IN THE UNITED STATES DISTRICT COURT

FOR THE NORTHERN DISTRICT OF TEXAS

FORT WORTH DIVISION

PUBLIC HEALTH AND MEDICAL PROFESSIONALS FOR TRANSPARENCY	)	CASE NO. 4:21-CV-01058-P
	)	FORT WORTH, TEXAS
vs.	)	
	)	DECEMBER 14, 2021
FOOD AND DRUG ADMINISTRATION	)	9:05 A.M.

VOLUME 1
TRANSCRIPT OF SCHEDULING CONFERENCE
BEFORE THE HONORABLE MARK T. PITTMAN
UNITED STATES DISTRICT COURT JUDGE

A P P E A R A N C E S:

FOR THE PLAINTIFF:
AARON SIRI
Siri & Glimstad, LLP
200 Park Avenue
New York, New York 10166
Telephone: 212.532.1091

JOHN HOWIE
Howie Law, PC
2608 Hibernia Street
Dallas, Texas 75204
Telephone: 214.622.6340

FOR THE DEFENDANT:
ANTONIA KONKOLY
U.S. Department of Justice
Civil Division
Federal Programs Branch
1100 L. Street NW
Washington, DC 20005
Telephone: 202.514.2395

COURT REPORTER:
MONICA WILLENBURG GUZMAN, CSR, RPR
501 W. 10th Street, Room 310
Fort Worth, Texas 76102
Telephone: 817.850.6681
E-Mail: mguzman.csr@yahoo.com

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P R O C E E D I N G S

(December 14, 2021, 9:05 a.m.)

THE COURT: We're here in Cause Number 4:21-CV-1058-P, the matter of Public Health and Medical Professionals for Transparency vs. Food and Drug Administration.

At this time I will call upon the -- I think for lack of a better term I'll call it the doctors group, unless you-all have a better term for me to call you-all. But I'll turn it over to the plaintiffs, if you could identify yourselves for the record, each of the attorneys, please.

MR. SIRI: Good morning, Your Honor. Aaron Siri on behalf of the plaintiff.

THE COURT: Thank you, Mr. Siri.

MR. HOWIE: Good morning, Judge. John Howie here on behalf of plaintiff.

THE COURT: Good morning, Mr. Howie. How are you?

MR. HOWIE: Just fine. How are you, sir?

THE COURT: Doing well.

And you, sir? Are you a client rep?

MR. ARMER: No, Your Honor. I'm just here to assist in an administrative capacity.

THE COURT: What's your name?

MR. ARMER: Nicholas Armer.

THE COURT: All right. Thank you. Thank you,

gentlemen, for flying down today.

Who do I have for the -- representing the Department of Justice?

MS. KONKOLY: Good morning, Your Honor. Antonia Konkoly from the U.S. Department of Justice. I'm here on behalf of the U.S. Food and Drug Administration.

THE COURT: Tell me -- pronounce your name for me one more time.

MS. KONKOLY: I'm sorry, what?

THE COURT: Pronounce your name for me once more.

MS. KONKOLY: Oh, Antonia Konkoly.

THE COURT: Konkoly?

MS. KONKOLY: Konkoly.

THE COURT: Okay. If I mispronounce it, just forgive me.

MS. KONKOLY: No worries. You won't be the first.

THE COURT: Let me make a few comments about what's going to be helpful for me on this and what's not.

You know, in today's hotly contested political environment, it goes without saying we're deeply divided. I mean, I think that we are probably closer in this country than we have been at any time since the civil war to right versus left, political fights, et cetera, et cetera. I am afraid that we are getting to the point that Abraham Lincoln warned us about, the house divided against itself won't stand. And I

hope that we're not there.

But none of that stuff is really helpful to me when it comes to the case before us. I mean, in my mind let's keep the politics out of it. Of course we see a lot of that stuff, and, you know, no matter what you do, when the Twitter world comes out or the media world comes out, you're always going to be accused of doing something that's political. Believe me, I strive not to, and I do try to follow the law.

So, none of the political arguments, arguing against the administration for some -- there being some big conspiracy when it comes to the vaccine, whether there is or there isn't, for the purposes of my hearing here today, and when and how the FDA can turn over the documents, is a different matter. So, that's just not very helpful.

I think that we have two administrations here, both Republican and Democrat, that are encouraging people to take the vaccine. And it's just not helpful to point fingers and make political arguments, that's not going to work with me. So, that's number one.

Number two, with all due respect, ma'am, I think it's safe to say that 55 years is a heck of a long time to have to make a request to turn this stuff over. And I'm hoping we can come together and try to reason.

And I look back in my own time and think about 55 years ago, what was going on here in this courthouse. My two

predecessors, one served to be 87, he was the Judge that I clerked for, he was a Nixon appointee; and the Judge that I replaced, the Honorable Judge McBryde, is 90, and he came on the bench in 1988 or '89.

So, I think back, who would have been here in 1966, 55 years ago? It would have been a judge who's probably been dead for about 30 years, okay? President Lyndon Johnson was in office. My parents -- and I'm no young man -- but my parents were in junior high school in 1966.

I'm not saying this flippantly. But if you're really going to tell me it's going to take 55 years to do this, I think it would be easier for me to get the Kennedy assassination files produced, okay? And I only say that in half-gist. So that's not going to work either.

And I told you a little bit about some of my background this morning. I've either had the privilege or, I guess, perhaps, the torture of being a Government attorney in various agencies where I've had to turn over and review various requests for information throughout my career.

Indeed, as I told you, I used to office in your office. And when I was at 1100 L Street, I dealt with failed bank cases related to the *Winstar* line of cases dealing with failed savings and loans. And in those cases, it would not be unusual for us to turn over, in one case, two- to three-million pages worth of documents.

The other stages of my career at the FDIC and the SEC, it's not unusual for me to have to review several terabytes of information. Much more so than the 300,000 pages that we have before us that are being requested in the FOIA request. And I can assure you that they had all kinds of customer information, social security numbers, banking information, the most private-type information, I would argue, even more important than trade-secret-types of information; that, indeed, I'm in agreement with the Government, that it needs to be protected. But I can assure you, we were able to do that in a manner in which we didn't need 55 years, nor even a year or, safe to say, even a half a year to do so.

I tried a health-care fraud case in this Court a few weeks ago, and in that case the Government turned over, related to a long-term scheme at a local hospital that had been going on for at least a decade, three to four terabytes worth of information. And they were able to do that and give all the information, including patient identifying information, the most private medical records on folks, in less than six months. And that's at a local U.S. Attorney's office with a paralegal and one attorney going through it, and maybe a case agent.

We're talking about the Federal Food and Drug Administration with 19,000 employees, possibly the biggest, at least the most controversial, matter that the FDA has ever

approved, and that would be the vaccine on the most important issue of our time, that being the COVID-19 pandemic. And if we truly and really want to encourage the public to continue taking the vaccine and the efficacy of the vaccine, to me, and I want you to persuade me otherwise, when we're saying it takes this long to produce the information, isn't that just playing into the conspiracies that the vaccine is not safe, that it was produced in a manner that wasn't given thorough peer review and it was a rush to get it approved?

