UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF FLORIDA
TALLAHASSEE DIVISION

AUGUST DEKKER, et al.,	)	
	)	
Plaintiffs,	)	Case No: 4:22cv325
	)	
v.	)	Tallahassee, Florida
	)	May 10, 2023
JASON WEIDA, et al.,	)	
	)	9:01 AM
Defendants.	)	Volume II
_____	)	

TRANSCRIPT OF BENCH TRIAL PROCEEDINGS
BEFORE THE HONORABLE ROBERT L. HINKLE
UNITED STATES CHIEF DISTRICT JUDGE
(Pages 251 through 507)

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P R O C E E D I N G S

(Call to Order of the Court at 9:01 AM on Wednesday, May 10, 2023.)

THE COURT: Good morning. Please be seated.

Dr. Shumer, you are still under oath.

Mr. Jazil, you may proceed.

MR. JAZIL: Your Honor, a housekeeping matter before we get started.

THE COURT: Sure.

MR. JAZIL: I spoke to my friend Jennifer Levi who is the lead lawyer for the plaintiffs in the Doe v. Lapado case, and I spoke with my friend Omar Gonzalez-Pagan about the issues we raised yesterday. And my understanding, Your Honor, is in the second case, once the bill is signed, the plaintiffs will be moving for TRO. They will also be amending their complaint to list the various State's attorneys as defendants in the case, because of one of the provisions in the bill that deals with criminal liability.

So as we were working through the issues of can this be a trial that addresses both cases, one of the issues that came up is the State attorneys will have to decide for themselves whether or not they want to cross-examine certain witnesses, et cetera. So that's a complication we're working through.

Anything else?

MR. GONZALEZ-PAGAN: As I said for plaintiffs, Your Honor, we have no problem conceptually with consolidating the evidence for both cases, as the conversation was happening yesterday, keeping the record, if you will, open.

We do have conceptually issues about having to, like, bring back experts to be reexamined, if you will. The testimony is not really going to change. And, of course, our plaintiffs are not suing the State's attorneys.

So --

THE COURT: All right.

MR. GONZALEZ-PAGAN: -- we are trying to work through those issues. I don't think there's a proposal to present to the Court right now.

THE COURT: We can do that other than when we've got a witness ready to testify.

I will say I looked briefly -- we'll address it. I think you have a real standing issue in this case. I looked at your provision about the obligation to pay for care rendered out of the state. If the State, indeed, had an obligation to pay for service out of state when it's not available in state in circumstances like these, it seems to me that would solve the standing problem.

At least on first look, I don't think the pay out-of-state provision applies in these circumstances. So you need to look at that. We can take that up, but let's -- none of

that is going to affect Dr. Shumer's testimony or the cross-examination, so let's take that up not on Dr. Shumer's time.

I think we do have the preliminary injunction in the other case, and we talked about getting that set. I recall your responses may be due, what, later this week?

MR. JAZIL: The 15th, Your Honor, Monday.

THE COURT: So that must be next week.

MR. JAZIL: Yes, sir.

THE COURT: And then we were going to deal with it after that. And at least in that case -- there is standing for at least some of the plaintiffs certainly in that case. So we'll have issues to address. In the meanwhile, let's keep -- let's keep going.

CROSS-EXAMINATION

BY MR. JAZIL:

Q. Good morning, Dr. Shumer.

A. Good morning.

Q. Yesterday you testified that you're an endocrinologist; right?

A. Yes.

Q. And as an endocrinologist, you follow the Endocrine Society's guidelines for treating gender dysphoria; right?

A. Yes, the Endocrine Society Clinical Practice Guidelines are certainly a tool that I rely on for providing this type of care.

Q. And, Doctor, you should have in front of you an exhibit that's marked DX24.

Would you mind grabbing ahold of that?

And are those the guidelines?

A. Yes.

Q. And, Doctor, yesterday when you were testifying, it was my understanding that you deal mostly with the adolescent population.

Did I get that right?

A. That's correct.

Q. Okay. So let's go ahead and take a look at the adolescent recommendations in the Endocrine Society guidelines. If we go to page 7 of the document -- and I'm going by the numbers on the bottom right -- now here Section 2 lays out the guidelines for the treatment of adolescents; right?

A. Yes.

Q. Okay. So after each recommendation, there is a cross-filled circle. Do you see that?

A. I do.

Q. And do you know what the cross-filled circles signify?

A. Yes. I believe in the beginning of this manuscript --

Q. Well, actually, let me help you out there. Let's go to page 8 of this document, bottom right.

A. Yep.

Q. Now, you'd agree with me that one cross-filled circle

signifies very low-quality evidence?
A. Yeah. So here they are outlining -- I think they're very transparently outlining how they came to these recommendations based on the evidence they reviewed, right. So they're talking about how much evidence they reviewed and what they are calling the quality of evidence that they reviewed for each one of these specific recommendations or suggestions that they're making throughout the article.
Q. Okay. And one cross-filled circle, according to this, signifies very low-quality evidence; right?
A. Yes.
Q. And two cross-filled circles signify low-quality evidence; right?
A. Yes.
Q. Three cross-filled circles signify moderate-quality evidence?
A. Yes.
Q. And four cross-filled circles signify high-quality evidence?
A. Yes.
Q. So let's go back to page 7 where the recommendations are.
Doctor, you'd agree with me that not one of these six recommendations is supported by high-quality evidence; right?
A. Yes. I think that deserves some explanation about how one would have high-quality evidence.

Q. Your counsel can ask you about the explanation. Let's go through some of these questions first.

And you'd agree that none of them are supported by moderate-quality evidence?

A. Yes, sir.

Q. And five of the six are supported by low-quality evidence; right?

A. Yes.

Q. And one is supported by very low-quality evidence?

A. Yes.

Q. So I'd like to focus on the one, 2.5, that's supported by very low-quality evidence.

If you would take a minute to read that, Doctor.

Now, there is a portion in there that says: *There are minimal published studies of gender-affirming hormone treatments administered before 13.5 to 14.6 [sic] years. As with the care of adolescents greater than or equal to 16 years age, we recommend that an expert multidisciplinary team of medical and MHPs manage this treatment.*

Do you see that?

A. I do.

Q. Do you agree that there are minimal published studies of gender-affirming hormone treatments administered before age 13.5 to 14 years?

A. So I think this is a very specific question, right. The

question is is there evidence in this specific age group providing gender-affirming hormones -- so this is separate from GnRH agonist. So there is more evidence outlining the use of hormones in people 16 and older and less below 16 in 2017 at the time of this publication; that's correct.

Q. Is that still the case?

A. Gosh. I think there's literature being published all the time, and I wouldn't be able to tell you, if they rewrote this recommendation, if it would still get one hash mark or two.

Q. And it says here that an expert multidisciplinary team should manage care.

Do you see that?

A. Yes.

Q. Now, you work on an expert multidisciplinary team at the University of Michigan; right?

A. Yes.

Q. And you called it the biopsychosocial team, if I got that right?

A. No. The biopsychosocial assessment is what the social worker on our team performs as part of our multidisciplinary team.

Q. I got it. And your multidisciplinary team at Michigan includes an endocrinologist, you; right?

A. It includes two pediatric endocrinologists, three adolescent medicine pediatricians, two social workers, one

pediatric psychiatrist, one pediatric nurse practitioner, a pediatric nurse, and medical assistants.

Q. That's a pretty big team; right?

A. I don't know. It's our team.

Q. Okay. And all of these people were good enough to be hired at the University of Michigan children's hospital; right?

A. Yes.

Q. It's one of the best children's hospitals in the world?

A. Thank you.

Q. So you agree with me, I take it?

A. Well, I don't -- I'm not sure we are rated in the top ten, but I'm proud to work there.

Q. And would you agree with me that a small subset of the transgender population that is dealing with gender dysphoria has access to a multidisciplinary team like the one you're a part of?

A. I would not agree.

Q. Would you at least agree with me that the WPATH guidelines and the Endocrine Society guidelines suggest that multidisciplinary teams like yours be the ones at the forefront of providing gender-affirming care to patients. Right?

