all those statements by other parties are still out there.

10:42:14 THE COURT: Okay. It's not just common sense

that it would be predictable that state boards would react to statements by the FDA in ways that they did?

MR. BELFER: So state board -- no state board has made any discipline against plaintiffs. There is an allegation that Apter was referred to a state medical board, but that's all we have. There is no indication there has been any action whatsoever by that state medical board and it's speculative, you know, if or when that medical board will take any action. And as we discussed in our brief, merely being referred to a state medical board is not adequate injury in fact. So, you know, again, it's purely speculative, you know, if or when that state medical board will act and then what weight it might give to that -- to that statement.

Importantly, it wasn't the state medical board that cited the FDA statements. It was some unidentified third party that included the statement in the referral to the state medical board.

So, you know, I think to close the loop on that, essentially, you have this simple allegation after it was referred for discipline but, you know, we don't know if or when the state medical board will act on the referral.

And, you know, if and when it does ultimately act, we don't know to what extent it will give the FDA statements any -- any weight and the fact that there are all these

statements by other organizations, like the World Health Organization and CDC and NIH, indicating that there is not a showing that simply taking away the FDA statements would make any difference or would cause them to act any differently.

10:43:42

THE COURT: Okay. And you are getting into redressability here. The plaintiffs say that I should presume redressability at this stage. Are you aware of any cases in which a motion to dismiss was granted on a failure to show redressability?

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MR. BELFER: Again, off the top of my head, I can't. I can't think of one right now. But we do cite a case in our brief. I believe it's the *Renal Physicians* case from the, I think, DC Circuit, which says that you can't presume redressability simply based on traceability.

10:44:10

So even if it's true that the government's statements caused a third party to make a certain action, you don't -- you can't presume redressability because it's possible that some independent factor is holding those third parties' actions in place.

10:44:26

So here, even if, you know, presuming that the FDA cited statements influenced some third parties to take adverse actions against the plaintiffs, you can't presume redressability because there are these independent third -- other organization statements, again, like the WHO and

10:44:40

NIH and CDC, that are out there; and those statements are still in place recommending against the use of COVID-19 -- against the use of ivermectin to treat COVID-19.

Additionally, you know, if the Court were to rule, for 10:44:55 instance, that the FDA does not have authority to make the cited statements, that wouldn't affect the scientific -- the third-party's scientific understanding of the risks and benefits of treating COVID-19. It would be a legal ruling on, essentially, procedural authority grounds. It 10:45:09 wouldn't go to the scientific merits. And so it wouldn't give the third parties any reason to change their understanding of whether you should use ivermectin to treat COVID-19.

And so for all those reasons, even if the Court were 10:45:21 to order that the cited statements be taken down, plaintiffs haven't shown that that would make any difference because there are all these other statements out there; and their requested relief itself wouldn't give the third parties any reason to change their understanding 10:45:34 of the risks and benefits of taking ivermectin to treat COVID-19. So, you know, the plaintiffs have failed to show redressability as well as traceability.

And, of course, that's only part of the jurisdictional analysis. There is also sovereign immunity. And we think 10:45:48 that's actually an even clearer case why there is no

jurisdiction here.

You know, again, these were -- these were tweets, social media posts in conversational language. They were nonbinding recommendations. They did not make -- they were not binding on anyone. They were not binding on private parties or the FDA. They did not set agency policy. They were simply nonbinding recommendations to the public. And so they were not agency action or final agency action.

10:46:15 And as discussed in our briefs, an important requirement for final agency action is that you need to have a direct effect on the regulated party. So, for instance, in the *Franklin v. Massachusetts* case, the Supreme Court held that the secretary of commerce's report 10:46:30 to the president was not final agency action because it was simply a nonbinding recommendation. The president's report to Congress about congressional apportionment did have a direct effect and was final; but the secretary of commerce's report to the president was not final agency 10:46:46 action because it had, at most, an indirect effect on apportionment. It was simply a nonbinding recommendation to the president.

And similarly, in the *Bennett v. Spear* case the Supreme Court upheld this notion that you need a direct 10:46:58 effect to be final agency action. And here, the

plaintiffs have not shown any direct effect of any of the cited statements on any other party. At most, they show an indirect theory of causation, whereby the cited statements influenced third parties, who in turn allegedly injured plaintiffs. But that indirect line of causation is not sufficient for final agency action.

THE COURT: And on exhaustion, is a citizen petition the only way that the plaintiffs could have challenged the FDA's actions with the agency itself in this case? What else could they have done?

MR. BELFER: So I am -- I think in this particular case I'm not -- I'm not aware of another mechanism that they could have used.

I think, generally, in terms of the issue of exhaustion, there is not only one mechanism. The focus is not on which mechanism you use. Instead, the focus is on just raising your issues somehow to the agency.

So, for instance, if there were, like, a drug approval, then you could raise the issue in the course of the back and forth with FDA about the drug approval or you could raise it, you know, as appropriate, as a citizen petition.

Here, I think a citizen petition would have been appropriate. They could have filed a citizen petition after FDA made its cited statements challenging those

statements and they could have presented all of the issues in their amended complaints to FDA in that citizen petition and that would have been beneficial to the agency by giving the FDA an opportunity to consider the issues, in the first instance, to apply its expertise and discretion, and it would have allowed the agency to compile an administrative record that addressed their issues.

And so, it would have benefited both the agency and the Court; but they failed to do that. The plaintiffs ran straight to court without giving FDA an opportunity to address their issues in the first instance. And under kind of core principles of administrative law, that's unacceptable.

THE COURT: Okay. Let me hear from the plaintiffs. I may have some more questions for you once I have heard from them.

MR. BELFER: Thank you, Your Honor.

THE COURT: Thank you.

MR. KELSON: Good morning, Your Honor.

THE COURT: Good morning.

MR. KELSON: As a general matter, the FDA has no authority to regulate the off-label use of drugs. It never has. That dates back to the -- to when the FDCA was first passed in 1938. It's been a repeated consideration

by Congress. They have never given the FDA that authority. Going so far as to add a provision in 21 USC 396 to expressly prohibit interference, courts across the entire country have repeatedly relied upon that provision to show that -- to show that it applies to the practice of medicine, including the prescription of drugs.