I'm not here to make policy decisions, but I think that if I were the United States of America, I would want to produce this information as soon as possible, even if it meant hiring as many contractors as possible. I don't know, perhaps under the Build Back Better program, we could dedicate $100,000 to hiring some contractors to produce this information. But if we truly want to reach a situation where 100% of Americans receive the vaccine, we ought to be able to show them what goes in the vaccine.

Those are my preliminary comments. I'll turn it over to Mr. Siri.

MR. SIRI: Thank you, Your Honor.

THE COURT: You'll need to use the podium.

One more warning about this old courthouse, you have to speak into the microphone, and you almost have to eat the microphone. It's very hard to hear. The courtroom was built

in the days when you used your church voices here in the courtroom and you didn't use microphones. So, just be sure you speak into the mic.

Go ahead, sir.

MR. SIRI: Yes, Your Honor.

THE COURT: And you heard my comments.

MR. SIRI: I did. I'm going to, Your Honor, try to -- I will avoid -- if there's something specific Your Honor would like me to address.

THE COURT: Let's keep it to why we're here. No dispute from the Government that these documents that you've requested -- you have a valid request, perhaps they would argue a little bit overbroad. There's no argument that you're entitled to these documents.

I think she's going to make some arguments with regards to the expedited request. Whether this is expedited and how you can treat it, it's fine to address that. But the real thing I want to consider, let's figure out the best, quickest way to get these documents. And rather than arguing that the Government is trying to hide something or there's some big conspiracy here, that the green alien people want to inject us with something, is not going to be helpful, okay? Let's figure out how do we resolve this, and save the other argument for outside of the courtroom.

MR. SIRI: Yes, Your Honor.

THE COURT: Does it make sense what I'm asking?

MR. SIRI: Absolutely. And I can speak for my client, and completely agree that I don't think that there's anybody in the doctors group that believes there's a conspiracy here. I think it's precisely what Your Honor said, which is transparency is important to give confidence to the American people that the medical product that they're being mandated to receive, the medical product that the Federal Government has said is the only thing that will be able to end this pandemic has, in fact, been properly reviewed, licensed and approved. That will increase confidence. That should, as Your Honor pointed out, increase uptake of the product.

In terms of turning to the more substantive components, as Your Honor would like me to do. In terms of actually reviewing the documents at issue here, in terms of the scope of what's being requested, I don't know if there's really much contest with regards to the scope that it's overbroad. That's because the scope of what's being requested here is precisely what's provided for in the FDA's own regulations, 21 C.F.R. 601 --

(Court Reporter interrupts)

MR. SIRI: 21 C.F.R. 601.51(e). And in that regulation promulgated by the FDA, it says that there are certain categories of information that are to be, "immediately available for public disclosure unless extraordinary

circumstances are shown."

The categories of information requested by this FOIA request are exactly what's delineated in that list. So, it's not like they're asking for anything that the FDA is not already aware of and didn't already itself make the policy choice, should be immediately available to the public directly upon licensure.

In terms of the review of the documents itself, Your Honor, they are claiming they need to review for two things. One would be personally identifiable information. Now, again, the FDA's own regulations, and we cited in our papers, 21 C.F.R. 20.63(b), already provides that Pfizer was to provide redacted, de-identified versions of the documents to the FDA. And I don't think there's a lot of contest with regards to those.

In fact, in their response papers --

THE COURT: So, in other words, if I am one of the patients that was used as a -- I can't think of the word this morning. If I was --

MR. SIRI: Clinical trial participant?

THE COURT: One of the trial participants, their information has already been redacted, so the FDA would not know that it's John Doe living at 1212 Mockingbird Lane in New York, New York; is that correct? So that's already been redacted?

MR. SIRI: I misspoke, de-identified. So, the information provided wouldn't have included names, it wouldn't have included home addresses already. In the clinical trials, they use identifier numbers including -- because there's blinding in the trials and so forth. So when the information is provided to the FDA, it is provided in de-identified form so that you can't identify specific individuals.

The FDA's only retort to that in their papers was, Well, we need to just make sure that Pfizer didn't miss anything. I would say that the -- that the interest to the American people in having transparency far outweighs any potential mistake and inadvertent disclosure. You know, they don't need to do a detailed word-by-word review in that regard. I mean, I think that that undercuts the whole purpose of FOIA in expedited treatment.

Separately, with regards to trade secrets, Your Honor, similarly there is a provision in the FDA's own regulations, and that is 21 C.F.R. 20.61(d), and that's also cited in our papers. And what it provides is that -- it provides that a sponsor, in this case Pfizer, has an opportunity, before submitting their documents for licensure, to, again, identify what information is trade secrets when they submit the documents or, as provided in the regulations, shortly thereafter. Pfizer has had an opportunity to identify that information.

But with that said, most of the information at issue here is not going to include trade secrets. Most of it is patient-level data. What the doctors group is most interested in, Your Honor, is doing an analysis of the primary data that the FDA analyzed when licensing this product. That data, which is mostly contained in data files of patient-level data, is not trade -- is not -- wouldn't have trade secret information. Those would be --

THE COURT: They're all that of the health condition of the participants, correct?

MR. SIRI: That's right, Your Honor. It would be the patient-level data.

THE COURT: Did you have any discussions with the Government as far as -- I know that they offered to do the big production by the end of -- 12,000 pages by the end of January.

I mean, I think, given the modern era, okay -- and I'm not so old that I -- before I went on the state court bench, this is something we frequently did. We had all types -- when I worked for the United States, all types of programs to be able to cull out certain documents. You know, you were able to contact contractors, you had the software.

I just cannot imagine the Food and Drug Administration does not have the same capability of at least three to four agencies that I worked for, including the

Department of Justice, where you're able to cull out certain information and do almost like a rolling production. So, if this is the most pertinent information, would that have been something that's in the first production that's proposed by the 31st of January 2020 *(sic)*?

MR. SIRI: That information is not there, unfortunately. We had an initial meet and confer, per Your Honor's order, in Washington, D.C.

And at that -- and during that in-person meet and confer, I expressed to the DOJ attorney who appeared for the meet and confer that the doctors group would like to get that data. And, you know, and the -- and the counsel for the FDA said they would revert on that.

We provided the FDA, through their counsel, an initial list, what they're calling the priority list, and we -- of certain information to be provided by November 17th. The purpose of that list was so that the doctors group can get an initial understanding of what was in the overall file.

THE COURT: Right.

MR. SIRI: It was not because it intended to have anything actually useful or valuable from it.

Instead, the DOJ has decided to use that and call it our -- the doctors' priority list and treat it as if they're providing something of value, when they're not providing anything of it. That's not what really is of value. The idea

of what was asked for by November 17th, what they're calling the priority list, was to understand, generally, what's in the data files.

