REPORTER'S RECORD
VOLUME 1 OF 1
TRIAL COURT CAUSE NO. 21-001887-CV

DUDLEY LEE CARROLL	*	IN THE DISTRICT COURT OF
	*	
VS.	*	BRAZOS COUNTY, TEXAS
	*	
BAYLOR SCOTT & WHITE HEALTH, AND IBRAHIM SALEJEE, M.D, KEVIN DIXON, MC.D, TIMOTHY MICHAEL BYRD, M.D., JESSICA WALKER, M.D., ANTHONY ZACHRIA, MS.D, JACQUELYN ROSE COVINGTON, MC.D, SCOTT HINTON, JASON JENNINGS, WILLIAM RAYBURN	*	85TH JUDICIAL DISTRICT

TEMPORARY INJUCTION

On the 28th day of July, 2021, the following proceedings came on to be heard in the above-entitled and numbered cause before the Honorable Kyle Hawthorne, Judge presiding, held in Bryan, Brazos County, Texas.

Proceedings reported by computerized stenotype machine.

APPEARANCES

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CHRONOLOGICAL INDEX

ALPHABETICAL WITNESS INDEX

EXHIBITS OFFERED BY THE PLAINTIFF

THE COURT: Going to call the case. This is -- this is Cause No. 21-001887; it's Dudley Lee Carroll vs. Baylor Scott & White, et al. We're here on a temporary injunction requested by the Carrolls.

Is the Petitioner ready to proceed?

MS. UBALLE: Yes, Your Honor.

THE COURT: Defense?

MS. ATWOOD: Yes, Your Honor.

THE COURT: All right. And you're Ms. Uballe; is that correct? U-b-a-l-l-e?

MS. UBALLE: Yes.

THE COURT: Ms. Atwood's going to be representing Scott & White and the doctors that are involved in that -- or the administrators?

MS. ATWOOD: Yes, Your Honor.

THE COURT: Okay.

Let me ask a procedural question right off the bat.

MS. UBALLE: Yes, Your Honor.

THE COURT: And I'm concerned that I don't have a signed pleading by an attorney yet in the file.

MS. UBALLE: Yes, Your Honor. We can remedy that. We can get an amended petition put in the file.

THE COURT: Well, my problem is I don't know that I've got a cause of action until I do that because, in effect, an

improper pro se litigant's pleadings are ineffective.

MS. UBALLE: Yes, Your Honor.

THE COURT: Don't take them into effect. So, you want to address that issue of how we move forward here this morning without signed pleading by an attorney?

MS. UBALLE: Your Honor, we can get that remedied if he can get a short recess and get it on file.

THE COURT: Well, I think it's -- I would feel more comfortable going forward with a pleading that's signed by an attorney.

MS. UBALLE: Yes, Your Honor.

THE COURT: How long do you think it's going to take you to do that?

MS. UBALLE: Give me 30 minutes. Do we have capability to print documents in the courthouse?

THE COURT: Well, we can get stuff e-mailed to Kristie or myself; and I assume you'll be e-filing it downstairs.

MS. UBALLE: I can do that. Less than 30 minutes.

THE COURT: All right. Let's do that.

MS. UBALLE: Okay.

THE COURT: I would feel more comfortable with a signed pleading. Been waiting for it. I checked this morning. I didn't see anything so I didn't know whether it was our e-filing missed it or what.

MS. UBALLE: Yes, Your Honor. Get that done.

THE COURT: Let me know when you get it done.

MS. ATWOOD: I filed a verified answered yesterday challenging capacity the way the pleadings are currently.

THE COURT: Haven't seen it yet this morning either.

MS. EVANS: It's on my desk. It's been e-filed.

MS. ATWOOD: In her defense it was late yesterday.

THE COURT: Going to give an opportunity to file the signature.

(Recess taken)

THE COURT: All right. Back on the record Cause No. 21-00187. Filed the first amended application for temporary restraining order and petition for temporary injunction.

Ms. Uballe, you ready to proceed?

MS. UBALLE: I am, Your Honor.

THE COURT: And, Ms. Atwood, you ready to proceed?

MS. ATWOOD: Yes, Your Honor.

THE COURT: Ms. Uballe, you want to give me an opening statement?

MS. UBALLE: Your Honor, Mrs. Carolyn Carroll is dying.

Your Honor, Mrs. Carolyn Carroll is dying --

THE COURT: You need to turn your mic on.

MS. UBALLE: She's not improving. We are here today to ask this Court -- Your Honor to show mercy and

compassion that for some reason Baylor Scott & White has not been willing to show.

We all have great respect for our hospitals and our doctors for all the difficult decisions they've had to make especially under the circumstances we have found ourselves in over the past 16 months. But we must remember that we need to balance the expertise of our hospitals and our medical providers with the desires and wishes of the patients and the patients' families.

In this case the patient's wishes through her medical power of attorney and her family have for all intents and purposes been ignored despite ongoing repeated requests. And no one is here to say a doctor should not have the final word for a patient's treatment, but I cannot imagine anyone here today would argue that a patient's wishes and a family's values should not be seriously considered especially when a patient is terminal.

The treatments the patient is receiving and has received are not working. The hospital's and doctors' moral and ethical obligations include basic patient advocacy. In many circumstances what that looks like is the hospital convening their staff with the family and having a collaborative discussion about what treatments are -- are available and -- and desired by the family. And part of that intent for the hospital is to seek to uphold the family's values especially under these circumstances. And the Carroll family is a Christian family,

they believe in showing mercy and compassion and beyond that they believe in miracles and they deserve to have those values considered.

In this case Mrs. Carolyn Carroll's family has never been provided any substantive opportunity to collaborate with Baylor Scott & White or any of its doctors on the family's outside doctor's recommended treatments. Baylor Scott & White's repeated response has been a simplistic no, it's not in her best interest. Your Honor, what does the hospital think is in her best interest at this point? She's dying. There have been no genuine efforts to discuss fully the recommended treatment because, in essence, it's not in line with what the CDC and NIH recommends?

Your Honor, our request here today is not to have you practice medicine. Under the Right to Try Mrs. Carroll has the right to off-label, experimental treatments. The recommended -- you will hear from our experts that the recommended treatment protocol in this case is safe. And we have to remember our standard is to give a little bit of hope to a dying patient.

But this treatment that we're going to hear about has demonstrated what doctors call signals of benefit.

THE COURT: What did you call it?

MS. UBALLE: Signals of benefit.

They have shown that it does work. And the family

does have a doctor -- you will hear from him, Dr. Edwards. He is willing to step in in this case and exercise his own independent judgment and prescribe this medicine and also administer it -- be in charge of administering it and monitoring this patient and making sure that when she does show signs of improvement, he can adjust it; if she does not, he can adjust those things.

We're also asking you today, Your Honor, to honor this patient's fundamental rights under the Medicare Act. Under the Medicare Act -- and I can give you the citation, Your Honor -- she has the right to meaningfully participate in her own treatment, and that has been denied.

All the family is asking this Court to do is order Baylor Scott & White to provide temporary privileges -- emergency privileges to Dr. Edwards so that he is able to step in and give this treatment and administer this treatment. He doesn't need to be in charge, he doesn't need to run the entire case. He will collaborate with other doctors, but we want him and his experience to be able to give this treatment and collaborate with the other doctors on this case.

Mrs. Carolyn Carroll is not a statistic, and she deserves the best fighting chance she can get. And as I said previously, we know hospitals and doctors have been experiencing extremely trying times over the past year and a half but Baylor Scott & White's stanch unwavering position in this moment today -- July 28th, 2021 -- with everything our doctors now know

about viable treatments is extremely puzzling and we will show that Baylor Scott & White is not upholding their legal and ethical obligations to their patient's rights.

And I know I do not need to remind Your Honor but I'm going to say it anyway: The harm this family is facing is obviously the most irreparable harm because it's the loss of a life that we can never get back. And I do not mean to sound callous, but I know Baylor Scott & White sees death every day so I'm sure one more death is not going to impact Baylor Scott & White the way it will this family. Your Honor, we are asking that this matter to you and for your mercy and to grant this family's request.

THE COURT: Do you have the cite on that Medicare Act statute that you're talking about?

MS. UBALLE: Yes, Your Honor. It is 42CFR -- I actually have a copy of it if you would like.

THE COURT: That would be great.

MS. UBALLE: May I approach?

THE COURT: Yes, ma'am.

MS. UBALLE: And I have highlighted the section.

THE COURT: Ms. Atwood?

MS. ATWOOD: We appreciate the opportunity to talk with you this morning and to -- to talk with you this morning and to provide you with some information to hopefully assist in making the serious and significant decision that's before you

today.

Every provider and every person affiliated with Baylor Scott & White takes as -- takes seriously every day, every life, and every patient including Ms. Carroll's. She's had providers working with her and her family around the clock to try to provide the best evidence-based medicine; the best, safest treatment protocols and plans that will give her the best chance as proven by the science to recover from COVID. They have not given up on her. They're being realistic about her. They continue to treat her and provide her with all medications and all interventions that give her the best right of recovery.

Their concern, however, is that what has been requested in the treatment protocol -- I don't know if Your Honor may have seen this, but we received yesterday a different treatment protocol than is in the application for temporary injunction.

As you can see there are 13 -- 13 different medications that are being requested at this -- at this juncture -- this cocktail of information -- or cocktail of medications that's being asked to be provided -- or recommended presumably by Dr. Edwards. We do have grave concerns about that.

I'm going to be calling expert witnesses -- physicians who can talk about what those risks and what the concerns are and why they're a risk to this patient. So I'm not going to try to go through those with you here, but I do want to

talk to you about the framework that I think is going to be important for the Court to consider as you look at the evidence that comes to you today.

Judge, I've handed you what's just a basic outline for what I think the Court is obligated to consider from a legal perspective and from the medical perspective based on what's in the record and what's going to be presented to you today. And so I'd like to just take a few minutes, if I could, to walk you through the issues that I think Your Honor's going to need to be aware of.

There are four reasons -- overarching reasons that the temporary injunction that has been requested in the pleadings that are on file before the Court cannot be granted. First, as Your Honor's aware, there are specific requirements for seeking the extraordinary remedy of a temporary injunction. This is not just a run-of-the-mill, if you will, temporary injunction. It is a mandatory injunction. It is asking you this -- these Plaintiffs are asking you to order Scott & White Hospital -- Baylor Scott & White Hospital and these physicians to specifically do something -- to administrator medications, to order this protocol that has been provided to us. To be entitled to that type of extraordinary remedy you have to meet requirements under the Civil Practice & Remedies Code. You have to be able to show that there is a viable cause of action that's recognized under Texas law; and without a viable cause of action,

there can be even no consideration of entering a temporary injunction. We believe and will demonstrate that that is not -- that the Plaintiffs cannot meet that requirement. There simply is not a viable cause of action under the Right to Try.

Likewise, we heard this morning for the first time -- though not in the pleadings -- that a right is being claimed under the Medicare Act. I would point out simply to the Court on the second to last paragraph -- the last statement there of the federal act says, "This right must not be construed as a mechanism to demand the provision of treatment or services deemed medically unnecessary or inappropriate"; and I believe that is, in fact, the controlling portion of that -- of this statute and is a reason this statute does not provide an independent basis for a cause of action or a right to seek a temporary injunction.

We will be offering to the Court in the evidence portion of the hearing evidence showing that there has been collaboration; there has been daily interaction between the health care providers, the team, the ethics team, and the family on the treatment options.

So -- but in terms of whether a temporary injunction can be considered by the Court on the basis of this statute, I believe that E2 is controlling there and there is none.

Under the right to act -- excuse me. The Right to Try Act there also is no viable cause of action. Judge, we

touched on this at the preliminary hearing, but -- pull this out. The statutory notes there -- never mind. Let me just -- I'll hand this to you, Your Honor, so you can see it. Be easier than trying to project it on multiple screens.

I've excerpted the relevant language from the Right to Try Act. Under the statutory notes of the Right to Try Act Congress has stated, "No liability or in a cause of action shall lie against a provider, dispenser, or other entity; and no liability shall lie for against a prescriber, dispenser, or other individual for its determination not to provide access." Judge, this is the crux of it. If you can't have liability for failing to provide access under the Right to Try, then there is no cause of action for failing to provide access; and that's what they -- the basis that they brought to the Court is that the Right to Try Act gives a legal right to select any medication they want.

As Your Honor -- as we discussed at the previous hearing that's not, in fact, how the Right to Try Act is set out. What it provides is an exception to FDA oversight of drug companies that would normally keep them from being able to provide medications that haven't been fully approved after the clinical trial process. It says under extraordinary circumstances that can be appropriate. The FDA can do that without being subject to FDA oversight if certain requirements are met. It does not, however, give the patient a unilateral right to declare that they want to try medications or treatments

that are not approved or recommended or prescribed by their treating physicians.

So, that's -- that's the primary and, frankly, the -- the threshold legal reason why the Court's not able to grant the relief that's been requested here. There's simply not a viable cause of action that can be brought to the Court for the remedy that they're seeking.

There is another reason, however, that the requirements of the temporary injunction can't be met and that is that the Plaintiff also has to prove that they have a probable right of recovery under their causes of action that are pled; and hereto even -- the Plaintiffs's -- hereto the Plaintiff's argument fails. They're not able to show that they have a probable right to recovery. The reason for that is if you assume that the Right to Try Act applies -- say, assume it could apply theoretically and a patient could invoke it, you still have to meet the requirements of that act; and they cannot do that as a matter of law. You'll receive the evidence that will establish this from the witnesses that we'll hear from; but the requested treatment protocol is not a, quote, eligible investigational drug under the Right to Try Act. The Right to Try Act says if you're an eligible patient -- we should assume for the purpose of this injunction hearing that Ms. Carroll is an eligible patient. Okay? She -- this still has to be an eligible investigational drug, and there are two components to that. They fail on one of

those which means they cannot seek recovery.

The two components are: The drug has to have passed a Phase 1 clinical trial. We're not disputing that for any of the medications on this list. But the other requirement in the statute that I've excerpted in the outline for you, Judge, is that an eligible investigational drug is a drug that has not been approved or licensed for any use. So this -- this Right to Try is for truly experimental, non-proven drugs that are not yet on the market. It is not for drugs that are -- that have been approved for some use and are on the market for some use because physicians can prescribe drugs off-label. There's nothing wrong with that, Your Honor. If the drug has been approved by the FDA and it's out there, a physician -- treating physician can decide, "Yes, I think the benefits outweigh the risks and I'm going to go ahead and prescribe that for my patient." Those drugs which includes every one on that protocol list are not in that category. The drugs -- the medications that are on this protocol that's being requested -- each one of them has been approved for other uses. They're just asking that these physicians be required to allow this patient to have access to these medications in dosages that haven't been approved and in an off-label way. What that means for the purpose of the temporary injunction, Your Honor, is that the Plaintiffs simply cannot establish that there is a probable right to recover on the cause of action that they pled the cause of action being a failure to

provide access to medications under the Right to Try Act. So not only is there not a cause of action by the actual language of the statute there is also not a probable right to recover because none of these medications qualify as eligible investigational drugs under that act.

So for those legal reasons, Your Honor, the Court cannot consider, cannot entertain, cannot give the relief that the Carrolls are requesting in this case.

Should Your Honor get over that and feel like you need to consider the merits, if you will, of the request, there are still both legal barriers to it, medical barriers to doing that, and there are public policy considerations that Your Honor needs to keep in mind.

At a very high level I want to tell you I think that there are four legal barriers that prevent you from being able to do what it is you're being asked to do. The first one is that judges can't practice medicine. We'll be hearing from an expert to help provide some additional -- for some reason, my computer is shutting down. No idea why that happened.

But -- but first -- first legal barrier to granting the temporary injunction is that judges simply can't practice medicine; and this is asking Your Honor to practice medicine, decide how an ill patient needs to be treated -- to pick between two different treatment protocols. Can't do that.

The second legal barrier is that hospitals can't

treat patients who do not have a treating physician willing to go along with the treatment protocol. Hospitals cannot unilateral dispense medications, nurses can't administer it, and hospitals can't on their own practice medicine -- just like a judge can't practice medicine neither can a hospital by law in Texas.

The third legal barrier is that hospital pharmacies and nurses -- pharmacies can't dispense, by law, and nurses can't administer medication without an order from the physician who's on the medical staff; and that does not exist.

And the fourth legal barrier is that doctors without privileges can't manage patients in the ICU, and that really bleeds over -- that is a legal issue because the law and the regulations affecting hospitals say you can only allow people who have privileges, you can only allow people who are appropriately credentialed to manage the care of patients in a hospital setting. That's administered through the federal government, through CMS regulations, and joint commission which is the overall accreditation entity for hospitals. On a state level there are regulations that say that hospitals can't treat patients who don't have -- who don't have a treating physician who's covering their -- who's managing their care. The state level -- that comes from the Department of State Health Services and from the statutes from the Medical Practice Act and the Nursing Act. Simply can't happen.

There are also -- those are the four legal

impediments that there are to being able to enter the orders that you've been asked to enter here. There are also some clinical and medical barriers that keep this from being an order that can be entered. Again, from a clinical and medical issue doctors without privileges can't manage patients in an ICU setting. We'll have some of the physicians speak to you more specifically about how practically that works and why practically this is not something that can be put into place in a way that is safe for this patient.

Another and perhaps the most compelling medical and clinical barrier is that this injunction, if granted as requested, would put Ms. Carroll at a greater risk of harm because it would interfere with the necessary adjustments to her care that have to happen with an ICU patient.

And third, Your Honor, from a medical and clinical basis the drugs and the dosages that are on that requested treatment protocol -- none of them are recommended by any of the recognized authoritative bodies who are helping providers across the country understand the best and most successful way to treat COVID-positive patients. The FDA has come out against this, the National Institute of Health, the World Health Organization, and the Infectious Disease Society of America -- we'll be introducing into evidence all of those official statements related to these various drugs. But suffice to say neither the Plaintiff nor their experts will be able to point the Court to any recognized

authority, any recognized organization that endorses the use of these based on evidence-based medicine and science.

And finally, Your Honor, we're going to ask you to consider the public policy considerations here. What these physicians and Baylor Scott & White providers are being asked to do is to violate the Hippocratic oath which is to do no harm. They believe and the reason that they have not endorsed the requested changes to the treatment protocol is that the providers believe that it may well and is likely to cause more harm to this patient than benefit to her and doing so -- and either ordering it themselves or carrying out these orders would do harm to the patients. It's not a good idea from a public policy perspective for the Courts to be in a position of directing health care providers to do things that they feel ethically, morally, and medically will cause harm to the patients and violate their Hippocratic oath.

Finally, granting the temporary injunction that has been requested here would fly in the face of good public policy because it prevents the oversight that is necessary in the health care system to make sure that there are checks and balances and assure that quality medical care is being provided to patients. There are two aspects of that that would be frustrated if the Court were to enter the injunction that's been requested: One, there's a credentialing process for every physician that's decided in advance. Hospitals say and hospitals

are required by their governing regulations to have in place credentialing requirements that says, "If you want to come on to the medical staff, you need to meet certain requirements." And we need to be able to establish that -- they have to do with education, do you have the appropriate experience, do you have the appropriate training to be able to do this in this case in particular; do you have training to handle critically-ill patients in an ICU setting who have multiple problems ongoing.

If Your Honor were to either order this treatment protocol to be implemented or to order the hospital to allow a physician who's not appropriately credentialed to get privileges at the hospital, it would take away the benefit to the public and the required role of the hospital and the medical staff in making sure that only qualified providers are delivering care to the most sick patients in hospitals.

In addition, if you were to either order this protocol yourself or order this -- the hospital to allow this physician to have privileges, you take away the ability of the hospital to exercise appropriate peer-review oversight and make -- and make sure that the providers under the roof are delivering health care in a way that is safe, effective, and meets standards of care for the providers.

And finally, Your Honor, we're in a circumstance where so -- tragically so many families are facing having loved ones who are ill and struggling with COVID. So many providers

are day in and day out in those trenches doing everything that they can to try to provide the best possible care and the best opportunity for a good outcome and for someone to survive COVID. We're in that situation; and if this Court were to -- and to my knowledge -- I believe this to be true. I believe this is the first time any judge in Texas has been asked to do this. If this Court were to grant this application for temporary injunction and say, "Yes, we are going to allow the family based on their own research to decide in collaboration with a physician who doesn't have privileges to demand a certain type of care that the providers don't think is in the patient's best interest," my concern and Baylor Scott & White's concern is that that opens the floodgates to every judge across the state having to address these same requests and ever increasing -- increasing requests and requests that are even more insupportable than the ones that are being presented to do this Court.

We have a system that says doctors have the right training to treat their patients; we have a set of laws in our state that say corporations, government, others shouldn't interfere with the doctor/patient relationship and we're going to trust providers to exercise the right judgment in delivering the best care to patients. And we have said, "Medical board you have oversight over that. You don't -- those physicians don't provide the right care, then they can step in." But it is not the role and it is not appropriate for the Courts to be asked to come in

and interfere with that.

So for those reasons, Your Honor, as we'll see through the evidence that's going to be presented, we believe that it would not be legally or medically appropriate for the Court to grant the request for the temporary injunction.

THE COURT: All right. That was one of my questions. Anybody have any idea whether there's any cases to date other than this one where this type of request is being made.

MS. UBALLE: I am aware of a case in Illinois where -- I know it's out of the state of Texas. But the judge did order the hospital to give the protocol.

THE COURT: Federal case or state case?

MS. UBALLE: State case is my understanding. We can look that up and get a --

THE COURT: Any idea who the parties were?

MS. UBALLE: Elmhurst was the hospital.

UNIDENTIFIED FEMALE SPEAKER: Carol Crevier (inaudible).

THE COURT REPORTER: I can't hear you.

MS. UBALLE: Carol Crevier was the patient?

UNIDENTIFIED FEMALE SPEAKER: Carol Crevier (inaudible) Fype --

(Simultaneous speaking)

MS. UBALLE: Sorry. Fype is the family.

THE COURT: Since we're on the record, we can't have all this discussion going on.

MS. UBALLE: Sorry.

THE COURT: Crevier --

MS. UBALLE: Is a witness, yes. She will be a witness. Wasn't planning on asking her about that, but we can.

MS. ATWOOD: Judge, it's my understanding -- in the interest of completeness -- that there has been one request of a trial judge in the Chicago area in Illinois that Ms. Uballe refers to and there have been -- I can't recall if it's three or four in New York state as well where a single judge has been asked to entertain a sort of similar motion.

It's my understanding that in all four of those matters -- the Chicago one and the New York ones -- the provider was willing to -- there was -- the treating physician was willing to administer but the hospital said, "We're not comfortable. It's not consistent with our protocol."

THE COURT: So that was a credentialed doctor?

MS. ATWOOD: Yes. A credentialed doctor on staff, is my understanding, in those instances was willing to recommend it but the hospital was saying, "No, we don't -- we're not in agreement with it." And the courts in those instances ordered -- my understanding -- that the hospital allow it.

I do not believe that any of those matters were addressed on appeal by whatever the next level of appellate court

would have been.

THE COURT: And the other question I had to you, Ms. Uballe, is -- I got information here -- it's not in evidence. I'm assuming I'm going to hear about it, though, in some way, fashion, or form -- of three different types of proposed protocols of drug cocktails.

MS. UBALLE: Yes.

THE COURT: One that was in a letter from the court -- law firm dated July 14th of 2021?

MS. UBALLE: Yes, Your Honor.

THE COURT: Different one that's in the pleadings?

MS. UBALLE: Yes.

THE COURT: And then a different one that's this --

(Simultaneous speaking)

MS. UBALLE: -- I think the differences are reflecting the status change of the patient. Our doctor has been looking at her medical records and --

THE COURT: Well, let me tell you one question that I'm going to really have --

MS. UBALLE: Yes.

THE COURT: -- to have addressed is -- as it relates to an injunction. I don't -- we can talk about that at the end of the evidence, but how do we manage -- let's just assume that I were to order this protocol.

MS. UBALLE: Yes.

THE COURT: How do I manage the fact that it changes tonight at midnight?

MS. UBALLE: That is how -- and we can put our heads together from a legal perspective if the Judge is so inclined to grant the Petitioner's relief.

We need our doctor involved. I don't know what that looks like, but he needs to be able to be involved -- be in direct contact with the nurses and other doctors, and I think that's well within your right to do because it is not practicing medicine. And because he --

(Simultaneous speaking)

THE COURT: Let me get this straight: You're telling me that your request is to have the doctor involved but not necessarily order a particular protocol?

MS. UBALLE: Exactly, Your Honor. Exactly.

(Simultaneous speaking)

MS. UBALLE: This doctor -- it will change.

THE COURT: So the request as it relates to ordering Scott & White to give this exact cocktail is not the request? It's --

MS. UBALLE: Currently we -- yes, Your Honor. We are asking for the protocol if that's all we can get, but we think it might be best if we allow -- if we have you order Baylor Scott & White to allow Dr. Edwards to manage it and administer

it.

THE COURT: So in essence the meat of this hearing is to allow Dr. Edwards to be collaborating with the physicians at Scott & White?

MS. UBALLE: Yes. And for his -- his decision to be final. Like, he will be the decision-maker as far as this protocol goes.

THE COURT: So he becomes the treating physician?

MS. UBALLE: For this protocol.

THE COURT: As far as my vocabulary understands the hierarchy in patient treatment by a hospital.

MS. UBALLE: And he can go more into this.

THE COURT: Okay. All right.

MS. UBALLE: But yeah.

THE COURT: Thought maybe that question was premature so...

Call your first witness.

MS. UBALLE: Yes, Your Honor. We call Dr. Ben Edwards.

THE COURT: You've been contacted to be a potential witness in the case of Dudley Lee Carroll vs. Baylor Scott & White. Do you understand that?

THE WITNESS: Yes, sir.

(Witness given instructions to testify by Zoom)

BEN EDWARDS

having been previously sworn, testified via Zoom as follows:

DIRECT EXAMINATION

BY MS. UBALLE

Q Good morning, Dr. Edwards. Can you --

A Good morning.