The government is trying to frame this case and its actions and its response to reports about the use of animal ivermectin. That doesn't explain why they then pivoted to talk about human-use ivermectin. There is a disconnect in what they are claiming the justification for these actions were and what they actually did.

This is reaffirmed by the internal FDA documents that talk about this new engagement strategy they had to promote their recommendations to the public and the United States. And it belies the fact that what they were trying to do was stop the use of ivermectin. Their tweets are explicit on that point.

So when the government says this was purely informational, conversational, essentially a PR scheme or a -- excuse me -- a PR endeavor, that doesn't explain why -- that doesn't explain the language they actually used, "Stop it. Stop it with the ivermectin."

In the government's brief when it refers to a number of these statements, including the statements why you

should not use ivermectin to treat or prevent COVID-19, the government has to qualify the statements in its own brief and say "if a doctor prescribes you ivermectin for the use of COVID-19." The government's briefs, therefore, implicitly recognize the title of that document; and the FDA's other actions clearly convey that this is not an acceptable way to treat these patients. The only reason the FDA would engage in these actions is because of their predictable effect, the only explanation.

10:50:49 The Court is right to understand -- recognize that this is a very much common-sense case. The Supreme Court recently, within the last year and a half, has made very, very clear that courts are -- that courts and judges are not required to exhibit a naivete from which ordinary
10:51:03 citizens are free. That was -- you know, that was -- excuse me. That was in 2019 in *Department of Commerce v. New York*. That was Chief Justice Roberts. That applies directly to this case.

To address some of -- to address upfront some of the
10:51:21 government's arguments and some of the government's briefing, I want to be very clear to the Court that the government did not move under 12(b)(6) to challenge any of these claims on their merits. The government is, thus, conceding that the plaintiffs have alleged plausible
10:51:32 interference in their practice of medicine, that they have

alleged plausible claims under the APA. The government has, instead, challenged them all on standing grounds or challenged them on administrative exhaustion grounds or sovereign immunity.

10:51:37 That should inform the Court's position and that should also -- the Court should also take that into consideration when the government tries to backdoor merits considerations into other aspects of this case.

Second, in the government's reply brief the government

10:51:54 replies or the government cites *TransUnion* and says that the plaintiffs are only alleging statutory violations. That is incorrect. We are alleging real harms to real people that are reinforced by the statute that Congress passed in 21, Section 396 and, to be honest, the entirety

10:52:10 of the FDCA, which does not give the FDA the authority that it is trying to assume.

More importantly, if the Court would like to look at -- if the Court would look at *TransUnion*, the government omits the rest of the case, which weighs heavily in favor

10:52:22 of the plaintiffs here. *TransUnion* is very clear that there is an injury in fact when there is a harm that is traditionally recognized as providing the basis for a lawsuit in America or if there is some sort of common-law analog. The Court is also very clear that it doesn't have

10:52:35 to be an exact duplicate. That Congress through statute

or Congress through its own expressions can recognize harms that might have been too trivial at common law but were, nonetheless, harms.

In fact, in *TransUnion* the exact example that the 10:52:48 Court used is various intangible harms, including reputational harm. That is one of the -- that is one of the allegations the plaintiffs have made here and, in fact, provided evidence that they have been maligned on line and that they constantly suffer reputational harm.

10:52:59 If the government is going to label ivermectin a horse medicine or a horse dewormer and promulgate the idea that it is only for animals, then the natural correlation is that doctors who prescribe it are horse doctors or quack doctors, which has been -- which has played out. That is 10:53:12 enough of a harm to get into court.

In addition, *TransUnion* also emphasizes the due respect that courts should pay to the decisions of Congress; and Congress has been very clear that the FDA should not interfere in the practice of medicine. Now the 10:53:27 Court has -- while the Court has recognized that that cannot completely -- that cannot completely remove the necessity of showing injury, it should inform the Court's decision that it is consistent with the Fifth Circuit's decision that the plaintiffs need only show an 10:53:39 identifiable trifle of an injury. The bar is low. Any

sort of injury will do, and the plaintiffs have alleged many here. That injury is sufficient, even if the harm is difficult to prove or difficult to quantify.

Moving forward, the government places a lot of emphasis on traceability. The government's arguments in this regard are flawed.

I'm sorry. I have one more thought I just had about the injury. When the Court talked about injury in *Lujan*, it discussed both a forward and a backward looking analysis. The exact language in *Lujan* allows plaintiffs to present evidence of harms that have accrued.

So even if -- I guess this transitions into the -- sorry. This transitions into traceability. So even if this wasn't predictable, which is a standard for traceability, if in retrospect the plaintiffs can show how these harms were determinative or were caused by the plaintiffs, de facto causality, that is traceability. The plaintiffs are not cabined into the predictability test, even though that is one way of establishing traceability under the constitution, recognized by both the Fifth Circuit and by the Supreme Court.

It's unclear what the -- what the government would have thought their tweets were going to do if -- by saying "stop it with the ivermectin" or "stop it" except to, well, stop the use of ivermectin. The government engaged

in a singularly effective campaign here to malign a common drug that has been used for a very long time and has been dispensed in billions of doses. It's one of the most famously safe drugs in the history of human medicine.

10:55:18 And when people did exactly what the FDA said to "Stop it. Stop it with the ivermectin," I don't understand how that would not be traceable back to the FDA.

So if it wasn't -- so it was predictable. It also, in retrospect, clearly points back to the FDA. When everyone

10:55:36 points to the FDA, there is a pretty good chance that that's where it is coming from.

The plaintiff -- or the government has repeatedly stated that people have their own scientific intuitions about the ivermectin. That's not what is happening here.

10:55:47 People are pointing back and saying, "The FDA said no. The FDA said no."

That is not a scientific analysis. That is a deference to the FDA, to an agency that the federal government set up to be an authoritative voice on the use

10:55:59 of drugs but limited that authority not to practice medicine and not to make recommendations about medicine.

So in that regard the FDA's actions cannot be excused simply because they presume that everyone else has these scientific understanding -- this scientific understanding.

10:56:14 That transitions into redressability. Again, this

is -- there is a common-sense intuition that when everyone points to these FDA statements if a court were to come out and say they were made without lawful authority and vacate them that they would somehow retain their same equal persuasive force. That seems to brink reality, as well.