For example, one of the things the doctors group wants to know is, what are the column headers in most of these data files? You know, there was a partial index that the FDA provided, and in that index it shows over 100 data files. Now, they all seem to be -- each file appears to be from various clinical trial sites. Presumably, Your Honor, the header across each of those files is the same, even the same column headers.

Well, my hope was, if I could see those column headers, we could quickly discuss and identify which columns might or might not contain any type of personally identifiable information.

I had an exchange just yesterday asking again for those column headers, and I was advised that since that wasn't something, apparently I didn't -- we didn't ask for it in our initial, what they're calling our priority list, they're not going to provide just the headers until after January 31. And in terms of when they would provide that, they won't even give us a date.

So, to your point, Your Honor, yes, there are these data files. They are supposed to be de-identified already. They probably are de-identified already. The one data file

they did provide had no redactions on it. We would like to get copies of all of them, but I can't even get the column headers from the Department of Justice.

I'm not saying that to -- I'm just saying that we're not able to obtain that. I would like to work constructively to obtain those. I suspect that those data files can be turned over without virtually any review. You'll have to ask, you know, obviously, counsel why that --

THE COURT: Let's -- let's go off the record. I'd like to see you-all back in my conference room.

(Short recess taken)

THE COURT: Back on the record at this time in the matter of Public Health and Medical Professionals for Transparencies vs. the Food and Drug Administration.

I took a brief break to go off the record and discuss some logistical issues in this case, and got I Mr. Siri interrupted in the middle of his argument. I'd like for you to go ahead and continue. And you can put anything you'd like to on the record. I'll try not to interrupt you.

MR. SIRI: Thank you, Your Honor.

THE COURT: Go ahead.

MR. SIRI: The doctors group certainly appreciates, Your Honor, that the FDA has said that they're going to proceed and produce in good faith and that they should trust the FDA that they will produce as expeditiously as they can.

But it has been more than 108 days since the FOIA request has been submitted.

One-hundred-and-eight days is the amount of time that the FDA took to license -- to review all of the documents that are being requested here and license this product in a process that the FDA says was the most rigorous, robust, detailed review they've ever conducted. That process took them 108 days. But yet, despite over 108 days passing, they have only produced, on average, a few pages per day to the doctors group of those 400,000 documents to date.

And I would point out in the declaration submitted yesterday by the -- by the FDA, their declarant says that, "Two of the subpoenas have yielded over hundreds of thousands of pages each." So it does appear that the FDA does have a precedent of responding to subpoenas and producing, apparently, hundreds of thousands of pages, and this, they were referring to since 2018. So, the FDA can, and it is practicable for the FDA to produce, apparently, hundreds of thousands of pages by their own admission, by their own declarant, in their papers.

Now, we all have to follow the law. That's -- you know, Americans don't get to say they don't want to follow the FDA's regulations nor the statutes passed by Congress. And the Congress here has passed a statute that the whole purpose of which is transparency, for the American people to have

transparency about Government conduct. And it's provided that in situations where there's an urgent need for the public to know about Government activities, there should be expedited treatment, or as the statute calls it, not just promptly -- yes, Your Honor?

THE COURT: The Government has made an argument that you haven't correctly made a request for expedited review. And, indeed, even if you had, that point is moot now because you're, essentially, getting expedited treatment.

What's your response to their argument?

MR. SIRI: I'm not sure -- the doctors group has certainly made an appropriate request for expedited treatment. A request for expedited treatment was followed -- excuse me -- it was filed with the FDA, and a copy of it is in our papers. It clearly lays out the grounds for why expedited treatment is appropriate here for two reasons.

First, as provided in FOIA, you get expedited treatment where there's an urgent need to review Government conduct. I can't think, Your Honor, frankly, of something more urgent right now than to review the FDA's licensure of the product that the Federal Government says is the only thing that's going to save us from this pandemic, that Americans are mandated to receive, that the Federal Government's provided immunity to liability for --

(Court reporter interrupts)

MR. SIRI: The Federal Government has provided Pfizer over $17 billion dollars from American taxpayers, where the review that the FDA conducted was done under significant time constraints, and where we -- what we're seeing -- and with political pressures. And what we're seeing is that the licensed vaccine, as we've seen on the news, there's waning immunity, there are variants that are evading immunity, and the CDC has said it doesn't prevent transmission.

We need independent scientists to review this data. We need all hands on deck. The FDA shouldn't be hoarding this data. If there was ever a need for immediate transparency, for urgent review of the public for Government conduct, this is it.

We need all -- we need the scientists from across this country who comprise the plaintiff's group here, some of the prestigious -- most prestigious universities in this country, who are independent of all these influences who don't have to work under severe time constraints, for our -- to review this data.

Yes, Your Honor? I'm sorry.

THE COURT: And assuming that I agree with you. I mean, even if you did represent a group of scientists and physicians, the American people are entitled to this information. I mean, they -- we are the Government. The Government is not some big ominous group here. We're a

republic, and the American people are entitled to this information. I think we can all assume that, including counsel for the United States.

What bothers me -- and if you did any research on me before you came before me, one of my big issues that I think is really -- and it's not just a product of the last couple of administrations, I think that this has been something that we've seen over the years, is that the Federal Government -- rather the Federal Judiciary continues being involved in things that it does not need to be involved in. One of the things that Thomas Jefferson warned us about 200 years ago is that the Federal Judiciary -- within the judiciary lies the seed and the dissolution of our republic, because we keep assuming jurisdiction and going into areas that we're really not supposed to be going into. That's not a new phenomenon, that's been going on for at least 75 years.

And me being the guy in the black robe that's a lawyer, not a scientist, has some hesitancy just saying, By golly, FDA, you have to produce that in 30 days.

What are the limits as far as what I can do? Assuming that we have this -- I have to balance this need for the information, but at the same time, obviously, I want to protect trade secrets, I want to protect personal information. What are you asking for?

And other than just producing in the most

expeditious way possible, what would be the dream order from the physicians group from me? That they must produce all of the information no later than January 31st or --

MR. SIRI: Yes, Your Honor.

That -- I think the dream request from the doctors group, and I think that large swaths of the American public, would be that Your Honor would order the FDA to comply with what FOIA requires, which is to produce it as soon as practicable. And what's practicable for the FDA here is that they can produce this in 30 days if they want to. They could muster the resources to do so.

Certainly if this were a request by Pfizer that related to getting the vaccine license, I would imagine they would get it done. Over the course of the last year, the FDA, the Federal health authorities, have given Pfizer millions of dollars per day of taxpayer money.

THE COURT: I think you bring up a good point. And I do apologize for interrupting.

MR. SIRI: I'm sorry.

THE COURT: No, I interrupted you.

In a case of this magnitude where the Government's basic defense is -- everybody agrees that the private information of these participants isn't something that the American public needs, and that's something that needs to be protected.

But when it comes to a large amount of these documents containing Pfizer and trade secrets, for example, I was a little bit surprised that Pfizer wasn't an intervening party here. I would think as much money as they have been given in this, and as highly confidential that some of their trade secrets are, that they would have intervened.