Q Can you please state your full name?

A William Benjamin Edwards.

Q And what is your occupation?

A I'm a physician.

Q Okay. So, tell me a little bit about your education and your background.

A Undergraduate from Baylor University, bachelor of science; medical degree from the University of Texas-Houston; and then the McClennan County Medical Research [...] Education Foundation Waco for family practice residency. And then also fellowship from the Academy of Comprehensive Integrated Medicine. Fellow of integrative medicine.

Q Okay. What does that mean?

A We integrate evidence-based modalities from around the world and oftentimes including natural therapies such as intravenous Vitamin C.

Q Okay. So, tell me about your experience as a doctor.

A Well, primarily it was as a rural family physician as the only physician in the county at the Garza County Health

Clinic that operated much like an urgent care as well as a primary care clinic since we were the only medical provider for the entire county, it wasn't a typical family practice setting. And prior to that was residency in Waco, and I did local attendance at emergency rooms in the area -- Groesbeck, Lake Whitney, Crawford, Clifton.

So, basically my goal going to medical school was to be like my granddad -- small town GP in central Texas. In fact, some of my family have worked as physicians at Scott & White. So that's kind of my experience, my background.

And about nine, ten years ago I discovered -- was introduced to integrative medicine and discovered that outcomes in certain conditions were improved when we integrated diet and lifestyle and integrated some of those other modalities. So I've been practicing this integrative medicine for almost ten years now out of Lubbock. We've expanded to Abilene and San Angelo. So I have seven nurse practitioners across these clinics in West Texas.

Q Okay. Do you have -- are you a member of any professional organizations or have any other medical certifications?

A Just the Texas Medical Association, the American Association of Physicians and Surgeons, and the Academy of Comprehensive Integrative Medicine.

Q Okay. What is your experience in treating patients

with COVID?

A Well, obviously we're an outpatient clinic; however, at the height of the pandemic certain doctors' offices were not -- were either overwhelmed or just not seeing patients. We stayed open the whole time. And we're a private share practice -- meaning, we're membership model but we decided to open up to all commerce not just our members of our clinic.

So we had a tremendous influx of patients. And in all total -- we don't keep accurate exact counts of COVID patients. But amongst all the nurse practitioners, we've seen in the hundreds. And, yes, we're an outpatient clinic; but we do have intravenous therapies that we offer at our clinics. We have an IV room with ten IV chairs and we historically have done intravenous therapies.

I will say that there were a few patients, one in particular, who was actually at the hospital with oxygen saturation in the 70 percentage range. Did respond some to oxygen but could not get out of the waiting room, the hospital was overwhelmed. He left against medical advice -- left the waiting room, showed up at our clinic. Of course, we administered the oxygen to get his oxygen saturations up, too; and then we proceeded to treat him because we felt like we needed to.

So, at times it felt like we were in a hospital setting.

We had another gentleman who was 99 years old. He was discharged from the hospital on hospice -- sent home on hospice and oxygen. There was nothing more the hospital felt like they could do. The family called us he was not previously my patient but at that time I made a house call on him and we were able to administer some therapies get him to our clinic in the IV room and start some therapies and those are just two examples. So I just have want to clarify we are an outer patient kilning but not typical. Able to offer some other therapies.

Q What --

(Simultaneous speaking)

A I'm sorry. Last thing -- this may come up later. Obviously I'm not an ICU doctor, I'm not a critical care doctor. But I've learned -- because we -- our normal practice tends to attract patients that have failed standard of care -- been to Mayo Clinic; they've been to Johns Hopkins; been to the big institutions, Southwestern Medical School in Dallas or wherever. And I'm not saying we're -- obviously we're not smarter than those guys, but with these integrated protocols there are other things we use.

So I've learned to go look through the literature for things that maybe aren't on the radar of a conventionally-trained physician only where these integrated guys have learned to integrate -- so, Professor Paul Marik who's an endowed professor of medicine and chief of the division of

pulmonary and critical care at Eastern Virginia medical school. That's Dr. Paul Marik. Well-known, I believe, in critical specialty medicine field. He assembled a team of ten other doctors, and all together this group of doctors -- I would put them up against any of the critical care doctors in the world. They've published over 2,000 articles in their careers amongst them. So I would say this is the all-star cast, in my opinion, of the critical care specialists -- ICU doctors.

And so although I'm not an ICU doctor, I have access to these ICU doctors. I can read their papers and their literature and I follow them in particular because they've been very outspoken and very vocal about some protocols that they feel like are very beneficial and have tremendous data to support them. And, in fact, Dr. Pierre Kory who's amongst this ten that was asked to testify in front of Congress a couple of times during the pandemic. So I just want to throw that in.

I am not officially trained, obviously, as an ICU doctor; but consult with and do read the literature and implement some of their -- some of their recommendations.

Q Okay. Can you talk a little bit about the treatments that you have used -- specifics of those treatments for COVID?

A Well, we're really a big proponent of the early outpatient treatment that we have found to be very effective and that does include the use of ivermectin, hydroxychloroquine, inhaled budesonide which is a steroid in combination with some

nutraceuticals including Vitamin C, Vitamin D, quercetin, Zinc in more-advanced cases we need to address the thrombolytic nature of this disease process. So, anticoagulants, simple aspirin up to prescription blood thinners, oral steroids, and IV -- intravenous -- Vitamin C in doses ranging from 5 to 10 grams in early stages of the disease up to 25 grams, 50 grams, 100 grams as needed.

Q So, for the benefit of the Court you have treated what you would consider more-critical cases of COVID; is that correct?

A Yes. Correct.

Q Okay. And what is your success rate on treating COVID with these protocols?

A As far as I'm aware nobody has died that's been under our care.

Q Okay. Is it true most of your drugs in your recommended protocol are what we call off-label uses?

A Well, in regards to ivermectin and hydroxychloroquine, yes. The inhaled steroids and blood thinners -- those are not -- and I will say probably 20 percent of all prescriptions doctors write every day across this country are written off-label.

Q Okay. When you're looking for an effective treatment, what are you looking as for as a doctor?

A Obviously you first look to the standard of care guidelines; but then beyond that I look to the literature, I look to colleagues specifically if they're in a field that is treating

that particular disease. You know, I consider them the experts. I mean, obviously I'm a family physician so I'm going to look to the colleagues that I consider to be well-versed and trained and they have data to back that up.

But I will say: I'm a clinician and more than anything I'm probably a patient advocate and I'm very much a proponent of sticking with evidence-based medicine in the original definition which I find that most physicians either weren't taught or have forgotten. And this is by Sackett, et al from 2000. In their -- I'm summarizing. But there's three basic components to evidence-based medicine. Yes, there's the published data and evidence in peer review journals; but the second part to that definition is the clinician' experience. And then the third part is the patient's values.

And I was taught -- and I think all doctors are taught the patient values trump the clinical expertise, and clinical expertise trumps the published data. For example, a Jehovah's Witness -- we all understand as doctors -- that come into the ER and they need a blood transfusion, we don't give them one -- even though they need it and it'll save their life, the patient's value, the patient's decision trump everything. So I'm very, very keen on the -- getting the patient's input, getting the family's input. Obviously in a circumstance like we're talking about today when it seems like all standard of care has been exhausted and we're in life-threatening condition, I'm very,

very much concerned about what does the patient want to do. What are their wishes, what are their desires and/or the family's desires?

So to me I try to balance those three when I'm looking for different treatments.

Q Thank you.

I'm going to switch gears just a little bit. So, have you looked at Mrs. Carolyn Carroll's charts -- her medical records?

A I've been able to look at some of them, what I can find online and then I've seen some screenshots of some of the flow sheet. So I wouldn't say that I've been able to have an extremely thorough look, but I have been able to see some of that. The medication list.

Q Have you seen enough to be able to give an opinion on what her prognosis is currently?

A From what I can see the prognosis is very poor.

Q Have you provided a recommended treatment protocol for Mrs. Carroll?

A Yes, I have.

Q In your opinion would this protocol be harmful to her in any way?

A No, it would not, in my opinion, be harmful.

Q Would you deem it unnecessary?

A No.

Q Would you deem it inappropriate?

A No.

Q In your opinion is there any medical reason not to provide this treatment?

A I don't know of any medical reason, no.

Q And I do want to ask you some questions for the Judge's benefit. Talk me through -- or talk us through how the administration of this protocol -- how you would envision it could go if, you know -- being where you are. If you were -- if you were given the ability to administer this protocol, how would you do that in Mrs. Carroll's case?

A The best case scenario to me would be just getting on the phone with the attending physician whose ever taking care of the patient now and just discussing the protocol because it's quite simple. It's just oral medication, subcutaneous injections, or intravenous drips. IV Vitamin C would probably be the main thing I would want to talk to them about because we're not trained in that at all. I was completely unaware of intravenous Vitamin C until actually it was around 2010 from *60 Minutes*. There was an ICU critical care patient who had succumbed to swine flu and was on life support, and the hospital in order to stop the life support the following day -- it just so happened there was a legal injunction where they started high-dose intravenous Vitamin C on a court order and the patient survived. That was the first time I'd ever heard of. So,

potentially these -- these current treating physicians haven't heard of IV Vitamin C and so that would be the thing I would probably want to talk to them the most about.

But as far as actual administration it's simple: It's a matter of drawing up Vitamin C from a vial, injecting it into a bag of saline or sterile water, and dripping it just like they're doing all the other IV therapies. So there's really -- it's a simple protocol, and a matter of a phone call would take care of it I believe --

Q Do you --

A Really easily.

Q Thank you.

Do you anticipate continued monitoring needing to be -- needing to be able to continue to monitor and adjust doses?

A Yes. For sure. I would want to walk alongside these physicians and give them recommendations based off her condition -- if she's not improving, recommendation is simply going to be let's increase the dose of intravenous Vitamin C. And if they have questions about that, of course, I'd be happy to answer; and if they feel more comfortable talking with their peers in the ICU field, I'm sure we can arrange that, too. I mean, doctors do best when we work as teams. That's why we do grand rounds every morning as a team. We throw out these tough cases, we get together as a team. You know, we talk about it.

So, I would expect this to be a friendly, cordial

team work event.

Q Thank you.

MS. UBALLE: No more questions at this time. Pass the witness.

CROSS-EXAMINATION

BY MS. ATWOOD

Q Dr. Edwards, can you see or hear me at least?

A Are you wearing white?

Q I am wearing white, yes.

A Yes, ma'am. I can see you and hear you.

Q Thank you.

If at any time you have trouble hearing or understanding what I'm asking, just let me know and we'll slow down and try to be sure we're communicating. Okay?

A Okay.

Q Dr. Edwards, your specialty and your training is in family medicine; is that correct?

A Correct.

Q And you are not trained as an infectious disease physician, are you?

A Correct, I am not.

Q Okay. There is -- well, I guess I should start. You're not trained in internal medicine either, in that specialty; correct?

A Correct. Family practice is the only training I have

which encompasses some internal medicine, OB/GYN, surgery, et cetera. It's a broad training.

Q Okay. You do not have fellowship or additional training, though, in internal medicine; correct?

A Correct.

Q And you do not have any training -- formal training in pulmonary or critical care medicine. Is that also correct?

A Correct.

Q I was able to locate your physician's biographical information on the Texas Medical Board. Do you believe that's all up-to-date information in there?

A I believe, but honestly haven't looked at that in a while.

Q Okay. Well -- and the part of it I wanted to ask you about -- there's a portion of your Texas Medical Board profile that asks if you have any current hospital privileges anywhere, and it says none. You do not have any hospital privileges. Is that correct and current?

A Correct.

Q Okay. And so is it -- so, are you -- you're in Lubbock; is that right?

A Correct.

Q Okay. So, have you ever had any hospital privileges at any hospital in Lubbock?

A Technically, yes. To be part of a health care plan in

the past with the University Medical Center and Physician Network Service. It was just a formal --

I did have privileges, yes.

Q So --

A At one point.

Q Sorry about that.

Did you have privileges to admit patients and manage the care of hospitalized patients?

A I believe I did. This was a number of years ago. So I believe that privileges included that.

Q When would the last time have been in your professional career that you had privileges to actually see, monitor, and write orders for a hospitalized patient?

A To be safe I'll say 2005 in Waco although technically I think I had -- I did have them, again, as just part of a health plan in Lubbock. I did not utilize those.

Q So, the last time you would have seen a patient who was hospitalized and been involved in managing a hospitalized patient's care you believe would have been in 2005 or thereabouts?

A Yes, ma'am.

Q And have you ever been in a position where you were the attending physician, the physician with primary responsibility for an ICU patient?

A No, ma'am. That was always under another physician.

Q And you understand -- and I guess -- or would you agree with me that patients who are in an ICU and on a ventilator like Ms. Carroll, they require a highly-specialized level of training to be able to manage that kind of complexity?

A I agree with that. My uncle's a critical care physician in Temple, and I would agree they have a unique set of skills.

Q And that's a set of skills that you simply don't have the training for. Would you agree with that?

A Correct.

Q Is it also correct that you have no experience utilizing this protocol that you've recommended for Ms. Carroll in any hospitalized patient?

A Correct.

Q I want to talk, then, a little bit about your protocol. Do you happen to have it there in front of you? We can put it on the screen, but that'll just make everybody even smaller. So I'm kind of -- if you have it where you can look at it -- we've all got a copy here we can see.

A Okay. I can pull it up on my phone if I'm allowed to do that.

THE COURT: You can go ahead and do that.

THE WITNESS: Okay.

Q (By Ms. Atwood) If you need me to bring it up, I can certainly do that.

A I've got it right here.

Q And --

MS. ATWOOD: Judge, I handed you that a little bit ago; and I assume that Ms. Uballe has a copy. But if you need one, you let me know.

Q (By Ms. Atwood) So are you looking, then, at your recommended treatment protocol for Ms. Carroll?

A Yes, ma'am.

Q And you said earlier that you had had a chance to look at some of her medical records. Could you be a little more specific and tell us what information you've had an opportunity to review?

A It was in a mina [ph] chart application a few days ago, and it was mostly her labs and chest X ray.

Q Have you had a chance --

(Simultaneous speaking)

Q Sorry. Didn't mean to interrupt you. Please go ahead.

A Some screenshots from the patient's daughter of some flow sheets. They were a little difficult to read so I don't want to comment on that.

Q All right. Did you have an opportunity to review the patient's history and physical?

A On -- all I could find were some outpatient records from that -- maybe her initial presentation possibly. I couldn't really tell if that was outpatient or inpatient note.

But, yes, there was a history and physical there I believe.

Q Okay. Have you reviewed any of the progress notes from the ICU physicians who have been managing her care on a day-to-day basis since she was admitted to the intensive care unit?

A No, I've not been able to see those.

Q Do you agree that in order to put together a patient-appropriate treatment protocol a physician should take into account the full patient's picture including history, physical, and current status of the patient?

A Most definitely.

Q Okay. And you've not had an opportunity to do that yet; correct?

A Correct.

Q Would you agree with me based on your review of the medications that you have seen that are in place that your recommended treatment protocol would change her treatment plan in material respects?

A Yes. We would be adding medications to that treatment plan.

Q And you'd agree with me that all medications carry risks of side effects and risks to the patient?

A Correct.

Q And the more seriously ill a patient is, the more risk

that can be attendant with changing medications?

A Correct.

Q Do you agree that Ms. Carroll is seriously ill?

A Yes.

Q She does not have a mild level of disease with respect to her COVID diagnosis, does she? You wouldn't characterize it --

A Correct.

Q -- as having mild disease?

A No.

Q And she doesn't have a moderate level of disease either? She has a severe level of disease; correct?

A Yes.

Q I presume that you have training as a family practice physician and when you did your rotations through hospitals during your education and training that you know that there are standards for physicians writing orders for either outpatient prescriptions or inpatient orders for medications; right?

A Yes.

Q And are you familiar with The Joint Commission?

A Somewhat familiar.

Q Do you know that The Joint Commission is the regulatory body that oversees hospitals in many respects, as a general matter?

A Yes. I understand.

Q Are you aware that they actually include medication management standards that apply in -- for hospitals?

A Yes, I believe so.

Q Are you familiar with those medication management standards that apply for hospitalized patients?

A No.

Q Are you familiar with the CMS requirements for -- or what they would call their elements of performance related to medication orders in a hospital setting?

A No, ma'am.

Q Let me ask you, then: If they define a complete order as an order that identifies the patient name, the medication name, a strength and dose, a route and rate of delivery, and dosing frequencies -- if CMS and The Joint Commission both say that all say of those are necessary to have an appropriate medication order, would you agree with that?

A Could you list those again?

Q Sure. Fair enough.

Name of the patient, No. 1. -- we need that.

A Uh-huh. Yeah.

Q All right. The medication to be named accurately. You agree with that?

A Yes.

Q An appropriate order needs to identify the strength or dose of the medication to be administered.

A Yes.

Q It needs to identify the route that the medication's going to be administered -- either take it by mouth or put it in the IV like you mentioned with the Vitamin C.

A Yes.

Q And needs to include the rate that IV medication would be administered?

A Yes.

Q And it needs to include the dosing frequency -- in other words, how many times or how often are we going to give this medication; correct?

A Yes.

Q So, all five things -- all five of those things, you would agree, are essential to have an appropriate medication order for a patient?

A Yes.

Q Okay. And if you take a look at your -- your protocol that you've got -- just looking at Solu Medrol, for example -- is that a -- that's, what, the fifth medication down? Do you see that?

A That's the Solu Medrol, 60 milligrams by IV every 12 hours.

Q Yes. Just pulling that out as an example: You've got Ms. Carroll's name at the top so we've got the patient identified; got the medication identified as Solu Medrol; got a

dose of 60 milligrams; you're telling us the route there, by IV; and you're telling us how frequently you recommend that it be given, every 12 hours; right?

A Correct.

Q And you provided that information because you felt like that was a complete medication order, if it were to be implemented?

A Yeah. I mean, if there's a technical point of -- the hospital needs it written a certain way or to include certain things -- whatever, you know. This was a -- but, yeah, the gist of the order is that, yes.

Q And then, of course, you've also recommended the other medications that we see on this protocol -- the Ivermectin and Colchicine and Lovenox, tislelizumab -- probably butchering the pronunciation of that -- and leronlimab and then various vitamins and quercetin, Thiamine, and famotidine.

A Right.

Q I want to ask you about -- well, first: Do you know if ivermectin is a medication that's been approved by FDA for some uses?

A Yes.

Q And has it been approved for some uses?

A Yes.

Q Same for Colchicine. Has Colchicine been approved for some uses?

A Yes.
Q And leronlimab, has that been approved for some uses?
A Yes.
Q And tislelizumab, that been approved for some uses?
A Yes.
Q Lovenox has been approved for some uses?
A Yes, ma'am.
Q All right. But would you agree with me that ivermectin, Colchicine, and leronlimab, at least, have not been approved for -- by the FDA for use of treating COVID?
A Yes.
Q And the dose that you have recommended for ivermectin is not a dose that's been recommended by the FDA for the treatment of any approved indication, is it?
A Don't know for sure. I can't -- I'd have to look that up.
Q Let me ask it this way: Are you aware of any FDA-approved indication for the use of ivermectin that would recommend 33 milligrams for a patient weighing what Ms. Carroll weighs?
A Honestly I'd have to look that up in a reference source, what their max approved or recommended milligrams per kilogram is.
Q So do you know what the FDA recommends as the dosage for ivermectin?

A I'd have to look that up. The doses we recommend in this situation are based off severity of the disease whether we're using .3 mix per kig or .5, .6.

But I'd have to look up what the FDA's approved label is for bano [ph] parasitical forms of it. I don't know that.

Q Let's look, then, at your -- the -- I guess two down from Solu Medrol is leronlimab. I tried to look that up and did not see that -- did not find a medication that was spelled that way.

Let me share a screen with you and ask you if this is perhaps what you intended to...

A I believe that may be misspelled.

Q So on your recommended protocol here have you properly identified the leronlimab?

A I believe that is misspelled.

Q Are you able to see the screen -- the document that I have included on the screen here?

A Yes.

Q Are you -- I'll give you a moment to take a look at this, but are you familiar with this statement from the FDA related to leronlimab?

A May have read that at some point. I don't recall really.

Q Doctor, we've had a little bit of a pause here while I

asked the court reporter to mark this as Exhibit 1 and --

MS. ATWOOD: And, Judge, I'd like to ask that you take judicial notice, if you will, of a publication from the FDA -- the FDA statement on leronlimab, and we'd offer it at this time as Defendant's Exhibit 1.

THE COURT: Any objection?

MS. UBALLE: No objection, Your Honor.

THE COURT: Defendant's Exhibit 1 will be admitted.

Q (By Ms. Atwood) So, while we've been doing that have you had an opportunity to take a look at --

Well, let me ask you: Are you familiar with the fact that the FDA puts out statements with respect to particular medications?

A I'm familiar with that.

Q And this particular statement refers to leronlimab as an investigational drug that was under development by CytoDyn and it --

A Yes.

Q -- is being studied to see whether it was safe and effective in treating patients with COVID-19. And are you familiar --

A Yes.

Q Are you familiar with the results of those studies?

A Couldn't speak to those results. That part of the

protocol was in consultation with some colleagues in the critical care that I mentioned earlier. So we -- we have -- I have not, my nurse practitioners have not used that monoclonal antibody part of the protocol.

Q So, have you ever prescribed leronlimab to any patient for any reason?

A No.

Q So if you were allowed to direct Ms. Carroll's care, would she be the very first patient that you have ever recommended receive leronlimab?

A Yes, ma'am.

Q I'm going to direct you down to the bottom. If you like to read the entire study -- this entire statement from the FDA, I'm happy to provide you with the time to do that. But do you see here that the conclusion of both the clinical trials, the FDA states it's become clear that the data currently available do not support clinical benefit of leronlimab for the treatment of COVID-19?

A Yes, I see that.

Q But it's your recommendation that she receive leronlimab?

A Yes.

Q And have you looked at any of the data underlying these studies that the FDA was relying on in making that recommendation?

A I don't know exactly what studies they were relying on so I would have to look at that document.

Q Have you looked at any studies regarding leronlimab?

A Yes. That was recommended as the -- during my consultations with these other physicians I did look at that because I, like I said, had not used that so I did look that up. But I don't know specifically what studies.

Q Are you able --

A Look at.

Q Pardon me. Didn't mean to interrupt.

Are you able to point the Court or any of the treaters to any specific studies that found a benefit to giving COVID-positive patients who are seriously ill leronlimab?

A I can look into that and send that if that would be helpful.

Q Today at the hearing where the Judge is being asked to decide this are you able to point to any specific studies that show a benefit to administering leronlimab to seriously-ill patients?

A No, I'm not able to do that right this minute.

Q Your proposed -- or your protocol includes tislelizumab "keep current dosage." Do you know what the current dosage is?

A I've not seen the chart this morning so I would say no. I'd have to go back and see what the last medication list I saw.

Q So, do you know how the dosing is done routinely for

tislelizumab? Can you tell us how much patients should be receiving, when they should receive it? Any of the particulars for prescribing that medication?

A No.

Q Is tislelizumab and leronlimab -- are they both medications in the same family? I'm wondering that because they both have the "mab" on the end of it. Is that what that means?

A No. No. One's I06 inhibitor, I06 is an inflammatory cascade molecule, the other one is monoclonal antibody.

Q All right. Do you know whether tislelizumab, which she is currently receiving and which you are in agreement with apparently. Do you know whether that has any risk of depressing the immune response of a patient?

A Yes.

Q And does it have -- carry that risk?

A Correct. Yes. It's trying to suppress the inflammation which is part of the immune response similar to steroids.

Q And you -- I think you may be anticipating, kind of, what my next question was: Are there any other medications on your recommended protocol that suppress a patient's immune response and inhibit their ability to fight infection?

A Right. Yes. A steroid.

Q The Solu Medrol?

A Correct. Yeah. Solu Medrol. I'm sorry.

Q Okay. And what about leronlimab? Does that inhibit the immune response or interfere with a patient's ability to fight infection?

A It could.

Q And do you know whether Ms. Carroll is currently or has been during her hospitalization fighting any secondary infections?

A No, I'm not aware of that.

Q Can secondary infections in a seriously-ill patient be life-threatening?

A Yes.

Q So, your protocol also recommends increasing the dose of Lovenox that she's receiving. Can you tell the Judge what's Lovenox?

A Lovenox is a blood thinner; and as the disease progresses with COVID-19, it's really a thrombotic disease -- meaning a blood-clotting disease. Small blood clots throughout the lung tissue and throughout the body. So blood thinners are given to combat that blood clot.

And the risk involved -- on the other side of that, the risk if you get too much of a blood thinner, obviously you can bleed typically from the gastrointestinal track or a brain bleed. So there's definitely risks.

Q And a bleed like that could be devastating or fatal for Ms. Carroll. Would you agree?

A Definitely. Just as blood clots could be devastating and appear to be devastating her right now.

Q So, is it your impression that she has devastating blood clots right now?

A The microthrombi is well-known part of the disease process. So, yeah, I think we need to assume that.

Q Do you know --

THE COURT: What was that term you just used? The micro what?

THE WITNESS: Thrombi. Blood clots -- the technical term for blood clots. So, there's large blood clots obviously that you can pick up on ultrasound or CAT scans and then there's micro blood clots that are indicated more by blood work. It's like a d-dimer level.

Q (By Ms. Atwood) So, do you know if the ICU physicians have been monitoring the d-dimer or other tests that would assess whether she's got clotting concerns going on?

A I believe I did see d-dimers in the blood work that I was able to look at.

Q And what range --

(Simultaneous speaking)

Q Sorry.

A I'd have to look back at the chart if we're going to talk about specifics like if the d-dimer is changing, elevating, coming down. I'd have to go book and look at that. I don't have

that in front of me.

Q Do you know what range of values would suggest that clotting is a significant issue for Ms. Carroll on that d-dimer test?