A. That's one of the Endocrine Society's recommendations.

Q. Okay. Doctor, I'd like to move on to another issue, fertility.

You testified yesterday that puberty blockers have no

affect on fertility; right?
A. Correct.
Q. But you still talk about fertility issues with your patients before putting them on puberty blockers; right?
A. Absolutely.
Q. And the Endocrine Society guidelines actually advise you to do just that; right?
A. Well, as I explained, you know, puberty blockers themselves have no impact on fertility. But I think it's helpful as a young person -- and their family -- who go on puberty blockers to be aware of subsequent decisions that -- and how those decisions may impact fertility in the future.
Q. Understood.
And so, Doctor, would you also agree with me that almost all of the patients that start off on puberty blockers go on to using cross-sex hormones?
A. I would say a vast majority of the patients that meet criteria for GnRH agonist who are having persistent gender dysphoria as puberty starts continue to have that gender identity in later adolescence and do qualify for -- for gender-affirming hormones, although not all, which is sort of the point of the GnRH agonists.
Q. And so for this vast majority, as you described it, who go from puberty blockers to cross-sex hormones, is there an effect on fertility for that population that goes from puberty blockers

to cross-sex hormones?
A. Well, as I tried to explain, the fact of the matter is you do need to go through puberty using your own body, at least partially, to achieve fertility. So someone assigned male at birth needs to progress through puberty enough, maybe to Tanner Stage 3 to make sperms currently, although there are investigations about taking, you know, premature sperm cells out, but that's not where we are at today in science.

So, yes, a person assigned male at birth needs to go partially through puberty to achieve the ability to make sperms. A person that is assigned female at birth, in order to participate in the pregnancy, needs to go through at least some puberty to produce eggs for fertility. The combination of puberty suppression using GnRH agonists, then hormones, you know, is intentionally, as part of treatment for gender dysphoria, forestalling the person from going through puberty using their own body. However, the only time I would say a person has no fertility potential is if the gonads are removed.
Q. So there is an effect on fertility? Did I understand that right?
A. Well, I would say, for example, if someone is assigned male at birth, right, and they are starting GnRH agonists at Tanner Stage 2, and then they're starting estrogen in later adolescence and never have started male puberty, that person, you know, has been, you know, treated for gender dysphoria, let's assume doing

well, and then later in adulthood says, You know what? I'd like to use my sperm to make a baby.

Okay. So what would that person do? They would stop their hormones and allow their body to go through some male puberty. And so anyone with testes in place, there is a chance that they could achieve fertility coming off of those hormones, allowing their body to go through a masculinizing puberty to some degree. You know, that would be the route that person would take if they wanted to achieve fertility.

Q. All right. I understood that. You said anyone with testes in place could potentially use those testes to have a kid later on in life?

A. Right. So how --

Q. Let me --

MS. COURSOLLE: Objection.

THE COURT: Overruled.

Here's what we are going to do. We are going to talk one at a time.

And, Dr. Shumer, it will help if you just answer his questions.

THE WITNESS: Sure.

THE COURT: And it will also help if things that have already been well established in the record, we just leave it alone and go on to the next thing.

MR. JAZIL: Understood.

BY MR. JAZIL:
Q. So, Doctor, someone with testes intact can still have a child, but the chances of that person having a child are lower after that person has gone through cross-sex hormones; right?
A. Yes. I think there's a couple parts to that. One is being on prolonged estrogen, how does that impact the testes, right?
If -- is the chance of fertility -- if someone were to be on estrogen for ten years and then discontinue, what is that person's fertility potential compared to if that person never went through that process in the first place?
I don't know the answer to that. It may be lower, but presumably not impossible.
Q. Are you aware of literature that supports the notion that withdrawal of hormones can allow a natal male to have a child?
A. I'm having a hard time thinking about a specific article, but I have patients that have done that successfully.
Q. Do you recall an article by Alexis Light that you cited in your expert report that deals with this issue?
A. Yes.
MR. JAZIL: Can we pull up Plaintiffs' Exhibit 188, please.
Can we go to the next page on this.
BY MR. JAZIL:
Q. Is this the article, Doctor?
A. Yes. So just to clarify, we were just talking about a

trans woman. So this article isn't necessarily about that. But I'm happy to review this article with you if you'd like.

Q. Okay. So what's this article about, a trans man?

A. Yes.

Q. Okay. And can trans men also become pregnant?

A. Yes.

Q. And this is one of the articles that supports that notion?

A. That's the -- sort of the topic of this article, yes.

Q. And this is one of the articles you relied on in forming your expert opinion in this case?

A. I don't exactly remember why I cited this article or what sentence I thought this article was helpful in citing, but I do recall citing this article in my expert report.

Q. And let's just quickly go through this article.

The first section, *MATERIALS AND METHODS*, it says that it was a web-based survey.

Do you see that, Doctor?

A. I do.

Q. Under *RESULTS*, it says: *Forty-one self-described transgender men completed the survey*.

Do you see that, Doctor?

A. I do.

Q. The *CONCLUSION* says: *Transgender men are achieving pregnancy after socially, medically, or both transitioned.*

Do you see that, Doctor?

A. Yes.
Q. Now, if we go to page 7 of this article, the second full paragraph -- page 7 on the bottom, the second full paragraph on the right, *Limitations to the study...*, do you see where it says: *Our eligibility criteria screened for transgender men who had a successful birth, impeding generalizable to those who attempt to get pregnant and cannot and those who do not carry to term.*
Do you see that, Doctor?
A. Uh-huh, yes.
Q. So you -- this study that you cited, you'd agree with me that it limited its eligibility criteria to transgender men who have had successful pregnancies; right?
A. Yes.
Q. And it concluded that transgender men can have successful pregnancies; right?
A. Yes.
Q. And it did so relying on a survey of 41 people; right?
A. So I think that the study is talking about the results of these pregnancies. I think the idea that trans men can have pregnancies is not controversial. This happens thousands of times across the country, you know, throughout the years. So I think the -- you know, just last week a person with an unexpected pregnancy who is a trans man currently on testosterone came to our emergency room. The fact that

transgender men can become pregnant is well known. So when I talk to my patients on testosterone, I always tell them, Even if you are not having periods, testosterone is not birth control, and that, You need another form of birth control, because transgender men get pregnant all the time.

So I think that that is not up for debate, necessarily. I think this article is interesting because it's explaining -- providing more detail about the results of those pregnancies.

Q. All right. Let's move on to another issue.

Dr. Shumer, bone mineral density, as I understood your testimony yesterday, you said the use of puberty blockers does have an affect on bone mineral density because we are suppressing natural puberty; right?

A. Yes.

Q. And you discuss issues related to bone mineral density with your patients; right?

A. Yes, similarly to how I discussed it with counsel.

Q. So as with the discussion with puberty blockers, is the idea that once you get off of the -- let me ask a better question.

If you are on puberty blockers, you discuss bone mineral density. And do you tell your patients that once you withdraw from the puberty blockers that bone mineral density will recover to where it should be for the natal sex at that age?

A. Well, how I talk about it is that puberty is an important

time for bone mineral density accrual, and everyone is going to go through puberty in some form or another, whether it's withdrawal from GnRH agonists or a provision of testosterone or estrogen.

You know, I think that the data that I discuss is having to do with the fact that, yes, when someone is on a GnRH agonist, as I said, you continue to accrue bone strength but not at the same speed as you would if you were going -- if you were continuing through puberty.

Upon starting puberty, in one way or the other, we would expect an increase in bone density relative to the speed that it's accruing prepubertally. And we do have evidence of catch-up. You know, there's an article demonstrating relative catch-up by 22. And as I also pointed out, we don't have data to suggest that there's a bunch of middle age trans people that took GnRH agonist that are now having the outcome that we really care about, which is fracture.

Q. Okay. When you're having these discussions, do you also order tests to get a baseline of what their bone density is before you put them on the puberty blockers?

A. My practice is to do a bone density scan in patients that have higher risk for low bone density. I don't -- I don't feel the evidence is compelling enough to require a bone density scan for every person that I prescribe GnRH agonists to.

Q. And do other endocrinologists in your practice have that

same practice of not taking a bone density scan to establish a baseline unless there is some other reason to do so?

A. I can't speak for all pediatric endocrinologists. I think perhaps some do DEXA scans on every patient starting GnRH agonists, and some use, you know, their professional judgment based on what the outcome of doing that bone density scan would be.

So sometimes I think about it like this. Anytime I order a test, I want to know what I'm going to do with the result, right. So if someone has lower bone mineral density than average prior to starting GnRH agonist, what would that mean?