Is that something that's unusual in these types of cases? And do you know why Pfizer isn't here?

MR. SIRI: I can't speak for Pfizer. But I can say this -- I can say two things. One is, they may not be surprised because Pfizer, at this time, is used to the Federal Government working on their behalf. The Federal Government is the one that has funded them with over a billion dollars to help develop the product. The Federal Government is the one that's given them immunity liability. The Federal Government's mandated -- the Federal Government spent over $18 million marketing their product. They've gotten maybe used to the Federal Government, through the Department of Justice, defending them, promoting their --

THE COURT: I guess I would, at least, have thought they would have filed some sort of amicus brief considering this is their secrets. You're basically having the United States Government determining what's a trade secret and what's not for a private company.

Do you understand?

MR. SIRI: I do. And if I'm Pfizer looking at this from outside -- and, again, Your Honor, I can only speculate.

THE COURT: I mean, I would think if I did a FOIA request to the DOT -- DOD for the ingredients for a thermonuclear weapon that Morton-Thiokol would be an interested party.

Do you understand my point?

MR. SIRI: I do, Your Honor.

But where the FDA is taking the position that they are willing to commit to 500 pages per month, which, by the way, based on the total number of documents that are not disclosed, that would come out to over 75 years. I hope that that's not taken as hyperbolic, that's just math.

If they commit -- if that's what they actually do --

THE COURT: All right. If I enter an order --

MR. SIRI: If I'm Pfizer, maybe I'm not so worried today. Maybe I'm waiting --

THE COURT: Because we'll all be dead by the time it all comes out?

MR. SIRI: You know, that's possible. The other thing --

THE COURT: I'm 46, I don't think I'll make it 55 years or 75 certainly.

MR. SIRI: And the FDA is saying they want to do a

word-by-word, line-by-line review to assure Pfizer trade secrets. I mean, if you read their papers, there's not a sentence in there that makes any -- any recognition of the importance of this to the American people to do an independent scientific review.

Frankly, I found it incredible that the FDA, at least, will not give a recognition to that. I mean, their duty is to the American public, not to Pfizer's trade secrets. At least they can recognize the interest of the American people and approach it in a more balanced manner. But if you read their papers, that is what they focus on is Pfizer's trade secrets. And if I'm Pfizer looking at that, I'm thinking the Federal Government is there to protect me.

The other piece of this is, too, is this, who's the one that's there -- with most drugs, Your Honor, whether it's Hepatitis C or any drug, the FDA is not out there promoting those products. They're not telling Americans to get it.

Janet Woodcock and Peter Marks, the acting Commissioner of the FDA and the head of the CBER, the biologics division, they have been promoting this vaccine before it was even licensed. That's -- there's no conspiracy there, Your Honor. It's just a basic, you know, when somebody goes out and promotes a product, it makes them probably a little less reluctant to admit there was a mistake, that's all, no conspiracy there.

And that's -- that's part of the reason why we have independent review. That's why --

THE COURT: And I get that, counsel.

MR. SIRI: Yes.

THE COURT: What I'm concerned about -- I'm not arguing you don't deserve this information, that it doesn't need to be produced posthaste.

Where does my authority go as the Judge?

MR. SIRI: Yes.

THE COURT: Do I -- is it going to be an order that stands up to review of the colleagues that grade my papers on the next two courts up if I enter your dream order?

MR. SIRI: Let me answer that directly this time.

THE COURT: And where does my authority go? Can I order the FDA to hire 100 contractors to help review this information? At what point does it become draconian what I -- the burden that I place on the Government?

MR. SIRI: Yes. Your powers, Your Honor, by the statutes passed by Congress, Congress has empowered you to enforce the FOIA statute that says the FDA, in this instance, must produce these documents as soon as practicable.

What that is -- what that means, certainly in this instance, it could certainly be done in 30 days; that is practicable. It happens all the time in commercial litigation, in other Government requests. By the very

admission by the FDA, in their own declaration, that they've responded with hundreds of thousands of pages to subpoenas. It is practicable for the FDA to do this. Your Honor is empowered to require them to do that.

To the point of what expedited treatment means. There's two pieces to it. One is, that you get to the front of the line, right? You jump ahead of all the other requests, the FOIA requests. And there's a second piece to it, and second piece to it -- and we've cited numerous cases in our papers that say that stale information, the information not timely produced is stale, it's of no value.

The whole point of why Congress put in expedited treatment in the '90s, was for precisely this situation where there's a unique need for the public to have access. And the Government should argue -- of course the Government doesn't want to do it, you're reviewing the Executive Department's conduct. Of course they're not going to want to provide it to you quickly. They're going to want to delay it as long as possible. Nobody likes having their own homework reviewed and double checked. They're not going to want that, of course. That's why courts always have -- often have intervened in the administration and forced them to do it in timely manner.

THE COURT: No, I understand.

Certainly that authority has limits and I can't order it to be produced tomorrow or the Fifth Circuit is going

to tell me that's being too tough on the agency. If the agency only has ten folks that they have employed to do this, and I enter an order saying it has to be done in 30 days, I just leave it for them to work out the details.

MR. SIRI: They can, number one, they can hire independent contractors to review these documents -- or professional contract document reviewers, excuse me, who conduct document review all the time, that they can hire.

They could allocate reviewers from the Department of Justice. Attorneys review documents all the time. They can bring in from other agencies. There are all types of individuals they can bring in from within or from without. They can also put the burden on Pfizer.

They've already given Pfizer $17 billion of the American's money. Why not make Pfizer do it in 30 days; certainly they can pull it off. I'm sure they've got a lot of large fancy law firms that they have on -- you know, that they have on retainer that they can review this pretty quickly, Your Honor, and provide, you know, what it is they think should be redacted for trade secrets and personal information and let the FDA know.

THE COURT: I think the United States is going to tell me that the cases you cited in your briefs are extreme outlier cases. Even if I take those cases at face value, what you're requesting and the timeline you're requesting still

goes far and beyond that.

How do you respond to that?

MR. SIRI: This is an unprecedented request.

THE COURT: This is a one of a kind?

MR. SIRI: I would say, Your Honor, this is one of a kind. And I don't agree with their characterization of the case law.

I pointed out two different cases, and we cite in our papers, in which the FDA was -- produced over 10,000 pages per month for products. One was a Hep C drug, and one was a very rare neuromuscular disorder. And in those cases the FDA warned them -- the FDA produced over 80,000 pages at a clip of over 10,000 pages a month, plus there were over a thousand electronic files in that case.

And we've cited in our paper -- the case name, Your Honor, is *Treatment Action Group vs. FDA,* 15-CV-00976. It was 82,000 pages, over 1,000 electronic files. They've identified here 126 data files. They said there might be more, but they're not telling us how many. And there the FDA produced it in seven months. Over 11,800 pages per month, plus electronic files.