A It kind of depends on the lab -- you know, whether they're using, you know, what deciliters versus milliliters, et cetera.

So kind of depends on the reference range; but these type of patients, their elevations will always be above reference range sometimes by double or triple or more.

Q And do you know --

A The rate -- excuse me.

The rate of rise -- if someone's elevated -- you know, doubling every day, et cetera. So the trend is important, also.

Q So would it be important if it's actually decreasing?

A Yeah. That'll be part of the clinical decision-making daily is what's the d-dimer doing -- going up, going down. Changes, you know, day by day.

Q And would you expect that physicians who have privileges in a hospital and practice daily would be familiar with the reference range for important lab work like d-dimers and things like that?

A Yes.

Q And is that one of the many reasons that you think it

would be important for a physician to only be treating patients in a hospital where they actually have privileges?

A Yes. For sure.

Q You've also recommended that her dose of aspirin be tripled from her current dose; correct? To 325 milligrams?

A Yes.

Q Okay. And is that also a medication -- and that dosing given for the purpose of inhibiting clotting?

A Yes.

Q And you agree that like Lovenox aspirin, especially when given in conjunction with Lovenox, increases the risk of bleeding in patients?

A Yes.

Q And is there any reversal agent -- if a bleed were to start and a patient's receiving aspirin and Lovenox, is there anything that can be given to that patient that would prevent those anticlotting properties?

A There's not really an antidote, no.

Q So, would you agree, then, that increasing the Lovenox at the same time that you increase aspirin also increases the patient's risk of having a fatal or devastating bleed event?

A Yes.

Q Your protocol also recommends ivermectin. You'd agree that ivermectin is not recommended by the Food and Drug Administration for COVID-positive patients; correct?

A I'm aware of that.

Q And are you also aware that the World Health Organization has recommended against using ivermectin to treat COVID-positive patients?

A Yes, I'm aware that they've done that.

Q We talked a little bit earlier about whether you were familiar with the recommended or approved dosing for ivermectin either by the manufacturer or the FDA. Do you know how many doses are recommended for any of the things that have been studied -- any of the indications that have been studied using ivermectin?

A I can answer that generally. Typically you're going to be around a 12-milligram dose one time -- one time a day but --

Q One time --

A -- other than that I'd have to look specifics.

Q One time a day or one time period?

A Depends on -- depending on what's being treated. Sometimes it's a one-time dose, sometimes it's a weekly dose, sometimes it's daily. But, again, I don't have the FDA -- you know what the dosing they've approved for whatever indication. I don't have that in front of me.

I do have the 60 studies that have been done across the world for ivermectin COVID that (Zoom distorted) share those with you.

Q And have you provided those to Ms. Uballe so that the

Court can take those into consideration or look at any of those studies that you say you're relying on?

A Honestly don't recall in all the e-mail exchanges back and forth if I sent this. There's a nice website that summarizes all these for the layperson and physician, too. I honestly just can't recall if I sent that to her or not.

Q You would agree with me that there are studies -- well-designed studies that have shown ivermectin to have no benefit in treating COVID patients?

A No. Honestly not aware of that. I'm not saying they're not. I'm not aware of them. I'm aware of these 60 that seem very well-designed. And to quote Dr. Paul Marik he calls it a mountain of evidence rarely seen in medicine, and Paul Marik spends his career looking at medications and looking at the data. And obviously he's an expert in data analysis; and in 30 years of medicine, it's a pretty bold statement. A mountain of evidence rarely seen in medicine. That's a quote from Pierre Cory ICU specialists.

Q And are you swayed by the notion that the physician who you're quoting Dr. Marik is an ICU physician and he has the type of training that you would rely on?

A Right. Not just one person independently but his team of the ten arguably -- again, arguably -- the ten most respected ICU doctors in the world, Dr. Paul Marik being the head of that group, would be a piece of what I would rely on but also my own

clinical experience with ivermectin and seeing patient's immediate responses like I haven't seen with any other medication.

Q Well, in all fairness you haven't seen any patients that were critically ill and hospitalized that have been treated with ivermectin, have you?

A I would say a 75-year-old gentleman with multiple medical conditions with oxygen saturation of 70 percent that if I were in the hospital probably would be going to the ICU and -- and he showed up in my clinic, as I mentioned earlier in the testimony. So...

Q Well, that patient was not admitted into the ICU, was he?

A No, he wasn't. Thankfully.

Q And do you know what the qualifications were of any of the physicians who the FDA consulted in coming to its recommendations with respect to -- against ivermectin?

A No, I'm not.

Q Do you know of the qualifications of any of the physicians who were consulted by the World Health Organization in coming to their recommendations against using ivermectin to treatment COVID patients?

A I am not. And I don't know if I'm allowed to go back on the FDA. The last time I looked -- it's been a few weeks so maybe it's not current. But the warning I saw was don't use the

animal version of ivermectin. And then they said we haven't reviewed the data. You know, I found that to be -- and, again, that was a few weeks ago so...

It's been an interesting time with these organizations that give medical recommendations versus the doctors on the ground treating patients. That's been something we have to wade through and really analyze for the benefit of the patient.

Q And I take it you think it would be important to take into account the knowledge of Ms. Carroll's treating physicians and their belief about the risks and benefits to her of any particular medication, don't you?

A Definitely. I would love the opportunity to speak with them. I have a similar situation. I have a patient in Boulder, Colorado. The ICU physician there was open to -- more open to what my recommendations were and I was able to speak with him on the phone and he was very surprised by all the data from Dr. Paul Marik's group and was very surprised when I sent him the testimony from the U.S. Senate that he hadn't been made aware of that by his hospital or his -- wherever he gets his information from. So I'm assuming it'll be some of these organizations.

So, I would love to speak with the doctors to be able to show them Dr. Paul Marik's credentials and all of his published data as well as Dr. Kory and the other eight doctors on that team. It's very impressive.

Q So, Dr. Edwards -- I mean, I understand that you're sitting in this place where you're being a bit of an intermediary; but you're being an intermediary without yourself having the training or background or experience to make independent judgments about what's in the best interest of Ms. Carroll; isn't that right?

A Correct. We need a team approach.

Q And should the treating critical care physicians not agree with your recommendations, do you still think your recommendations should be followed for the patient?

A I think that's too broad of a question. I would need specifics, you know, on what the exact disagreement was. I think that's too broad.

But ultimately I'm going to defer to the doctor that's looking at the patient in the eye and examining them which, obviously, I'm not there. Again, in the perfect world I think doctors can communicate and talk to each other and be on the team and -- so, I think I'll leave it at that.

Q Do you think that the best practice for the patient would be to have the physician at the bedside making the ultimate decision about what treatment is in the best interest of the patient?

A Yes, I do believe in that. I also believe physicians aren't experienced in certain things we call consultants in. For instance, a gastroenterologist would be called in if there was

diarrhea that started that was uncontrollable and there was no known source. We'd call in a consultant who understood and had more expertise in that. And the same I would say in this situation: My experience talking with ICU doctors at multiple hospitals around the country, they were simply not aware of the data and aware of the potential benefit. And because of the use of the Internet, there are many patients and family members and patients who are aware. And it seems like, unfortunately, it's come down to where are we getting our information from and is that information being broadly disseminated. And when it comes to these ICU experts who are -- who have discovered the benefit of these other medications that other doctors simply were not aware of it. And so most doctors I talked to have been quite open-minded when they've been made aware of it.

So, I would look at it as a team approach whether -- but ultimately, yes, the physician on the ground who knows the patients -- seeing them every day, is there all day long, watching their vital signs and everything else and talking to the nurses -- those doctors need to make the final call on it after consulting with all the various people who are trying to help the patient. And I think that's really what we're trying to get to here.

Q So, would you agree that that patient who is on a ventilator in the ICU needs to be monitored minute to minute, hour to hour, and potentially have all of their medications and

treatment regimens adjusted in realtime?

A Yes, I agree with that.

Q And are you proposing to come to or be available 24/7 in Bryan/College Station?

A I am not proposing that.

Q Do you have any reason to question or doubt the qualifications of the team that is currently managing Ms. Carroll's care?

A I don't qualify they're highly trained. I'm concerned they may not have been exposed to all of the data --

Q Do you have any reason to believe they do not have appropriate training to be managing a critically ill patient in the ICU?

A I'm sure they're quite well-trained to handle critical care patients in this unique circumstances of the new pandemic -- viral pandemic in talking with other ICU doctors around the country. It's clear to me that they're not all fully up to date on all the data. It's hard to stay up to date when these studies are coming out almost daily seems like.

Q Well, for example, you've recommended the leronlimab even though there are several studies that would suggest that that is of no benefit to the patient, and those are studies that you yourself haven't had a chance to look at?

A Correct.

MS. ATWOOD: Pass the witness, Your Honor.

REDIRECT EXAMINATION

BY MS. UBALLE

Q Dr. Edwards, in your opinion is Mrs. Carroll terminal?

A Yes.

(Simultaneous speaking)

A I do believe so.

Q And I want you to -- you said something about family values. Where -- where does that rank in your priority and when you're considering treatments for patients?

A It's No. 1.

Q And would you consider a request for a particular treatment regimen as the family expressing a family value?

A Yes.

Q And you did mention you would not be able to be physically in College Station available 24/7, but what would your availability be for Mrs. Carroll?

A By phone or Zoom 24/7.

Q And are you familiar with the CDC and how the CDC and NIH currently characterize ivermectin?

A As far as I recall, the last time I looked (Zoom distorted) a little bit NIH was neither for nor against. They moved off their possession of against to neutral, not for or against --

Q Right.

A -- but I haven't looked, you know, currently today.

Q And in your medical experience what does that mean? Or does that have any significance?

A It has -- it tells me they've -- somebody's looked at some data and they've come to a conclusion. My opinion has shifted some over the past few months -- many months really since COVID-19, that possibly there's some other influences in the way they put the recommendations out. It's very difficult for me to listen to Dr. Kory's testimony at Ron Johnson Senate committee hearing and then go look at all the data that he referred to and then look at the NIH sitting on that and not making a firm call on that.

As a clinician I have a hard time -- and ultimately I'm going to go with the clinician who's treating patients and not the institution. It is potentially influenced by other factors.

Q Yeah.

And to be clear the original position of the CDC and NIH was against ivermectin; correct?

A That's correct. And I will say they were also against Solu Medrol, the steroid we were talking about. And Dr. Kory to his credit testified in May of last year and then a study followed and now it's standard of care.

So, it's clinicians on the ground in the time of a pandemic in particular who are treating the patient and making judgment -- clinical judgment calls -- risk benefit judgment

calls. And then it seems that institutions tend to lag in their recommendations or their decisions. So, sometimes we need to make a clinical decision based off the best-available evidence; and as I mentioned earlier, clinical experience in patient counts.

Q And just one more followup: You've had limited access to her records because you're not on the record as her -- as any type of treating physician; is that correct?

A Yes.

Q And so if you were granted those rights, you would be able to answer these questions and fill in these holes and know the direction to take; is that correct?

A Yes.

MS. UBALLE: No further questions, Your Honor.

RECROSS-EXAMINATION

BY MS. ATWOOD

Q Dr. Edwards, you don't have privileges at any hospital to treat any patients; correct?

A Correct.

Q And you are not, therefore, subject to any oversight or peer review in the recommendations that you are making to your patients or other COVID patients; correct?

A Correct.

Q Do you recognize that it is an appropriate and necessary role for hospitals to evaluate whether a physician has

the appropriate background, training, and credentials before they're given privileges to treat a patient in their facility?

A Yes.

Q And, likewise, it is a necessary and -- serves a legitimate public policy interest to have physicians be subject to peer review particularly when they're treating our most medically-fragile patients?

A Yes.

Q And it has been at least since 2005 since you have been subjected to that type of credentialing and peer review oversight; correct?

A Correct.

Q And this treatment protocol that you've recommended has not been subjected to any peer review assessment, has it?

A As a complete protocol as specifically written, I don't think so; but most of that protocol is based off of peer-reviewed evidence. As I mentioned, the 60-plus studies on ivermectin and the mountain of evidence rarely seen in medicine. So individually yes.

Q But you don't have any of those 60 studies to tell the Judge about or explain to him today, do you?

A I'm looking at the website with them. I can send that if he was interested in that.

The most recent being Bryant and Hill December, 2020 meta-analysis. And meta-analysis is summary of studies. So

this particular analysis looked at 24 different study, 3300 patients. And that's significant in the doctor world. That's a large analysis. And it's clear the benefit of ivermectin.

Q That meta-analysis is looking -- that you're referring to right now is actually looking at accumulating information across all the studies that can be gathered up and found; right?

A Correct. So, there are peer-reviewed, Evans [sic] based published data on not the protocols as a whole but the individual pieces of much of it.

Q Do you know how many of those 24 studies and the meta-analysis you just referred the Judge to were deemed to be of low risk for bias?

A No, I'm not aware of that.

Q You recognize, don't you, that if a study has a high risk for bias, then it's not as reliable as those that have a low risk for bias?

A Yes, I'm aware of that.

Q All right. And -- but you don't know how many of those 20 studies were low risk for bias?

A No, I do not.

Q Do you know that the largest study relied on in that meta-analysis is Reference No. 36 by Elgazzar has actually been withdrawn from the medical literature since the meta-analysis was published?

A I'm aware of that, and I'm aware of the 23 other

studies that have not been withdrawn. The conclusion hasn't changed.

Q Do you know how many of the 24 studies were actually peer reviewed before they were pushed out on to the Internet?

A No, but I'm aware of 39 peer-reviewed studies I'd be happy to send you.

Q So --

A Which, again, is a mountain of evidence unlike any other therapy that we've known.

Q So, Doctor -- Dr. Edwards, if only 8 of the 24 studies that are even reported in that meta-analysis were peer reviewed, do you have any reason to disagree with that?

A To disagree with eight peer-reviewed studies?

Q Right.

A That's excellent evidence. And that's just one meta-analysis. Again, there's 60 other studies, 39 of them are peer reviewed. This is a mountain of evidence. I'm happy to share that with the Court.

Q So, were all of the studies -- are you familiar with the term heterogenous, referring to medical studies?

A I am familiar.

Q Okay. Is it important, if you were evaluating the reliability of studies, to know whether the studies are heterogenous, or comparing similar things?

A Yes, that would be good to know.

Q So, if the doses being studied reported across these 24 -- or, I guess, now 23 studies since 1 has been withdrawn. If the doses are different, of the ivermectin, does that affect the reliability of the studies?

A Not necessarily.

Q If the durations were different among the studies, does that affect reliability?

A Not necessarily. There could be a small study with small duration, a small dose, a one-time dose; and if it showed benefit would give even more confidence.

Q Do you know whether there were confounding therapies given simultaneously with the ivermectin in any of those studies?

A I believe some of those have confounding therapies.

Q And when there are confounding therapies, that makes it hard to draw any reliable scientific conclusions from those studies, doesn't it?

A Not necessarily. There's always confounding factors. You have to take that into account, make a judgment call. And really I think there's no argument to be made. If we want to go down the data in the post-study rabbit hole with ivermectin, you have the top critical care guys in the world saying there's never been a drug more -- more studied, more published; and mountain of evidence rarely seen in medicine.

Q Do you know whether --

(Simultaneous speaking)

Q -- top critical care providers in the world who also are equally adamant that ivermectin is not safe, is not proven for the treatment of COVID patients?

A I've not spoken to any. The one in Boulder, Colorado, I spoke to. He referenced the exact study that you referenced that got pulled out of the meta-analysis; and that was all he could speak to. So, I'm concerned that some physicians may just be seeing the headlines and not diving down into what actually happened and going deeper. And he wasn't aware at all of the 60 studies that I sent him.

So, that's my concern: If these doctors can look at all these studies and even talk to Dr. Kory and Dr. Marik. You know, these are pillars in the pulmonology critical care community. You know, I really think they would be open to this. The data's really just inarguable.

Q Do you think it would be (simultaneous speaking) to have the input of a trained epidemiologist in evaluating these studies?

A Absolutely. There have been. I'd be happy to refer you to those. One of the top epidemiologists in the world at Yale, Dr. Harvey Risch. He also testified at the Senate.

Q Well, with all due respect, Dr. Edwards, Dr. Marik, Dr. Risch -- none of these folks that you are referring to are here testifying for the Court today. The Court is being asked to evaluate your qualifications and your recommendations, and you do

not have training as an epidemiologist; is that correct?

A Correct.

MS. ATWOOD: Pass the witness, Your Honor.

MS. UBALLE: No more questions, Your Honor.

THE COURT: Okay, Doctor. I've got some questions for you obviously.

THE WITNESS: Okay.

THE COURT: And understand my medical vocabulary is narrow, at best. So I'm going to try and put these in terms that hopefully you understand.

Q Can -- can I take it that there is not a consensus on these studies that are coming out about the -- how appropriate it is for ivermectin and some of these other drugs that we discussed here, that we would -- if we went across the country and talked to every recognized epidemiologist, we may get -- we may not get a consensus on what -- whether they should be in part of a protocol or not? Can I take that --

A Correct.

Q Okay. And is it -- I don't think this is correct because we had some discussions before you were asked to be a witness that the family is not asking me to order a specific protocol. And I think you alluded to it, also, that it needs to be a team effort.

So I'm -- I take it that you're not asking me to take this protocol that's listed as having been signed by you on

July the 27th of 2021 and order the hospital to do that. Is that a good assumption on my part?

A Yes, that's a good assumption.

Q Okay. So, basically what the -- what the -- what the gist of this is: Is you think the team needs to be expanded, to some extent, to take into consideration some of these other studies and data and information that's out there related to the treatment of COVID?

A Yes.

Q Is that a fair assessment?

And can I take it that because of your limited access to the records that you would not come down to a final conclusion about what should be done until you had access to all those records -- patient history, how -- what her reactions to the current protocols have been, and things of that nature; is that correct?

A Correct.

Q And there's the distinct possibility and medical probability that your opinion could be that Scott & White's doing what they're supposed to be doing?

A That's always a possibility, yes.

Q Well, I didn't say possibility. I said a medical probability. There's a possibility for anything to happen. I'm stepping it up a little bit to ask about a medical probability.

A Based off my experience with other hospitals in the

similar situation with COVID ICU ventilated patients, no. I think the probability is they're not doing some things in the protocol that we would think would be very beneficial.

Q And I don't know if you know the answer to these questions, but the -- some of the requests are being based on law one of which is the Right to Try Act. Are you familiar with that Right to Try Act?

A I'm familiar with it, yes.

Q From the medical perspective is it your position that this request comes under the medical Right to Try Act? This seems to me to be more of a protocol and not necessarily an experimental drug that's not been approved by the FDA. All of these are drugs, I think, except maybe this leronlimab that have been approved by the FDA.

So, I'm having a little confusion of how that meets this Right to Try Act provision.

A Right. My understanding on Right to Try -- without having legal counsel to say. But if the patient requests it, if it's at least gone through a Stage 1 clinical trial -- so not even approved -- then that's basically what we're talking about.

Q And has to be --

A Family.

Q I'm sorry. Go ahead. I cut you off. Broke my own rule.

A No. That's okay.

I was just going to say if the family is requesting that, then, yeah, that's my understanding.

Q But it basically -- is it your understanding that it basically comes from the provider and not the family. The provider has to kind of agree and make that request to whoever the manufacturer or the device manufacturer -- things of that nature? You agree with that?

A Agreed.

Q Okay. And the same thing with -- as it relates to the Medicare Act. I've had that quoted to me. That basically said it's not the right of the patient to make that request as to mechanisms as far as treatments and plans and things of that nature. Is that your understanding?

A Yes.

Q And I don't know that you've got the answer to this either, but it's just a curiosity: If there's such a mountain of evidence related to this, I'm concerned of why it's being ignored. I mean, is it being ignored or is it just not known or -- and these doctors are such -- have such reputations...

A Well, just my opinion -- my opinion is there's institutions that have gotten too big and have gotten in between the doctor and the patient. And most doctors work for institutions as opposed to being independent. So, my opinion is there's some conflicts of interest from the institutions.

Q You said -- is Dr. Paul -- is it Marik, like

M-e-r-r-i-c-k? Or Merit with a T?

A M-a-r-i-k.

Q Oh, okay.

And can I assume when you're talking about the three prongs -- and I can't even remember what the title was, but the last one was the patient's desires basically. You gave the example of getting a blood transfusion of some sort. I -- it makes common sense to me that if somebody came in there and asked for a drug protocol that was just nowhere close to anything that may be helpful to them that you wouldn't rely upon their comments in that situation, would you?

A Correct. I mean, I tell my patients they're the boss -- meaning, they're paying me to consult and give them my best judgment, my best recommendation; but at the end of the day I'm not going to prescribe hydrocodone just because they're telling me to prescribe hydrocodone. We still use our clinical judgment, we still look at the peer-review evidence. I think we pendulumed a little too far into the peer review only is what we're going to look at especially if the peer-review process has been compromised by some of these institutional influences.

Q And just as a matter of practicality have there been attempts between you and the hospital one way or another to contact them to talk about all this.

A No. Everything's been through the family and through the family's attorney which I always prefer direct communication.

Happy to visit with these doctors. I, you know, can't speak for the family. Obviously there may be some concerns since the doctors are employed by an institution. There can be some other factors involved but -- besides doctor/patient care only.

Q So, up to this point neither one of you, as far as the physicians are concerned, have known anything about -- directly the comments of the other -- between the doctors; is that correct?

A Correct.

Q Okay.

THE COURT: All right. Does anybody have any questions based on the questions I asked?

MS. UBALLE: I would like to say, Your Honor, I did give Dr. Edwards' phone number to Ms. Atwood yesterday and asked her if she could pass it along to Dr. Rodriguez.

THE COURT: I was just curious. More of curiosity.

Got any questions based on the questions I asked that you want to follow up?

REDIRECT EXAMINATION

BY MS. UBALLE

Q I do want to follow up on the patient's right and patient advocacy.

Dr. Edwards, in your opinion do doctors in hospitals have an obligation to engage in collaborative

discussions with the patients regarding their treatment?

A Absolutely. It's at the core of the doctor/patient relationship.

MS. UBALLE: That's all I have.

MS. ATWOOD: Nothing further, Your Honor.

THE COURT: Doctor, we appreciate you appearing for us today by Zoom. I'm fixing to remove you from the hearing. Okay.

We'll take about a ten-minute break.

(Recess taken)

THE COURT: Call your next witness.

MS. UBALLE: Call Dr. Ralph Grams.

(Zoom witness instructions provided to witness by the Court)

MS. ATWOOD: Judge, may I ask one question? Would it be possible -- I think I've got a witness maybe in the waiting room. Can they listen? Is that --

THE COURT: It's fine with me. I guess I just -- is that -- who is that?

MS. ATWOOD: Dr. Murphy; and Steve Wohleb's in there, too --

THE COURT: Dr. Murphy is not on.

MS. ATWOOD: Is he not on now?

THE COURT: May want to contact him. If he joins up, I'll put him on when he comes in.

RALPH GRAMS

having been previously sworn, testified via Zoom as follows:

DIRECT EXAMINATION

BY MS. UBALLE

Q Good morning, Dr. Grams. Can you state your full name for the record?

A Ralph Raymond Grams.

Q And what is your occupation?

A I am a physician, a researcher, and now a COVID practitioner.

Q Okay. So, tell us a little bit about your education and your background.

A I was raised in Minnesota, and I went to medical school and undergrad at Minnesota. I did a general practice residence or internship at Bethesda Hospital. I spent thee years in pathology doing a pathology residency, getting boards in pathology. And I spent two years in Texas at San Antonio for the Air Force taking care of Vietnam vets coming back in the air lift working at Wilford Hall, working in the emergency rooms in Texas, and taking care of hospital patients in Texas.

So, following that I was given an offer to go to the University of Florida as a full professor; and I stayed there 43 years with tenure. I've been doing at the University of Florida laboratory medicine which is basically diagnostic services. I ran the lab. I did consultations on the floor in

hematology, immunology, virology; and essentially did most of the data processing for the hospital -- ran the hospital data processing services, the finance and accounting office, and any and all other jobs that the hospital didn't want me -- didn't want to do.

So, I've done virtually everything you can do in a hospital. I've been in the hospital systems for 60 years.

Q Okay. Do you have any additional certifications?

A I'm board certified in pathology, I'm board certified in medical enthametics [ph]; and those are the two credentials that I'm -- I'm also licensed -- or I was licensed in Minnesota, Texas, and Florida.

Q Okay. What professional organizations are you a part of?

A College -- Fellow of the American College of Pathologists, and so that's our major group. And also I belong to the American Association of Physicians and Surgeons, AAPS.

Q Okay. What is your experience in treating COVID?

A Well, it's kind of a difficult situation because I had never heard of it before 1999. Nobody had. And so I was working as a research scientist for European Space Agency on the Space Station, and they were very concerned about this virus that got into the astronaut population. So I started, beginning immediately in 1999, finding out everything I could about COVID.

And so at that point this thing took on the life

of its own, and the space agency essentially toned down because of the shutdown of virtually the entire world because of COVID. And then I started searching for ways -- how on earth are we going to treat this because the FDA, the CDC, and the NIH had no help for anybody that got COVID unless they had such a bad situation that they had to go to the hospital; and that was it. There was no outpatient treatment for COVID. And there still isn't to this day.

So, that started the journey. And then I came into the situation where I found people that were looking for treatments -- that we had thousands of doctors that were treating patients successfully with COVID and getting them well, and I could not believe that there was something out there and that we weren't using it. And so what we found out is that people in India and people in Europe and Germany -- because I was working with German scientists in the European Space Agency, they were using drugs to treat COVID. Unheard of.