It wouldn't change the fact that that person is eligible for GnRH agonist, but it would make me, as an endocrinologist, more cognizant of the fact that we need to keep this person's vitamin D in the normal range, talk about calcium intake, and that we would, you know, perhaps follow up with subsequent DEXA scans.

Someone without risk for low bone density, you know, the utility of that assessment, in my opinion, wouldn't change practice. So that's why personally I'd get a bone density scan if there is a history of fracture or low BMI, but not in someone that I'm not expecting to have a low bone mineral density for the reasons that sort of we discussed.

Q. What about your patients who go from puberty blockers to cross-sex hormones? How do you -- do you keep track of their

bone mineral density by taking a scan and then monitoring it over time?

A. No, I don't, because at the time that they start hormones, at that point we know that bone mineral density accrual increases, and watching that increase on a bone density scan wouldn't change the decisions that I would make with that particular patient.

Q. And, Doctor, you said that you reviewed the medical records of the plaintiffs in this case?

A. Yes.

MR. JAZIL: Your Honor, I'd like to discuss with the doctor some of the medical records. I was hoping we could not present the material on the larger screens.

THE COURT: Okay. The public screens are off, and the display will be shown there to the lawyers and to me and the witness but not to the public.

MR. JAZIL: Can we go to Plaintiffs' Exhibit 235, please.

BY MR. JAZIL:

Q. Now, Doctor, do you recognize the name of the institution on the top left?

A. I do.

Q. It's an institution that in your estimation provides world-class health care in this field; right?

A. I think that it's an institution I used to -- I was trained

at, and I have a high opinion of the care provided there, yes.
Q. Understood.
MR. JAZIL: Can we go to the page Bates labeled 43?
BY MR. JAZIL:
Q. Doctor, I'd like you to take a look at the second paragraph.
It says: *If the puberty blockade is discontinued, then the body would mature and the female puberty changes would occur. The potential risks include the effect on bone mineralization and fertility.*
Based on your review of the medical records for this patient, do you have any reason to disagree with this statement?
A. No.
MR. JAZIL: Let's go to the pages Bates labeled 45 and 46, please.
BY MR. JAZIL:
Q. Doctor, I'd like you to take a look at the very last sentence that begins on page 45 and then goes onto the next page.
Now, this says: *The risks of the procedure/treatment that have been discussed with me are*, and then the sentence goes on to say: *Studies of long-term side effects in this population* -- in this population here we are talking about a natal female who is in Tanner Stage 2 -- *is limited and may include a potential negative impact on bone health, growth, psychosocial development*

(including exploration of gender identity) and future fertility.

Do you see that, Doctor?

A. I do.

Q. First let me ask you this, Doctor: You disagree that puberty blockers may have an effect on future fertility if given long enough, right?

A. So as I have explained, GnRH agonists themselves do not have an impact on fertility. I think that this -- the verbiage here is obviously this provider's sort of boilerplate risks and benefits statement that they've discussed fertility with the patient.

She's not saying in this that the GnRH agonists themselves cause infertility, but she's saying that she had, presumably, a discussion around the same topics that we've been discussing in this trial.

Q. Do you disagree with anything that's listed there as the general verbiage from this physician?

A. Well, I think in previous testimony we talked a little bit about psychosocial development, to the extent that that may imply the topic we were talking about of cognition or brain development. So my answer to that one, you know, that I previously discussed may make me disagree with that part of the statement. Otherwise, you know, I don't have strong feelings about disagreeing with anything else.

Q. Understood.

MR. JAZIL: Can we take that down and go to Plaintiffs' Exhibit 236B.

Which is also medical records, Your Honor.

If we can go to the page Bates labeled 708.

BY MR. JAZIL:

Q. Now, Doctor, these are the medical records for a natal male who is almost a Tanner Stage 2.

If we go to the bottom of the page, the physician's notes, it says: *We have discussed that blocker therapy is reversible, but may have an affect on future fertility if given long enough. Furthermore, future fertility will almost definitely be compromised once cross-sex hormone with estrogen is ultimately started.*

That sentence, *Furthermore, future fertility will almost definitely be compromised once cross-sex hormone therapy with estrogen is ultimately started*, do you disagree with that statement?

A. I do. That's not how I would put it. I think the nuance of how I described it would be more accurate.

Q. And then it goes on to say: *For now, I have advised that we get a bone age and baseline labs below.*

So when the physician there is talking about bone age, is that the scan that you were mentioning?

A. It's not.

Q. It's not?

A. No.
Q. What would that be?
A. What is a bone age?
Q. Yes, sir.
A. Bone age is an X-ray of the hand. It's looking at the growth plates to help understand how much more height growth potential a patient has. So it's often used by pediatric endocrinologists when evaluating someone with short stature, for example.
Q. And then for someone who is being put on puberty blockers, would you be concerned about their bone age, and would you measure it before putting them on puberty blockers?
A. So a bone age itself isn't something to be concerned about. It's a test to assess how much taller someone is going to be.

So I don't know how tall this person was or if there was concerns about this person's final height. But I'd get a bone age frequently if I'm being asked a question about how tall someone is going to be. In gender clinic I get bone ages more rarely, only if there is a question or a concern about someone's final adult height.

Q. Understood.

Doctor, a few more questions.

THE COURT: Before you go on, let me just say for the record, I think you misread one of those scripts. There was a reference to the one in red on the screen now. *Furthermore,*

future fertility, it says, *will most definitely be compromise*d. You read it as will almost definitely be compromised. And I'm sure the transcript will have what you read and not what it says here.

MR. JAZIL: Understood, Your Honor. I apologize. It was inadvertent.

THE COURT: I understand. It's better for your side the way it's actually written than the way you read it, but I just didn't want there to be a confusion about the transcript.

BY MR. JAZIL:

Q. Doctor, yesterday you talked with my friend about the *DSM-5*.

Do you recall that testimony?

A. Yes.

Q. But you're not a psychiatrist; right?

A. That's correct.

Q. And you've never made a diagnosis for gender dysphoria using the *DSM-5*, have you?

A. Well, I'm very familiar with the *DSM-5*. And making a diagnosis using *DSM-5* isn't very complicated. So if you meet this criteria, this one and this one, you have a diagnosis of gender dysphoria.

That being said, my role on our multidisciplinary team is not to perform that assessment. It's -- that part is being done by a social worker.

Q. Understood.

And, Doctor, you're a member of a group called Stand with Trans; right?

A. I'm not a member of a group. I'm on the advisory committee of that organization.

Q. Okay. And that organization that you are on the advisory committee of, it's an advocacy organization for transgender issues; right?

A. Yeah.

Primarily they organize support groups for trans youth and for parents of trans youth in southeast Michigan.

Q. But they also put out literature critical of state efforts to regulate gender-affirming care; right?

A. Well, fortunately there aren't a lot of state efforts to eliminate transgender care in Michigan, so I don't think they have been very active in that regard.

Q. Have you written anything for that organization that criticizes, say, the State of Arkansas for it's gender-affirming care approach?

A. I have written about legal efforts in Arkansas, but I'm not sure that was related to the organization Stand with Trans.

Q. Okay. Fair enough.

MR. JAZIL: Your Honor, I have no further questions.

THE COURT: Redirect?

MS. COURSOLLE: Thank you, Your Honor.

REDIRECT EXAMINATION

BY MS. COURSOLLE:

Q. Dr. Shumer, when my friend Mo was asking you questions just now, you mentioned that the quality of evidence related to the Endocrine Society guidelines reviewing deserves further explanation.

What is that explanation?

A. Yeah. So I can -- I can understand consternation when one line in a long report says, This is based on very low-quality evidence. And I think the previous witness talked about this a bit, but I wanted to elaborate from my perspective that -- that the Endocrine Society, for example, publishes Clinical Practice Guidelines on many, many, different topics; congenital adrenal hypoplasia, thyroid cancer, adrenal insufficiency.

When you read all of those Clinical Practice Guidelines, they all start very similarly with an explanation of these hash marks, and then the multitude of very many suggestions and recommendations are all assigned different markers of quality that the Endocrine Society Clinical Practice Guidelines in this arena reads very similarly to all of these other Clinical Practice Guidelines, where if you have, you know, 35 different things, some of them are going to be higher or lower quality. And that quality means what type of evidence is that recommendation specifically being relied on, right?