And that was for something that was not what they said could be the only thing that could end the most important issue addressing America today. The pandemic has resulted in incredible economic disruption. It has resulted in

impingements, if I may, on individual rights we've never seen in the history of this country. Just the ability to leave your home, to go to work, to walk in the street. It has disrupted, virtually, every single aspect of American life.

There is no product, that I'm aware of, where the Federal Government mandates you to get it, can't -- gives the company that sells it immunity from liability, you can't sue for injuring anybody, gave the company the billions to develop it; and then, when they licensed it in 108 days, doesn't want to expeditiously produce the product. That's unprecedented. It truly is unprecedented.

There is no other product of this nature. There is no other situation that I can think of that's even comparable. If they can do 11,800 pages plus electronic documents in the Hepatitis C case, and that was in 2016, over a seven-month period, this case calls for, at least, ten times that rate.

And we cited another case called *Seife vs. FDA*, and that was from 2020, and it's 492 F.Supp.3d 269. And over a four-month period was over 10,000 pages a month, where a rare neuromuscular disease, which I will point out, just like the Hep C, was not in the news, had not been the focus of the media's attention every single day and is not urgently needing review, because that is not -- there's no claims that there's waning immunity, there's no claims that there's variants that arise in the data, there's no claims by the CDC that it's not

preventing effective transmission.

I mean, we need -- this doctors group, they want something very simple, Your Honor. And it's -- and it's -- it couldn't be more practicable. We just want to independently review the documents submitted by Pfizer and that the FDA reviewed to license this product. That is critically important for every American. And I do think that, unlike the precedent that the FDA is citing, this calls for unprecedented speed. They did operations warp speed to get the product licensed.

THE COURT: You don't need to harp on it. I'm in agreement.

I think that this is -- in my mind I couldn't think of a more important FOIA case in the entire country or a more important forefront issue that the American people are entitled to know.

When you're being asked or, indeed, mandated to take something and insert a foreign substance in your body, I would think, first and foremost, that the Government ought to have to -- in our system of Government, we're not in communist Russia or China or in Nazi Germany -- when the Government has mandated something, I would think the American people are entitled to know the underlying efficacy of what they're being asked to do.

I think it's no doubt in my mind that this is

something that needs to be produced posthaste. The only question I have in my mind is when and how it can be done in a manner in which I'm not shutting down the entire FDA. I mean, what if there's a pending request for a drug that's going to cure cancer, and I have to enter an order that 19,000 people at the FDA have to go and review information for privilege and we don't get a cure for cancer. And in the meantime, we're fighting over the documents underlying COVID-19, which as bad as it is, certainly -- what is the survival rate of COVID-19, 99.5%?

Do you understand my point?

MR. SIRI: I do, Your Honor.

And that's why we went out and we tried to provide as many metrics as we can. We were not able to obtain them from the FDA, unfortunately. But we did provide, in our papers, Your Honor, number one, we got a quote from a professional document review company, that's all they do.

We explained to them that the review here requires for personally identifiable information and for trade secrets. We've got a quote from that company, we provided it in our papers. They say they can conduct that entire review with about a hundred-grand budget, ten reviewers and a few weeks.

Also, we've taken a look, and we provided in our papers, for the more difficult task of reviewing for commercial -- in commercial context, which involves, not just

those two bases, but you have to review for privileged, for attorneys-eyes-only documents, confidentiality, a whole host of other things. Most law review articles, ABA journals and trade publications, they average about 50 hours -- 50 pages per hour for those reviews.

THE COURT: And I think it's safe to say, everyone in the room that's been out in practice for awhile that's been involved in modern-day commercial litigation, indeed, you can even see this in tort litigation, 400,000 documents in modern-day litigation is really not a lot.

In fact, some of the prosecutors out here are frequently involved in health-care fraud claims. We had one recently where the Government had to review four terabytes of information for the same exact thing we're looking at here now, private information, trade-secret-type information. Four terabytes, that's a lot of information, and they had to do that in about two weeks.

So, it's not something that's unusual in the grand scheme of things. Certainly in the litigation context, 400,000 documents just ain't a lot of documents in this day and age.

All right. I'd like to hear from the United States.

MS. KONKOLY: Thank you, Your Honor.

I'd like to begin by, again, emphasizing that the 55 years being cited by the plaintiff is not a number that the

FDA has ever cited. It's very much a hyperbolic calculation that rests on, at least, two faulty assumptions. One that goes to the FDA, and one that is within plaintiff's own control.

The faulty assumption that pertains to the FDA, is that it is not acting in good faith; when it is repeatedly representing to this Court that it's making every effort to move forward as quickly as possible, and if it can process the documents faster, it will. That commitment is demonstrated by the efforts that it has already made to date. It's released 3,000 documents, as of yesterday, and the proposal that its making to release close to 9,000 more by the end of January, which is a matter of six weeks from now.

So, in those other FDA cases, they are outliers. I can't speak to the particular circumstances of them. But every FOIA case is different. Some are easy, some are hard. The point is that where we're standing right now, at this very early juncture in this FOIA case, the FDA simply has not had an adequate opportunity to get its arms around these 400,000 documents at issue here.

THE COURT: How long is that going to take, ma'am? How long -- and I'd like to note, I'm very, very disappointed that no one from the FDA bothered showing up for this. I understand that we're living in a time of COVID and it's probably more difficult to travel.

But I, particularly, did not put this hearing for an immediate hearing after I issued the order, because I wanted enough time, having been a Government attorney, knowing how long it takes to travel, to get it authorized, so I would have someone from the FDA here, so I'd have firsthand information with regards to how long this is going to take. I'm very disappointed that we don't have anyone here. I hope you communicate that with your client agency.

MS. KONKOLY: Your Honor, I will -- you can rest assured I will convey that in no uncertain terms to the FDA. The message will be received.

THE COURT: Go ahead. I've been really bad about interrupting.

MS. KONKOLY: And let me reiterate on the record, that no disrespect was intended by that. It was simply a function of the FDA's travel policies, which are restricted in this time of the pandemic.

THE COURT: I guess the reason I'm disappointed, I would think that this would be in the -- at least in the top five of the most important pieces of litigation they have at the moment.

MS. KONKOLY: Your Honor, this case very much has the FDA's attention. They started processing documents even before we got to this point, that's not how it normally works in a FOIA case.

As we noted in our reply brief, even though, you know, formal expedition was denied, it's really a moot point because the FDA, is, in effect, expediting this case. It is processing documents and is making a full-court press in putting every available resource that exists in the real world that they are operating in into moving this forward as quickly as they can.

They've made -- we've made extensive efforts to confer with plaintiffs. The FDA has bent over backwards to try to get them the information that they wanted. We heard from plaintiff's counsel that they wanted the raw data from the clinical trials, and so we identified that as Section 5.2 and 5.3 in the product file.

We went through and tried to create a detailed index for them to help them identify where the FDA can start most productively for them. The parties agreed on a priority list. I understand that plaintiff's counsel is taking some issue with that term. The plaintiffs have been using that term themselves. It's right there in some of the correspondence the plaintiff introduced in his appendix, I believe it was appendix 637. He, himself, uses priority list.