And so none of this was coming through to us through the FDA, CDC, or the NIH. Or even the Public Health Service. The doctors were given no guidance whatsoever and the patients had no hope whatsoever. So I started getting calls from my family, from my friends, from relatives -- people I didn't even know -- asking me if there was anything that they could take to stop this virus. And so I started looking around, and I found out that the American Association of Physicians and Surgeons had

published a home health care protocol that basically was online, available for free for anybody to copy and download, and that had the whole protocol of how you basically treat COVID in the outpatient setting. And I was shocked because I hadn't seen any of that in literature. There wasn't anything on the Internet, there wasn't anything coming through the professional associations on what could be done with this disease; and people were helpless. So, I said, "Well, I better try this on my family. If I'm going to give advice, I'd better talk about something I've actually used."

So I put the protocol to use in our family, and we have never had any problems with COVID. We put it into all of our relatives now. We have probably 50 to 75 of our relationships all on the COVID protocol from American Association of Physicians and Surgeons. Nobody has had anything problems with this -- any COVID disease at all. I've had this -- now we're doing seminars and conferences for churches because pastors are coming to me and saying, "Can you tell us what you can do for COVID? We don't have anything we can do." I say, "Okay. Fine. I'll tell you how -- you can go online, you can get this thing; and I'll be a coach" because right now I'm retired, but I'm spending more time with this disease than anything else.

And so we're going out to churches right now and doing seminars. And I did a video for this on video, and we're sending it all over the country. In fact, I just got a call

before I was online with you from New Mexico.

THE COURT: Could we have question and answer, please?

MS. UBALLE: Yes, sir. Yes, Your Honor.

Q (By Ms. Uballe) So, can you talk about the treatments -- the specific treatments that you've used?

A Well, protocol specifies the key ingredient here is ivermectin. And there's all kinds of dispute on this whole thing because there's people in Washington with NIH, CDC, and all these basic organizations that have done nothing but throw dirt on this thing and basically try to make it look like it's evil. But I can tell you that that's the key ingredient, but it has to go with others. It's a cocktail. When you treat AIDS, you cannot give one drug. You have to give a cocktail of drugs to get AIDS under control.

The same thing is true with COVID. You have to have quercetin, you have to have Zinc. You have to have essentially enough D3 on board -- you have to get between 60 and 90 micrograms of D3 on board to be able to fight that virus. Most people are really low on D3. And you can test it on your own blood any time you want by going to Ultra Lab.

Q Yes. Have you --

(Simultaneous speaking)

Q Sorry.

Have you treated patients that have been infected

with COVID?

A Absolutely. We've had them right out of the emergency room. They were turned down. They couldn't breathe, they came out of the emergency room. We've had patients from two or three hospitals that came to us. We basically got them the ivermectin, gave them the protocol of the AAPS; and within 24 hours they were back on their feet, they were out shopping. I've had this happen five, six times now; and so now it's just -- I haven't had any failures. Not one.

Q Have you -- have you seen Dr. Edwards' proposed protocol in this case?

A I looked at what he was looking at about a week ago, and I think I would basically say that --

You see, this is the problem here. We're dealing with a really different situation. I work in the outpatient. Carolyn is in a serious -- very serious position in the inpatient sector -- and especially the ICU. So I can say -- I can only opine on what I see with my patients in the outpatient -- I wouldn't call them patients. I'm just an adviser because I don't practice medicine anymore. I just do consults and I give advice and I help them do what they need to do.

And so I would say that I have never had to treat a patient this bad and this serious ever, and I hope I never have to because we don't get them there. If we can treat them early, they never get to the ICU, they never have these problems.

Q Well, in this case would you consider Mrs. Carroll to be terminal?

A Well, I have not seen the patient. I do not know what her current status is and so that puts me in a situation where I don't understand -- I can't really make a determination of that, but I can say if she's on a ventilator and in the ICU -- and I submitted to do the Court a paper from the Mass General Hospital published in March of this year in a table that shows you the death rate of people on ventilators in the hospital with COVID, and it's not good.

Q Well, what is --

A When you reach -- when you reach this stage -- and I don't know her exact age, but I would put her in the late Seventies.

Q She's 75.

A When she's in that -- when she's in that age range, she's in the 65 to 85 percent death rate. And now she's been on a ventilator for probably a week, as far as I know, and probably in the 90 percent category now. I would consider her extremely critical. In fact, by the time we finish this hearing she could have died. I mean, this is how close we are to the end here.

And so that's why I think the questions have to be reframed here in a certain sense because we're really dealing with an issue of -- not a Right to Try but a right to live. We're passed the trying stage. And I know all the -- I've got

the documents here from the FDA on what all the legal hurdles are for Right to Try, and it's not easy. I mean, this is a tough sell.

I also understand the incredible problems with the hospital having somebody coming in from the outside and telling them what to do. I understand the hospital rules, I understand the legislation and the protection the hospital has to give their physicians. I see both sides of this case. And, Judge, I really -- I really have to think about what -- the situation you're in right now because this is a life-and-death case and these are really hard and both sides have rights.

Q Dr. Gram --

(Simultaneous speaking)

A Yes.

Q Sorry. In your opinion is there any medical reason not to give this treatment to this patient given her current status?

A I don't see any logical reason not to, but I can understand if the hospital has reservations that they have to have their considerations also mixed into this whole thing. And so this is a complex problem. We are dealing with a very serious patient, we're dealing with a medical emergency here. It's a 9-1-1.

And I would like to propose a solution which I hope both counsels and both sides could agree with because I've looked at problems like this in the past and I've had to really

scratch my head and had to say, you know, both sides are right. If we don't do anything with -- based on the track record we have right now, she's going to be dead soon because we just don't know what else to do. We've tried everything, we've done our very best. Everybody has worked hard. Nobody is at fault here, nobody's pointing fingers. And shouldn't be an adversarial presentation. And yet the family wants to know is there anything more we can do.

So what I would like to propose to both sides is what I have always done with my cases: When I come to a situation and we can't figure out what to do, we get a second opinion. And the second opinion here means that we need to get somebody to step in in this case who has the gravitas and the credentials to be an expert in this field. We need somebody who is nationally -- internationally recognized that's an expert so that everybody is satisfied that he is a qualified person to speak. We need somebody who is an expert in this field of emergency medicine or ICU care and especially COVID medicine. We need somebody who also meets all the requirements of the Baylor health care system of confidentiality and all the legal requirements that have to be on board that can actually look at the chart, do a physical exam on Carolyn, talk to the staff that is there, and then have a conference and decide what can be done.

Q Yeah.

A And if anything can be done, then they can do it as a

joint venture.

Q Yes.

A And I think the thing that's most important here is that Baylor is in an incredible situation of power. Your hospital system has just such a man. He is a world expert in COVID, he is a world expert in every form of research in this disease. He knows every treatment protocol that's been used around the world. You have a world class star at Baylor. He's not at the hospital where Carolyn's at. He's in Dallas. He's at the major center there. He's chairman of the medicine department and he's chairman of the cardiology department.

I am asking -- and I think the proposal would be to you, Judge, that you ask for a second opinion from Dr. Peter McCullough -- the chairman of medicine, the chairman of cardiology; that within the next 24 hours. It's only a couple of hours' ride from Dallas to College Station --

Q Doctor?

A -- that he be asked -- and write a personal consultation with the staff and the faculty.

Q Dr. Grams?

A Yes.

Q Thank you for your input.

Just have a couple more questions for you. In your opinion --

A Sure.

Q -- for -- in a family situation like this -- as a doctor, where would you prioritize the family's values and the family's requests to have a treatment tried?

A I think that's generally the top of the line. I mean, every family wants the best. They want to know at the end of the day everything was done to save my family member. I don't think anybody in the room there wants her to die. We don't go to work in a hospital to try to kill patients. We're trying to save them.

And that's why I'm hoping that we can come from this meeting or this hearing with a win-win proposal because the hospital needs to be happy that they've got an expert that's coming to give a second opinion, the family needs to know that they've got an expert coming on their patient's -- their family member's behalf.

Q Thank you.

A That's all you can do. And if they agree upon a protocol together, then I know that Peter McCullough is the expert in this area; and if there's any changes that need to be made, he can work it out internally -- not legally but internally within the Baylor system. And that's what I would like to see happen here is that we have a meeting of minds on how we go forward. And we can do this expeditiously and in such a way that both sides can leave this meeting thinking that we really did the right thing.

Q Thank you, Dr. Grams.

MS. UBALLE: Pass the witness.

CROSS-EXAMINATION

BY MS. ATWOOD

Q Dr. Grams, my name is Missy Atwood. Are you able to hear me now? Got my microphone turned on.

A I do.

Q Great.

I'm the attorney for Baylor Scott & White Medical Center here in College Station, Bryan. Have a few questions for you.

You mentioned that you have training as a pathologist and as a researcher, but I think I heard you say that you were retired. Are you practicing medicine anymore?

A No, I'm not.

Q Are you licensed currently in any state to practice?

A No. No.

I'm a health coach. I give free advice.

Q Gotcha.

And when you were practicing and as part of your training, did you ever have privileges to practice in the hospital in the area of infectious disease?

A Yes.

Q Did you have -- do you have formal training and have you done fellowship work in infectious disease?

A I have not done fellowship work, but in pathology we run the laboratories where all viruses are isolated and we run all the equipment. So the PCR equipment which has now been obsoleted and all the antibody testimony and the immunology that's done, that's where we do it.

Q Gotcha. And have you ever worked as a critical care physician managing patients in the ICU, where that's been your primary role?

A I worked seven years in emergency room physician. So, I mean, that's about as critical as you can get with gunshot wounds. And I've handled all the patients that came through Dallas, Houston, Fort Worth, San Antonio, and Corpus Christi. So I worked in probably 20 different hospitals in Texas in the ER. So trauma is my second name.

Q And so when was this that you were doing this work in Texas in these emergency departments?

A This was back when I was in the Air Force --

Q So --

A -- in Texas. I was '71 to '73.

Q So, would it be fair for me to say to the Court that the last time you took care of a hospitalized patient where you were the primary provider managing that patient's care was sometime during the 1970s?

A That's correct.

Q And is it true that you have never been credentialed or

had privileges as a pulmonary and critical care medicine physician?

A That's correct.

Q And you agree, I take it, based on your earlier statements, that the proper training of the physician -- or physicians to treat and evaluate Ms. Carroll's current situation would be a pulmonary and critical care physician?

A Absolutely.

Q Would you -- as a medical coach or medical consultant would you typically refer someone who was in an ICU on a ventilator to a family medicine physician to manage their care?

A That wouldn't work in our hospitals here because they wouldn't have privileges.

Q And to your understanding having been in -- sounds like an academic setting there, are you familiar with any hospitals that would allow someone trained as a family medicine physician to have attending physician responsibilities in a pulmonary -- in an ICU setting? That wouldn't --

A I'm not aware of any hospital that would allow that.

Q You --

A In fact, our hospital in Gainesville has a special ward for family practice doctors which is part of the hospital, but they can't admit to the other part of the hospital.

Q Okay.

A So it's segregated.

Q And that's because family physicians simply don't have the training -- not that they're aren't great at doing family medicine but they don't have the training to manage critically-ill patients; correct?

A That's correct.

Q You mentioned that you have treated two or three hospitalized patients who walked out of the ER and then -- I guess maybe not treated but had consulted on a couple of patients who had left the ER COVID positive and then you became involved in their care.

A Yes.

Q Have you ever treated any hospitalized COVID-positive patients who were in an ICU setting?

A No way.

Q And your -- these speeches that you've talked about where you're recommending a COVID treatment protocol that features ivermectin -- those -- is it accurate to say that that -- those recommendations that you are making are limited exclusively to an outpatient setting?

A I can only say from my own experience -- and, again, the recommendations are for outpatient use. But we have got, again, other doctors like Dr. McCullough who can opine on that situation. He's far more experienced than I am.

Q And I understand. I'm asking really specifically about your experience since you're in front of us today. And so my

question is: Is your experience treating -- or trying to prevent COVID limited to patients who are not sick or have, at worse, a mild version of the disease?

A Well, we deal with them all the way up to the point where they're admitted to the hospital. I mean, they can't breathe, their oxygen saturation levels are down in the low eighties, they're desperate, they're almost comatose. And I've had them up to that point. But once they go in the hospital, that's all I see. So that's taken over by the hospital.

But the problem here is that we don't want to get them in your hospital. We want them to stay home and we don't want to get these kind of cases like this on our books because they are difficult and very hard to deal with. And that's why you have -- all your expert staff to take these things in and that is why I'm making a plea to both sides for a second opinion because I believe that you have a super rock star in Dallas in this area who can aside -- deal about with both sides of this issue and give a reasonable settlement to what can be done. And that's why we just -- I would say give a second opinion to Carolyn Carroll.

Q And just so that I'm clear -- and so that the family is clear: You're not recommending that the -- any second opinion or input would be appropriate from a family practice physician, are you?

A Not in this case. Not in this case. And I think

that's the whole point is that -- this case is so complicated and you got so many specialties involved here. You need a man who has the great after and the academic credentials to step in and be an expert.

Now those are rare. I mean, these are, like, a hand full in the world that qualify in a case like this; and your hospital system is very blessed to have such a man in Dallas who can fill this role and could be there within 24 hours to meet with your staff and to settle this peacefully and academically and scientifically and medically proper and not deal with the court.

Q Have you spoken with this Dr. McCullough about this case?

A No.

MS. ATWOOD: No further questions, Your Honor.

THE WITNESS: I do speak with him every day; but when I was listening to the dialogue here, I don't think that we're going to win or lose this case on Right to Try or anything else because the legal bar is so high here that you're forcing the Judge to make a terribly difficult decision and saying we can't do this.

And so what I'm trying to do is give both sides a win because I believe that Dr. McCullough is the right person for Carolyn at this time; and if he will come -- and I think he will -- I think he will be down there within 24 hours to do an

emergency consult and actually physical exam of that patient -- I want -- he needs to see the patient, examine the patient, look at her equipment -- whatever she's on, the respirator. Whatever they're doing -- look over the chart because he's the only that's qualified and has the credentials to have access to her chart and to see what's been done and talk to the doctors, talk to the nurses, and then have a conference and decide what can they do. Is there any other thing that hasn't been done? If at the end of that day that conference and she -- whatever they decide to do -- because I can't tell them what they're going to do. This is way above my paygrade.

But we're talking the expert of probably the world on COVID, that's what we're talking about here. He is that much of a super star. And he will give her the best choice she can get. And that's all we can do. I think that's the best option we can come out with is to have her have a consult from Dr. McCullough and soon before she dies and see if there's anything that can be done.

MS. ATWOOD: Thank you for your input, Dr. Grams.

Nothing further, Your Honor.

MS. UBALLE: Nothing further, Your Honor.

THE COURT: All right. I'm going to remove you from the hearing. Have a good day.

THE WITNESS: God bless. Bye-bye.

(Witness provided Zoom instructions by the Court)

CAROL CREVIER

having been previously sworn, testified via Zoom as follows:

DIRECT EXAMINATION

BY MS. UBALLE

Q Hi, Ms. Carol. Can you please state your full name?

A It's Carol Lorraine Crevier.

Q Okay. What are your credentials or your education?

A I'm a registered nurse in the state of Illinois. I hold a baccalaureate in nursing from Rush University, and I hold a masters in public health from the University of Illinois at Chicago.

Q And what is your experience -- your job experience?

A My professional experience is varied. I began medical nursing at Rush University. I moved on to do home care with a Visiting Nurse Association of Chicago. There was a break in my career to care for my family, and I returned to nursing in 2009 as the administrator on the Center for Primary Health Care which is a primary health care clinic with full spectrum care across the entire health spectrum for our patients.

Q And do you have a knowledge of patient advocacy?

A Yes, ma'am.

Q So, what is patient advocacy?

A Patient advocacy is giving voice to patient concerns. In my profession this is addressed in the American Nurses Association's code of ethics. Provision 3 addresses this very

directly and informs and reminds nurses that advocacy is involved with the promotion of healing with the protection of patient's rights and also the protection of themselves, their safety, and the protection of their lives.

Q And how does a family's values come into play in that scenario -- in patient advocacy?

A Family values come into play with patient advocacy in a number of important ways. First of all, health care professionals are taught and regularly practice to consider a patient as a member of a family system. We study family systems, and we're taught to be compassionate and sensitive to a patient's family. So we do not view the patient in an atomized way. So, we are required to be sensitive to the relationships that a family has with the patient and be aware.

Secondly a family's values comes into play particularly when patients are severely ill, perhaps near death in some cases and unable to speak for themselves. We look to families as caregivers for all kinds of information in lieu of that patient being able to speak. That's everything from how do they like their toast done to what do you think that they would do -- want you to do for them with a very serious decision about their life. So, health care professionals first look to families -- when a patient is not able to speak for themselves, we look to see how is the family translating -- and, obviously, we have legal provisions. That's more your bailiwick than mine.

But, you know, when we're caring for patients, we are constantly looking around us at the family and looking to see what are they telling us so that we can take the best care of the patient as possible.

Thirdly I think it's important to point out that family and patient values are a formal part of what is known in the medical community as evidence-based clinical practice. The American Medical Association has published a manual of evidence-based clinical practice. It's in its third edition. I'm referencing the 2015 edition of this manual. And in that manual they articulate that there are three components of evidence-based medicine: One is clinical expertise, the second is the examination of a body of evidence for any given medical intervention under consideration, and the third component is the patient and family values. And this manual makes it very clear that two out of the three -- the first two that I mentioned -- are not complete without the patient and family values being folded into the decision-making process.

And interestingly as I reviewed this in preparing for today what especially caught my attention was this manual's pointed counsel to health care professionals wanting to practice evidence-based medicine that when the confidence that we have in a given benefit of X, Y, Z medical intervention is low, it is crucial -- and I am quoting them -- crucial that patient values are considered.

So, if the Court would allow a short example for contrast, we do have situations in which the confidence of a benefit is very high. If you will, medically indisputable. If we have a toddler, he presents to the emergency room, he's posed an accident and he is bleeding out and his parents are Jehovah's Witnesses, we have a conflict because the patient values and the family values do not coincide with what is the universally-understood medical intervention that would save that child's life. And we do see -- we do see family values set aside. I'm sure not all the time, but that's a very grave thing if we do that -- if we set a family's values aside because these are deeply-held religious beliefs of Jehovah's Witnesses.

In contrast when we have a situation similar to what is being considered today in a court in which the confidence of the benefit of any given protocol or individual treatment is very low, this is the type of scenario in which we are advised professionally to weigh in that family's values very carefully. It has to do with humility as practitioners. We are not even 24 months into treating what two years ago was an unknown illness. And medicine is kind of a slow thing. We cannot run randomized controlled trials quickly. Just doesn't happen that way. And so all of us who are caring for COVID-19 patients recognize that we know a little bit right now. We don't have a lot of confidence in what we're doing. We are doing our best, but our confidence in terms of comparatively to things we have

treated for years is low.

Q Thank you.

Would you consider a family's request for a particular treatment to be an expression of their family values?

A Oh, definitely. In a sense every family has a culture and there are theologians who refer to culture as religion externalized. So, when you're particularly dealing with severe illness and, you know, very morbid, close-to-death conditions people's values about life and death are right underneath the surface. And as nurses we are taught to be very careful about reserving our own judgments in these matters and to elicit and elucidate what is a family's culture that they're bringing to this extremely difficult situation. And we must listen very carefully to them and we must honor what their beliefs are whenever it's possible.

It's not always possible. But whenever it is possible, we are to do that. And we are also under obligation by our own standards of care and our own code of ethics that if a patient's needs are being neglected, we must advocate. This is what it is to be a nurse.

Q Thank you.

Are you familiar with what an ethics conference is or an ethics process is?

A Yes.

Q Can you describe that in general terms?

A Yes. I will use general terms because every institution has their own specific process. In general -- in the last three, four decades as medical technology has become increasingly sophisticated and more people face difficult end-of-life decisions -- and there's technology involved the clear -- the clear -- the clarity of what to do has become less, the water has become more muddied. And so hospital systems across our country and other western nations have developed different processes in which families and medical teams have a process to sit down -- typically this is done in a quiet conference room. And sometimes you just have one person an ethicist who is sort of mediating all the voices and all the stakeholders. So, you would typically have all of the important leaders in someone's medical team -- you may have nurses there, you may have allied health professionals, there may be chaplains there, and the family -- typically who would ever have power of attorney on whoever the family wanted to have there.

And at such a conference the ethicist is to be -- if it's a singular person mediating that meeting, they're expected to be a neutral party and to use frameworks which allow all parties to put their concerns on the table. The ethicist would be trying to help people clarify what questions are we trying to ask; and the goal of such a meeting would always be to try to have a win-win in which when everyone gets up to leave, there is a plan of care in which the family's and patient's

values have been honored and integrated into the plan of care that the medical team is developing. And that does mean that sometimes not everyone's desires are met; but you are looking to develop a plan of care, again, that is evidence-based and has shared decision making so that that family is cared for because that family's experience in their loved one's difficulty is also our obligation as health care professionals. We do not just care for an atomized patient. We care for an entire family.

Q In your experience if you -- have you seen a terminal patient receive treatment that might be considered non-traditional, experimental, not approved? Have you seen that in your experience?

A Yes, I have. Yes, I have. In my current position there is a patient who has cancer, and the vitamin therapy that this person receives and believes in is -- his belief is not shared by the medical director of the facility where I work. However, there is no -- there's no attempt on the part of the primary care physician to block that because he doesn't think that it's necessarily to block something that is safe that he doesn't necessarily believe is efficacious.

Q So, the question is not whether it's effective; correct?

A In this particular case that I'm giving to you, yes. Correct. Because these are water soluble vitamins that when given in excess are excreted through the urinary system. And so

there isn't a question of -- efficacy is not really the issue at all. He would -- he would act if he was concerned for the safety of the patient, but that's not of concern.

Q Are you familiar with the circumstances in this case with the Carroll family and how the hospital.

(Simultaneous speaking)

Q Yes. Go ahead.

A In the most general sense, yes.

Q And I'm referring specifically to the patient advocacy piece.

A That piece is the piece that I have been -- I've received communication about.

Q In your opinion, based on your knowledge of patient advocacy and how that process works, has Baylor Scott & White provided a proper avenue to this family for patient advocacy?

A So, of course what I'm about to say is resting on what has been told to me not my direct observation. I have not been inside of Baylor Scott White [sic] and I want to make that very clear because in my mind that it is someone else's testimony that I'm passing on into the court.

I have spoken with Jodi Carroll, the patient's daughter. My question to her specifically was: Has your family requested an ethics consult or an ethics conference, and the answer I was provided was that her brother had made this request some time in the past and had made the request of someone from

the chaplaincy department. And that rang a bell for me. I've been involved with that kind of thing before. And I -- I was encouraged by that. But in the ensuing time since I've met Jodi it's my understanding that such a conference as I had previously described -- in which all parties are seated and this is not just an in-the-hallway conversation or telephone conversation with one family member -- has not occurred.

So, if I am allowed -- and if I'm not allowed, someone just tell me -- I would like to refer to the hospital's code of conduct in answering this. May I do that?

Q Please do.

A Okay. I'm not a Texan. I'm from Illinois. So I have no familiarity at all with Baylor Scott & White; however, I am very familiar with the way hospitals in most jurisdictions conduct themselves. So I went to the Internet to look for their standards of conduct for themselves.

And when I went to the Internet, I found the November, 2020 version of their code of conduct with an introductory letter from Jim Hinton. It's very clear in his communication that the document I'm referring to -- and I'm quoting -- is their foundational compliance program which informs -- now, I'm not quoting, I'm paraphrasing. Informs their daily conduct -- that actually is a quote -- which means that what I'm about to say is the document that if I were an employee of Baylor Scott & White and had a question about how I was

supposed to conduct myself as a nurse, this is the first place I would go because this is telling me how am I supposed to behave every day, what are the values that inform this institution and I must conform to. So they say, "We serve faithfully. We act honestly. We never settle. We are in it together."

As a guiding principle we are to listen to patient's perspectives -- and here I am quoting, "We will communicate effectively and maintain positive relationships with patients, members, families, and customers, by explaining our role in their care and responding to each patient's clinical needs and requests in an open and honest, respectful manner.

"We will respect the rights and human dignity of each patient and member.

"We will respond to patient and member questions, and concerns [...] in a timely and sensitive manner.

"[...] We will include patients in clinical and ethical decisions about their care, treatment, and services."

And finally, "We will protect the patient from real or perceived medical, physical, sexual, or verbal abuse, neglect, or exploitation from anyone including" physician, staff, or other patients visitors or family members.

Using this as the referential document, I perceive a significant gap in several places. This is a family who is seeking a therapeutic protocol that they believe could bring their mother out of the bed and back home and restored to her

family. They, however, as of two days ago could not even get a medication list from the staff and wrangled to get it. That is completely not reflective of what I just read, nor is it my experience that that would ever be a problem. If someone needs a medication list in a family -- especially with an elderly father and he has given permission to that daughter to be the point communication person -- that's just going to the computer; pressing print; and saying, "Sure. Here you go." Why this Texan has had to wrangle like she's in a rodeo for a medication list is beyond me. Absolutely beyond me. And is the opposite of what is described here.

To not have sat down with this family, carefully listened to them, demonstrated that you care about what their values are when in your description of spiritual care you state that you uphold the sacredness of human life, I don't understand that either.

I further would like to say --

THE COURT: Let's have question and answer, please.

MS. UBALLE: Yes. Sorry.

Q (By Ms. Uballe) Let me ask you -- let me ask you: How does -- how does mercy play into a situation like this in -- you know, weigh in the family values and choosing -- choosing a facility, choosing a hospital?

A Everyone has a choice of where they go to choose care.

The Carroll family must be, you know, close to Baylor Scott & White. I really don't know the geography; however, I do know that they are a confessing Christian family and that Baylor Scott & White has in their mission statement that they are -- they are founded as a Christian health ministry.