So if you were going to give something four hash marks,

presumably that would be something that, for example, was subjected to some sort of double-blinded randomized trials, which, as we discussed, is not feasible in complicated medical problems such as gender dysphoria, but also such as many other complicated medical problems.

That -- the one here that was with the lowest, the one hash mark, was referring to a very specific question providing gender-affirming hormone care in this narrow age group between, I think, 13 and a half and 16.

So there hasn't been -- while there is maybe some literature about that, that literature isn't it as robust as the literature regarding 16 and up, for example, which isn't surprising to me. When I -- if I'm evaluating a 14-year-old and thinking about hormonal care, what I'm doing is, first of all, thinking about that person as an individual, looking at the literature to suggest is there relevant literature related to this specific patient that I'm seeing today? Is there literature -- more literature about 16-year-olds? Can I -- how does that literature relate to the question that I have in front of me; hormone care for a 14-year-old? Is that totally irrelevant because it doesn't talk about 14-year-olds, it's talking about 16-year-olds? Probably not totally irrelevant.

That -- you know, for that particular line to be higher, you would need to conduct another study that was specific to that age group, for example. And presumably that type of work

is continuing to be done.

None of those will ever be four hash marks, right, because we can never do the type of research in this particular field that would result in that, similarly to other Endocrine Society recommendation manuscripts such as this that are talking about very complicated, multifaceted medical problems that will never have four hash marks, but at least as a way for the reader to understand why the Endocrine Society made that particular suggestion or recommendation.

I'd also say that one hash mark is saying that, All right. We aren't assigning this a higher level, but we did review all of the data and we could have come up with one of two statements. One statement is, We recommend this or suggest this, and the other statement is, We do not recommend or suggest this.

So based on the review of the entire body of work, you know, while they weren't able to assign that particular item a higher score, rather than say, After reviewing all this, we don't suggest it, they said, After reviewing this, we do suggest it.

You know, I think that with any area of medicine more study and more literature is welcome. What I'm concerned about, though, in this particular field is that it may never be enough, right, for people that oppose gender-affirming care, that if we, for example, were able to do a randomized controlled trial where

we have 13-year-olds or, let's say -- let's say people at Tanner Stage 2 that are going to be randomly assigned GnRH agonists or no treatment, and hypothetically we could find people that would participate, right, because we wouldn't be able to find people that would participate, but let's say we did -- that what would the end point be? Would it be one year later how are we doing comparing these people to these people? We can do that. We could publish that. But then they would say, Well, that doesn't answer the question about how they are doing when they are 20, okay.

So let's continue this randomized controlled trial. Let's continue to treat these people from age 10 all the way to age 20 and say, You guys, you are going to stay in the control group and not receive any care for the next ten years, okay. And then we can publish data about how those people are doing.

And then they would say, Well, that doesn't tell us on how -- let's compare them on how they are doing as 50-year-olds, because that's what we really want to know, okay. So we are going to say, All right. This group, we are going to continue your hormones. This group, because you were assigned to the control group when you were 10, you are going to receive no care for your gender dysphoria until you are 50, but then you'll be done with the study. Then that's published, right.

I think that it's clear that that could never happen, right. But even then I think that people would still say

there's not enough high-quality evidence to support gender-affirming care. Not because there's not enough evidence per se, but because they have a problem with the care.

Q. Dr. Shumer, the type of theoretical study you just described, could that kind of study be blinded?

A. Of course not, because puberty is something that you can tell if you are going through or not.

Q. So it would be impossible to have a -- a blinded randomized control study of the effect of puberty blockers for that reason --

A. Correct.

Q. -- is that right?

A. Correct.

Q. You spoke with my friend about the effect of hormones on fertility. Are there any studies that quantify the effect of hormone treatment on fertility for people who receive hormone treatment for gender dysphoria? To your knowledge, of course.

A. Not that I recall.

Q. So there's some evidence that hormone treatment may impact fertility. Do I have that right?

A. Yes. So I think some of that we've reviewed, but I would say, yes, there is some evidence that hormone treatment can impact fertility.

Q. But we don't know the extent of that impact, in other words?

A. Correct.
Q. And some people who never receive gender-affirming care also experience infertility; is that right?
A. That's correct.
Q. You mentioned that you have clinical experience with your own patients who have received hormone treatment and have been able to achieve fertility.

Can you tell us a little bit about that?
A. Yeah. So, actually, just last week I was talking to a patient on estrogen who impregnated someone. And so our conversation was about becoming a parent. It was not an intended pregnancy, but the person was excited. They were in a relationship with a cisgender woman, and she's delivered a healthy baby.

So, you know, I think another just example of the fact that, you know -- that you can't use hormones as birth control, right, so I keep plugging away on that one. But also that, you know, everyone has different levels of fertility and infertility. And that -- that it is quite a complicated topic, right. That is complicated because we all don't know our life story, how it's going to unfold, who we are going to fall in love with, how we want to create a family. Of course, there is many options to create a family. But, you know, talking about fertility, you know, is a really personal and individualized thing. On top of that, everyone's individual capacity for

fertility is different. And everyone's response to these medical interventions that we are talking about is likely different.

So it's something that I think deserves sort of the breadth and depth of the conversation that I try to have with each patient, but it is not a topic that very well lends itself to black-and-white answers.

Q. Thank you.

You also spoke with my friend about using DEXA scans to measure bone density for people who use GnRH agonists.

When you use GnRH agonists to treat precocious puberty, do you ever order DEXA scans?

A. No.

Q. When you prescribe other medications that could impact bone density, what is your practice regarding DEXA scans?

A. Well, I think a DEXA scan is a test, and so it's a tool that one would use if you feel like knowing someone's bone density would be helpful in medical decision-making.

So I'd say the times where I use DEXA scans the most is someone with frequent fractures, right. So, as an endocrinologist, I might see someone who has, let's say, juvenile arthritis, and they've been on chronic steroids during childhood, and they've had some fractures. And the question that they are asking me is does this person need treatment with bisphosphonates to strengthen their bones? I might order a DEXA

scan to assess bone density. And then the DEXA scan, you know, comes back with the result -- zero is average. Negative 2 and lower is below average. Plus 2 or higher is above average. So if that person had a DEXA score of less than .2, then that might be an indication to start bisphosphonates, for example.

Q. My friend showed you the medical records of our two child plaintiffs in this case -- or some of their medical records.

The medical records that you were shown reflected the informed consent process that those two plaintiffs went through; is that correct?

A. Yes.

Q. And was that the informed -- is your understanding that that was the informed consent that the provider prescribing those medications reviewed with those plaintiffs's parents?

A. Well, it's what was in the medical records, so there may have been additional information verbally discussed with the family that I'm not privy to. But yes, it seems like it was included in the medical record as sort of an overview of the informed consent conversation that was had with that particular patient.

Q. In your opinion was the discussion of risks in those informed consent -- in that reflection of the informed consent conservative?

A. Yes.

Q. Why?

A. Well, you know, I think that it's hard to -- you know, some of the discussions that we've had about each of these topics, you know, I've spent five, ten minutes talking about the nuance, right. So when you're putting something in a medical record in a sentence, it's hard to distill all that nuance.

But I think, you know, for documentation sake, you know, the inclusion of those things implies that those types of discussions were had. But, like, for example, with -- including things like cognitive development, or however it was put for the first example, I would consider that conservative because the evidence for that particular isn't there.

You know, in a second case when it says most definitely, or whatever, would impact fertility, you know, I hoped to have conveyed the nuance that I would convey to patients, which is, you know, I would -- we consider that example to be conservative.

MS. COURSOLLE: Thank you, Dr. Shumer.

I have no further questions, Your Honor.

THE COURT: Dr. Shumer, you told us you're in clinic a couple of times a week.

You're also a medical professor?

THE WITNESS: Yes.

THE COURT: So part of your week is spent teaching medical students?

THE WITNESS: That's right.

THE COURT: Mr. Jazil asked you about the University of Michigan and your clinic and its quality; it's one of the good medical schools.

There are also a couple of schools in Florida that folks think highly of. University of Florida, University of Miami both had, I understand, gender clinics.

Are you familiar with those clinics at all?

THE WITNESS: Yes.

THE COURT: My understanding is they are now shut down. Do you know whether that's so or not?