The idea wasn't -- the initial priority list is the things they want first. We understand that this is, in a certain sense, the tip of the iceberg. The FDA took the plaintiff's priority request to heart. It is starting with

that set. It is making every effort to get through that initial set as quickly as possible. It's proposing to produce close to 9,000 more documents, bringing the total, I believe, close to 13,000 documents six weeks from now.

So, these outlier cases -- to return to the point I was making a few moments ago, that plaintiff's counsel has cited, the FDA is moving at a pace, you know, roughly akin to that. And it is committing that if it can maintain that pace or even pick it up, it's going to do so. At this moment, however, it just has not had sufficient time to get its arms around the entire corpus of the 400,000 documents at issue, especially to make a firm commitment as to how quickly it can get through that.

The FDA certainly hopes, and I don't know if I can use the word expects, but we are very much hoping that there are going to be efficiencies and there are going to be certain portions of this that can be gone through very quickly. It just depends on what's on the data. Some portions of it are going to be slow going, some are going to be fast. We can work with plaintiff's counsel to identify the parts that we can get out quickly.

I assure you that this has the FDA's attention and that they are putting every available resource into moving forward, even --

THE COURT: One of the things that I had hoped --

and I do hope that the parties are able to talk. I mean, this is -- this should not be World War III, this is a FOIA case.

And as counsel has pointed out, and I think the Government agrees, this is something that should be at the forefront of the agency's attention, particularly when we're in an environment where we're encouraging all U.S. citizens to take the vaccine. I think transparency and forthrightness on behalf of the United States is more important here, possibly, than any other case in recent times. So, it's disappointing for me no one here is from the FDA to tell me exactly what's going on.

Can you tell me the extent of the discussions between the parties? I mean, is it the parties that can't discuss this? Do -- have y'all sat down and actually talked about, This is what it incurs, this is what we're able to do, this is what we're not able to do?

MS. KONKOLY: Yes, Your Honor.

THE COURT: And again, the original request was sent back in November. We are beyond that now. I would expect at least one, maybe two meetings, between the parties.

Do you communicate, is what I'm trying to ask?

MS. KONKOLY: The FDA has been bending over backwards to try to give plaintiff the information that it needs to make an effective priority list and to move this forward as quickly as possible.

When plaintiffs said that they wanted the raw data, the FDA went ahead and identified for them the parts of the file where that would be likely to be located. They made the time investment to make a 90-page -- they had to go manually, take screen shots of those 90 pages and break out the folder to create that index. That's in our first appendix filed with our first brief.

Plaintiff's counsel --

THE COURT: Does the FDA not have all this on an electronic database? I mean, that's -- I'm an old guy. And so when I was working and representing Federal agencies, even 15 years ago, Federal agencies had databases of information that were searchable, via FOIA searches, via certain categories and types of information.

I would be shocked that an agency as advanced and scientifically oriented as the FDA did not have some sort of a program to organize these documents. They had to have known the FOIA request was coming.

MS. KONKOLY: Your Honor, I think -- I don't want to, you know, speak beyond what I, you know, have confidence I can represent here. But I can say that the seed documents, the point I was trying to get to eventually, that plaintiffs have made the argument that this really shouldn't take that long because all of the information has already been redacted, and this is just not so.

There is a regulation that does ask the manufacturers to redact identifying information, but whether it's because by either read differently or some stuff got past them, in the production that went out yesterday of 3,000 pages, the FDA found several dozen instances of PII that needed to be redacted. And that was the product of a line-by-line review that needed to be done to protect the privacy interests of the child participants, which as I noted in conference, is I think a very important interest that everyone here can recognize.

THE COURT: And certainly I agree.

Let me ask you another question with regards to document production. In the world of litigation, where we have big productions, we have what's called a claw-back mechanism. I would assume that the parties can enter an agreement that says before the plaintiffs take any of this information and do what it is with it, if they come across something that has personally identifiable information and/or something that is clearly a trade secret that was inadvertently produced, isn't there something akin to like a claw-back agreement that the parties can make amongst themselves?

MS. KONKOLY: Your Honor, that's a --

THE COURT: Is that ever done in FOIA litigation?

MS. KONKOLY: That's a fair question. I understand

why you would have that question. But the answer is, no, that does not apply to FOIA litigation. Once the release is made, it's made to the public. There's no such thing as a protected order or a claw back in the FOIA context.

THE COURT: So, in other words, the parties couldn't enter -- the Government couldn't enter into an agreement with plaintiffs in a case like this?

MS. KONKOLY: No. That's not -- that's for civil discovery, it's not a FOIA concept.

THE COURT: All right. Go ahead.

MS. KONKOLY: I would also like to note that one of the things that is a very substantial factor in the amount of time this is going to take on the ground is the breadth of the plaintiff's request. They're certainly entitled to the full 400,000 documents under the scope -- you know, under the FOIA statute, the FDA doesn't dispute that. But it is a choice that the plaintiffs are making to ask -- I should clarify, that's somewhere in the ballpark of 400,000, once we added in the two additional categories of documents that I think plaintiffs are saying, if I understand them correctly, they want FBI to -- I'm sorry, FDA to expand its construction of its request to encompass. That will bring in an additional several tens of thousands of documents and pushes that somewhere close to around 400,000.

That is their choice to make, and there are

consequences on the ground, just like anything else in the world, work takes time and the more work you need to do the longer it's going to take. So, there is very much a responsibility on the plaintiff for having brought such a broad request. It just can't be the case that you asked for 400,000 documents and get them overnight, which is, essentially, what they are asking for.

THE COURT: It would seem the vast tranche of the documents are something that would not contain information that's clearly personally identifiable-type stuff.

The mere underlying data, why is that not something that couldn't be produced in, let's say, even 90 days?

MS. KONKOLY: Well, Your Honor, the documents do need to be reviewed line by line for that PII. There is also exemption for the commercial trade secrets.

The Government cannot simply outsource that, despite their -- I very strongly doubt that plaintiffs would actually like that world. If the drug company had the final say on what was, you know, protected under the exemption, formal or confidential, there would be absolutely nothing stopping them from just drawing a big black box over the entire set of records.

The FDA has an independent obligation under FOIA to make that --

THE COURT: I don't think that that was what I was

asking. My question was more towards the cases like this. Is the party that's effectively the most concerned with the production, in this case that would be Pfizer, I don't think anybody can argue that, the party that would be most affected by this information being produced, taking out the individual patients or participants in the study, would be Pfizer itself.

Are there any instances where that party appears as either an intervenor or an interested third-party or, heck, even an amicus-type situation?

MS. KONKOLY: I'm not aware of any in the FOIA context, Your Honor. I can't speak definitively to that.

THE COURT: And I'm not a FOIA lawyer.

MS. KONKOLY: Well, we do a lot of FOIA work in my office, but I haven't seen that come up. I can't say definitively whether it's ever done. It would certainly be very unusual, I would think.