So, this is a family whose stated confession ought to have alignment with the stated foundational documents of the hospital. And I am also a confessing Christian and can easily state that mercy is at the core of Christianity. And just to define for the Court: Mercy is when we receive an unexpected act of love from someone else. And the unexpected aspect is important because in this situation the medical team, from what I understand, doesn't believe in any of the efficaciousness that the family believes in. And it would be an unexpected thing for very powerful people within a health care institution to concede their power and say, "No, your mom. We think she's dying. We totally don't believe in this. But we also know that we told you -- really, you know, in our minds tomorrow she could be 6 feet under. And so safety isn't even a concern. We don't think it's efficacious and we totally don't believe in it; however, safety --"

THE COURT: Question and answer, please.

(Simultaneous speaking)

THE WITNESS: Go ahead.

MS. UBALLE: No more questions.

CROSS-EXAMINATION

BY MS. ATWOOD

Q Is it Ms. Crevier? Am I saying that correctly?

A Yes, ma'am.

Q Ms. Crevier, my name is Missy Atwood; and I'm the attorney for Baylor Scott & White Health. I have just a few questions for you. And I do want to particularly talk about two of the things that you brought up. One you mentioned you felt that the standard of care and code of ethics played a part in how health care providers need to address a situation so I want to talk to you about that. And I also want to talk to you a little bit about your concerns about their -- your understanding that there's not been an appropriate avenue for advocacy perhaps through an ethics committee consult. I don't expect this will take real long, but that's where we're going.

First of all, in the standard of care and code of ethics -- would you agree that the standard of care or codes of ethics for health care providers requires that they not order or administer medications that they feel are medically unnecessary for a patient?

A I am not a prescribing clinician so I do believe I ought to decline that because I don't have a license to prescribe medicine. I can observe what goes on as prescribers do their work, but I don't think that I have thought that through to the bottom because I am in school to get my nurse practitioners

through the NP program. But I'm not a prescriber.

Q Fair enough.

So -- then let's look at it from the nursing perspective that you do have. Would you agree that from the -- that nurses would have to have an appropriate physician order to be able to administer medications to a hospitalized patient?

A Could you repeat the question?

Q Sure. Do nurses need or require having a valid physician's order before they administrator patients medications in a hospital setting? You have to have an order before you can give it?

A Yes. An order is required by the practice act and -- certainly in my state. I can't administer medication without an order, inpatient or outpatient.

Q And you would expect -- realizing that you're not licensed in Texas; but you'd expect that the same is true for nurses in Texas, that they can't administer medications without a valid physician's order?

A Unless Texas has a different practice act. If Texas practice act for nurses is the same as Illinois; but, again, I'm not a Texan so...

Q If as a nurse you believed that a medication that was ordered was medically inappropriate, the nurse would have an obligation to say, "No, I'm not comfortable administering that"; correct?

A Yes, ma'am. Correct.

Q I understood your testimony to be that based on your information that you receive from, perhaps, Ms. Carroll's daughter Jodi -- that you didn't feel that Baylor Scott & White had provided an appropriate avenue for discussing the concerns about the requested treatment protocol. Is that a fair kind of summary of your opinion?

A Yes, I think that's fair with the emphasis that it's only what I heard and not what I observed.

Q And did you have an opportunity to look at the patient's medical record?

A No, ma'am.

Q Are you aware that Ms. Jodi Carroll was provided with a complete copy of the medical record?

A No, not until you stated so.

Q Okay. I do want to show you something -- show you a consultation note in the record and ask you to help the Court decipher that.

When you have been involved in ethics consults that you talked about before, is it typical to see that those are documented in the patient's medical record?

A Yes, ma'am.

Q I'm going to show you what I believe to be an ethics consultation note in Ms. Carroll's medical record. I want you to look through it with us; and if you need to tell me to slow down

as I scroll or something, let me -- tell me that because I want to give you a chance to see it.

But right here it says that Dr. Rodney Light is documenting on July the 20th -- so a week ago -- week and a day ago -- that there was summaries -- providing a summary of an ethics committee consultation that says that consultation was requested by the chief medical officer. Do you see that?

A Yes, ma'am.

Q Okay. Would that be appropriate if there was a concern over whether family's requesting one thing, providers maybe don't think that's appropriate for care -- would it be appropriate, then, for one of the administrators at the hospital -- the chief medical officer to say, "Hey, let's get folks together and see if we can get some information exchanged"?

A Yes. Anyone in the hospital caring for a patient at multiple levels can make this type of request, yes.

Q All right. And that -- doing so would be consistent with those values that you found for Baylor Scott & White that you read to the Court?

A It's consistent in that it is the initiation of a process, yes.

Q Sure. And it's -- at least Dr. Light documents here that after reviewing the medical records in discussion with multiple physicians and nursing members and the patient's designated alternate contact sister Linda, I understand there to

be a problem with a conflict between the desires of the patient's family to receive treatment for her COVID and the complicating conditions -- what -- that the treatment team does not believe are beneficial to the patient.

Does that seem to be a summary of this dispute that you felt would be appropriate to take to an ethics committee and make sure that advocacy was happening?

A I apologize. I'm in a rented hotel room and someone was knocking at the door while you were asking me the question. It's just the best situation I have.

Could you kindly repeat it for me?

Q Sure. Just looking at that first paragraph where Dr. Light is summarizing the reason for this consultation -- I'm just trying to figure out: Does that look to you to be an appropriate way of saying, "Look we've got a dispute over what the family has asked and the providers think is not beneficial for the patient"?

A It's a statement of the dispute --

Q And that's the --

A -- yes.

Q Is that the same dispute that you were saying needed to be addressed?

A After... I believe it is the description of the dispute as I understood it; that we have a family that is expressing a desire for certain treatment and a medical team that does not

agree and they're not on the same page.

Q And would it be the right thing to do, in your view, to have one of these ethics consult meetings?

A Yes. As I described before, I would expect that this dispute then would be taken into a room with all of the family members involved and all of the team taking care of the patient -- all the point people.

Q Now -- and I don't know how much of this you've had a chance to read. You're welcome to read any of it -- any or all of it. Let me know when you're ready for me to move it forward.

A Okay. You can advance it. Thank you.

May I ask a record of the question, ma'am? The word "died" is after the word husband in the first highlighted yellow. Her designated medical power of attorney is her husband died. Dudley Lee Carroll who I am unable to reach by phone on multiple attempts.

Q So, do you see that there appears to have been an effort to reach her husband multiple times to discuss these issues?

A I do see that, ma'am.

Q Okay. And are you aware of whether her sister Linda is the person that the patient designated as her alternative if the health care providers were not able to get in touch with her husband? Do you know whether Linda's designated as the alternate?

A It states that here. I do know that the husband is cognitively challenged, particularly with his phone, because this was a point of discussion between myself and the daughter Jodi yesterday. And I said, "Well, why don't you just call your dad" and she said, "He leaves his phone. He doesn't even know how to use his phone properly. And I have had my dad tell the hospital that I am to be the point person of communication." And so if the dad needed to be reached and I were the nurse, that's how I would have gotten to the dad, through the daughter.

Q Are you aware that that designation to contact Mr. Carroll through his daughter came to the hospital yesterday?

A She did not tell me what time.

Q Okay. Do you know whether that designation had been made by the 20th, the day that this ethics consult took place?

A No, I do not have knowledge of that.

Q And if the patient has specifically designated an agent as a power of attorney and an alternate, is it -- you would agree with me that it's appropriate for the hospital to attempt to reach the designated agent and the alternate?

A Appropriate, yes; perhaps not sufficient.

Q Well -- and the ethics consult indicates that the chart indicates a request by the patient when she was alert and had capacity that communication not go to her daughter Jodi. Do you see that?

A I see it, but it doesn't mean a lot in terms of who

should be at the table.

Q If the patient has expressed specific direction as to who her medical power of attorney should be, who the alternate should be and who should not or should have access to her information, is that something that you would expect the hospital to respect?

A As a nurse I would want to know was that on the original power of attorney. I have questions. In other words, I don't have enough information really here to know what that means. I see that the chart indicates a request; but was that witnessed by only one nurse, was it -- like, there's all kinds of questions. I don't -- yeah.

Q Have you been made aware that Ms. Carroll had at one time designated her daughter Jodi as an agent or an alternate agent and that she actually executed a new power of attorney removing her from that role?

A No, ma'am. I'm sorry. No, ma'am. I did not have knowledge of that.

Q If that's the case and if the chart also indicates that the patient requested when she was alert and had capacity that communication not go to her doctor, would it be appropriate to reach out first to the husband and then to the patient's designated alternate her sister?

A I think that is appropriate to reach out. Again, as I stated earlier, this is the beginning of a process that's

described.

Q Sure.

A In my mind.

Q Let's look here at the last paragraph under that section. Says, "The record indicates there have been multiple discussions with multiple treatment team members explaining that these treatments are not believed to be current evidence-based standard of care and the treatment team believes these medicines to be potentially harmful without the reasonable probability of improving her underlying condition."

Assuming those communications took place, do you think that's appropriate information for the health care providers to provide to -- what does it say? Through multiple discussions.

A I would expect that hundreds of discussions would have happened between this medical team. I don't look at this as sufficient to say that this hospital has exercised their standard of care which I described earlier to complete what is necessary to communicate clearly with this family, to include the family in the clinical and ethical decision making. Not at all.

Many elderly people do not answer their phone. And it is now the end of the month and this happened on the 20th so there was a continuing opportunity to bring family members into a room and, as Scripture says, "come let us reason together" so that hostility can be dissipated and care can be given. I do

not consider that they have discharged their obligations to include the family in ethical and clinical decision-making by the record here, no.

Q Has -- has your only communication about the communications with the family come from the patient's daughter Ms. Jodi Carroll?

A Yes, ma'am. And from her designated attorney present today.

Q Okay. Have you spoken with Mr. Carroll, the patient's husband and designated power of attorney?

A No, I have not.

Q And are you aware, then, that he had multiple conversations over the last several days with multiple of the health care providers?

A No, I have not spoken to him.

Q And I take it you would agree that if a patient has designated someone as their agent under a legal power of attorney document that the health care provider should be communicating with that person on the patient's behalf?

A Yes, ma'am.

Q And is it your understanding that Mr. Carroll is the designated agent under Mrs. Carroll's power of attorney documents?

A That is what I was told.

Q Has anyone ever told you that Ms. Jodi Carroll was the

designated agent?

A No, ma'am.

MS. ATWOOD: Pass the witness.

REDIRECT EXAMINATION

BY MS. UBALLE

Q Just for clarity, Ms. Carol: In a situation like this where we have a family that's very involved at the hospital -- in your experience would it be just one person from the family on this ethic -- in this ethics process, or would it be multiple members of the family collaborating with the doctors and health care providers?

A In my experience it is normative for whatever family members the POA wants in the room to be in the room.

Q Okay.

MS. UBALLE: That's all.

THE COURT: All right, ma'am. We're going to excuse you from the hearing. Have a good day. Thank you.

THE WITNESS: Thank you, sir.

MR. CARROLL: Also I'm not dead.

THE COURT: I understand.

We're going to take a lunch break. Be back here at 2:00 o'clock. Let your witnesses know I accidentally shut down Zoom. I'm going to start it back up. I'm going to go ahead and send the invitation, but it won't come in -- we're not going to start till 2:00 anyway. Want to go ahead and sign in, they

can be there.

Let me just make sure we're going in the right direction here, from what I understood. I mean, I've heard the two doctors tell me they do not want me to order this protocol.

MS. UBALLE: Yes, Your Honor.

THE COURT: Okay. And it's not my intent to kick this can down the road. It's my intent to get a decision out on this today, but I've got to know -- this is smelling like mediation which does not thrill me a whole bunch.

MS. UBALLE: Yes, Your Honor.

THE COURT: From the standpoint that I can't make people talk. All I can do is order them to show up.

MS. UBALLE: Our desire is to have a doctor willing to prescribe this protocol, which is Dr. Edwards, have a seat at the table and have a serious seat at the table.

THE COURT: I understand. Okay. I just want to make sure I'm hearing things correctly.

All right. We'll see y'all at 2:00 o'clock.

(Lunch recess).

MS. UBALLE: I'd call Clover Carroll.

CLOVER CARROLL

having been previously sworn, testified as follows:

DIRECT EXAMINATION

BY MS. UBALLE

Q Can you please state your full name for the record?

A Clover Jason Hughes Carroll.

Q And where are you from?

A I live in Brenham, Texas.

Q And who is Carolyn Carroll to you?

A She is my mother.

Q Tell me a little bit about your mom.

A My mother is the most considerate, dearest person who lived a life of sacrifice and presenting values to us. One of the mottos that all of our family will attest to is that she said constantly, "Carrolls don't quit." She's a fighter. Those are the values she instilled in us and she would expect from us, her children.

Q Tell us about when your mom got sick.

A Well, she -- she was -- I think this is the third or fourth week -- fourth week that she has been ill. It started when she was ill and we called her, checked on her. She didn't know what it was. And she ended up going to the hospital, and she was told she needed to come home and observe. If it gets worse she can come back.

It obviously got worse and she came back and she was admitted to the hospital and -- yeah, what else can I speak to?

Q So, tell us about your -- your and your family's efforts to express your wishes for your mom.

A Well, when we first -- my wife and I -- her name is

Rachel. Our first visit to the hospital after -- there's a lot of information here: My father was put in quarantine, wasn't able to be there and there was a window there and then there was an infectious period of my mother and we couldn't get into the -- understandably we could not get into the COVID wing.

But we -- as soon as we were able and allowed, we showed up at the hospital to get a status report on my mother. Information had been kind of fragmented. He was in quarantine, he lives in a -- they live in an area that has bad cell phone service. You can only get it through the Internet and half the time Internet doesn't work.

So, we went to the hospital and we were asking about just an update. And we waited for some time. I didn't know if that was standard procedure or not. I'm sure COVID and this pandemic is kind of a big deal. So, that was understandable. We spoke to a nurse. I believe her name was Stephanie. She was very kind. African-American woman. And we asked to speak to David Murphy the chaplain. And he was not available at the time. The reason we wanted to speak with him is because we wanted an ethics consult. We had been talking with the family.

And David wasn't there at the time and Gary Balrain -- I can't remember his last name. But --

Q Balmain [ph]?

A Balmain. Thank you.

He was there, and we spoke in his private office and expressed our concerns. He was a very generous man, prayed with us; but he said that he would try to put us in contact with David Murray -- Murphy.

Q Murphy. And this was to express your family's desires for treatment --

A Absolutely. So, we expressed this to Gary; and he listened. We didn't know if we were following the right path so we wanted to start -- we hadn't had any counsel about patient advocate or patient relations. We had no idea there was such a thing. No one had told us anything about that. And believe me, I've scoured the website looking for different avenues to speak to someone. And just looked like the logical thing to do to speak to a chaplain.

So, we expressed our concerns that my mother was not getting the treatment that we would -- we were asking for. We weren't demanding anything. There was no -- no one got out of turn. It was a pleasant conversation despite the circumstances. And --

So, we finished that and then we waited in the lobby for an update on my mother. And in that time David Murphy, after he got out from whatever he was doing -- and we were standing in the hallway and we had a brief moment with him and we were talking with him; expressing the same things to him and that's when one of the nurses walked up and our conversation was

cut short. And though he had -- he gave us an ear to our concerns I don't believe we had the time to really address what was going on. What was more important at that moment was to find out how my mom was doing.

Q So, did you feel there was collaboration?

A Being somewhat ignorant to the whole process of ethics consultation, patient advocacy -- he said at the end of that, "Thank you. I'll have some meetings and get back to you."

Q Were you ever invited to any meetings?

A No.

Q Are you aware of any of your family members being invited to any meetings?

A No.

Q I want to switch gears just a little bit. Tell me about your interactions with staff specifically when your mom was on the COVID unit.

A The main information that we -- our first interaction was with a nurse named Ilda, I-l-d-a. I don't remember her last name. Our first request -- we waited 30 minutes to get a status update on my mother while she was in the COVID unit. And she came out and very -- I understand if you're not on a list, you can't get information. I understand that. So she didn't know who we were. But we told her who we were. And I said, "I'd like to get an update on my mother." And she said, "What specifically do you want to know?" I thought that was kind of cold given the

situation. But, again, I understand. After I told her who I was that -- give me a little compassion.

She left and came back about 30 minutes later -- 30, 40 minutes later and she gave us a rundown of her status and she gave us SPO2 readings and blood pressure and things like that. Just the facts. We had brought her a gift from the grandkids, they had signed a card; and we wanted to give that to her. And she was able to tell us that she could -- she was on the bipap unit at this time, she was not intubated on the ventilator. And the nurse said that she was able to acknowledge it -- she smiled with her eyes. She said she could do it.

At the end of that conversation it sounded like just a -- kind of a positive update. She switched the conversation to something to the effect of, "I hate to ask you this right now; but did your mother have any end-of-life wishes?" And I was taken aback by that.

Q How did that make you feel?

A It got icky really quick. It was inappropriate. Very inappropriate. And my -- my wife was right beside me; and I said, "I can't answer that." And she pushed. And she said, "No, I understand; but if she was standing here right now, what do you think she would say? Would she like to be hooked up to all these tubes --" her words. Not mine.

Q To get the timeline correct this was before she was ventilated; correct?

A Yes, it was.

Q And are you on a list -- are you on the power of attorney or any authorized party list --

A No.

Q -- for the family?

Are you aware of any meaningful discussions that any member of your family has had with Dr. Light or any other person in a position of patient advocacy?

A Not to my knowledge.

MS. UBALLE: Pass the witness.

CROSS-EXAMINATION

BY MS. ATWOOD

Q Mr. Carroll, I know you've been in the courtroom today; but I haven't had the opportunity to meet you. I do want to express to you my sincere feelings and hopes that your family is able to bond together during this time and have comfort in each other.

A If she was alive it would be a lot better, a lot easier.

Q Is your mom's sister's name Linda?

A Yes.

Q And are you aware of whether your mother designated her sister Linda to be her alternate power of attorney?

A No, I was not aware of that.

MS. ATWOOD: I have nothing further.

REDIRECT EXAMINATION

BY MS. UBALLE

Q Just a couple of follow-up questions.

Your family espouses Christian values; is that correct?

A That is correct.

Q Tell me about your belief in miracles.

A Scripture calls our Lord and savior the great physician who is capable of doing -- He raised Lazarus from the dead, He healed and his apostles healed and he's a healing God. And He has the power to do that. God does -- puts us in situations like this for our good and his glory.

We believe that through the power of prayer and good medication and trying everything -- that we're in God's will to try everything to honor my mom's legacy of Carrolls don't quit.

Q Thank you.

MS. UBALLE: Thank you, Your Honor.

THE COURT: Anything further?

All right, sir. You can step down.

MS. UBALLE: I have no further witnesses at this time.

THE COURT: Ms. Atwood, you ready to call your first witness?

MS. ATWOOD: I am, Your Honor.

THE COURT: Who will that be?

MS. ATWOOD: Dr. Seth Sullivan.

SETH SULLIVAN

having been previously sworn, testified as follows:

DIRECT EXAMINATION

BY MS. ATWOOD

Q Dr. Sullivan, could you introduce yourself to the Court and the folks who are here?

A My name is Seth Jerrod Sullivan. I'm an infectious disease physician by training. Went to medical school University of Missouri - Kansas City. Was on a Navy scholarship during that time. Served as a Navy flight surgeon for four years. Finished out my time in the Navy before going to the Mayo Clinic to finish my training.

Moved down here in 2011 with my wife and kids to start as a hospitalist/infectious disease doctor. So I worked in both capacities and been employed at Baylor Scott & White since 2013. I also work as the Brazos County Health Authority in the current capacity.

Q What -- in your role as Brazos County Health Authority what falls under that umbrella as it relates to COVID?

A All things COVID. I mean, anything that would impact public good really is our mission. And so a lot of this is communication, frankly. And communicating what is -- you know, what -- what guidance is out there. It's very confusing. And so

our role is to sift through that best that we can and to communicate that as clearly as we can. And we are also data monitoring continually. We do case investigations which involve patients who are positive, identifying those cases; and then ensuring they have the right guidance with what to do thereafter. And then, of course, you know a lot of coordination, collaboration, schools -- Texas A&M -- hospitals, clinics, nursing homes. So all that collaboration is involved as well.

Q Throughout this time when you've been serving as the county health official have you continued to be involved in caring for patients?

A Yes, ma'am.

Q Okay. Give us just a brief rundown on what is your role and involvement in caring for patients. And specifically if you will direct the bulk of your comments toward your role caring for COVID-positive patients.

A Well, as an infectious disease physician we are essentially consultants. And so attending physicians will consult us in the hospital. We also get outpatient consultations as well, patients we'll see in the clinic. These are typically directed questions. For example, "This patient is having a fever and we're not sure why, could you help us with the evaluation and management of this patient"; and our role is to provide guidance and value to the patient.

And we -- as directly your question about COVID:

So that would fall within the purview. We give consultations around COVID. We get a the lot of -- it's been hard, frankly, to keep up with all of our COVID patients -- to see all of them. And so a lot of what we do is consultation over the phone as well. We cover a hospital in Brenham as well. And so we get a lot of calls from Brenham. And, of course, just help patient questions that come as well -- from physicians in the community asking for guidance.

Q So, are you seeing patients in the hospital and patients who are hospitalized with COVID?

A Oh, yes. Yeah.

Q Are you seeing patients regularly in the ICU setting who are battling COVID?

A Unfortunately, yes.

Q In your role as an infectious disease physician and a treater in the hospital and clinic and community settings and in your role as the county health official do you -- or what effort do you make to stay abreast of the publications and the literature related to COVID treatment?

A Constant effort.

Q Do you feel that you have a good understanding and good working knowledge of the COVID literature that's out there?

A I do. I will qualify that to say that there is a lot of information that comes. And so I do my best in collaboration with other physicians as well to discern what is out there and to

sift through it. It's lots of information. It's a constant effort and duty.

Q Before Ms. Carroll was a patient at the --

Well, let me ask: Have you been her treating physician?

A No, ma'am, I have not.

Q Okay. There was another gentleman in the court today. Do you know who that is?

A Yes, I do.

Q Okay. And can you tell the Court who that is?

A That is Dr. Kevin Dixon.

Q Do you know if Dr. Dixon has been a treating physician for Ms. Carroll --

A Yes, ma'am.

Q -- in the hospital?

A He has been.

Q All right. Prior to the time that Ms. Carroll was hospitalized -- even before that -- were you aware of and following literature and publications that spoke to any of the things that are on this recommended treatment protocol from Dr. Edwards?

A Yes, ma'am.

Q Dr. Sullivan, can you take a look -- Dr. Sullivan, I'm going to hand you here what has been marked as Exhibit 6. Can you tell us what that is?

A This is my CV, curriculum vitae.

Q Is that what some of us might call a resume?

A Yes, ma'am.

Q This is your resume reflecting your education, background, professional accomplishments, papers, things like that?

A Yes, ma'am. Dated as of 14 July.

Q Okay.

MS. ATWOOD: At this time we'd offer into evidence Defendant's Exhibit 6.

MS. UBALLE: No objections.

THE COURT: Defendant's Exhibit 6 will be admitted.

Q (By Ms. Atwood) And, Dr. Sullivan, I don't think I asked you about this when you told us that you were working as an infectious disease physician; but are you board certified in infectious disease?

A Yes, ma'am.

Q And what's involved generally in getting that board certification, being able to hold yourself out as an infectious disease physician?

A Well, to be board certified first you need to be board eligible; and to be board eligible means that you continue -- or you complete, rather, a training program under supervision essentially of treating infectious disease patients. And so this

is a minimum of a two-year program; and these are at institutions that have, if you will, programs that have in place physicians who are teaching as well often as fellows and other residents who you are learning from. It's a learning environment. I mean, as I mentioned, was at the Mayo Clinic.

Once you finish that training -- that time -- then you sit for a test which is the certification process. And so that board certification test is a -- once that's completed, then there is also a renewal process. And so there's a test that I take every two years to remain current as a board certified physician. These tests involve what would be expected for all infectious disease physicians to know.

Q Okay. And do you -- I see on your CV or your resume here that in addition to M.D., medical doctor, after your name you also have the initials MPH. What does that stand for?

A That's a master in public health. So, that's a master's program that I completed when I was in the military.

Q And as a part of that program did you do additional study in epidemiology?

A Yes, ma'am.

Q Okay. And tell us what is epidemiology?

A Epidemiology broadly characterized would be that it's a -- it's really trying to understand what happens in populations. And it involves studies -- it involves the design of studies. We make observations all the time, question really

is that observation -- is it something that is significant, is it something that matters, is it something that we either through a public health intervention or through an individual intervention as a physician will make a meaningful impact with the patient.

So, epidemiology is a discipline to try to get to the heart of the truths.

Q So, is it -- this may not be quite right, but I guess in my mind I have the thought that the study of epidemiology is sort of a field that -- does that let you understand how to evaluate scientific studies and how to set up reliable and useful scientific studies?

A Yeah. That was part of my motivation in getting this masters was I wanted a deeper understanding of studies. There's a lot of information out there, and I wanted to better understand how those studies were designed and to really follow my calling of helping people. And so really at the end of the day it was a discipline to understand that -- the study -- what we call the methodology of these studies -- so the methods that these are set up.

It's important the studies are designed appropriately because there are things we don't know that are happening, and we can't -- we can't control for those things. And so we have to do our best to set up studies that don't have bias that don't throw us off. There's a million and one examples of us getting thrown off in medicine; and when we get thrown off,

grave damage can occur. And so we need to stick to truth. And it's a hard thing to do, but it requires a thoughtful analysis and a deep analysis of studies to do our very best to get the truth.

Q We heard earlier today -- and you've been in the courtroom throughout this hearing -- that there was a, quote, mountain of evidence in support of utilizing ivermectin in these doses and this type of treatment protocol. Do you agree with that?

A I do not.

Q Do you believe there's a mountain of evidence supporting that?

A I do not agree with that.

Q Can you explain to the Court why is that?

A The studies that have been done -- and there are many studies that have been done -- and the challenge -- I'll take one step back.