THE WITNESS: I'm not sure. I would say that I've had a few patients from Florida that have come to Michigan for care because their grandparents live in Michigan. Usually people's grandparents live here and they live there, but I guess this was the other way around.

THE COURT: Have you talked with anybody about how that will shake out now that Florida apparently has legislation that would allow taking children away from their parents if they go to Michigan to your clinic?

THE WITNESS: Well, that's -- that makes me sick to my stomach, to be honest, because, you know, I just am really worried about the health and well-being of those kids. But it's also saying, you know, not only do we disagree with this particular evidence, but parents that may agree with it we think are committing some sort of child abuse.

And so, yeah, it makes me very worried about the health and well-being of children and families in that sort of situation.

THE COURT: Now, I haven't seen evidence on exactly your clinic or of the Florida -- University of Florida clinic or Miami. But my guess is nobody is going to disagree with the proposition that these are all very high-quality institutions that provide high-quality medical care in general. There will be a lot of disagreement about the care in this particular area, but all good institutions.

Here's a concern, and tell me what you can about this. The concern is the quality of care that you are providing with the team you've described may be different from the quality of care that someone gets from a single doctor in a single city in Florida where there is not a major medical research institution, and so that's a concern.

If care is properly provided in the University of Michigan setting or University of Florida setting, how does that compare to what may be provided in an individual city by an individual provider?

THE WITNESS: Yeah. You know, I would say that it's -- I think it's different when you are thinking about pediatrics versus adult. So I think, in general, most solo practice pediatricians, for example, aren't deciding that they are going to start providing gender-affirming care, because they

recognize that that care may be better provided in more of a multidisciplinary center. On the other hand, there's more, you know, family practice docs or internal medicine docs that are providing care to adult trans people sort of across the country.

So, for example, in Michigan, we have patients coming from all corners of the state. Just like Florida, it's -- we've got two peninsulas, not just one, but people coming from, you know, the Upper Peninsula traveling six hours to Ann Arbor for care. Virtual visits have made that a little easier for follow-up.

But I would say, if not all, the vast majority of adolescents receiving gender-affirming care are getting that care at -- at not necessarily universities, but centers with experience and centers of excellence.

You know, so I think that -- I agree with you that, you know, if I had -- if I had a transgender child, I would want to them to be seen by someone that was an expert. And, you know, fortunately, in -- I would also not say that that's not so different than other endocrine problems, right. So if I had a child with hypophosphatemic rickets and I lived in Florida, I might travel to Gainesville for care. Because that's a rare condition, I want to see an expert pediatric endocrinologist.

And so I think that is an important topic, but I also think that most kids are getting seen by people that are in this field because they are passionate about it, but they have also

taken the time to really become experts in providing the care.

THE COURT: Questions just to follow up on my questions, Mr. Jazil?

FURTHER EXAMINATION

BY MR. JAZIL:

Q. Dr. Shumer, do you know of colleagues who provide the same care kind of services you provide to transgender youths at the University of Florida?

A. I can't say their names off the top of my head, but yes, I have interfaced with colleagues at the University of Florida before.

Q. Have you interfaced with anyone, who provides the services you provide, here in Tallahassee, Florida?

A. I don't recall.

MR. JAZIL: Thank you.

THE COURT: Thank you, Dr. Shumer. You may step down.

(Dr. Shumer exited the courtroom.)

THE COURT: Please call your next witness.

MR. GONZALEZ-PAGAN: Thank you, Your Honor.

MS. McKEE: Plaintiffs call Dr. Loren Schechter.

(Dr. Schechter entered the courtroom.)

MR. GONZALEZ-PAGAN: Your Honor, if it's okay, the witness has requested to take a two-minute -- five-minute bathroom break, if that's okay.

THE COURT: Surely. Let's go ahead and take the

morning break. Let's take ten minutes, and we'll start back at 10:10.

(Recess taken at 10:00 AM.)

(Resumed at 10:10 AM.)

THE COURT: Please be seated.

Please swear the witness.

THE COURTROOM DEPUTY: Please stand and raise your right hand.

DR. LOREN SCHECHTER, PLAINTIFFS WITNESS, DULY SWORN

THE COURTROOM DEPUTY: Please be seated.

Please state your full name and spell your last name for the record.

THE WITNESS: Loren Schechter, S-c-h-e-c-h-t-e-r.

DIRECT EXAMINATION

BY MS. McKEE:

Q. Dr. Schechter, what is your profession?

A. I'm a plastic surgeon.

Q. Are you a board-certified plastic surgeon?

A. I am.

Q. Would you please summarize for the Court your formal education and training?

A. Undergraduate degree at the University of Michigan, medical degree at the University of Chicago Pritzger School of Medicine, and training in general and plastic surgery at the University of Chicago, and a fellowship in reconstructive microsurgery at the

University of Chicago.
Q. What is your current position?
A. Professor of surgery and neurology at Rush University Medical Center, and director of gender affirmation surgery.
Q. Do you have any additional role within the division of plastic surgery at Rush?
A. I serve as the patient safety officer for the division of plastic surgery.
Q. You mentioned gender affirmation surgery. In basic terms, what is gender-affirming surgery?
A. Gender-affirming surgery represents a constellation of procedures that are designed to align a person's anatomy with their gender identity.
Q. Is gender-affirming surgery performed to treat particular condition or conditions?
A. Performed to treat gender dysphoria.
Q. How long have you been performing gender-affirming surgery?
A. As an attending physician, since 2000, and also during my medical school and residency as well.
Q. Over the course of your career how many gender-affirming procedures have you performed?
A. Over 1500.
Q. What percentage of your current practice consists of gender-affirming procedures?
A. Approximately 90 percent.

Q. And what percentage of your patients who undergo gender-affirming procedures are under age 18?
A. Currently under -- under 2 percent.
Q. And how many would you say -- or what percentage would you say are under age 21?
A. Under 5 to 10 percent.
Q. Have you published any articles in peer-reviewed publications?
A. I have.
Q. About how many articles?
A. Approximately 70, perhaps a bit more.
Q. And roughly what percentage of those articles are related to gender-affirming surgery?
A. Approximately 15 percent, maybe 20 percent.
Q. Have you written any medical textbooks on gender-affirming surgery?
A. I have.
Q. Could you tell us what those are?
A. I've written for *Surgical Atlas* on *Surgical Management of the Transgender Patient*, published perhaps 2006 or 2017. Edited textbooks similarly on gender-confirming surgery.
Q. Are you one of the authors of the WPATH Standards of Care?
A. I am.
Q. Which chapter did you contribute to?
A. I was the co-lead author on the surgery and aftercare

chapter, Chapter 13.
Q. Are you involved in training other surgeons to perform gender-affirming procedures?
A. I am. I started the first fellowship in the U.S. in 2017, and regularly work with surgical residents, medical students, fellows.
Q. Do you have a leadership role in any professional associations?
A. I do. I'm currently on the executive committee of WPATH. I serve as treasurer of WPATH. I chair the finance committee for the American Society of Plastic Surgeons.
Q. What is the American Society of Plastic Surgeons?
A. That's a professional organization. Membership requires certification by the American Board of Plastic Surgery and represents plastic surgeons, both nationally and as well as internationally, international members.
Q. When you submitted your expert report in this case, you provided a copy of your CV; correct?
A. I did.
(Reporter requested clarification.)
BY MS. McKEE:
Q. When you submitted your expert report in this case, you provided a copy of your CV; correct?
A. Yes.
Q. And does that CV present an accurate summary of your

qualifications and professional activities?
A. Yes. There's probably been some more publications since then, but yes.
MS. McKEE: Your Honor, Dr. Schechter's CV is Plaintiffs' Exhibit 362 and is included on our list of stipulated exhibits.
THE COURT: That is admitted.
MS. McKEE: Thank you.
At this time I move to have Dr. Schechter qualified as an expert in plastic surgery, and specifically the surgical treatment of gender dysphoria in adults and adolescents.
THE COURT: Mr. Jazil, questions at this time?
MR. PERKO: No questions, Your Honor.
THE COURT: You may proceed.
MS. McKEE: Thank you.
BY MS. McKEE:
Q. So you mention you're a member of the American Society of Plastic Surgeons.
Are you a member of the American Medical Association?
A. I am.
Q. What about the American College of Surgeons?
A. Yes.
Q. What about the American Burn Association?
A. Yes.
Q. Do any of those four professional medical associations I

asked about engage in advocacy?
A. Yes, to those four and many others.
Q. On behalf of what or whom do those organizations advocate?
A. Typically on behalf of the patients for whom we care, as well as members of the organization.
Q. And in your experience do most professional medical associations engage in advocacy?
A. Yes, they do.
Q. Would you summarize for the Court the various gender-affirming surgical procedures that are performed?
A. So there are procedures on the face, often referred to -- or maybe referred to as facial feminizing or masculinizing; procedures on the chest or breasts, typically either mastectomy or breast reconstruction, sometimes referred to as breast augmentation; procedures on the genitalia, and procedures on the body.
Q. Could you give an overview of gender-affirming genital surgeries that you mentioned?
A. Pardon me?
Q. Could you give an overview of gender-affirming genital surgeries?
A. Yes.
So for transfeminine people, vaginoplasty. For transmasculine people, either phalloplasty or what's referred to as metoidioplasty, m-e-t-o-i-d-i-o-p-l-a-s-t-y, which refers to

lengthening of the hormonally hypertrophied or virilized anatomy.