There is a process, and part of the reason that time will be required just necessarily to work through this, we explained this in a couple of places, but most recently in our reply brief on page 20. There's something called informally reverse FOIA, which here, if the FDA determines not to withhold information that might be confidential pursuant to its regulations that, you know, as plaintiff's counsel has hastened to point out, is required to comply with its own regulations, which in this instance would require the FDA to

notify Pfizer and give Pfizer an opportunity to object.

That is certainly just a process that, you know, takes time, like anything else, to happen. And I think it can be reasonably anticipated to happen in various instances if the FDA works its way through this massive set of documents.

Again, I would note that the order that plaintiffs have asked for, they want apparently everything produced by March 3rd, that is 80 days from today, folding in these new documents, under an expanded construction of their request, that works out to 5,000 pages per day or 150,000 pages per month.

I will, again, just emphasize that, you know, plaintiff's counsel clearly did his research, he found a handful of extreme outlier cases in which the courts have ordered a pretty extreme processing schedule, that I know, in at least one instance, it was a case I was monitoring. The *Open Society* case in New York, it threw the State Department into absolute turmoil for a great deal of time. It really did shut down some things for them in order to comply with that order, and that was 5,000 pages a month.

THE COURT: But --

MS. KONKOLY: The plaintiff is asking for 5,000 pages a day.

THE COURT: But why is this not an unusual outlier case? It's not like they're making a request for the studies

that were done behind the MHMR vaccine that was approved in 1972. We're asking for -- this is the most -- I cannot stress this, I don't think anybody in the entire courtroom disagrees -- this is the most important issue of our time.

MS. KONKOLY: The FDA --

THE COURT: No doubt about it. This is as important as World War II. This is -- this is the most important issue of our day. This is -- in many ways I think it would trump September 11th. We are asking every single American to insert a foreign substance into their body. And the response from the Government is that, Well, this is too much trouble for us to get the underlying data out.

Do you see how this looks very, very bad?

MS. KONKOLY: Your Honor, the FDA -- I would just like to state on the record, again, absolutely understands the very substantial public interest in this, it's effectively expediting it. It went immediately into production. Three-thousand pages have already gone out. It is moving full-steam ahead to get $9,000 -- 9,000 pages out the door by the end of January.

And if it can maintain that pace or increase it, it will. It has repeatedly said that. We are just not in a position, as I stand here today, to make a commitment about this very large universe of documents that the FDA has not had an opportunity, given all the work that it's doing to process

those documents as quickly as we can, to get a handle on what's in there, and, you know, how quickly they think they might be able to get through it.

Which is why the FDA has said, If you would please enter our proposed order, we're moving full-steam ahead, give us a little more time to confer with the plaintiff, try to get them some more information, give the plaintiffs an opportunity to narrow their request, because there is a very large degree, in which, things are in their control, if they reasonably narrowed the less documents at issue, it stands to reason that it will take less time.

THE COURT: Just to be quite frank with you, that was part of the reason that I scheduled the hearing today. I had hoped that someone -- a client rep would have been here so I can let you-all go back and talk. It's always good to talk face to face.

I have the luxury of having two jury rooms that are very spacious and comfortable, and you guys could have spent the day here talking this out and perhaps reasoning together and coming up with something that everyone could have agreed with or, at least, could have narrowed the issues for me. But, apparently, that's not possible.

Go ahead and conclude your argument.

MS. KONKOLY: Can I --

THE COURT: Ma'am, I have a full criminal docket --

MS. KONKOLY: Okay.

THE COURT: -- that I have to get done.

MS. KONKOLY: I will conclude. But let me -- I just note that if Your Honor would like --

THE COURT: But the answer "no" or "it's too much work" is just not going to get you there.

MS. KONKOLY: The FDA agrees that it would be productive for the parties to have more time to try to work together to come to an agreement on this.

THE COURT: But if they agreed, why didn't they bother sending somebody up? And don't give me the bureaucratic answer.

MS. KONKOLY: Your Honor, again, I apologize. I explained that I can't --

THE COURT: I have not -- I cannot think of a more important issue at the Food and Drug Administration right now than the pandemic, the Pfizer vaccine, getting every American vaccinated, making sure that the American public is assured that this was not a rush on behalf of the United States, that they really had the safety of the American people in mind to try to quash the pandemic.

We're hearing an omicron variant, we're probably going to get shut down again. By golly, we ought to be able to get all hands on deck, get this information out, okay?

MS. KONKOLY: Your Honor, can I --

THE COURT: This ought to be as important in getting the information out as it was in approving the vaccine in the first place.

MS. KONKOLY: I absolutely take that point. Can I say one thing in response? Which is just that I would, again, note that the FDA agrees that more conferral would be productive. The FDA will receive, I assure you, in no uncertain terms, the Judge's message they should have been here today.

THE COURT: You know --

MS. KONKOLY: I'm sure we can get the FDA to come back down here, I can come back down here. I'm not sure if there's a magistrate judge who you can, potentially, refer, you know, to mediation session to where the parties can sit at the table with agency counsel here to try come to an agreement that is practicable, and as you said, will not, you know, require FDA's very important public health operations in areas, like, cancer research and approval of lifesaving drugs in other contexts to come to a halt in order to agree to a production schedule that is 15-times larger than anything that's ever been entered in the history of FOIA, as far as I'm aware.

THE COURT: Yeah. And I figured this is 15-times larger than anything that the FDA has ever had to approve in such a short amount of time, too.

Let me make a point. I think that Mr. Howie, and certainly some of my AUSAs that are out there can attest, the previous occupant of this courtroom is a guy named John McBryde. John McBryde is still alive and still hearing cases. And you can do some Google searching for him, if you'd like to know what he was like as a judge.

But he was known during his tenure, when he would get answers like this -- one time he went so far as to order the Secretary of the Treasury to be present for settlement negotiations to try to talk it out because no one from the IRS showed up for negotiations like we have now.

I am not prepared to do that. But if I do have another hearing, I am going to order someone from the FDA with the appropriate authority to come and discuss exactly what this entails. Because, quite frankly, I've been in your shoes before, I've been a main justice attorney, I know you're limited on what you can say. But this is not summary judgment in a typical case.

This is a FOIA case involving the Pfizer vaccine, something we all agree that the American people are entitled to know and they're entitled to get to as quickly as possible. Making all the legal arguments, frankly, are just not that helpful, all right?

I get the main point that that is an overbearing case and the entire FDA is going to go over the mountain if I

order this to be expedited too quickly. The burden is too heavy, I get it, that sums it.

Brief reply, and then I need deal with my criminal docket.

MS. KONKOLY: We can make a mediation conference happen.

THE COURT: All right. Thank you.

And again, I'm not saying this to be rude, these are just my concerns. I wouldn't be doing my job if I didn't tell you.

MS. KONKOLY: Understood.

THE COURT: Go ahead.

MR. SIRI: Thank you, Your Honor. I'll be very brief.

In terms of the scope of documents. As the doctors have made very clear, unless they have all the data, the entire production, they can't do a proper review. If even one data set is missing, they don't know if their analysis is correct.