The challenge is that as we -- we've entered a new world; and this world allows us to, if you will, publish information that has not been vetted. And so we get a lot of studies that get thrown out that will later often be redacted or once they start getting -- going through a peer-review process, and those who understand methodologies of these and ask questions -- very basic questions about, "Why did you design it this way? What about these questions? Why did you --" because

we're always trying to discern what happens with chance, what happens because of cause and effect.

And so the studies for ivermectin have been well-outlined and well-flagged. There are some that do show, as we mentioned, signals of benefit; the majority show no benefit. There's been varying doses used. When we talk about the use of ivermectin, we have to be clear about what we're doing to a patient. Ivermectin is a medication that is an anthelmin -- means it's used for worming. Common in veterinarian applications. In humans we use it for something called strongyloidiasis which we don't see a lot of in the United States and onchoreciasis which we don't see a lot of in the United States, but there are some uses for ivermectin that are FDA approved. The FDA approval process requires that medications not only are effective but they're safe, and it's a very important process. Both have to be there.

Q And when you say the FDA has looked at whether medications are effective and whether they're safe, are they looking at whether they're safe at the dosages being recommended by the manufacturer, being studied by the FDA?

A This is the importance of a study. A well-designed study will ahead of time say, "This is the dose we're going to use and this is the placebo we're going to use." The placebo looks like the medication. And ideally those treating don't know. We call it double blind: The patients don't know and the

treating physicians don't know. And we allow whatever standard of care there is for ethical reasons. And then at the end what we do is we discern -- we unblind and say, "Who did well? Who did not."

And that is the best-designed study. But that is a predefined dosage. There are times where we'll do multiple arms in a study -- do higher doses, intermediate doses, and lower doses when there are -- and some of the ivermectin -- have been small studies that have tried to do that as well. Looking at varying end points.

Q So, there was discussion earlier in the day about a meta-analysis for -- first, a meta-analysis of studies related to ivermectin. Can you tell us what is a meta-analysis?

A So, meta-analysis comes from the term met as an aggregate -- aggregate analysis. And the idea is that it's taking -- it's pooling studies together. And so where we have smaller studies, the hope is that if we can grab all of these studies together and pool them together, that we can make meaningful conclusions.

Meta-analyses are a tool for sure, but they have -- they have limitations. Limitations are -- as we've mentioned the methodologies of studies, how important those are. But when you have a bunch of different methodologies and try to pool them all into one, you can get some misleading conclusions.

Another very important part about meta-analyses is

they're -- you know, one study can make a very big difference, and meta-analysis -- there's two meta-analysis -- one showed no benefit the other showed a mortality method. It's very important that we talk about the latter because I think it's confusing. The only two studies -- two very small studies -- one was from Egypt, one was for from Iran -- neither were peer reviewed.

Q Let me stop you there. Why is it significant to you -- or is it significant that those -- the only two studies that showed potential benefit were not peer reviewed? Is that significant?

A Well, because there's so many questions; and some of these questions, for example, are why were your patients so much different than everyone else's? Why were -- for example, one of the key things is a small majority of these patients were PCR positive. You know, that -- 95 percent of -- by PCR, I mean the nasal swab. By the time you're seeing a sick patient, all of these patients should be positive. So the first limitation a reviewer would have in a peer-review process is why are so many your patients negative on testing? That doesn't make sense.

And so we'd say let's back up and let's see. It doesn't mean that there's not truth here. I mean, we need to vet this. This is critical. You know, we don't discard it out of hand; but we say why is this? Very smallest study -- both of these were small studies; and one of them as we've mentioned has been redacted. And I'm assuming -- I don't know all the reasons

it was redacted other than I know it wasn't a well-designed study; but I'm sure those have to do with the peer-review process. But what's important is it was just these to. If you take those two out there's no mortality benefit which is consistent with larger studies that have been done.

(Simultaneous speaking)

Q Are you familiar with meta-analyses that have been done for ivermectin that do not show a benefit?

A Yeah. There was one previously done that was -- did not show benefit. Again, all meta-analyses, though, are subject to these limitations; and what I mean by that is that all treating physicians are skeptical of meta-analysis. Let's just be clear: All epidemiologists are skeptical of meta-analysis. What I really want to know about and what treating physicians want to know about and what epidemiologists want to know about where are the good studies? And a good example of that, if I may -- I don't want to get too far out.

Q Let me be sure I'm asking you a question: Are there any, in your opinion, as an infectious disease physician and epidemiologist -- are there any well-designed studies that demonstrate a true benefit to using ivermectin in the type of dosing that's been recommended for Ms. Carroll?

A Do not exist. Does not exist. And some of the studies -- we should also clear about different patient populations. And so our well-intentioned physicians who are

trying to help folks -- I mean, we have to -- we have to also decide who are we working on right now, who are we trying to help? A patient who just got diagnosed with COVID is very different from a patient who is in the ICU on a ventilator. Okay? So there's -- and there's an outpatient and there's an inpatient and these are different patients. They're frankly just different. They're different patient populations. As we mentioned, epidemiologists are looking at populations. We have to do our best to put a population into one group because if we're treating different populations, we're going to get different results.

Q So, let's talk about the population that you would put Ms. Carroll in. Would that be the population of patients who have severe COVID disease?

A Yes, ma'am. Severe COVID disease.

Q Are there any studies that demonstrate a beneficial effect of ivermectin for severely ill patients like the patient population that Ms. Carroll is in?

A There are no studies that I would ever, ever treat upon -- I think -- take one step back on something called biologic plausibility. This is an important consent. Biologic plausibility is do we think -- do we have a reason to think that this would be helpful? Why would an anthelmin help with a viral, you know, process?

Q Is that, sort of in laymen's term, can we theoretically

connect the dots?

A Yes. From all we know --

(Simultaneous speaking)

A From all that we know to this point sitting here today -- the vast data that's aware -- that's available to us. Does that make sense? It's very important. Because we can come up with study after study after study if we don't want to make sense of it. So we have to be appropriate with our resources and say, "Does this make sense?"

So, need to take a step back on the ivermectin story. The idea here is ivermectin has shown beneficial invitro. That means that we take cells, we grow cells, and we infect those cells with a virus -- and this has been multiple viruses. We've done this with Dengue, as an example. It's a mosquito-born virus. In this case Coronavirus causes COVID. The virus does not replicate well and there are --

Q Is this like in a Petri dish?

A Yes, ma'am. That would be a good way of saying it, a Petri.

So, we don't see the same viral application when there are high levels of ivermectin around. These are not biologically achievable in the human body.

Q Let me stop there. So, is what you're saying that some people would posit that it's biologically possible or plausible that ivermectin could diminish COVID, you know, or help treat

COVID because in a Petri dish at very high concentrations the COVID virus doesn't replicate as fast?

A Yes, ma'am.

Q Okay.

A And that would be --

(Simultaneous speaking)

Q What do you mean by the piece of it -- you said at the end was we couldn't attain bio something. What was that?

A Yeah. And I apologize. So, what we're talking about here is something called bioavailability. So, whenever we take a medicine and we absorb it, it gets -- swallow it, goes through out intestines, goes through our body. It needs to get to concentrations that are effective wherever the virus is. Unfortunately with COVID virus it's everywhere. So, the lung, for example; right? So the lung has cells in which the virus is replicating. That viral replicating phase is in the outpatient phase. That's where it's happening. When we get to a point that our lungs are full of inflammatory tissue, the viral replication phase is no longer the issue. It's an inflammatory insult.

Q The aftershocks?

A The aftershocks, yeah. And this is not a time when ivermectin even would have biologic plausibility. What's effective at this point is attenuating the best that we can the exuberant inflammatory process here. And this is why steroids and the medicine tislelizumab that we mentioned -- that's its

role. And --

Q Has Ms. Carroll been on all of the things and the treatment protocols that would be expected to provide benefit for the stage of the disease that she's at?

A Yes, ma'am. So, when she hits the, you know -- when a patient comes into the hospital -- at that point we're getting beyond the viral replicating phase. At this point we're getting into the immune immediate phase. And at this point -- this is -- what we're trying to do is, for lack of a better term, ride the storm out; and the storm is what we call cytokine storm. And the cytokines are proteins that our body disseminates throughout the body saying there is a problem and our body responds. And unfortunately that response sometimes can be worse than the virus itself.

Q Is there any study that would suggest that ivermectin is effective at treating the cytokine storm?

A No, there is not. There are some who would say is it possible that it could have some immune modulating effects -- and we'll see this often. But what we mean by immune modulating is we have to remember that the immune system is enormously complex. We are -- think about the galaxies and we have a couple of stars that's great. There's so much more beyond that. And we're learning about new proteins and pathways that will forever go on. We're mapping ourselves through this. But when we talk about immune modulation what we're saying is, well, what if we affect

this protein that affects this protein that affects this protein. You can imagine how it becomes --

Q That's the connect the dots thing?

A Connecting the dots. And that's immune modulation.

What's most effective, though, is shutting it down which essentially is what steroids and other medicines that are more potent can do.

Q And are you familiar with any of the national or international organizations that have looked at some of these medications that are on the recommended treatment protocol? Do you need to see it to see what's on there?

A Yes, ma'am. I've seen the protocol; and to answer your question, yes, multiple organizations have looked at many of these. I don't know that every one of them has been reviewed.

Q Are you familiar then with the World Health Organization?

A Yes, ma'am.

Q We want World Health Organization for dummies here. What is --

(Simultaneous speaking)

A I would say CDC for the world is the way that I would say it.

Q Okay. Has the World Health Organization evaluated ivermectin in the treatment of COVID patients?

A Yes, ma'am. They viewed the studies that are

available.

Q The same studies you were talking about earlier?

A Yes, ma'am. And I should also say that when I'm talking about they, I'm talking about expert panels. And so what the WHO will do is they will hire -- and it depends on the particular problem, and sometimes it's 20 or 30 or 40 scientists from different disciplines including eplicalthal [ph] epidemiology infectious disease, critical care, hospital medicine -- who review these as a committee.

Q And the folks that the World Health Organization would put together on their panel, are they considered renowned experts in their field?

A Yes, ma'am.

Q Widely respected?

A It is an honor to be asked.

Q All right. Can you tell us what this is?

A This is World Health Organization advising that ivermectin can only be used to treat COVID-19 within clinical trials. March 21st, 2021.

MS. ATWOOD: At this time, Your Honor, we offer Defendant's Exhibit No. 2 into evidence. I've provided copies to counsel.

MS. UBALLE: No objection.

THE COURT: Defense Exhibit 2 will be admitted.

Q (By Ms. Atwood) Can you read for the Court what the

recommendation is of the World Health Organization with respect to ivermectin?

A Yes, ma'am. "The current evidence on the use of ivermectin to treat COVID-19 patients is inconclusive. Until more data is available WHO recommends that the drug only be used within clinical trials.

"This recommendation, which applies to patients with COVID-19 of any disease severity, is now [a] part of WHO's guidelines on COVID-19 treatments."

So I should mention the guidelines are then -- from these types of studies, these committees do their best to provide frontline clinicians such as myself opportunities to think through this and to give us guidance.

Q And you said this -- this guidance was published just in the last several months in March of this year?

A Yeah. This statement is from March 31st.

Q Okay. And are you familiar with the National Institute of Health?

A Yes, ma'am.

Q Are they also putting out guidelines for treatments using various medications?

A Yes, they are.

Q And have they included treatment recommendations for use of ivermectin?

A They have. They have commented.

Q And show you Exhibit 4. Is that a printout of the publication from the National Institute of Health related to the recommendations on ivermectin?

A Yes, ma'am.

Q Okay. And --

MS. ATWOOD: At this point, Your Honor, offer Defendant's Exhibit 4 into evidence; also ask that the Court take judicial notice of the governmental publication.

MS. UBALLE: No objections, Your Honor.

THE COURT: Defendant's Exhibit 4 will be admitted.

Q (By Ms. Atwood) Can you tell the Court what's the recommendation currently for the -- from the NIH for use of ivermectin? Is it recommended by them?

A Ivermectin is -- their recommendation is that there's insufficient data for COVID-19 treatment guidelines panels -- they're the same panel that we referred to earlier, the scientists -- to recommend either the use of ivermectin for treatment of COVID-19.

Q Has the -- have any of these sort of national organizations -- NIH -- also looked at colchicine. Colchicine is one of the recommended treatment protocol from Dr. Edwards. You saw that?

A Yes, ma'am.

Q Hand you Defendant's Exhibit 3. Can you tell us if

that's the FDA's recommendation with result to colchicine?

A I didn't particularly -- this panel recommended against the use of colchicine for the treatment of hospitalized patients with COVID-19. They qualified this as an AI recommendation. An AI recommendation -- A --

Q Let me stop you --

MS. ATWOOD: At this time, Your Honor, we would offer into evidence Defense Exhibit 3, the NIH recommendation against use of colchicine.

MS. UBALLE: No objection.

THE COURT: Defendant's Exhibit 3 will be admitted.

Q (By Ms. Atwood) You mentioned that had the recommendation of the FDA is specifically not to use colchicine?

A Yes, ma'am.

Q Right? And you said, I believe, that it was based on Level AI evidence?

A Yeah. So it's an AI recommendation.

Q What does mean?

A The A is the strength of the recommendation, A stronger than B stronger than C. The level of evidence is the roman numeral that follows I, II, III; and that is strength of evidence So an AI recommendation is as strong as a recommendation can be made.

Q And how do they know if it gets to be a strong AI

recommendation versus a II, 1 or II-III?

A When we talk about -- when we talk about studies, we talk about an analysis that's not a great study; right? It's a bunch of little studies. Meta-analysis is the best -- would be randomized-controlled trials.

Randomized-controlled trials, as we mentioned earlier, we have a patient who's taking a medicine -- a patient taking a placebo that looks just like it; the treating physician and the patient do not know; and they are -- completely randomized at baseline.

Q So is that the kind of study you would describe as a well-designed study? Or a reliable study?

A It is the most convincing data we have.

Q Okay. And if there is the most convincing data because of a well-designed study that's this randomized blind trial that you're talking about, is that the kind of study that results in the AI level of recommendation?

A Yeah. It is either a study like that or there are an aggregate of studies that are very compelling, might be the way of saying it. But it does require a high level of evidence, and that is the best level of evidence; and in this case that's what they're referring to.

Q And so to be clear: The colchicine which has been recommended by Dr. Edwards, is that the same medication that the NIH, based on this level AI study, is saying, "We don't recommend

it. Don't use that"?

A Yes, ma'am.

Q Can you just tell us why? I mean we're hearing all these names of these drugs, but why not use colchicine? What's the problem?

A Well, any of these medications -- you know, we have to remember that just because it's a medication that's used often in ambulatory patients -- patients that are -- you know, by the way colchicine I should clarify is a medication used for gout. And treatment of gout, prevention attacks. So the way that it works is that it decreases neutrophil aggregations. Neutrophils are types of immune cells. They come and they cause a lot of pain or there's a lot of inflammation -- classically in the big toe. So what colchicine does is it attenuates that.

Q Makes it go away?

A Yes, ma'am. Yeah.

And so in this case the biologic plausibility for colchicine would be not that it's going to do anything to the virus but is it possible that has some type of effect on the immune system. And so, you know, that's -- that would be the idea. But colchicine also causes side effects. And -- especially if we're talking about high closes, we're talking about using it frequently we have to be concerned about GI side effects. We always have GI, gastrointestinal -- vomiting, diarrhea. We always have to be careful with drug interactions

especially when we were physiologically unstable.

So, in a critical setting we're doing our very best to hold on with respect to our heart condition, our lung condition, our liver condition -- all of which are tenuously doing their very best. And so when we have drug interactions, these medicines increase the levels of some, decrease the levels of others; and it can become very confusing to the body and to those treating to know what is what.

Q So, with respect to the colchicine recommended by Dr. Edwards is it the -- is it your understanding that it's the recommendation of this expert FDA panel that that would not be an appropriate medication to give to a severely-ill person?

A Yes, ma'am. So, not helpful; potentially harmful.

Q Okay. And finally you talked to me about some guidelines that were put out by the international -- excuse me. The Infectious Disease Society of America. Can you tell the Court: What is the Infectious Disease Society of America?

A Yes, ma'am. So the Infectious Disease Society of America is a professional organization comprised of infectious disease clinicians, infectious disease pharmacists, epidemiologists, public health professionals; and the purpose of the society really is to disseminate best practices. There is an annual conference that is the best conference because of the collaboration of infectious disease physicians who -- and as I mentioned the pharmacists, epidemiologists -- come together to

learn from one another about best practices. And the society has multiple modules with respect to continuing education and learning. And so it's -- it's -- it's where we -- it's where we learn from each other, be a way of saying it.

Q It's well-respected professional organization?

A Yes, ma'am. Very.

Q Can you think of any other infectious disease professional organization that is more highly regarded?

A Not in the United States.

Q All right. So, let me show you then what's been marked as Exhibit 5 here. And can you tell us -- just identify for us: Is that a copy of the Infectious Disease Society of America's guidelines for treatment of COVID?

A Yes, ma'am, it is.

MS. ATWOOD: At this time we offer into evidence Defendant's Exhibit 5.

MS. UBALLE: No objections, Your Honor.

Q (By Ms. Atwood) And what recommendation does the Infections Disease Society of America make --

THE COURT: Let me admit it.

Defense Exhibit 5 will be admitted.

A Their recommendation as of May 28th was that the IDSA panel suggests against ivermectin use outside of clinical trials. They outline that although it has in vitro -- that's the fancy term for cell cultures -- against some viruses including SARS

CoV-2 -- that's the virus that causes COVID-19 -- has no proven therapeutic utility. In vitro activity against cell culture against SARS CoV-2 requires concentrations considerably higher than those achieved in human plasma and lung tissue to reach in vitro -- that's getting back to what we were talking about earlier, the likelihood of being able to achieve what we see in cell culture in the lungs would require astronomical doses of ivermectin that would be potentially very harmful.

In doses typically used -- and this is something they outline. Use for the treatment of parasitic infections ivermectin is well-tolerated.

We should mention that the way that ivermectin works is it paralyzes worms, and it only takes a dose to do that. Sometimes need to repeat the dose. But we --

Q Are you saying it only takes one dose?

A One dose. Sometimes we give another dose to make sure all the worms are gone.

We are unable to exclude the potential for adverse events in hospitalized and severe adverse events in non-hospitalized persons with COVID-19 treated with ivermectin rather than no ivermectin.

So what they're getting at here is that, you know, hospitalized patients are sick and sick patients -- their organs are doing their very best they can to hold on, their lungs are doing the best they can to hold on; and this is a time we don't

want to upset whatever that chance is of them pulling through and concern for harm.

Q The dosages recommended there by Dr. Edwards, it looks like -- I believe it's for ten days. Do you have an opinion whether that would increase the risk of harmful side effects from the ivermectin?

A Well, that's a high dose; and it's for multiple days. And -- but the -- I think the crux of it is that it's unknown. It's unknown to what degree that would cause -- especially in this patient's case -- in any patient's case who's critically ill. It has not been studied. And when we -- when we doubt the benefit to put a patient at further risk is a grave concern always.

Q And from that point -- I actually want to step back. I mean, I -- we've heard Ms. Uballe say on behalf of the family and the family in a compelling way say, "Look. She's in a dire situation. Why don't we just try some of this?" And as a medical provider can you help us answer: Is there a reason medically that we wouldn't just try it under these circumstances; and if so, what is that?

A Yeah. I get this question a lot from patients. And they're good questions. And, you know, we're talking about survivals that are not good. You know, let's just say it's 10 percent; let's say it's 20 percent. It's not good. That's the best we got. And so what we need to do is stick with what we

got. We have to give the best that we know; and when we are in a situation where we are experimenting, we get into the unknown very quickly. And we need her at her best, we need her organs at her best; and we cannot experiment in those situations.

Now, one of the things that all these guidelines call for I notice is that where there is uncertainty -- by the way, I think it was Dr. Edwards -- sorry if I was wrong -- but mentioned the steroids issue. That there was a time when there was a recommendation for or against steroids. And that is standard of care now. We give steroids to every patient. The reason why is we've had good data since then. So the point is now we know there's benefit. We know there's harms with steroids as well. But there is a reason to use the steroids.

And so when we are in a situation where we have no biologic plausibility of benefit, no demonstrated study of benefit, all that we can do is harm in that case. And that is our most solemn duty to the patient is to first do no harm with our doing our very best to help her survive.

MS. ATWOOD: Pass the witness, Your Honor.

CROSS-EXAMINATION

BY MS. UBALLE

Q Good afternoon, Dr. Sullivan.

A Good afternoon.

Q Thank you for being here.

A Absolutely.

Q Just have a few follow-up questions.

You are mentioning -- would you acknowledge that ivermectin has been successful in treating COVID?

A I would not acknowledge it.

Q There's --

A -- I don't know it to be true.

Q You don't know of a single patient who has taken ivermectin and recovered from COVID?

A I know that people recover from COVID all the time. And I don't know if they do that on their own or if they do that because somebody gave them ivermectin and that's why you need studies to know the difference.

Q So even anecdotally you are not aware of doctors giving ivermectin and having that be successful?

A I know of anecdotes that we've heard today and anecdotes elsewhere where folks will give ivermectin and swear that it worked for the patient.

We have to remember: Not all patients get sick with COVID, and that's the challenge here. We also need to do a better job of knowing who is going to get sick and who is not, and that's part of data that we need to get. And then you can know who you need to be treating.

But if we just give everybody who we see who walks into a clinic who is healthy and we give them all ivermectin, the likelihood of them getting sick enough to require ICU and to

require severe -- have severe consequences of COVID that would require intubation and all the terrible things we're talking about today -- you know, the likelihood of that is low.

And so, you know, that's why you have to do these studies. You have to know is there help here, is there benefit here; and until that these are what we call anecdotes and these are stories. And stories are important, by the way. Stories are important. And they can help us understand this better which is why our guidelines call for the use of this within trials. And trials are monitored and -- they're monitored for safety and they are -- there's an understanding, by the way, of anybody entering into a trial that there could be bad things happen here. And if you are aware of those risks and you will be subject to this monitoring, then we can proceed. But that is a critical part of every research study that's done.

Q You speak a lot of research studies -- and I don't discount their authority. But is that the only thing that doctors rely on, is studies?

A No, of course not. We rely on our training, we rely on our education, we rely on our experience, we rely on patients, and we very much rely on patient's values and -- so we -- you know, those three things that were outlined before of -- really was that experience, evidence, and patient's value are critical, critical pieces; and there is not one excluding the other. We don't do that in medicine. We treat humans. So we are very

interested in how the human is fairing -- human wants. Does the human want the surgery, doesn't want the surgery. Those are values. But when we are asked to do something that we think is not going to help but could potentially cause harm, that is a tough position to be put in.

Q So what is -- what is the ultimate harm?

A Well, the ultimate harm is -- you know, I guess you could argue -- you could look at that several ways. I mean, probably asking me to say death. But I think there are some who would say that suffering is worse.

Again, that's a patient value question. If you're asking my patient -- about what is my value, what is worse? I'm not that afraid of death. If you're asking me my values.

Q Do you think -- I'm sorry.

Do you think Mrs. Carroll is not suffering on a ventilator?

A I think that she is. I think that -- I think the family's suffering. I think this is -- frankly, our world is suffering right now. I think this is as bad as it gets, frankly.

Q And she has been given all of the treatments that are recommended by the guidelines; correct?

A She has been given the -- absolutely. She's been given the best that evidence has available to it right now.

Q And --

(Simultaneous speaking)

A -- this guidance.

Q Sorry. And she has not gotten better; correct?

A She is with us.

Q But she --

A No, she's not gotten better. No. And I'm sorry. I think what I'm doing by the way -- this is my first time ever been up here. And apologize if I'm jumping ahead, thinking what you're trying to ask me.

But, no, she's not gotten better to answer your question.

Q You can just answer the question that I'm asking. Yeah.

So, if she's not getting better, these treatments aren't effective; correct?

A Well, you know, anybody who's done this for a while recognizes that things happen. And I believe in miracles as well. And our job is to hold on, our job is to give the best evidence available and give compassion and to be there and to see what happens. I believe in power of prayer as well. And I believe that we give patients our best. That's what we do.

Q And just following up as well: You've -- we've looked at the guidelines or have the guidelines with us. Again, is that -- is that the end all/be all for a doctor to rely on?

A It's a critical thing to rely on, but I don't know if I answer your question --

Q Is it the only thing a doctor --

(Simultaneous speaking)

A No, ma'am, of course not.

Q What else should a doctor rely on?

A A physician should rely on experience, on others -- and by others, I mean that we should collaborate and we should be speaking with other infectious disease physicians -- this is an infectious disease and that training but then also speak with critical care doctors, et cetera. In this particular case that's what we're talking about here. So -- and as mentioned patient values. I think all of these things are critical in coming up with a -- what we'd call a shared decision making model.

Q Let me ask you this: Have these medicines on this list -- have you ever administered those for COVID treatments?

A Yes. So, the steroids -- let me look at the -- Solu Medrol is listed there. Solu Medrol is -- if you will, it's a cousin of dexamethasone; and there are times where if, for example, was a dexamethasone shortage that we would be using Solu Medrol. But dexamethasone is demonstrated superior to Solu Medrol.

Lovenox is a medication that is widely used. It's used at a dose less than this, called a prophylactic dose.

Aspirin is continued in medication -- is a medication in folks who have already been on it before.

Tislelizumab is given to patients who are

worsening -- clinically worsening. Mentioned that cytokine storm before: If we get the sense that they're in the storm and getting worse, that's when tislelizumab has proven effective.

Famotidine is a medication that would -- you know, it's -- is a prophylactic medication -- we call stress ulcer prophylaxis is used to try to prevent gastric ulcers, stomach ulcers.

But on that list that would be -- that would be it.

Q And just to clarify: Even as a -- as a combination -- as a cocktail, as Dr. Grams mentioned, have you administered these drugs as -- in combination with each other for the treatment of COVID?

A To qualify: Are you speaking of COVID in an outpatient sense and hospitalized patients? Where is the patient I'm treating?