Q. And what surgical procedures do you perform in your own practice?

A. I perform all of those procedures, less so face now. I have colleagues who specialize in facial surgery and craniofacial surgery.

Q. Are the various surgical procedures that are performed to treat gender dysphoria performed to treat other conditions as well?

A. Yes, they can be.

Q. And what other conditions is mastectomy performed to treat?

A. A mastectomy may be performed to treat breast cancer, it may be performed as what we call risk reducing or prophylactic, to reduce the risk of a person having breast cancer, may be performed for gender-affirming purposes.

Q. So other than when performed for gender-affirming purposes, have you ever performed a mastectomy to prevent or treat cancer?

A. Yes.

Q. And other than gender dysphoria, what conditions is vaginoplasty performed to treat?

A. Vaginoplasty may be performed for congenital differences, for cisgender women either born without a vagina or incomplete formation of the vagina; may be performed for oncologic reconstruction, so for cisgender women who have had portions of

the vulva or vagina removed for cancer; may be performed to treat traumatic deformities, infection, and gender-affirming.

Q. So have you ever performed a vaginoplasty to treat any of those conditions other than gender dysphoria?

A. Yes.

Q. And other than gender dysphoria, what conditions is phalloplasty performed to treat?

A. Similarly, it may be performed for traumatic reconstruction, oncologic reconstruction, congenital differences, infection.

Q. Have you ever performed a phalloplasty for any of those reasons?

A. I have.

Q. How long have surgeons been performing gender-affirming procedures?

A. Well, in the modern surgical history, really dates back to the 1930s. The first modern reports of vaginoplasty performed in Germany in Berlin in the 1930s. Subsequent to that, really, the father of plastic surgery, Sir Harold Gillies, performed the first phalloplasty procedure on a World War II veteran in the mid-1940s, using a series of flaps, tissue we transfer from one area of the body to another.

Sir Harold Gillies, actually in association with Dr. Ralph Millard, who had served as chairman of plastic surgery at the University of Miami, was a world-renowned plastic surgeon, also

performed a vaginoplasty in the '40s or '50s, again on a World War II veteran.

Subsequent to that, a gynecologist practicing in Casa Blanca, really credited with developing much of the modern basis, the surgical techniques that we use today, really still form the basis of those procedures.

We move forward to the '80s or so, and many of the more sophisticated reconstructive and microsurgical procedures were then performed for how we now create -- perform a phalloplasty.

Q. How does a doctor become a board-certified plastic surgeon?

A. So following graduation from medical school, entering an accredited residency; following that, passing written examination, and then an oral examination. And then to maintain one's board certification, there is a ten-year cycle, that we now refer to as maintenance of certification, requiring a variety of ongoing education efforts and tests.

Q. Is gender-affirming surgery part of the core curriculum in residency for a plastic surgeon?

A. It is.

Q. Is gender-affirming surgery a component of the written or oral board exams in plastic surgery?

A. Yes.

Q. And can gender-affirming surgery be a component of the maintenance requirements of a plastic surgeon?

A. It can, yes.

Q. I want to turn to talk about clinical guidelines.

Are there clinical guidelines for the surgical treatment of patients with gender dysphoria?

A. Yes.

Q. What are those guidelines?

A. Those are the Standards of Care, currently Version 8.

Q. When you say "Standards of Care," are you referring to the WPATH Standards of Care?

A. I am.

Q. When were those Standards of Care first published?

A. The first version was published in 1979. Prior to the 8th version, the 7th version was published, I believe, in 2012. The 8th version was released in September of '22.

Q. And do you practice in accordance with the WPATH Standards of Care?

A. I do.

Q. Do you regularly talk with other surgeons who perform gender-affirming procedures about those procedures?

A. Yes.

Q. And roughly how many surgeon who perform gender-affirming procedures would you say you regularly talk with?

A. Over 100.

Q. In what context are you having those discussions?

A. A number of different contexts: Meetings, seminars, conferences, collaboration in various clinical research

programs, patient care.
Q. Are all of the surgeons you are talking with based in the United States?
A. No.
Q. Where are some of those other surgeons living and practicing?
A. Throughout Europe, South America, Canada, Asia.
Q. And do most of those surgeons consider the WPATH Standards of Care to be the prevailing clinical guidelines for gender-affirming surgery?
A. I believe so.
Q. And, to your knowledge, do most of those surgeons practice in accordance with the WPATH Standards of Care?
A. I believe so.
Q. Under those Standards of Care, is surgery indicated for every patient with gender dysphoria?
A. Well, not every patient who is transgender or who has gender dysphoria seeks surgical interventions. Not every person seeks every possible surgical intervention and not every person is a candidate for a surgical intervention.
Q. Under the WPATH Standards of Care, is gender-affirming surgery ever appropriate for treatment for an adolescent under age 18?
A. It can be.
Q. Which surgeries are considered appropriate treatment for an

adolescent?
A. Overwhelmingly, mastectomy.
Q. Is general surgery ever considered appropriate treatment for a patient under 18?
A. In extremely rare situations it can be.
Q. Does the number and sequence of surgical procedures vary --
(Reporter requested clarification.)
BY MS. McKEE:
Q. Does the number and sequence of surgical procedures vary from patient to patient?
A. Yes.
Q. And based on what factors?
A. Based on patient factors, patient goals, patient expectations -- any number of factors -- ability to have time off work, depending -- or school, depending on the complexity and the nature of the procedure.
Q. Do the WPATH Standards of Care envision the surgeon working in a multidisciplinary manner to decide if a particular patient is a candidate for surgery?
A. It does.
Q. What kinds of providers can be part of that multidisciplinary team?
A. It can be surgeons; it can be medical professionals; it can be mental health professionals.
Q. In your experience, are any of those providers working as

part of that team ever in private practice?
A. Yes. And I was in private practice for a number of years.
Q. And when you were in private practice, did you still work as part of a multidisciplinary team for patients undergoing gender-affirming surgery?
A. I did. And we regularly -- I regularly work with professionals from around the country and around the world. So multidisciplinary doesn't necessarily imply that all of the professionals are housed, so to speak, under one roof. We regularly communicate and interact with people outside of our own institution, and I have done that throughout my career.
Q. Can you explain for us how the multidisciplinary process works?
A. Sure.

And so it depends, of course, on the individual case. But, for example, in my practice when I see someone in consultation, we'll meet with them, obtain a history and physical, listen to what their goals are; we'll discuss possible treatment pathways, which may mean no intervention, but we also discuss, if appropriate, relative interventions.

Subsequent to that and before making a decision to proceed with surgery, we'll obtain assessments. Those are typically assessments from mental health professionals, typically medical professionals as well. Those assessments are reviewed. If additional information is required or warranted, or additional

consultations, we'll obtain or request that. And then we'll, if appropriate, move forward with surgery.

Q. And under the WPATH Standards of Care and in your practice, does the surgeon make the ultimate determination as to whether to proceed with surgery?

A. Yes. Ultimately it's the decision of the surgeon.

Q. What goes into making that determination?

A. Well, it's much like every decision we make, every surgical decision we make in many areas of surgery. We meet with the patient; we take a history and physical; we listen to them, listen to their goals, their expectations. We make an assessment as to whether a procedure is indicated; if so, what types. We discuss the options, the risks, the benefits. We obtain the consult -- the assessments that we just discussed and hopefully arrive at a treatment plan that is in mutual agreement through this shared decision-making process.