10:56:30

In addition, the government points to a number of other entities that have taken positions on ivermectin. Each of them are severely flawed. I am not aware of the FDA ever pointing to a pharmaceutical company and saying that its statements have the same force and effect or are of the same persuasive nature as the FDA. That, to me, is a strange argument I have never heard from the FDA before.

10:56:44

And I don't suspect the FDA plans on deferring to pharmaceutical companies in the future. In addition, the FDA regularly disagrees with the World Health Organization. Remdesivir is a great example of that. And the FDA seems to think that its -- that its voice on these drugs is more important than the World Health Organization's. That's enough to undermine reliance on the World Health Organization, which also is not an American body and doesn't have the same effect in the United States.

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10:57:14

The CDC regularly cites to the FDA, and the CDC does not specialize in the use of drugs in America. And the NIH for a long period of time took no position on

10:57:23

ivermectin, a long period of time during which harm was caused to these plaintiffs. So the FDA can't point to the NIH and say that it has some sort of -- that it has the same effect.

10:57:38 In addition, the Fifth Circuit has made very clear with redressability, especially at this stage of litigation, that plaintiffs have established their standing if a favorable ruling could potentially lessen the plaintiffs' injury. It's a very low bar, and there is

10:57:54 absolutely a potential chance that the injury could be lessened here. That case is *Sanchez v. R.G.L.* It's 761 F.3d 495. I believe it's cited in our brief, as well.

But it seems very clear that when everyone is pointing to the FDA that if this court were to vacate those FDA

10:58:12 statements that there is a potential chance or that it could potentially lessen the injury that these doctors are suffering.

In addition, in *McClure v. Ashcroft*, the Fifth Circuit as well, says you only need to show an arguable chance

10:58:25 that a third party might consider changing its policy. The government points out that Dr. Apter is subject to current investigation or current proceedings against his medical license. That referral came from the Iowa State Board of Medicine. It came from another state board.

10:58:39 This was not some random person throwing a document into a

referral and sending it to a state board.

The FDA's actions here, their statements, their tweets, they are showing up in court filings. They are being relied upon by courts as the standard of care in malpractice proceedings. They are showing up in state board proceedings, as we have shown here. They are showing up in public discourse as a way to malign and ruin the reputations of doctors who have been working their level best to fight a pandemic.

10:59:04 What the FDA has done is pervasive throughout the entirety of healthcare and has caused significant injury to these plaintiffs. And for this court to declare them unlawful and to vacate them and to enjoin the agency from engaging in an unlawful practice of medicine in the

10:59:19 future, it undoubtedly would not only address those injuries it would -- it would undoubtedly redress those injuries.

More importantly, the practice of medicine is so well established in this country in the use of off-label drugs.

10:59:32 Up to about 40 percent of off label -- of drugs are used off label in critical care. The presumption there should be that if the FDA -- if that has changed somehow for ivermectin and it started with the FDA, if that -- if that action by the FDA is vacated that will -- that somehow

10:59:46 that normal will resurface. It's been that way since the

beginning of the practice of medicine in this country and it's unclear why the FDA has decided in this particular case to try and interfere with it but that's exactly what's happened.

10:59:59 On the sovereign immunity points that the government points out, I would like to respond in a few ways. The first is that this court should be careful to make sure that -- to view the ultra vires claim and the APA claim separately. They are separate claims, and the standards 11:00:14 for them are separate.

First off, under *Larson* the Supreme Court has been clear that when you are seeking injunctive relief against federal officers for exceeding their authority that that's not barred by sovereign immunity. *Larson* resolves the 11:00:28 case for the ultra vires -- *Larson* resolves the sovereign immunity issue for the ultra vires case.

THE COURT: Wait. Say -- say that again, please, on *Larson*.

MR. KELSON: *Larson* resolves the sovereign 11:00:41 immunity issue for the ultra vires claim. The government has exceeded its authority; and under *Larson*, sovereign immunity does not bar -- sovereign immunity does not bar injunctive relief against, quote, a federal officer that acted in excess of his authority or under authority not 11:00:56 validly conferred. That's *Larson* at 333 -- sorry -- 337

in the U.S. Reports, Pages 690 to 691. It's also cited in our brief extensively.

In addition, the government decides -- the government waited until the reply brief to challenge the plaintiffs' interpretation of Section 396. Not only have multiple circuit courts applied that -- the plaintiffs' interpretation of Section 396 about prohibiting the interference of the practice of medicine, but this case is not dependent upon that provision.

11:01:13 11:01:28 11:01:44 11:01:56 11:02:13

Whether or not Section 396 is in effect, the FDCA does not give the FDA authority to do what it's doing here. That provision is an emphasis that was added by Congress to make sure the FDA did not overstep. But if you go back to the debates leading up to the 1938 Act and all through the present, Congress has repeatedly expressed that the FDCA does not have the authority to interfere with the practice of medicine. This is nothing new.

And so whether or not this court finds that Section 396 applies here, it doesn't change the outcome of this case. Section 396 is merely an exclamation point showing that Congress really did not want the agency doing what it's doing now.

Moving on to the APA waiver of sovereign immunity, in 5 USC, Section 702, again, the difference between the ultra vires and the APA claims is important. The ultra

vires claim does not require final agency action. It only requires agency action. That is very, very clear from the Fifth Circuit's precedent, for example, the *Alabama-Coushatta* case.

11:02:27 The Fifth Circuit has also been clear that pretty much everything an agency does qualifies as an agency action under the -- under the APA. There is Fifth Circuit precedent that is directly on point.

I don't how to pronounce the case, *Avoyelles Sportsmen's League*; but that one is very explicit that 11:02:42 anything the agency does is at least an agency action. The question then becomes if it's final.

In addition, you have the *Data Processing* [sic] case, which very clearly says for even informational statements 11:02:51 or agency action the debate will be over whether they are final.

So to be very clear, as soon as the agency acted they waived -- Section 702 waived sovereign immunity for an ultra vires claim. Finality is not a requirement.

11:03:03 For the other APA claims where finality would be a requirement, it is also clear the agency has acted with finality here. The agency has maintained this position for a year and a half. While they say -- while the agency has said that they might change their position based upon 11:03:17 further factual analysis, the Fifth Circuit expressly

rejected that argument recently in the *Data Processing* case -- or the *Data Marketing* case. If you would like a citation, that's 45 F.4th at 854.