Q Hospitalized patient.

A No.

Q Okay. Does a treatment -- a treatment doesn't have to be proven effective to be able to use it; correct?

A Let me make sure I understand your question.

Q Well -- let me ask it another way: What percentage of the time does a doctor prescribe medications off label or in a sense where it's not necessarily tested or proven?

A Well, we give off label medications when we have

confidence that they're going to work; and that is not uncommon. We -- you know, there are -- studies can be done on medications that are not FDA approved; and, you know, that's what I'm assuming you're to by label -- is the FDA label?

Q Correct.

A Yeah.

And so if we have confidence that a medication is going to work for a patient from our experience or from another study that has been done -- again, the things that we've been talking about, what we rely on to make decisions -- then absolutely we would give the medicine.

Q What you just said a doctor's experience -- even if there isn't a study, a doctor's experience can make it okay to prescribe that medicine -- that in his judgment that's okay to prescribe that medicine?

A Yes. I think if there was judgment that a medication would work -- if there was experience that a medication would work but a trial is not available might be what you're asking me?

Q Sure.

A You know, I think that, again, we would have to look at the entire patient here in that situation.

Q But are -- can you acknowledge -- or would you acknowledge that a doctor is -- he's within his, you know, his -- doing his duties if he uses his own clinical judgment?

A Yes.

Q As opposed to a study?

A Yes. For sure.

Q And, you know, if he has -- especially if he has a signal of benefit from such a treatment?

A I think we should qualify one thing -- again, sorry if I'm getting off from you here.

Q Go ahead.

A We have to be clear that we're talking about when there is no evidence to the contrary -- meaning, that there's evidence it does not work.

I'm trying to understand you're question. Are you saying --

Q I'm sorry. If a doctor makes a clinical judgment and he has signal of benefit, he doesn't need to rely on a study?

A Where is the signal of benefit coming from?

Q Experience.

A So, if we were to take it -- make sure I understand your question. If I am confident a medication will work for a patient by gut -- maybe I can just say it this way: You know does that happen? Absolutely. You know, we -- we have to qualify, though, every decision that we make that is not an emotional one and that it, you know, is not going to hurt the patient.

So, I don't know if I'm answering your question -- or if I understand it completely.

Q Yeah. And apologize if my question wasn't well-worded.

Yeah.

MS. UBALLE: I don't think I have any further questions, Your Honor.

REDIRECT EXAMINATION

BY MS. ATWOOD

Q Dr. Sullivan, in your opinion is the recommended treatment protocol that Dr. Edwards put together medically inappropriate for Mrs. Carroll?

A Yes, ma'am.

Q Why?

A I'm worried about harms, and I could outline them here. But -- if you'd like me to. I'm -- I don't know why -- first of all -- so, again, do I think ivermectin is going to be helpful? No, I do not think it's going to be helpful. I think it could potentially be harmful.

Aspirin at 325 milligrams, I don't understand the role of that. She's already on the 81 milligrams.

Lovenox at that high of a dose -- only if I was worried about clotting. Again, we're filing the d-dimer for that reason. That's what we do.

Colchicine -- for me to prescribe colchicine to the patient would be to say that all of these folks are wrong; and they have told me, you know, through this -- and it's not just they telling me. You know, I agree with them. I've

reviewed the same data.

And so Solu Medrol -- she's already gotten dexamethasone. So there's no purpose in giving her another steroid on top of that.

(Simultaneous speaking)

Q -- side effects of giving more steroid?

A Absolutely. Then the concern is that she's critically ill. And so our concern is that she gets other infections -- bloodstream infections, pneumonias, urinary tract infections. And these are deadly.

And so if we are tinkering around with things and lowering her immune system lower than we know is safe, then we risk -- we risk fatal infections.

Tislelizumab, we've already given and so to give another does of that, would be -- wow. This says keep current dosage. Not sure what that means.

The leronlimab -- we would never give that. That is -- is not FDA anything approved. It's a medication that was -- it's old, frankly; and nobody's looking at that.

Vitamin C: Lots and lots of data out there on Vitamin C that it's not helpful. Well-designed studies since then have looked at IV administration of Vitamin C in critically-ill patients. As a matter of fact, there was a time we used to do this. We used to give Vitamin C because there was an observational study that showed that there was some benefit.

And, again, observational studies are we made an observation: It is it true or is it not. You have to do the studies. We did multiple studies -- study after study shows it's not helpful and so we don't do it anymore.

Vitamin D -- again, this is way upstream. What I mean by that was months ago, you know, if our patients are Vitamin D deficient, they need to be Vitamin D replete.

Zinc: There's lots of information out there about Zinc. And, again, in this situation not going to be help.

Quercetin: Never prescribed that, and I'm not sure what that is. I think it's a biopharmaceutical.

Thiamine: That has been looked at, and no benefit.

And then, again, the famotidine: Wouldn't have an issue using if I was worried about, again, stress ulcer prophylaxis; but we have more potent medicines than famotidine and that's always a concern when using steroids we could be providing a setup for gastric ulcers. So...

Q And in a patient that's also on aspirin and Lovenox, both anticoagulants, does that create additional risk of bleeding and death?

A Bleeding. Very high risk, and that's a concern. Again, we mentioned -- you know, we're talking about organs holding on. One of our organs is our clotting cascade, and in sepsis our clotting cascade can go haywire and call that DIC.

And get bleeding and we get clots at the same time. And when that is happening, we really -- for lack of a better term -- lose control. And so that is -- that is a risk as well.

So, we have to be very careful with our clotting system in a critically-ill patient especially.

Q So, in your opinion is the Dr. Edwards' recommended treatment protocol medically unnecessary in addition to being medically inappropriate?

A Yes.

MS. ATWOOD: No further questions.

MS. UBALLE: No further questions.

BY THE COURT

Q Has this patient leveled? Does that make sense to you?

A Leveled?

Q Leveled. Not getting better, not getting worse?

A Yeah. And, again, I've not been involved with her care directly from; but what I understand she has not done well.

Q She's not what?

A Not done well. Wouldn't say plateaued. The family would know better than I would, but I think she's done worse even in the past couple of days from what I've been able to hear. Getting nods so maybe so.

I would say not plateaued. Unfortunately doing worse.

Q And when you talk -- I may have misunderstood. When we

were talking about off label this morning. Is off label to you mean not an FDA-approved drugs?

A Yes, sir. By label -- the label is the FDA, if you will, putting a label on a pill box that says that this has been studied for this indication; and its safety and efficacy have passed the threshold for, you know, safety for --

Q And can a drug be FDA-approved for one purpose and not for another?

A Yes, sir. And that's common.

So, what could happen is -- we see this in antibiotics often. For example, a pharmaceutical company will say, "Hey, here is a new antibiotic and it'll treat urinary tract infections." But we know well it works against these particular bacteria, it's likely it could work against an ear infection as well. It did not -- studies were not set up and purposed for that but we have biological plausibility and we develop experience with it and recognize it works.

Q So, does that not fall under the realm of a Right to Try question? If you've got a FDA-approved drug for one purpose but not for another, that is -- that meets all the other criteria of a Right to Try -- it's passed a Phase 1 study and -- for the treatment of ear infections, so to speak, for the example you used?

A I am not familiar enough with Right to Try. I don't know if I could answer that question.

Q And when you -- you mentioned -- you said that y'all spoken to others. Is that others outside of Scott & White? I mean, do you talk with other professionals outside of the Scott & White family?

A Are you referring to me specifically? Like, what I do or talking about in --

(Simultaneous speaking)

Q Well, I think it was kind of thrown out there generally, that you -- in questions from the family's attorney about what you make your decisions on. And you said studies, experience, speaking with others.

A Who we learn from.

Q Would that include, like, going to a continuing education thing and talking to some doctor there that's associated with Memorial Hermann or somebody else?

A Yes, sir. Yeah. So -- and I think if I remember right we were talking about the idea, say, Infectious Disease Society of America and its conferences and --

Q So, in situations like this do you talk with other people that are not involved with Scott & White and say, "Look. We got a problem here"? What --

A Yeah, we commonly -- we'll talk with -- you know, we all have friends, for example, from medical school. You know, we have people that are in our social network as well, you know, constantly talking with. You know, so each one of us is

different obviously. I can for myself what I do but -- but I do that, I speak with other doctors; speak with other infectious disease doctors, other doctors of...

Q So, whenever you're talking about examination of a drug to possibly use in treatment of a patient, you kept talking about a signal of benefit; that you evaluate the drug based on whether you've got studies that give you a signal of benefit. And I think when you were talking about -- and I can't pronounce these drugs. Colchicine.

A Colchicine. Yes.

Q Colchicine. You said the evaluation on it was not helpful, potentially harmful. If you get a study that says not helpful, not harmful do you eliminate it as part of your potential -- hate to use the word experiment or drug treatment on a patient, if you've got some information that it could be helpful?

A When you -- when you have studies that show -- and I hope I'm answering your question here. But if you have studies that show no benefit, then you don't give the medicine because all that could happen is harm. There is no benefit.

Q So, you don't get a, likewise, suggestion of not harmful?

A Not harmful is harder to prove.

Q Okay.

A And as we're seeing -- for example, you know, with

vaccines, for example; right? We have studies that are set up and they do their best to show safety; but then after the vaccine has been out and out and out, we pick up other safety issues.

Q So, if you've got a response that says not beneficial, inconclusive otherwise then you're not going to touch it?

A That's a danger zone for sure, yeah. And -- I guess make sure I understand your question: Not helpful and --

Q Not beneficial, inconclusive as to harmful.

A If it's not helpful, I would not want to give that to a patient for a concern that all I'm going to be doing is causing harm.

Q So, what's it take for a hospital to get out of its comfort zone -- talking about treatment of somebody?

A Well, Your Honor, I'd say we're out of our comfort zone for a year and a half. And, you know, we -- we all struggle with this. We struggle together. And it is -- it's a challenging time for sure.

But, you know, go back to the hydroxychloroquine question. That's a good example of a time where we struggle. And there were reports out there that this was beneficial and so studies were done and, of course, those studies show it was not. But it took time to get that data. And so now the medical community feels comfortable with that. But there was a time we were uncomfortable with that.

Steroids -- we're always uncomfortable giving

steroids to a patient who's critically ill or patient who comes in with an infection because we know we're lowering the immune system. Again, there was some concern out there -- there was some reports out there it was helpful and some folks who were using it and so studies were done and showed that it was beneficial. Now we're using it wildly.

But I think that, you know, to -- I don't know if I'm answering your question; but the uncomfortable sense is, you know --

I do want to take one step back and COVID is new but, you know, viral pneumonia and, you know, flu for example -- flu acts very much similar to this. Flu causes a cytokine storm once the viral replication is gone and goes into -- so, we've been dealing with flu for a long time.

Q What are you calling that storm?

A It's cytokine, c-y-t-o-k-i-n-e.

And what this is is that the body has just -- just released, you know, its inflammatory -- just milli. Just the whole thing just going after it. And our immune -- our immune system can do damage and do more damage than the virus itself was going to cause.

Q And I think I'm okay in understanding that this is a -- basically a fluid situation. I mean, it could be changing from day to day. Is that fair to say?

A Are you referring to the patient experience itself?

Q Treating a patient that's going downhill.

A Yeah. We're constantly having to monitor what's going on with the patient. And we have, you know, daily labs for example where we're monitoring their kidney function; their liver function; their coagulation; you know, their inflammatory markers that we follow as well; the vitals, obviously blood pressure is doing. So...

Q I don't know that you can answer this question. It may be more of a legal question. But if this Court said, "Okay. You're going to start giving them this cocktail at 5:00 o'clock this afternoon" and then something changes at midnight and you're following a Court order, are you going to have to go through a decision-making process because one of these drugs is showing a determent to the patient that you've got to change something, then you're caught between a rock and a hard place? Is that fair to say?

A Yes, sir. I'll answer -- tell me if I'm answering you correctly. But if this order for a critically-ill patient was given -- what the treating physician would do is say, "what are the potential harms going to come out of this" and target the monitoring to look for those.

Q But if it changes at midnight and you still got a Court order says you got to continue to give them this cocktail regardless of what the health response would be...

A Never been in that situation, sir. I don't know what I

would do, frankly.

Q You kept talking about the mortality benefit. Am I understanding that to mean that it's going to help somebody from passing away?

A Yes, sir. The most common end point -- talk about a little bit in studies. When you set up a study, you need to identify what you're trying to determine. For example, are you trying to show that this will improve survival. The most common end point used in COVID literature is a 28-day survival rate.

Q And so when you say it's a positive mortality benefit, that means it's going to help in that situation?

A Yes, sir. A positive benefit. So -- or a mortality benefit would be a way of saying. We would say that at 28 days those who got this treatment were more likely -- and more likely means statistic, outside of probability to survive. And so not by chance alone could this have happened. This is beyond what we would expect by chance. That would be a mortality.

THE COURT: All right. Does either attorney have any questions based on my questions?

RECROSS-EXAMINATION

BY MS. UBALLE

Q Correct me if I'm wrong, but you -- this patient is on a steroid; is that correct?

A I -- I'm not -- she definitely has been. I don't know if she is right now.

Q And there's risks associated with a steroid in her situation. You said that, too; correct?

A There are risks with steroids, yes.

Q So, you're not trying to say that even this protocol that the family has asked for has to be risk free to be able to be appropriate, are you?

A I don't know of anything we do that is risk free.

Q Okay.

A We do our best to try to mitigate risks.

MS. UBALLE: Okay. That's all my questions.

MS. ATWOOD: Nothing further.

THE COURT: All right. You can step down.

(Witness provided Zoom testimony instructions by the Court)

STEVE WOHLEB

having been previously sworn, testified via Zoom as follows:

DIRECT EXAMINATION

BY MS. ATWOOD

Q Mr. Wohleb, could you introduce yourself to the Court and tell us how you are employed currently.

A Certainly. My name is Steve Wohleb. I am currently the senior vice-president and general counsel of the Texas Hospital Association. That's my employer.

Q And are you board certified in any area of the law?

A Yes. I am board certified by the Texas board of legal

specialization in health law. I have been continuously since 2010.

Q And I guess I missed the important stuff first. You should probably tell us where you did your undergraduate work.

A I am a proud Aggie, and I graduated from Texas A&M University in 1990.

Q And have you spent your entire career working in the health law field?

A I have.

Q Give us just a quick overview of that. How you started and how you landed as the general counsel of the Hospital Association.

A Certainly. I graduated from law school in 1992, and passed the bar in spring of 1993. I was employed for the first seven years of my career by a law firm in Austin, Texas -- Davis & Wilkerson -- practicing primarily in the areas of insurance litigation, medical malpractice defense, and general health law.

In 2000 I went to work -- took a job -- an in-house position with Seaton Health Care Network which is now known as Ascension Texas. It's a regional hospital system based in Austin Texas consisting of 12 hospitals. And I worked there in an in-house capacity for 17 years.

Since March of 2018 I've been the general counsel of the Texas Hospital Association.

Q And you had occasion to be a frequent lecturer over the

last several decades on legal issues affecting hospitals or the delivery of health care in the state of Texas?

A Yes, I have. I have given numerous talks and presentations in various different settings. I have spoken for, I think, five years running now at the University of Texas Health Law Conference that's held every spring in Houston. I have been a speaker at the Texas Health Law Conference that's held in Austin in the fall.

We hold at the Texas Hospital Association bi-monthly calls with our in-house counsel group which is a group of in-house attorneys that work for Texas hospitals and hospital systems, and those are CLE-accredited calls where we present on substantive legal issues affecting hospitals and health care systems. And I am frequently either the primary or one of the speakers on those accredited talks on various health law topics.

Q So, would it be fair to say, then, that over the course of your experience -- and particularly as a general counsel for Texas Hospital Association -- that you're familiar with the state and federal statutes and regulations that govern the delivery of health care in the state of Texas?

A I believe it's fair to say that is an extensive body of law but; I am, yes, generally familiar with that statutory and regulatory fame work.

Q And since the health care industry and the world has been contending with the COVID pandemic, what role has the

Hospital Association played in trying to facilitate making sure that care could be provided in a legal way?

A Well, certainly we were -- very early on in -- since the beginning of the pandemic in the mode of mobilizing our resources to make sure we were doing everything we could do -- everything we could do to assist our member hospitals in the delivery of care during this unprecedented crisis. We have been, since the beginning, in frequent contact with -- not only the Governor's office but also various state agencies as the Governor's office and those agencies tried to coordinate Texas' approach to responding to the pandemic.

So, our role has primarily been in two areas during the COVID pandemic: One, interfacing with those components of government and making sure that they understand what hospitals and health care systems need since hospitals and health care systems have been, since the beginning, have been on the front line on this war against COVID. Making sure that we are communicating the needs and concerns of hospitals as the pandemic unfolded and then communicating to our members what we're hearing from those government agencies as well as advocating on behalf of our members with those government agencies to the extent they needed accommodations or flexibilities in the existing regulatory framework to help members respond to the COVID pandemic.

Q And so have -- in conjunction with -- and based, I

guess, in part it sounds like on the input, perhaps, that the THA has provided, has the Governor's office and have various state agencies and regulatory authorities -- have they issued any orders adjusting any of the regulations or statutes affecting hospitals?

A Yes. And I would say that our state government has been extremely flexible throughout the pandemic in trying to understand the needs of the hospitals and health care systems and trying to be accommodating within that regulatory framework where they can be. So, for example, Health and Human Services Commission which is the primary regulatory body for hospitals has issued and has had in place since the beginning of the pandemic various flexibilities in their regulatory scheme to allow hospitals to, for example, add more bed capacity and do it in a way that's -- in sort of an expedited manner and not having to go through these sort of rigorous normal process. It has allowed facilities that have recently closed -- health care facilities that have recently closed to open back up and provide care during, as I said, these unprecedented times. There have been regulatory flexibilities issued, for example, in telehealth and telemedicine rules to allow a delivery of care in a way that it doesn't have to be done in an in-person setting.

So there have been, I think, numerous ways that both the state and the federal government have tried to make sure that the health care delivery system has what it needs to be able

to respond to the pandemic going back to March of 2020.

Q And I've been receiving something that was called the THA COVID-19 update from the Hospital Association. Is that a service that the Hospital Association put together to keep health care providers and those of us who may be advising health care entities of these waivers and changes and modifications to the existing laws and rules?

A Yes. So, we started doing that very early on. Beginning in March of 2020 we were issuing daily updates. That had -- depending on the day and sort of the volume of information we needed to put out, maybe three to four to five kind of topics of interest for that day.

As I said, that was coming out daily. And our communications staff and the rest of us working on that internal COVID team would all give input into what those relevant, topical issues were needed.

We've since moved -- initially to a biweekly update and it goes out weekly. But serves the same purpose.

Q Sure.

And given your -- and have you been directly involved in that effort, to make sure that that was accurate information going out to the hospitals and other health care providers across the state?

A Yes. Yes. Many of us internally at THA give input into that, but I certainly have given my input on those updates

from time to time.

Q I've had an opportunity to talk with you to some extent about the nature of the hearing, but I think you understand that we're here before Judge Hawthorne because there's been a request from the family for the Judge to enter a temporary injunction ordering the hospital and health care providers to allow a physician who's not on the medical staff to issue orders for medications to treat an ICU patient.

With that background I -- my question for you is: Do you have concerns about the legality or legal authority of the hospital to do that?

A Well, certainly, yes, on many fronts. You know, I understand this is an extremely sad and sympathetic case first and foremost; but I think the one hurdle that -- first hurdle sort of comes to mind that I believe to be really an insurmountable hurdle is you're asking the hospital in this sense to practice medicine because what you're describing here is a circumstance where there's a physician somewhere making a treatment recommendation but he's not on the medical staff there at the hospital, doesn't hold clinical privileges, is not authorized to treat patients in the hospital. So you would have a hospital sort of carrying out a treatment regimen and a treatment plan, and I believe that would be very much in violation of the doctor and the corporate practice of medicine doctrine which is essentially a doctrine long established in

Texas which basically says you can't practice medicine in this state unless you are a natural person holding a medical license issued by the Texas Medical Board. So corporations can't practice medicine, entities can't practice medicine. Only licensed individuals can practice medicine. And I believe that scenario would run afoul of corporate practice of medicine doctrine.

Q There's also been a suggestion that the hospital could or -- could perhaps be ordered to grant temporary privileges or grant some type of emergency privileges. First of all, can you give the Court just a brief overview of what is the role of hospitals in granting privileges to physicians and why is that -- why is that in place? Is there a public policy reason for that; and if so, what is that?

A Certainly. Try to make this brief, but it is a very extensive process. It's started by a physician who's wanting to be able to practice in a facility -- to fill out a very lengthy written application containing their full education training and work history and experience. Once that application is completed -- and this, by the way, is a -- literally a month's long process. It does not happen quickly because it's extremely involved. So, once that written application is completed; turned in; the hospital then sets out on a very rigorous validation and verification of the information contained in the application.

So, what hospitals are required to do -- not only

by public policy and just standard of care that they're held to but also both by state and federal regulation is to validate and verify that information from the primary source. So, hospitals literally go to the medical school that the doctor says they graduated from and validates that from the primary -- from the source itself and not just taking a copy of a diploma, for example, as evidence of that. Validating all of the references that the physician provided, validating all of the continuous course of employment and following up on any gaps in the employment that may be evident in the written application.

So, it is an extensive process designed solely to ensure that the --

(Simultaneous speaking)

Q -- ask is there a -- you're talking about the process that hospitals routinely go through. Is there any federal or state or regulatory requirement to go through this process the way you're describing it?

A Yes. Yes. The basis of it is both at the state and the federal level so that Medicare conditions of participation that apply to all hospitals who participate in Medicare -- which is essentially all hospitals in the U.S. -- have these standards requiring hospitals to validate the education, training, and experience of physicians and the competency and the quality of care that the physicians render on medical staff. That's at the federal level.

The State also has rules and the hospital licensing rules in the Administrative Code requiring the governing body of the hospital and the medical staff to have these processes to ensure that people practicing in their hospital are competent and qualified to do so.

But in many hospitals are accredited by The Joint Commission. The Joint Commission has extremely extensive requirements on credentialing physicians -- again, to make sure those physicians have the education, training, and experience to provide quality care within the hospital.

So, those are the regulatory bases of these requirements -- of this process.

Q And can a physician -- if a physician is a natural person and they're licensed and they've gone through a residency program, does that mean that hospitals are likely to give any physician privileges to do anything at a hospital, or are they particular to the training of the physician?

A Right. So, the physician would request privileges within a given area of medicine; and the hospital would validate the physician as the training qualification and experience to -- to actually exercise and provide the care within that -- what they call delineation of clinical privileges. So, it's not -- so, the answer is no, any physician can provide any service at the hospital they have to -- they're only allowed to provide the service that the hospital specifically authorizes them to provide

as a result of and at the end of this credentialing process we've been talking about.

Q Based on your background, knowledge, and experience -- both in-house within the Ascension hospital system, serving as outside private counsel through a law firm, and now in-house as general counsel for the Hospital Association -- do you have an opinion about whether it would be likely that a physician who has trained in family practice would be given privileges at any hospital in the state to care for ICU patients or manage their care?

A I don't think so. I would imagine that most hospitals would require specific ICU and critical care privileges to be requested and then they would have to validate that physician's training and experience within that discipline. And I do not believe a physician who's been through a family medicine residency program would qualify for those specific privileges.

Q There has been some discussion over the course of our hearing today about the peer-review process. Is -- what role does the peer-review process play at a hospital in overseeing the quality of care that's delivered to the patients at the hospital?

A Right. So, we've been talking about how you are granted permission to practice in the hospital. Once you are granted that permission, that's when the peer-review process sort of takes over from a quality and oversight standpoint.

So, every hospital has structures in place where

physicians of like specialties sort of keep track and review each other's care within the facility. So, family medicine physicians would be reviewing the care rendered by other family medicine physicians; orthopedic surgeons, other orthopedic surgeons; and so on.

So, the peer-review process is a structure within the hospital's medical staff to ensure that the quality of care that's rendered in the facility would follow up on any sort of outliars or untoward events that happened within that particular discipline to try to understand whether the standard of care was met or whether there were quality concerns that need to be concerned about the medical care that a particular physician is rendering.

Q If a physician were to recommend or order medications or treatments that were outside the standard of care or were felt to be unsafe, would that be something that would typically be reviewed in a peer-review process at a hospital?

A Yes, it definitely would. And, in fact, if the care were even allowed to be rendered there may be (Zoom distorted) or even before that would prevent the care from being rendered in the first place. But if it were and it was perceived to be outside the standard of care, it would definitely be reviewed through those peer-review processes.

Q Is the peer-review process limited to physicians who are on the medical staff or who have privileges to practice at

the medical staff -- or hospital?

A Yes. I mean, it necessarily is. And sort of think of it as sort of a jurisdictional issue. A medical staff doesn't have any jurisdiction over somebody that's not on the medical staff and so that's how that works.

Q And is this peer-review process that you've described for the Court, is that required by statute or regulation or any governing body?

A It is. Both -- all of those processes that I described -- both at the federal level and the Medicare conditions of participation and those Joint Commission standards require extensive ongoing practice evaluation of decisions on the medical staff. So that's where that peer-review process resides.

MS. ATWOOD: Pass the witness, Your Honor.

MS. UBALLE: I have no questions, Your Honor.

BY THE COURT

Q Are these protocols that you've mentioned, are they universal across the United States as far as hospitals and getting on staff and getting privileges in a hospital?

A I think you will find some variation, but because there is this sort of regulatory underpinning -- this regulatory framework that it's all based on -- they're going to more or less look the same. Everyone has to do that primary source verification that I mentioned; everybody has to validate that education, training, and experience. That's all going to be

consistent. There may be some variation in what you call those processes within a particular medical staff, but it's going to be a fairly consistent process really across the country not just in the state of Texas.