Q. And does the surgeon obtain informed consent from the patient?

A. Yes. And informed consent is very much a process. Just as we've described, it culminates with memorializing this typically in what we call the informed consent document, but typically involves this discussion between the surgeon and the patient. We encourage people. We provide written information. We review, for example, representative photographs of results. We encourage patients to go home, to consider, to discuss with

whoever is relevant in their decision-making process, to return to us, if needed, in person, by phone for additional information. And then, again, if the decision is to move forward, memorialize that with the documentation.

Q. Can a minor provide informed consent to surgery?

A. So minors, in order to proceed with surgery, need to assent to a surgical procedure, which is very much a parallel process to the informed consent which is provided by the parents or guardian.

Q. Can a patient with a mental health condition provide informed consent to surgery?

A. So patients with mental health conditions can provide informed consent. Now, if someone, of course, is actively psychotic or delusional, they cannot do that. But we do see patients not only in the realm of gender-affirming care, but many other areas of care -- oncologic care, traumatic reconstruction -- who may have mental health conditions and routinely provide informed consent.

Q. Are there other areas of surgery in which a similar kind of multidisciplinary approach is used?

A. Multidisciplinary care is common in cancer care, transplantation, bariatrics.

Q. What distinguishes a medically necessary surgery from a surgery that is not medically necessary?

A. So medically necessary procedures are typically done to

treat a medical condition or prevent progression of that condition.

Q. In plastic surgery is a medically necessary surgery generally referred to as reconstructive?

A. Generally, yes.

Q. And a surgery that is not medically necessary is generally referred to as cosmetic?

A. Correct.

Q. Are there any gender-affirming surgical procedures that you consider to be medically necessary?

A. Yes.

Q. And why do you consider them to be medically necessary?

A. Because -- excuse me -- they are used to treat the medical condition of gender dysphoria.

Q. Does the broader medically -- let me start over.

Does the broader medical community generally consider gender-affirming procedures to be medically necessary?

A. Yes.

Q. And how do you know that?

A. Well, I'm a member of professional organizations. I've spoken at a number of these professional organizations at various conferences, routinely work with other professionals who are members of these organizations.

Q. Does the American Society of Plastic Surgeons consider gender-affirming procedures to be medically necessary?

A. Yes, they consider many of these procedures to be reconstructive and, in fact, list that on their website under the description of these procedures.
Q. Are there other medical associations that agree with that, that these surgeries are reconstructive?
A. American Medical Association, WPATH.
Q. One of the experts for the defense, Dr. Lappert, contends that gender-affirming surgery is never medically necessary because the patient is healthy before the surgery.

What is your response to that?
A. I disagree with that. As we've discussed, we operate on people who are oftentimes, quote, otherwise healthy. So, for example, performing a risk reduction or prophylactic mastectomy where we remove a breast on a cisgender woman who may be seeking to reduce her risk of cancer who is otherwise healthy; a person with appendicitis, but for the appendicitis would be otherwise healthy.

So otherwise healthy is not a distinguishing criteria for medical necessity of a procedure.
Q. Dr. Lappert also contends that a gender-affirming mastectomy is not medically necessary because it causes a complete loss of function, specifically, the loss of the ability to breastfeed and a loss of erotic sensibility.

What is your response to that?
A. I also disagree with that.

So for many transgender men, the breast is not a source of erotic sensibility, and they do not desire the ability to breastfeed. And, in fact, romantic relationships are typically enhanced following the removal of the breasts, following the mastectomy.

But we perform other procedures on the breasts on cisgender women. The ability to lactate, for example, is not necessarily known to me. If we have a woman who is seeking breast reduction, we don't test her ability as to whether she can lactate. Many cisgender whom who seek breast reduction do not have erotic sensibility of the nipples. The breasts may be quite large; they stretch the nerves.

So neither of those, in my opinion, would determine medical necessity of the procedure.

Q. Is there peer-reviewed literature examining the effectiveness of gender-affirming surgery?

A. Yes.

Q. Do you keep up to date with that literature?

A. I do.

Q. Why do you do that?

A. Well, clinically for patient care. I teach -- routinely teach students, residents, fellows, present at meetings, conduct clinical research.

Q. And what does the peer-reviewed literature show about whether a surgery is effective in alleviating gender dysphoria?

A. Literature demonstrates both safety and efficacy.
Q. Do some of the studies look at whether surgery, when used to treat gender dysphoria, has any effect on patient quality of life?
A. Yes.
Q. And what do those studios show?
A. Improvements in quality of life.
Q. Is it common for researchers to examine the effect of a surgical procedure on patient quality of life?
A. Yes.
Q. In what other areas of surgery do researchers use patient quality of life as an outcome measure?
A. Many in plastic surgery, but certainly in breast cancer and breast reconstruction.
Q. And am I correct to say that surgeons generally agree that surgery to treat breast cancer is medically necessary as opposed to reconstructive -- as opposed to cosmetic?
A. Yes.
Q. Does any of the peer-reviewed literature look at the effectiveness of gender-affirming surgery in adolescents?
A. Yes.
Q. And what does that literature show?
A. Similar, both safe and effective.
Q. Are you familiar with the American Society of Plastic Surgeons's levels of evidence?

A. I am.
Q. Could you explain what the levels of evidence are?
A. The levels of evidence are listed I through V, I typically being randomized controlled trial, V typically being expert opinion, II, III, IV vary, for example, with case series, cohorts, et cetera.
Q. And are those levels of evidence similar to the levels of evidence used in other areas of medicine?
A. They are. They may have subtle variation, but generally speaking, yes.
Q. Is it possible to perform randomized controlled trials to evaluate gender-affirming surgery?
A. It's not. Number one, we can't blind people to a surgical procedure. Obviously, if you've had a procedure, you will know. There's no placebo in surgery. There's not a pill, that is, a sugar pill, versus a medication. Of course, it would be unethical to deny people medically necessary care. And so those are limitations not only in the realm of gender-affirming surgery, but in many other areas of plastic surgery.
Q. Are studies that are rated as a lower level of evidence ever used in clinical decision-making?
A. Yes.
Q. And how are they used?
A. Well, levels of -- studies of lower levels of evidence may be helpful in guiding treatment, understanding a condition. The

medical literature is one component that informs our clinical decision-making, but it's one component. Of course our experience -- not only our experience, our discussions with colleagues across the globe; speaking with our patients, listening to our patients, understanding their values, their preferences. Those are all some of the factors that guide and go into clinical decision-making.

Q. How does the level of evidence supporting gender-affirming surgical care compare to the level of evidence supporting other accepted plastic surgeries?

A. Similar. So, for example, in the area of cleft or cranial facial surgery, there are very few randomized controlled trials and for many of the same reasons: Small population size, vulnerable population, inability to blind, to have a placebo, can't deny people medically necessary care. And these are just inherent limitations we face in surgery.

Q. So you mentioned studies aren't the only way that you determine the appropriate course of treatment for a condition; that's right?

A. Correct.

Q. In your clinical experience, do patients benefit from gender-affirming procedures?

A. Yes.

Q. And how so?

A. Well, overwhelmingly, in terms of relief of dysphoria,

improved quality of life.
Q. Have you seen patients who have been unable to access gender-affirming procedures due to lack of insurance coverage or other financial barriers?
A. Yeah. That was really the natural history. Certainly, early in my practice when access to care was limited, people had to leave the country. People very tragically had a result of self-surgery, castration, autoamputation. So, unfortunately, I've seen the natural history of untreated gender dysphoria. And, unfortunately, that was the norm here in the United States until we were fortunate to have expansion of access to care.
Q. You testified earlier that various surgical procedures that are performed to treat gender dysphoria are also performed to treat other conditions; correct?
A. Yes.
Q. Are the procedures any more or less safe when performed to treat gender dysphoria as opposed to another condition?
A. Procedures we use in gender-affirming surgery are established techniques that are routinely used to treat other conditions.
Q. Are the complication rates for the procedures any different when performed to treat gender dysphoria as opposed to other conditions?
A. Complication rates are commensurate with those other procedures, other conditions.