The Fifth Circuit was very clear and actually chastising the government that it recycles an argument the Supreme Court has repeatedly rejected. The action isn't final because the agency can change its position after more fact finding. This argument is squarely foreclosed by numerous Supreme Court decisions.

11:03:33 11:03:44

It would also mean that no agency action is ever final because the agency can always change its mind after further fact finding.

Looking at this case then, the agency has maintained its position for a year and a half. Their statements are not qualified: "Stop it" and "Stop it with the ivermectin," "Should I take ivermectin to treat COVID-19" or "Should I take ivermectin to treat or prevent COVID-19? No." Those are not qualified statements.

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And the fact that they are followed up with "if my doctor gives me ivermectin, take it exactly as prescribed" -- whatever that language exactly is -- does not change the fact that they have just stated unequivocally, "Should I take ivermectin? No." Period.

11:04:08

And so even if -- in reading those statements together, it's very clear that the government is either --

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it's very clear that the best way to interpret that statement is that -- the best way to interpret that statement is that if my doctor prescribes me ivermectin for something else.

11:04:37 If the government was -- wanted to be clear that if the government -- that doctors could prescribe ivermectin for COVID-19 and then should be taken exactly as prescribed, it could have said that; but it chose not to, instead, putting all its emphasis and references to

11:04:50 COVID-19 to tell doctors and to tell patients they should not -- to tell patients they should not take it and to tell the public that they should not take it either.

I'm sure that this court is aware that doctors and patients are part of the public and that patients are

11:05:01 consumers. So saying that this document -- saying that the government's main document why you should not take ivermectin to treat or prevent COVID-19, by saying that that was directed to consumers is not a fail proof -- is not some sort of argument to get out of the real effect

11:05:17 that that document had or the fact that it is directly talking to people that are in the doctor-patient relationship.

In addition, on the finality point, the Fifth Circuit and the Supreme Court have been very clear that finality

11:05:28 is flexible and pragmatic. As part of that flexibility

and that pragmatic consideration, this court should be mindful of the fact that Congress in Section 396 said that the FDA can't interfere in the practice of medicine.

It would be very passing strange if the agency could 11:05:44 do exactly what Congress told them not to and they could turn around and say, "Our action wasn't final though. So it's okay." Congress recognized that there was some sort of real-world effect of the agency interfering in the practice of medicine; and in so doing, that agency action 11:05:57 would have to -- would be final.

In addition, the Fifth Circuit has said it's a -- the action only has to be binding as a practical matter, where private parties might rely on it as the norm. That's the *Texas v. EEOC* case. And it's very clear that it's become 11:06:13 a norm. Courts are relying on it as the standard of care.

Like, directly under the Fifth Circuit's precedent in *Texas v. EEOC* you would -- as a practical matter the FDA statements have now become a norm in society. They have been the norm that is being relied upon by professional 11:06:28 bodies, by advisory bodies and by courts.

In that same case, the Fifth Circuit continued that private party -- an agency action is final if private parties are reasonably led to believe that failure to conform will bring adverse consequences. I think it's 11:06:42 safe to say that failure to conform with the FDA's

position here has brought adverse consequences to these doctors both reputationally, the fact that Dr. Apter is now facing board charges.

So viewed in that flexible and pragmatic sense, there are numerous factors which weigh in favor of finality here, not to mention the common sense -- not to mention the common sense view of what the agency has done in reading its own language.

As an additional point, just in response to the government, in *Bennett* the government was acting on a third party. So there is -- there is some -- there is other cases where the fact -- the fact of the matter is there are legal consequences. The government can't launder its actions by making -- setting up some sort of standard that can then be relied upon as a third party to impose those -- by a third party to impose those consequences.

In addition or finally, in response to the government's reply brief, I would like to point out to the Court specifically that on page, I believe it was, 21 the government makes very clear in its reply brief that it is not arguing a citizen petition is required. That concession is incredibly important because the Fifth Circuit has been very, very clear that unless exhaustion is required by statute or by regulation, the only time

administrative exhaustion is necessary is when there is some sort of adversarial proceeding below.

In fact, the government cites repeatedly *Palm Valley*. In Footnote 6 of that opinion Judge Costa is explicit that the administrative exhaustion requirements only apply in that case because there is a regulation that requires it.

If there is no regulation, you have to have adversarial proceedings below. You have to have something tantamount to a judicial proceeding. That is not present here. That is not in any way present here because the government gave no process. Instead, it acted unilaterally to push its -- to push its public campaign.

In fact, the examples that the government gives talk about when there is, for example, some sort of agency proceeding over a drug approval, when there is some sort of existing agency proceeding. There was none here. And if a citizen petition is not required, which we contend it is not, based upon the plain language but also based upon the government's own admission that a citizen petition is not required, then we are in a separate world of administrative exhaustion.

And what the government would purport to this court would be a fundamental change in how administrative exhaustion has been run in this country and they would impose a brand new requirement that has never been

recognized that a party must go to an agency and litigate its case with an agency before it goes to the government when the agency gave no process ahead of time.

The whole purpose of administrative exhaustion is to avoid parties sandbagging an agency and waiting until court to raise their claims or to give the agency the opportunity to engage -- to apply its expertise during its proceedings.

None of that applies here. None of these considerations are relevant. There were no proceedings. The government has acted. It's been final. In addition, this is a legal question. This is not some sort of factual dispute for the agency. And so the fact that there is no agency expertise here that the Court would need to defer to, none of the factors that weigh in favor of agency exhaustion would otherwise apply.

So agency -- by the government's own admission, agency exhaustion is not required by the law. It is not required by a statute. By very clear Fifth Circuit case law and by -- it is not required as a prudential matter; and even if it were required as a prudential matter, there are ample reasons for this court to weigh that exhaustion requirement because none of the factors that weigh in favor of exhaustion are present here.

I think that that is -- those are my main responses to

what the government has said. If you have -- you know, if the Court has any questions, I would happy to answer them.

THE COURT: Sure. No. I appreciate that. Are you aware of any cases anywhere else where patients are the plaintiffs suing over the FDA's comments on ivermectin?