Q All right. This is going to be a really bad question and I don't know how you're going to answer it, but how do hospitals deal with judges sticking their noses in the -- making medical decisions for the hospital?

A Well, I guess they go out and hire good lawyers like Ms. Atwood. I mean, I --

Honestly, Your Honor, to kind of be serious for a moment I don't know how a hospital would handle a judge's order that purports to require the hospital to do something that really does constitute the practice of medicine. I mean, if you put the hospital, to put it bluntly, in an extremely difficult position -- and I don't even know if legally the hospital could carry out a judge's order that essentially constituted the practice of medicine.

Q And how -- how do we deal with getting somebody that may have an opinion about a patient's care into the arena of treating physicians to render an opinion about how that patient should be treated if they are not on staff and have no privileges at the hospital at that time?

A Well, I certainly think the physicians who do have privileges at that hospital could consult with that doctor and

held a particular area of expertise, be willing to listen to what he had to say and factor that into their medical decision making. But ultimately if that physician -- in order to have care rendered or carried out under his orders, would need to be privileged at that hospital.

Q So, it would just be a matter of professional for lack -- I don't have the right term here so take it in the fact that I'm a Judge and not a doctor. But within the realm of professional courtesy to call somebody else and say, "Hey. We got a problem here. What do you think"?

A Right. And I think that happens all the time every day in the medical arena. Physicians may feel like they need additional input do reach out to colleagues or others that they trust in order to, you know, gain another perspective.

THE COURT: Okay. Any questions based on my questions?

MS. UBALLE: No, Your Honor.

MS. ATWOOD: No.

THE COURT: Thank you very much. I'm going to remove you from the hearing. Have a good day.

Next witness?

MS. ATWOOD: No more witnesses, Your Honor.

THE COURT: All right.

Any rebuttal?

MS. UBALLE: No, Your Honor.

THE COURT: Ms. Uballe, tell me what you want. Argument?

MS. UBALLE: Yes, Your Honor.

We've had a lot of discussion about the effectiveness and what treatments to use. You've heard differing opinions. What this truly comes down to is patient's rights.

You've also heard testimony from the family and from a patient advocate expert that expressed an opinion Baylor Scott & White didn't even do its minimal duty to provide patient advocacy, and what that means in this case is that they have not had a voice. That's why we're here today. I don't think there's any of us that wanted to end up here in this setting and put you in this position.

So, first and foremost there's been a failure to have this collaboration -- this discussion. I know we looked at the notes and the chart, but that's a family member that I've never even heard -- and she's not one of the ones that I've even been dealing with. So, I think there's some arguments there that that was -- you know, form over substance. There wasn't much substance there.

We have Dr. Edwards who has had success with this protocol. And I think it's very important, too, that he -- he wouldn't be acting alone. I want to craft some creative solution -- I understand the privileges issue. I understand that. I understand not asking you to practice medicine. But

this family has a right to be heard, as we've said before. Mrs. Carroll is dying. We're saying first do no harm but the hospital is essentially saying, "Well, we're just going to let her die" because that's what's happening. She is -- she is dying and she is suffering. She's on a ventilator. That's not a pleasant experience even though she's sedated.

So, we -- like I said, the hospital's position is they don't even want to let her try. And I would even argue based on Dr. Sullivan's testimony these are not FDA approved for these uses. That gets us under the Right to Try with all the other elements.

THE COURT: Except they're not recommending them. That's one of the elements.

MS. UBALLE: Yes, Your Honor. But -- so the other -- I do, also -- you know, we have the patient bill of rights, we have laws, we have ethical rules that patients have the right to participate in their treatments; and we have not gotten that in this case. And I think it's the failure of it that has caused the family to feel like they had to come here and do this and ask you to intervene.

And I understand we need to be careful. We have to consider public policy considerations. But the public policy consideration of patient rights is just as important. Right now with all the testimony from -- from the Scott & White experts and her cross of our experts where is the discussion of the patient

and their role in their ability to be treated.

THE COURT: Okay. Let me ask you this -- I mean, I'm -- obviously I'm having a difficult time with this.

MS. UBALLE: Yes, Your Honor.

THE COURT: As is everybody else, I think. And so I'm being very choosing in my words, but what I know is the law.

MS. UBALLE: Yes, sir.

THE COURT: I don't know medicine. And I'm grappling for where this fits in the law because the patient bill of rights doesn't necessarily give me authority to do anything -- and I can't even remember. I meant to remember the three elements, the last one of which is family values or the patient values. I forget what y'all called that. But that's a -- that's a -- either a medical policy or a medical moral statement or medical mission statement. It's not a statute, and it's not -- now, I can understand -- I'm very cautious to use this because it's always after the fact. It may be something that's a standard of negligence. I -- you know, I don't -- so, that -- but that's not on the front end of a lawsuit for an injunction.

MS. UBALLE: Yes, Your Honor.

THE COURT: So that's...

MS. UBALLE: It's challenging times we find ourselves in because it's puzzling why -- it's really puzzling why they're fighting so hard considering her condition.

THE COURT: That's kind of why I mentioned that

before we went to lunch. I mean, if this were a normal lawsuit, y'all would be going to mediation.

MS. UBALLE: Yes.

THE COURT: But this isn't a normal lawsuit. We don't have time for mediation.

And as I told y'all, I'm not interested in -- I'm interested in being definitive in this decision because whether it's good or bad for one side or the other at least they have a decision and you know how to act on it versus being wishy-washy or saying we're going to kick this can down the road and let someone else deal with it. So I want to deal with it today.

MS. UBALLE: Yes, Your Honor.

THE COURT: And to take Dr. Gram's comments -- all good comments, but a different time and place to say we all need to get together and talk. Well, we got to talk real fast if we're going to talk seems to me. And who knows? I believe in miracles, too. She may wake up tomorrow and be perfectly okay. Doesn't seem to be what the scenario is right now. And just as in mediation as you're well aware the only thing I can order people to do in mediation is go to mediation and have the people there that have the authority to settle. I can't make them talk.

MS. UBALLE: Yes.

THE COURT: And that's what everybody seems to want in this situation. I was really scared y'all were going to ask me to order this protocol.

MS. UBALLE: Yeah. I recognize the inappropriateness of that, Your Honor.

THE COURT: And then when I saw three different ones, it even made it worse.

MS. UBALLE: Exactly. Exactly.

There's been -- in the family's view there's been a complete lack of collaboration.

THE COURT: Well --

MS. UBALLE: -- and if there's something even along those lines...

THE COURT: Well, I went and looked at your case -- your Chicago case. The Elmhurst case in Chicago as I was sitting up here. Case kind of surprised me a little bit, what the decision was; but it seemed to be totally over the issue of ivermectin. That was the only thing. It wasn't a protocol; it wasn't a patient advocacy situation, didn't seem like. And for some reason, the short blurb I read, said the doctor told the hospital, "Get out of the way and get somebody in there that'll give her this drug." That's why I asked him the question: How do you do that?

MS. UBALLE: Yes.

THE COURT: Doesn't seem like it's a process that can happen tomorrow, and -- and I think that's -- I think that's gotten dangerous because I don't have any idea who put it in there to give them this protocol.

MS. UBALLE: Right.

THE COURT: Got a -- not disparaging any of his qualifications. He's certainly a doctor so he's a lot smarter than me, but we've got a family practitioner versus people that are treating somebody in ICU and even he said, "I'm not qualified to do that."

If I could make y'all talk to each other, that would be great. Just get his input. They can say we're not going to do that. I don't know that that would satisfy the family by doing that.

MS. UBALLE: I think they just want the chance at the treatment.

THE COURT: Anything else from you?

MS. UBALLE: No, Your Honor.

THE COURT: All right. Ms. Atwood?

MS. ATWOOD: Keep this brief because I know you've been thinking on it and studying on it and heard from me a couple of times, but I think we need to start from the place of look at what the law is because we find ourselves here at the court. And we're here in the court because there was an application for a temporary injunction filed that said we want a protocol recommended by our selected doctor. It has been a bit of a moving target; but I think we've at least got one as of today that's, you know, what's being requested. And so what we have to look at from a legal perspective is that's a protocol that's

being recommended at least by Dr. Edwards. And under their pleadings they're asking you to mandate something -- I mean, the pleadings themselves actually only say implement the recommended protocol. I mean, that's sort of one of our first big problems here.

What is being requested is, itself, a little bit of a moving target. But on the pleadings at least what you're being asked to do is to order the hospital to implement a recommended protocol. And I won't go back through it, but I think Your Honor's aware I think there's just insurmountable legal hurdles to being able to do that because of other things that are already in place with the law that mandates how health care gets delivered. So that's one big issue.

But if you were to step back and say, well you know, you've got the discretion to let people amend their pleadings, you know, on the fly -- I understand that. And so maybe they amend and they say, "Well, we really don't want you to mandate that protocol. We want you to mandate letting our guy apply for privileges or get on staff" or something like that. You still run into the same issue of you have to have an underlying cause of action to be able to come to the court and ask for an injunction -- a mandatory injunction, and they're continuing to fall short. We can't ignore the fact that the one and only item in the pleadings that sets out a cause of action is under the Right to Try Act -- the federal Right to Try. We've

heard about the Medicare patient rights today; and, again, if Your Honor were inclined to entertain a motion to amend pleadings to add that -- you know, let's talk about those two things. Those are the only two bases that have been presented to you as a cause of action that would enable them to get to the next step -- the next essential element necessary to show that an injunction is available, something that you could even theoretically do; but you have to start with identifying a cause of action. And under both of these -- the Right to Try Act and this -- not sure what to call it so --

THE COURT: She called it the Medicare Act.

MS. ATWOOD: The Medicare Act -- that's been provided. Both of those very explicitly say, look, we're not mandating that any provider has to deliver any care. You know, we're not -- there is no right -- there's no cause of action you don't have an ability as a patient to mandate that you have access to something. And that's true under the Right to Try Act, it's -- the language is quoted for you in the outline that I handed you, Your Honor; but, you know, it's -- there's no liability for a determination not to provide access. So if there can be no liability, that cannot be the basis for a cause of action because that's what they're complaining of here is they're not providing access to a drug.

If we're going to set aside the Right to Try Act and say that's not really where we're going, that would apply

only if we were doing maybe single ivermectin or something -- and we look at the Medicare Act. The last sentence of Section 2 under exercise of rights says, "This right must not be construed as a mechanism to demand the provision of treatment or services deemed medically unnecessary or inappropriate." That's why I wanted Dr. Sullivan to spend some time talking to you about whether a qualified health care provider felt that this was medically unnecessary or medically inappropriate care. And that's what her treating health care providers have testified to. The only -- let me take that back. Dr. Sullivan is not a treating health care provider. But that's what the only qualified physicians that you've heard from have said about this issue; they've said what's being requested, what's being considered is medically unnecessary and medically inappropriate.

And so this statute as well -- this Medicare statute also does not create -- create a viable cause of action that they can show -- which is the first and threshold element for coming to the Court asking for injunctive relief. You have to somewhere in the law have a viable legal right to get where you want to be. And I -- I understand that this is tremendously frustrating for everyone involved, but there are reasons that there is no viable cause of action for this because I think that folks in Congress and the folks in -- that are passing this legislation have gotten good counsel and have recognized we have to leave the practice of medicine in the lane of the people who

can practice medicine. And even if patients really want something and even if they're in a dire situation, ultimately that decision has to be governed by whether the treating health care providers believe it is feasible, it is medically appropriate, or it would be medically necessary.

If we step away from that and we say, "No. If a patient's in a bad enough situation, they're going to be able to have a right to access or right to demand care because their situation otherwise feels too futile --" Dr. Sullivan went to some effort to talk to us about why we can't look at it in that manner because there are still risks to the patient and we do have miracles happen, for one, and also because even though Ms. Carroll's prognosis is poor right now -- no one is disputing that -- she still does have a chance to pull out of this nosedive with the treatment that's being provided. And what you've heard from the experts that have come before you is that doing additional things that are recommended by Dr. Edwards her providers feel would keep her -- would do more harm than good. And so that's -- that's where we end up here.

So from a legal standpoint when you're looking at it without a viable cause of action you can't go to the next step. But even if you did and you said, "Okay. I'm going to feel like there's something in there somewhere that would let you find a viable cause of action," you still have to be able to show that they're likely to recover. And under the Right to Try --

which, again, is the only thing that's in the pleadings that we've got right now. The Right to Try says it has to be an eligible investigational drug and that means a drug that has not been approved or licensed for any use." And I very specifically had -- actually Dr. Gram as well as Dr. Edwards and Dr. Sullivan go through and make sure that this record shows that all of these medications are licensed for other uses with the possible exception of leronlimab but that -- because they're licensed for other uses, they cannot serve as a basis for seeking an exception, if you will, under the Right to Try Act.

THE COURT: So you're saying even if they are not approved for another treatment and it's going through clinical studies or Phase 1 whatever -- because it's already approved for some other purpose then it doesn't mean the definition?

MS. ATWOOD: That's right. Right to Try is for truly experimental drugs. Like we've got something and it's a new formulation it's something that's under investigation for is it going to treat cancer -- something like that -- it's past those clinical -- Phase 1 clinical phase trials and we're now on down the pike but it hasn't gotten approved for any other purpose yet because it's a new and investigational drug. That's the type of drug and the only type of drug that's available under -- theoretically available under the Right to Try Act. That's simply not the situation that we're in right now. And without this qualifying -- this either -- any of these drugs individually

or the cocktail and protocol as a whole -- without them falling into the category of eligible investigational drug, there's simply not a basis for -- legally in the law not a basis for entering a temporary injunction and a mandatory injunction at that.

And I'll wrap up quickly by just -- I think it's important -- we've heard a lot of evidence here today, but it is important to step back and realize that not a single witness -- not one doctor that you heard from has ever ordered or administered to any patient this protocol that we're talking about here. And Dr. Edwards hasn't done that despite his research into the issue. He says, "That's right I don't treat hospitalized patients. I haven't had any privileges since May of 2005, and I've never treated a COVID patient in an ICU and I don't have any experience with ICU patients" who are by definition medically fragile. And I think -- well, get there in a moment.

But we've heard from Dr. Edwards who simply doesn't have the qualifications to be opining in this lane; we heard from Dr. Gram who's not licensed, who's a research pathologist, and who was very clear and careful as he should be to say, "I'm not treating patients. I'm not licensed. I can give some advice here and there." But even he said, "Nope. I haven't recommended this to anyone." His focus is on outpatient, more preventative -- that front end of the disease like

Dr. Sullivan was talking about before you get to where Ms. Carroll is right now. So you literally got a complete vacuum of evidence that would support going down the path that you're being asked to go down here.

On the other side of that, when you're trying to balance what's been presented to you, you have the combined statements of the World Health Organization, the NIH with respect to ivermectin, colchicine, and leronlimab -- all of these medications have been considered by multiple of these world-recognized authorities and not one of them -- not one has endorsed the use of the medications either individually or as a cocktail that are on this treatment protocol.

And while I'm -- I can't say this enough. I am sympathetic to the idea that we are looking for anything that might be helpful we cannot ignore -- as Dr. Sullivan said we cannot ignore the real and tangible risks that providing unproven treatment without any proven benefit to a patient.

And that gets me to the place where I think I've seen Your Honor struggle several times and it, frankly, is the practical push-point in this that makes it just not feasible from a medical standpoint. We've been talking about legal things, been talking some about the science; but let's just talk about the practicalities of the situation that we're in. If there were a protocol that was ordered by some -- by Your Honor or by a physician not on the medical staff, we've got uniform agreement

that giving Lovenox and aspirin which is part of this -- part of what the patient's already on, albeit at different doses. We've got uniform agreement from all of the health care providers that you've heard from that that increases the risk of bleeding which could be devastating if not fatal to this patient. Let's imagine the situation where these orders get put in place either because you order it at an injunction or Dr. Edwards orders it because he's somehow going to be allowed to do that and then this patient starts having symptoms that are consistent with a brain bleed or a GI bleed or their blood pressure -- her blood pressure drops out. And so by definition as a medically-fragile patient in the ICU her care needs to be monitored minute to minute not day to day, not business hours of the day to business hours of the day. They're literally making adjustments and titrating her medications with nurses at the bedside constantly. And any of these medications in this protocol can have known or unknown interactions with other things that are going on. And as her condition changes, which it inevitably will, there will have to be adjustments made to that; and if the providers at the bedside think that there's any risk that a -- her condition is worsening or she's having complications because of one or more of the combination of this cocktail medications, they would have their hands tied; not be able to do anything about that, have to leave the patient in a situation where the patient was receiving care that they actively thought might be hurting them to wait to come

back to the Court or get a hold of a physician who's in Lubbock and not here and is not subject to being within call range of 30 minutes of the hospital. That's a circumstance that, you know, you're putting the providers who will be at the bedside -- because while she's in the ICU, there will be a there doctor there 24/7 and nurses there 24/7. And they're going to be faced with the, "Do I violate a Court order and risk of that or sit and let the patient suffer or deteriorate without doing something which is maybe going to put my license at jeopardy because I'm not intervening under those circumstances or do I just guess and make some changes to her health care because I don't really know what the interactions are, I don't --" you know these providers don't routinely administer ivermectin, you know a parasite drug -- you know, a worming drug that's given to animals. They don't administrator that in ICUs; right? This is not something they're familiar with. And so we're putting them in a situation where they literally do not have an option that is good for the patient, good for them, or acceptable.

And so I would just urge Your Honor to step back and realize that from a legal standpoint this just can't be done. It's not wise from a medical perspective, and from a practical perspective it's a setup for a true disaster. And as difficult and as anguishing as it is to ask you to make that decision, I think the only right decision under the circumstances is to deny the relief that's requested.

And I will say I -- I want to encourage and will encourage the hospital -- and I believe they will do that -- to have another family conference if that's something that will help the situation. I was in contact yesterday with Dr. Barker. Haven't heard from him, but Dr. Barker is the palliative care physician who's been following and managing with Ms. Carroll for the last several weeks. And Dr. Barker indicated to me that he met with Mr. Carroll personally at the hospital yesterday and had two additional phone conversations with him. They were discussing treatment plans. Dr. Dixon who was here earlier but had to leave before he was able to testify has said he has personally talked with Mr. Carroll about the treatments that have been requested. And I know that having a loved one in the hospital -- I know from personal experience is completely overwhelming, and it can be difficult to take in all of the information that's coming your way under such stressful circumstances. But I think that the medical records -- both the ethics consult and the information that we've had from the other providers would say that there has been communication with the family. But the bigger issue is if the family feels like there has not been adequate communication, we want to step back and see if we can't address that and make that right, you know, and talk to them about what are the considerations and have some explanation. I don't want to give false hope that the providers are likely to change their mind about what's in her best

interest. I'm not a physician so I can't say that for sure. But I've had a lot of communications with them and I know they feel pretty strongly about this situation, that it is not good for her to do these things. But I think that they would be open to having an additional meeting with additional communications to try to have another opportunity to discuss what the family is wanting and why that may or may not be a good idea.

MS. UBALLE: Just in brief response. I understand the concerns with Dr. Edwards. The family is also in contact with other medical providers. They know they have an ICU nurse that travels around. I don't know if that's an option. But if we can somehow get just a bit of relief in having Dr. Edwards have some sort of seat at the table so that his voice is heard on, you know, the medical side for what the family is requesting.

You know, the family does believe that there is some success in this treatment. This is not just from Dr. Edwards. If you'll recall he testified that he works with a whole group of experts; that some of them are intensive care doctors. So it's not just himself that would be a part of this. And, in fact, our request would necessarily name Dr. Edwards -- or the order wouldn't do that. But if we could get some sort of order from the Judge -- if the hospital is not willing to agree. We want to make sure that there's an actual substantive conversation where the family does feel heard; and if the continued denial for the treatment goes forward, it's because the

family understands fully why. And, you know, that's -- that's their decision, too.

Again, I understand the -- the challenge we face here but these are challenges we've never faced before and so a lot of us have to come forward and maybe take a stand to shake things up and do something a little bit different. And as you've heard the testimony: The medical realm and the science realm and the studies, they can take a lot of time, you know. And we do have experts, we do have doctors that have used this treatment or variations of this treatment, but I can promise you this treatment is not Dr. Edwards alone. He -- you know, we didn't have time to have all the experts come and testify before you.

But we just don't want the family's wishes to be -- to be only nominally heard or heard on the surface and cast aside.

Your Honor, would you mind if Mr. Carroll spoke to the Judge?

MS. ATWOOD: Certainly have no objection.

MS. UBALLE: Would that be okay?

THE COURT: That's fine. Go ahead.

MR. CARROLL: Mrs. Atwood alluded to the fact that Dr. Barker and the other doctor has talked to me and consulted and there's going to be some kind of path where we're going to be in harmony. Dr. Barker has and my conversation ended with him yesterday saying, "Well, my obligation is do no harm" and smiled.

There's no communication. It's their way or the highway; and if you think it's anything else, you're all fooling yourself. We're not going anywhere, you're not changing anything.

THE COURT: You need to address the Court, please, Mr. Carroll. You need to address the Court not other counsel.

MR. CARROLL: They're not going to change anything. There's no communication. They did not consult us in the beginning. Linda Brown is not the power of attorney. I was. You can check my cell phone. Those people did not call me, they did not talk to me. Nobody says anything but their way or the highway. There's no open communication, there's no indication that they're going to change anything. So don't anybody fool themselves that it's going to get better after you make your decision.

THE COURT: So, this is a question I forgot to ask: What keeps this patient at Scott & White?

MS. UBALLE: I think at this point -- and I don't want to misspeak for the family; but it was like let's get through this hearing, let's not create any additional complications or -- yeah. I don't want to speak on their behalf, but there's nothing other than -- I think Scott & White is willing to but there has to be a receiving hospital.

THE COURT: I got you.

MS. UBALLE: So there's things like that.

THE COURT: Thought there was some prohibition

against that.

MS. UBALLE: No, there's not.

THE COURT: Okay. Assuming we can get over these legal hurdles tell me how we fashion an order that skips the process of getting somebody hospital privileges to be in the conversation and to order substantive conversation?

MS. UBALLE: Just like that, Your Honor.

Yeah. Let me --

THE COURT: I mean, that would basically entail myself or somebody else being there as a Judge to say, "You're not -- you're not -- you're not in a substantive conversation" or, "You're just being -- it's a sham meeting."

MS. UBALLE: And yeah -- what you just heard.

(Simultaneous speaking)

MS. UBALLE: That's how the family feels.

THE COURT: This is the notes I was putting down here. I've said -- you know, to me this train probably got a little bit too far down the road for -- because my suggestion's -- not a legal requirement on anybody's behalf -- is that you need to get together and talk, but I don't think I'm telling y'all anything -- that doesn't take the wisdom from the bench to say that. And -- but I also understand that reparations are probably too far down the road to where there's any trustworthy conversation that goes on regardless of what it is.

MS. UBALLE: Well, and we would be open to the

hospital's suggestions. We've heard a lot from them about what they can do and what they don't want to do. You know, I would be open -- we would be open to hear what their suggestions would be to help give this family what they want.

THE COURT: Well, I don't necessarily -- I don't want to make it a practice of the Court just to enter orders just to be entering orders.

MS. UBALLE: Absolutely.

THE COURT: Obviously I've got to follow the law.

MS. UBALLE: Absolutely.

THE COURT: And so on this rope on the side of the cliff trying to climb it to find some satisfaction and, for lack of a better term, comfort for the family -- and it's a long rope and a big cliff.

I would -- I would dare to say -- not requesting the hospital to give any suggestions right now. But it would just be an effort on their part to get up and start guessing about what suggestions are. I mean, I'm assuming -- again, not requiring anybody to do anything. As Ms. Atwood said they're willing to talk -- or sit down and try to start that process over again if we can get all the horses back in the coral and start that same place. But as Mr. Carroll has said I think that's going to be difficult.

Really don't think there's any legal way we can issue this injunction. So I'm going to deny the injunction.

MS. UBALLE: Yes, Your Honor.

THE COURT: I don't know that there's anything I can say that comforts y'all. If I could find those words, I would. As I said the last time we were in here I -- I -- I don't even know if I can understand y'all's situation, what I would be doing in that same situation. So it's kind of hollow words coming from me to say I understand. Probably sitting there saying, "No, you don't"; and you're probably right about that. I do think that I am a little bit weary at the precedent we set by the courts getting involved in issues related to medical care.

MS. UBALLE: Yes, sir.

THE COURT: I understand. I'm not -- I hate to use the term unprecedented. I've heard it too much over the past 16, 18 months and how this situation has changed our society and world, legal system, medical system, educational system, economic system. The whole thing.

And I agree with Dr. Sullivan -- didn't get the answer that I expected when he said it. But he said we're out of our lanes for the past 16 months. I want to get back in my lane. I know everybody wants to get back in their lane.

But I appreciate everybody's input.

MS. UBALLE: Thank you, Your Honor.

THE COURT: Appreciate y'all coming in here and the civility and the manner that you did. Again, I don't know if I would have been as civil so...

So, with that anybody's got any questions or anything?

MS. ATWOOD: Judge, to the extent this might be something the family would be -- can you.

THE COURT: Need to be on the record?

MS. ATWOOD: No.

THE COURT: Let's go off the record.

(Off-the-record discussion)

THE STATE OF TEXAS *

COUNTY OF BRAZOS *

I, Paula K. Frederick, Official Court Reporter in and for the 85th District Court of Brazos County, State of Texas, do hereby certify that the above and foregoing contains a true and correct transcription of all portions of evidence and other proceedings requested in writing by counsel for the parties to be included in this volume of the Reporter's Record, in the above-styled and numbered cause, all of which occurred in open court or in chambers and were reported by me.

I further certify that this Reporter's Record of the proceedings truly and correctly reflect the exhibits, if any, admitted by the respective parties.

I further certify that the total cost for the preparation of this Reporter's Record is $1,605 and was paid/will be paid by the Plaintiff.

WITNESS MY OFFICIAL HAND this the 2nd day of November, 2021.

Digitally signed by Paula K. Frederick
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