In terms of the actual scope that was requested. As I pointed out, I believe earlier, this FOIA request is for the precise scope of documents that the Code of Federal Regulations, that the FDA's own regulations say, should be made immediately available after licensure.

And then in terms of -- and this is really

important, Your Honor. While the cases that we cite, the two that I pointed out earlier, have a rate of about 10, 11,000 pages per month, and that's, you know, I think 50-times greater rate than any other case, I think that's a bit hyperbolic, but there is something consistent through all the cases. And that is, when there's expedited treatment, the documents must be produced in a timely manner to make them useful. Meaning, it's the end date that the courts have consistently found needs to be done within a timely manner, not the rate, that's typically been focused upon.

And I quote the Fifth Circuit, which says, you know, FOIA was to "pierce the veil of administrative secrecy and to open agency action to the light of public scrutiny." And that "stale information produced pursuant to FOIA requests is of little value." The quotes go on and on and we have them all in our papers, in our initial brief and second brief, where courts repeatedly affirmed the principle that when there's expedition warranted -- there couldn't be a more clear case of expedited treatment here -- that it's the end date that's critical, and the agency has to come and do what's needed to meet that deadline. And that is what Your Honor is empowered to do.

They would like to tell us, Trust us, we're going to act expeditiously, but it's now been 108 days since the FOIA request and the doctors group has received about an average of

a few pages per day, essentially, if you average out all the documents they've provided, that doesn't provide a lot of confidence.

And in terms of bending over backwards in negotiations, I respectfully say -- and I do always hope to work with opposing counsel on every case. But here we've not been able to get an accurate number of the pages. We can't get an index. Literally, an index of the file that they have, they won't provide a full index to us. We can't get the headers of the Excel spreadsheets that are repeated over and over again. We don't know the total number of data files, that won't be provided to us.

And as I mentioned when we met to confer in person, I'm sure there's a universe of pages that don't require a lot of review. And if they can identify those we can have that discussion, but that's never happened.

In terms of the PII, the personal information redactions, there were a few made the other day, but they were very limited and many of them did not seem necessarily, particularly, I would say, they looked a bit like they're looking for redactions, given that there's no names, there's no -- it's almost impossible to identify the information by, you know, some of the stuff that was redacted.

In any event, one last point I'll make, Your Honor, and it's this, is that in terms of licensing this product,

Pfizer actually directly paid the FDA over $2 million to actually do the licensure process. It's, you know, it's part of the way the FDA operates. And, you know, in this instance, we actually even offered, the doctors group, to provide money to the FDA, we directly offered to provide them funds but they rejected that.

THE COURT: Here's the problem with that, and I'll say that, because -- again, I've been interrupting counsel way too much. This has been my own experience, both as a Government employee and as a judge, and counsel for the United States may say this, do you see how the table that you're at, that the glass is broken in front of you.

MS. KONKOLY: Oh, it's fine.

THE COURT: Well, let me tell you a story. I was trying a case in here a couple of weeks ago involving a products liability matter where the product at issue, the counsel dropped it and cracked my glass, and he graciously offered to pay. Here's the issue, and I've run into this in the courthouse, the Government has a lot of other regulations where they are unable to take private money to pay for things such as that, in the same way the attorney couldn't pay for my glass, okay?

It's an important point, and I get the point you're trying to make. But, at least, my understanding -- and I'm just a poor country judge from Fort Worth -- is that the

Government can't accept private funds for things like that, as much as we would like to.

MR. SIRI: You know what, I completely understand it, because it corrupts and can create conflicts.

THE COURT: Let me give you an example.

MR. SIRI: Yes.

THE COURT: One of the things that we would like to do here in Fort Worth is to be able to create an exhibit on the Constitution downstairs for school kids to come through. I told you-all in chambers about some of the historic things that happened in this courthouse, everything from school integration, to civil rights cases, to Lyndon Johnson running in the Senate.

I had several private foundations that wanted to give money, the Government could use carte blanche to do whatever it wanted, I could not take the money. I am familiar with this.

That's a good point, but it doesn't get you there.

MR. SIRI: Well, then it certainly does, even further, bring into focus why these documents should be public, because the FDA did take over $2 million directly from Pfizer to pay for the licensure process.

THE COURT: Okay. This has been -- I won't say it's been helpful. What I expect to accomplish, you guys haven't told me anything that we didn't agree upon when we came in

here.

I really wanted somebody from the FDA here that I could talk to, that you-all could go back and talk to, to work out an agreement, work out a schedule. And I'm sorry, ma'am, but the excuse they couldn't get down here because of constraints under COVID in a case like this. Perhaps I should have made my order clear that said client reps have to be here, too.

I just assumed, from all my years at the Government, that you would have been required to bring somebody from the FDA with you. All these legal arguments, they're important, but the real issue here is what's the burden on the FDA to get this information out? Do I want to kill that agency where they can't get the cancer drug treated? Of course not. The American people have a right to know. And I'm disappointed that you-all haven't come to any more agreement than we have today.

I'm planning on getting an order out over the next couple of weeks. And it may be that I bring you back, and I just have to order, whoever at the FDA is working on this, to show up and spend a couple of days here out west in the hinterlands of Fort Worth talking about these issues. But I do plan on getting an order out with the scheduling soon.

I don't think that 30 days is feasible, but I don't think that what the Government is proposing is at all

feasible, particularly given the magnitude of what we're here on. I don't think anybody can disagree that this is the number-one issue in the entire world at the moment. We ought to be able to get out the information posthaste underlying the vaccine that we're trying to force everyone to take, whether right or wrong.

And I say that, I've been double vaccinated, I fully anticipate getting the booster. And I think many of us in this courtroom that have had the Pfizer vaccine would like to know exactly what we're being told to take.

All right. We will issue an order, and maybe that you're brought back and maybe we just issue the order pursuant to what's in front of us. I think the briefing is very good.

If I would have known that no one was here to visit, I wouldn't have made everybody come down here. You guys coming from New York as well, I'm sure they had better things to do this time of year.

Thank you all. You may be dismissed.

(Proceedings Adjourned)

REPORTER'S CERTIFICATE

I, Monica Willenburg Guzman, CSR, RPR, certify that the foregoing is a true and correct transcript from the record of proceedings in the foregoing entitled matter.

Further, the proceedings were held during the COVID-19 Pandemic and some parties, including witnesses, were speaking while wearing masks.

I further certify that the transcript fees format comply with those prescribed by the Court and the Judicial Conference of the United States.

Signed this 16th day of December, 2021.

/s/Monica Willenburg Guzman
Monica Willenburg Guzman, CSR, RPR
Texas CSR No. 3386
Official Court Reporter
The Northern District of Texas
Fort Worth Division

CSR Expires: 7/31/2023

Business Address: 501 W. 10th Street, Room 310
Fort Worth, Texas 76102

Telephone: 817.850.6681

E-Mail Address: mguzman.csr@yahoo.com