MR. KELSON: I don't know of any -- I am not aware of any cases where patients are suing the FDA.

THE COURT: All right. Any idea why there aren't any -- I guess this is a doctors' case, not a patients' case is why there aren't any --

MR. KELSON: It's a doctors' case.

THE COURT: -- patients among the plaintiffs in this case here today.

And another kind of general question.

MR. KELSON: Just as one consideration for the Court, when it comes to the need for ivermectin, the plaintiffs see these things every day. They are well immersed in the science; and they are well immersed, actually, in the practice of medicine prescribing ivermectin or trying to prescribe ivermectin and dealing with the public backlash they get for doing so.

With patients, most patients are only seeking treatment for COVID; and then once it's over, it's done. But the benefits of a lawsuit and the motivation for a

lawsuit are significantly diminished in that regard.

Whereas with these doctors, they have been living in this world for a year or a year and a half now and they have suffered significant reputational harm as a result of it. They see this interference with their practice of medicine every year -- every day. It takes an extreme toll on them but also then makes it difficult when they are constantly battling trying to write prescriptions and get prescriptions for their patients and then they are fighting with pharmacists who are saying, "Well, the FDA says no."

And so, just as a practical matter in that regard, the explicit answer or the exact answer to your question is I am not aware of any plaintiffs that are suing the FDA. I do know some plaintiffs -- I do know of some plaintiffs who have sued hospitals to try and get ivermectin in the past. There were a few of them in the news.

But it also is very easy for the Court to see why this is a particularly problematic issue for doctors, and that is why the three plaintiffs in this case that I represent have been willing to undertake the expensive burden of litigation to try and rectify the injuries that they have suffered.

THE COURT: I believe the government noted that it was, like, 26 months or something from the time the FDA

first started making these statements that the lawsuit was filed. Is there a reason for that delay?

MR. KELSON: So I think there are -- there are a number of reasons that could be relevant. I'm not sure that they are in any way required to bring a lawsuit within a certain -- they have a four-year statute of limitations under the APA or six-year statute of limitations.

When the government first started in 2020 or early 2021, the statements were significantly more benign. They were problematic, but they were more benign. It really took off in August when they started with the "You are not a horse. You are not a cow" campaign and when they started labeling doctors as essentially horse doctors or quack doctors. And so that -- that exacerbated the injury. The government then doubled down recently, I believe it was in April, with another tweet.

So to say this is anything about animal ivermectin is even more problematic under the light of the fact that they are continuing the horse trope many, many months afterwards.

As a result, because the government has maintained these documents and has been doubling down on them, like, the injury has been increasingly severe. And, quite frankly, sometimes it takes a while to find a lawyer who

will take your case.

There are a number of considerations and then, you know, we put an extensive amount of work into trying to find all the publicly-available examples we could have to track down what was going on and to make sure that we could substantiate the plaintiffs' claims.

So for those reasons and the fact that the plaintiffs have a significantly long runway, six years to bring APA claims, 26 months isn't actually unreasonable at all.

11:13:56 THE COURT: You argue for a very broad interpretation of agency -- of what constitutes agency action. If everything an agency does is agency action under the APA, then does that mean the APA is kind of a general waiver of sovereign immunity? That's kind of what 11:14:15 it sounds like.

MR. KELSON: No. No. Because, yes, everything -- the Fifth Circuit has been explicit that everything an agency does is going to fall under the definition of agency action; but to bring a claim under the APA, for 11:14:27 example, and to claim a waiver of sovereign immunity under the APA, you have to show final agency action. So that is one distinction.

The ultra vires claim, which is not -- which does not have a finality requirement to it under the Fifth 11:14:38 Circuit's precedent, yes, if an agency acts then there is

a waiver of sovereign immunity but it's very limited and it only applies to injunctive relief, not damages. That also should not concern the Court because it only becomes relevant when the agency has acted unlawfully.

11:14:51 All the government's arguments here have nothing to do about whether or not their actions were lawful. They have everything to do about setting up barriers for the plaintiffs to begin a course to seek remedy.

And so to the extent that the agencies act unlawfully,

11:15:01 then, yes, they would be subject to suit. If the agencies haven't acted unlawfully, it actually becomes immaterial whether or not agency action is brought because any agency action that would be -- any challenge to any agency action -- I'm sorry. I might have been speaking to quickly.

11:15:15 Any challenge to any agency action that is lawful will be promptly dismissed, and so it's not going to be a burden on the agency either.

THE COURT: Is any informational statement that the FDA makes an ultra vires act by the agency?

11:15:31 MR. KELSON: That would be an agency specific inquiry, Your Honor. The FDA in this particular case is -- the FDA sits in a very unique spot in the United States because of the authority that the government has given it to regulate the approval of drugs to let the

11:15:49 drugs enter into the market and withholding the ability to

interfere with the practice of medicine.

Most informational statements are not going to be problematic. The FDA talks about how, well, we've issued warning letters in the past. That's not -- that might be an agency action, but it's not unlawful for them to issue a warning letter to a doctor or to someone who has -- to someone who is marketing a drug -- who is marketing a drug contrary to the FDCA.

The statements here go far beyond purely informational. These are not informational statements. These are directives to the public. These are directives to patients or these are strong medical -- these are medical recommendations. That is the heart of the practice of medicine.

And so this case needs to be viewed in the context-specific capacity of the fact that we are dealing with the FDA which has significant authority in this area, which has outsized -- which throws around outsized weight in this area and the fact that Congress has explicitly recognized the problems that the FDA could cause if it started meddling in the practice of medicine. It's relevant throughout the debates. It's relevant in Section 396 of Title 21.

And so in this particular case we are not talking about informational statements only. We are talking about

statements that are making recommendations about medicine. We're talking about statements that are directing the public to "stop it" or to "stop it with the ivermectin."

So in that regard, this case is not about whether or not informational statements are illegal. It's about the statements here that the FDA has made.

Also, if the government -- the government has mentioned or has tried to make the argument that it's just -- that it can speak freely. That's a merits argument, and that should not be resolved at the motion to dismiss stage because the government has not raised a 12(b)(6) motion challenging the merits of the claims.

THE COURT: You mentioned warning letters. Warning letters seem like they are more than informational. They can approach being a directive, too, can't they?

MR. KELSON: The FDCA has the authority to police how drugs are marketed. That's like -- that is within their express statutory authority. So it's -- it's somewhat of a red herring or a straw man where the government says, "Look, we send out these warning letters telling a pharmacist we heard that you are promoting this drug and saying that it is -- it should be used for these purposes."

That is separate from what is going on here because we

are not talking about advertising drugs for this -- for sale and distribution. We're talking about how doctors deal with their patients and what drugs should be used for particular treatments off label.

11:18:11 The FDA has authority over what -- over when drugs can be admitted to the market, what labeling they can use, and how they can be marketed. If they issue a warning label on those conditions that is within their authority, then they are within their authority; but that's not what they

11:18:25 are doing here. They are telling people to stop -- they are telling consumers, not distributors. They are telling consumers to stop it. They are telling doctors, the public, to stop it. That is a totally different thing that is outside of their authority.

11:18:38 THE COURT: I know that courts have held that warnings letters are not final agency action. If warning letters aren't, then how can the statements in this case be?

MR. KELSON: So, in the first instance, a warning

11:18:56 letter is more tentative than a statement like "Stop it" or "Stop it with the ivermectin." So there is a difference in the tone of the letter -- of the statements.

In addition, Section 396 should inform this court's flexible and pragmatic approach to finality.

11:19:13 In addition, the warning letters -- the warning

letters are explicitly, by their terms, in preparation for a potential enforcement action. And so they are very clearly non-final by their nature. They are issuing a warning that in the future they may choose to take action; whereas, these statements about ivermectin have no such future action attached. They are not -- they are not in anticipation of something else. They are not a warning. They are not an initial volley in an ongoing conversation with a regulated party. These are direct and final statements to the public, to doctors, to consumers, to patients. And so, in that regard, they are different.

And in the event the Court feels otherwise, none of that affects the ultra vires claim which, in any event, should proceed.

THE COURT: Okay. Well, thank you. I'm going to see if the government has anything else, but I appreciate it.

Counsel, you are welcome to -- go ahead. You are welcome to cover whatever you would like in response to the plaintiffs' arguments; but I would like you to specifically address, for one thing, the allegation that the statements the FDA made that the plaintiffs are complaining about in this case were not merely informational but were more like directives.

MR. BELFER: Yes, Your Honor. The cited

statements were not directives. They were not mandatory. They were recommendations. They said what parties should do. They said, for example, why you should not take ivermectin to treat COVID-19. They did not say you may not do it, you must not do it. They did not say it's prohibited or it's unlawful. They also did not say that doctors may not prescribe ivermectin.

THE COURT: Well, they very flippantly say "stop it" in the tweet.

MR. BELFER: Yeah. They use informal language, that is true; but they did not -- they did not say you may not do this or it is unlawful. If you look at the language they used, it is -- yes, it's informal. It's conversational, but it's not mandatory. It never said this is unlawful, it's prohibited. And so that contrasts with, you know, other things that FDA might say where it is more -- more mandatory.

And if you look at the kind of statements at issue here, we are not talking about a publication of the CFR or an official memorandum. We're talking about tweets and Instagram posts and website posts. These are much more informal fora.

And so if you look at the informal fora, the fact that this is informal conversational language, plaintiffs cannot show that it was predictable that anyone would look

at these statements and think that they were prohibited from taking ivermectin to treat COVID-19, especially given that, you know, the tweets both linked to the article and the article said that doctors have discretion and that if your doctor prescribes ivermectin, take it exactly as prescribed.

So a few general points before we get into the specific issues that plaintiffs raised. So plaintiffs argue that -- they tried to frame this case as about the off-label use of drugs, off-label prescription; but this is not a case about off-label prescription. This is a case in particular about the use of ivermectin to treat COVID-19.

No one is questioning that doctors generally have authority to prescribe off-label in appropriate circumstances. Instead, what FDA is saying here is it's warning consumers about the risks of using ivermectin to treat COVID-19.

And the fact that FDA generally does not prohibit doctors from prescribing off-label has never been taken to be a limitation of FDA's authority to communicate publicly. FDA communicates publicly about the risks of drugs all the time. And, in fact, in the amended complaint the plaintiffs concede that FDA generally has authority to communicate to the public about the risks of

drugs. So there is no dispute that FDA generally has authority to communicate with the public about the risk of drugs.

Plaintiffs argue that Section 396 is a limitation on that authority. But tellingly, in their argument, the plaintiffs don't really defend 396 and for good reason. Section 396 is directed to medical devices, not drugs. And even beyond that, 396 is -- does not establish any general interest in -- against interference with the practice of medicine, let alone any interest to get into FDA communications. It's not about that.

Instead, 396 is very specific. It's about doctors' authority to prescribe or administer medical devices; and even if you could strike out the word "devices" and replace it with "drugs," it would still only be about doctors' authority to prescribe or administer drugs. And here there is no allegation that doctors' authority to prescribe or administer drugs was ever impaired.

The plaintiffs, by their own admission, have continued to prescribe ivermectin. So they always had the authority. It may be that patients were not able to fill prescriptions, but the doctors themselves always had the authority. So Section 396 is not applicable, and there is -- there is really no general interest against interference with the practice of medicine at issue here.

So I would like to respond in particular to a few of the arguments that have been made on the various issues in this case. Starting with sovereign immunity, plaintiffs argue that their ultra vires claim is essentially an exception to sovereign immunity.

But in the *Danos* case from the Fifth Circuit, the court said that it's not enough simply to allege that an agency action is unlawful or unauthorized. You have to do more. You have to show that the agency had no colorable basis for its exercise of authority; and plaintiffs have not done that here because, again, they concede that FDA generally has authority to communicate with the public about the risk of drugs. They argue that 396 is a limitation on that authority; but as we discussed, 396 is inapposite here.

And so plaintiffs have not met the standard under *Danos* of showing the FDA had no colorable basis for the exercise of its authority. Right.

And so with regard to agency action, plaintiffs take the position that essentially any -- any statements by the agency is agency action. And they say that the Fifth Circuit has held that essentially everything an agency does is agency action, but that's simply not true.

If you look at cases like *Alabama-Coushatta* or *Walmart*, both Fifth Circuit cases, those make clear that

not everything is agency action. In their briefing, plaintiffs rely specifically on their contention that the agency -- the cited statements are a rule. That is their basis for saying there is agency action.

11:25:37 So let's look at the definition of a rule. The definition of a rule -- I can pull it up right here. So, essentially, to be a rule you need to be binding on either the agency or a private party or you need to interpret a substantive rule or you need to set agency policy. Those

11:25:53 are all the rules. But here the cited statements are none of those things. They are not binding on anyone. They don't interpret any rule, and they do not -- they don't set agency policy.

And so you need to meet -- plaintiffs rely on a rule,

11:26:09 but here the cited statements simply don't meet the statutory definition of a rule.

And then, with regard to final agency action, I guess starting with consummation of the agency decision-making process, we do not argue that the consummation prong is

11:26:25 met simply because the cited statements might be revised in the future.

Sure. An agency can always take future action, but that's not what we're arguing. Instead, our argument is that if you look at the face of the cited statements

11:26:38 themselves, they are expressly tentative. They state that

they are based on currently available data, that more data is needed, and that clinical trials are ongoing.

So if you just look at the face of the statements, they are expressly tentative and based on currently
11:26:50 available data. They do not state FDA's final definitive position on the use of ivermectin to treat COVID-19.

You know, plaintiffs say that these statements -- going to the legal consequence prong, plaintiffs say that these statements are unequivocal. They are not
11:27:06 unequivocal. They generally recommend against using ivermectin but they also say if your doctor prescribes it, take it exactly as prescribed. And there is no allegation that anyone read part of the statement but not the entire statement. And so plaintiffs have not shown that
11:27:18 plaintiffs would not read the entire statement and see that nuance in the statements.

Plaintiffs cite *Texas v. EEOC* regarding this notion that if the agency establishes a norm that that's final agency action; but the *Texas v. EEOC* case is plainly
11:27:33 inapposite. In that case, the agency established a norm; and if private parties did not comply with the norm, they were subject to legal liability. They could be sued for failing to comply with the norm. That's a direct effect on those third parties by changing their legal liability.

11:27:47 Here, there is no effect. The cited statements have

no effect on anyone's legal liability. There is no direct legal consequence on anyone.

And, similarly, the plaintiffs cite the *Bennett* case but *Bennett* -- and that's *Bennett v. Spear* with the Supreme Court -- is, again, different. In *Bennett* the Fish and Wildlife Service issued a biological opinion; and if other agencies did not comply with that biological opinion, they could be subject to criminal and civil liability. So in *Bennett* there was a direct legal effect on other agencies. If they did not comply with the Fish and Wildlife Services statement, they could be subject to criminal or civil liability.

Again, here there is no similar direct effect. No one would be subject to criminal or civil liability if they prescribed ivermectin to treat COVID-19. Instead, the statement expressly acknowledged that doctors can prescribe ivermectin for that purpose.

So I would like to say a few words about standing. So the plaintiffs argue that FDA is trying to stop the use of ivermectin and that its purpose -- its purpose was to stop the use of ivermectin; but again, if you look at the language of the statements, FDA never said that doctors cannot prescribe ivermectin to treat COVID-19. They said doctor -- if your doctor writes you a prescription, fill it and take it exactly as prescribed. So the FDA

expressly acknowledged that you can use ivermectin for this purpose if your doctor prescribes it.

And, you know, looking at FDA's intent, FDA was really focused on consumers. It was advising consumers who could buy this product over the counter that they shouldn't take it. They did not say that if your doctor prescribes it, don't take it. They said follow your doctor's advice. If your doctor prescribes it, take it exactly as prescribed.

11:29:20

You -- right. So regarding the *TransUnion* case, you know, plaintiffs say that essentially that there is injury in fact here, and they cite that case. So what the Supreme Court held is that you cannot presume an injury in fact just because there is an alleged statutory violation. You still need to look under Article III at whether plaintiffs have met the requirement for standing.

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So, as we discussed, there is no violation of 396. FDA did not exceed its authority. But even if plaintiffs had shown a violation of Section 396, that is not itself alone -- that itself is not alone -- that alone is not sufficient to show standing. You would still need to show an injury in fact under Article III.

11:30:10

And because the alleged violation, interference with the practice of medicine, is a vague conclusory allegation and plaintiffs were always able to prescribe ivermectin, they have not shown any injury in fact under Article III.

11:30:26

Regarding traceability, you know, plaintiffs try to minimize their burden to show traceability; but importantly, the standard is that -- or, sorry. Under the *Daves* case from the Fifth Circuit the Court held that it's substantially more difficult to show traceability when the causal chain relies on independent third-party conduct. And so to meet that much higher burden when, as here, plaintiffs rely on this indirect causal chain, you need to show that the third-party conduct would be a predictable response to the cited statements.

And because FDA statements were directed at consumers, they were, you know, informal, conversational, and because they expressly acknowledged doctors' discretion to prescribe ivermectin, it would not be predictable that, for example, a hospital would punish a doctor for prescribing ivermectin when the statements themselves acknowledged that doctors could prescribe ivermectin to treat COVID-19.

You know, plaintiffs state that everyone is pointing to FDA. So, surely, FDA must have caused the third-party conduct. But if you look at what is alleged in the complaints in the exhibits, it's clear that third parties are not just relying on FDA.

For example, Exhibit 12, which is the statement of Sentara, which is a former employer of Dr. Marik, they did

not simply rely on FDA. Instead, they cited statements from many organizations -- FDA, CDC and several other organizations -- and they provided independent medical analysis. They said there is no randomized control trial that supports use of ivermectin to treat COVID-19.

So, you know, plaintiffs' employers, pharmacies, insurance companies, these are sophisticated entities that make independent -- that exercise independent professional judgment as shown by Exhibit 12. They did not simply take what FDA said and accept it at face value. They looked at FDA statements in combination with the statements made by many other organizations. They also performed independent scientific analysis. They looked at the data. And based on all of that, they concluded that they would not recommend prescribing ivermectin.

And so, you know, that undermines redressability because it shows that even if you took away FDA cited statements, just those statements, you would still have all those other third-party statements that Sentara and other organizations relied on.

And I would just give you a few more citations. Exhibit 25, which is the joint statement by the American Medical Association and other organizations, also. So it's not just FDA but many other -- many other statements.

And the *DeMarco* case the plaintiffs cite, that cites

not just FDA but many other organizations.

And so simply taking away these particular FDA statements, plaintiffs have not shown that that would likely cause third parties to reverse their past conduct; and again, that's the standard. You have to show -- you have to -- you have to have allegations that plausibly allege that it would be likely that third parties would reverse their past conduct and redress plaintiffs' injuries, and plaintiffs have not shown that it would be likely. Right.

So I think, for all those reasons, plaintiffs have not shown that there is any waiver of sovereign immunity because they have not shown agency action or final agency action. And they also have not shown that they have standing because they have not shown injury in fact for many of their injuries, and none of their injuries satisfied the traceability or addressability prongs.

So unless Your Honor has any further questions.

THE COURT: No. I don't think I do right now. I appreciate it. I'm going to give the plaintiffs the last word. Thank you, Counsel. Appreciate it.

MR. BELFER: Thank you, Your Honor.

MR. KELSON: I believe the government began by saying that these were only informal tweets, these were only informal Instagram posts or LinkedIn posts.

The government can't launder unlawful action as a good PR scheme or as a good PR endeavor. The agency acted. Whether it acted through an informal way with definitive language or whether it went through the Federal Register doesn't change the fact that the agency acted here.

11:34:33

The government is trying to -- tries to downplay *TransUnion;* but *TransUnion* explicitly recognizes that while you can't merely allege statutory harm, other injuries can be drawn from past precedent, from common-law analogs. It specifically points out reputational harm, which we have alleged here.

11:34:52

There is a common-law analog to tortious interference with a doctor-patient relationship that's recognized in Texas. If you -- you know, if you want a case for that, you can look at the *Garcia* case from the Northern District of Texas. It's 1999 -- it's an unpublished case; but it cites a number of other Texas cases -- 1999 Westlaw 362787.

11:35:02

So *TransUnion* squarely supports the plaintiffs here. It shows that their injuries are real, that while there is a statutory violation, which should inform the Court's interpretation of the injury, and since they only need an identifiable trifle, there is also plenty of common-law analogs to show exactly what it is the doctors have alleged here.

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One of the amicus briefs, the American Association of Physicians and Surgeons also points out the *Tozzi* case where an agency labeling something as dioxin was enough to cause harm. It was enough to establish standing.

11:35:43 The FDA has labeled this a horse drug. The FDA has maligned the use of ivermectin and that the agency has told people to stop it. If there was standing in the *Tozzi* case from the DC Circuit, then there is definitely standing here.

11:35:59 I am not in any way backing away from the plaintiffs' interpretation of Section 396. That statute has been repeatedly interpreted by circuits across the entire United States as applying to the practice of medicine, including the prescription of drugs.

11:36:12 The government in its briefing says that by using a "see" statement, a "see" signal to introduce the citation that the government is -- that the Fifth Circuit was saying that it was an unrelated -- it was a related but not directly on point case. That is not what a "see" 11:36:26 signal means. A "see" signal means that the cited -- or the citation directly supports the proposition stated in the preceding sentence. That is Bluebook Rule 1.2.

As a result, all these courts have recognized that it applies. If you look at the -- to the extent there is a 11:36:41 scriveners error in that provision, so be it; but that

provision was clearly intended to stop the FDA. And even if it wasn't, the FDA doesn't have this authority. That has been very clear for 100 years.

I don't -- I don't -- unless the Court would prefer otherwise, I don't need to walk through all the -- I don't need to re-walk through all the arguments that we have already made in response to the government, except I would -- the only additions I would make is to point the Court to *Avoyelles Sportsmen's League* where the Fifth Circuit was explicit that the APA defines the term "rule" broadly enough to include virtually every statement an agency may make. That's a direct quote from a Fifth Circuit case.

In addition, the definition of "rule" in the rule -- in the APA is not exhaustive. It is prefaced by the word "includes." That means that there -- it is giving examples of a fall within a rule; and as the Fifth Circuit has recognized, that includes every statement an agency may make.

And if the Fifth Circuit's precedent isn't sufficient to satisfy this case, which we believe it is, there is also a DC Circuit case on the finality issue called *Ciba-Geigy Corp.* It's cited in our briefs. But it talks about how a hyper-technical approach is not appropriate and that a series of pronouncements may constitute final agency action if their cumulative effect causes injury.

That case is directly on point.

So to the extent this court wants to look outside the Fifth Circuit, the DC Circuit has a case that is directly on point with both *Tozzi* and *Ciba-Geigy*, both of which are cited either in our brief or in the amicus brief.

11:38:13

In sum, the doctors here have been suffering -- have suffered injuries at the hands of the FDA's public pressure campaign for a long time now, well over a year. And this court has the power to stop that or to give them the possibility of seeking relief. The redressability standard is low. They just have to show the potential for some sort of relief.

11:38:39

Especially at this stage of the proceedings, the standard is plausibility; and the plaintiffs have unquestionably made plausible arguments, cited numerous -- numerous public statements, numerous public actions by the agency that establish more than a plausible injury, more than a plausible traceability back to the FDA, and more than plausible redressability. That's all that is required at this stage in the proceeding.

11:38:51

11:39:10

And that just -- that is only the publicly-available information that we have been able -- that we have seen, that we have been able to find. Recently, in *Biden v. Missouri* it's become very apparent that government officials have been acting in nonpublic ways to pressure

11:39:24

-- to pressure private parties.

All we can say is that in this case, from the publicly-available information, it is more than necessary to satisfy the plausibility standard that is necessary at this stage of the proceedings.

Unless the Court has any further questions.

THE COURT: No, I don't. I appreciate the -- the issues are very interesting; and the briefing and the argument has been very helpful to the Court. And we'll get a ruling out as quickly as we can for y'all.

MR. KELSON: Thank you, Your Honor.

THE COURT: All right. The Court stands in recess.

COURT SECURITY OFFICER: All rise.

(Proceedings concluded at 11:39 a.m.)

Date: November 2, 2022

COURT REPORTER'S CERTIFICATE

I, Laura Wells, certify that the foregoing is a correct transcript from the record of proceedings in the above-entitled matter.

/s/ Laura Wells

Laura Wells, CRR, RMR