Q. Okay. I want to switch gears to talk about regret among patients.

Is there peer-reviewed research looking at rates of regret among people who have had gender-affirming surgery?

A. Yes.

Q. What does that literature show?

A. Extremely low. The -- and regret may be subdivided into different types. Regret regarding one's identity -- I was wrong. I'm not who I am -- extremely low, probably .3; .6 percent, regret regarding external factors -- marginalization, stigmatization, loss of relationships, loss of professional opportunities.

But regret in -- regret also implies that someone would have made a different decision. And so regret occurs far more commonly, far more commonly in other areas of surgery and, in fact, is very low in gender-affirming surgery as compared to many other areas of surgery.

Q. And is there peer-reviewed research looking at rates of regret in other areas of surgery?

A. Yes.

Q. What kinds of surgery?

A. Breast cancer -- treatments for breast cancers, breast reconstruction, prostatectomy, orthopaedics.

Q. And you mentioned, I believe, that rates of regret are much higher in those areas of surgery.

Can you describe for us at all what magnitude we're talking about when we say they are higher?
A. On the order of exponential.
Q. In your clinical experience, have you seen many patients expressing regret after undergoing gender-affirming surgery?
A. Very few.
Q. In your opinion is gender-affirming surgery experimental?
A. No.
Q. What is that opinion based on?
A. Well, it's based on my knowledge of the procedures, the fact that they use established techniques that are widely used in other areas of surgery, that the procedures that we've discussed have been performed in the modern history since the 1930s. I've presented at numerous national and international conferences. I've never been required to identify any of these procedures as experimental in those conversations.
Q. Are you aware of any professional surgical societies that characterize gender-affirming surgery as experimental?
A. I am not.
Q. In your opinion is gender-affirming surgery an effective treatment for gender dysphoria?
A. Yes.
Q. And what is that opinion based on?
A. Again, my providing care for over two decades, my discussions with patients, discussions with colleagues, the

literature.
Q. In your opinion does denial of coverage for gender-affirming surgery harm patients?
A. Yes. I mean, we're going back to the days where there were no -- there was no access to care and see the, you know, regrettable consequences of people who lack access to medically necessary medical care.
Q. And in your experience what are some of those consequences?
A. Well, in the surgical arena for me it's autoamputation, self-castration, self-mutilation, worsened dysphoria.
MS. McKEE: That's all I have for this witness.
THE COURT: Cross-exam?

CROSS-EXAMINATION

BY MR. PERKO:
Q. Good morning, Dr. Schechter.
A. Good morning.
Q. Dr. Schechter, you went into a lot about the gender-affirming surgery that you perform. And that includes mastectomies on gender dysphoric patients?
A. Yes.
Q. And you have performed mastectomies on gender dysphoric patients as young as 14 years old; is that correct?
A. That is correct, on three occasions.
Q. Now, you also mentioned that you were a chapter -- co-author of chapter -- co-lead author of Chapter 13 of the

WPATH Version 8 Standards of Care?
A. Yes.
Q. Let me pull up Plaintiffs' Exhibit 34, please.
MR. PERKO: Your Honor, may I approach the witness?
THE COURT: You may.
BY MR. PERKO:
Q. Turning to Bates page 6268 in the back.
A. Okay.
MR. PERKO: Can you blow up 6268.
THE WITNESS: I'm sorry. 62?
BY MR. PERKO:
Q. I'm sorry. At the bottom, 6268. It's at the very end.
A. Oh, I'm sorry. I'm looking at the Bates --
Q. If we could look at the third paragraph under *Section 3.3, Selection of chapter members*.
A. Okay.
Q. It states that: *Each chapter also included stakeholders as members who bring perspectives of transgender health advocacy or work in the community, or as a member of a family that included a transgender child, sibling, partner, parent, et cetera.*
Did you seek out the perspectives of opponents of gender-affirming care?
A. I would say I didn't necessarily know the opinion before selecting the chapter member.
Q. So were any of the members opposed to gender-affirming

care?
A. I would say -- based on our discussions, I would not say people were opposed to gender-affirming care.
Q. I'd like to show you Exhibit DX24. I believe you have that with you. It's the Endocrine Society guidelines.
You have it there for you?
A. I do.
MR. PERKO: Can we bring that up, please.
BY MR. PERKO:
Q. I'd like to go to Bates page 29. And you -- in your expert report, you refer to the Endocrine Society guidelines, and you said it was a leading medical organization; is that correct?
A. It is a leading medical organization, yes.
Q. And are you familiar with the Endocrine Society guidelines?
A. I am.
Q. Okay. Referring to *Section 5.0, Surgery for Sex Reaassignment and Gender Confirmation*, do you see that?
A. I do.
Q. The second sentence says: *The type of surgery falls into two main categories: (1) those that directly affect fertility and (2) those that do not.*
Do you see that?
A. I do.
Q. Do you agree with that statement?
A. I don't know that I would characterize -- when describing

procedures that I would use that characterization, but there are procedures that direct fertility -- that affect fertility and those that don't.

Q. Okay. Paragraph 3, the first full paragraph under Section 5, the first sentence says that: *Surgery that affects fertility is irreversible*.

Do you agree with that statement?

A. No. I guess I would need to know what the particular procedure they are referencing is. Orchiectomy, removal of testicles, would be sterilizing, yes.

Q. It actually goes down later in paragraph 4, *Gender-affirming* -- I'm sorry -- I apologize. Yeah, paragraph 4: *Gender-affirming genital surgeries for transgender females that affect fertility include gonadectomy, penectomy, and creation of a neovagina.*

Do you agree with that statement?

A. Yes.

Q. Moving on to the next page, under the heading Evidence, first sentence says: *Owing to the lack of controlled studies, incomplete follow-up, and lack of valid assessment measures, evaluating various surgical approaches and techniques is difficult.*

Do you agree with that statement?

A. This statement refers to the specific techniques. So in terms of a head-to-head comparison, there are a number of, for

example, vaginoplasty techniques, a number of phalloplasty techniques, a number of mastectomy techniques. So in terms of a head-to-head comparison between each of those techniques, I'm still not sure that I would agree with that statement. No, I don't think I would agree with that statement.

Q. Okay. If we could go up above that, there are a number of recommendations and ungraded good practice statements. Do you see that? They are labeled 5.1 to 5.6.

A. I see 5.1 to 5.6.

Q. Okay. And it shows the level of quality of evidence for each of those recommendations; is that correct?

A. I think that's referencing what I just heard in Dr. Shumer's deposition, the -- I think these hash marks after each of their statements.

Q. Do you understand what those hash marks represent?

A. I'd have to go look at their specific -- I don't recall by memory what each represents.

Q. Do you know what an ungraded good practice statement is under 5.2?

A. I don't know how they are using that term. I'd have to look at the definition.

Q. If we could go to the next page, 31, last sentence of the first paragraph, it states: *We need more studies with appropriate controls that examine long-term quality of life, psychosocial outcomes, and psychiatric outcomes to determine the*

long-term benefits of surgical treatment.

Do you disagree with that statement?

A. Well, I'm just going to take a look and see what paragraph it is. But, as a general rule, I would say I'm unaware of any area of medicine or surgery where we would say there's no need for further study or research.

But looking at this paragraph. So it seems to me this refers to the sentences before it*: Reversal surgery in regretful male-to-female transexuals after sexual reassignment surgery represents a complex, multistage procedure with satisfactory outcome. Further insight into the characteristics of persons who regret their decision postoperatively would facilitate better future selection of applicants eligible for sexual reassignment surgery. We need more studies*. That's the last sentence.

So I don't think I would disagree with any report saying we need continued study or ongoing understanding.

MR. PERKO: Your Honor, at this time I wanted to pull up some of the confidential medical records, so if we could turn off the big screen.

This would be Exhibit -- Plaintiffs' Exhibit 234A. And about ten pages down, Bates No. 000848, please.

BY MR. PERKO:

Q. And, Doctor, I think you can take a look at this. This is a record of a MD who met with one of the plaintiffs to discuss

chest masculinization surgery.

Do you see that?

A. I see this, yes.

Q. About three-quarters of the way down it states: *I discussed the risk of surgery, including but not limited to bleeding, infection, scarring, loss of nipple graft, asymmetry, contour irregularities, need for revision surgery, regret, sensory changes, and need for additional procedures.*

Do you agree that those are some of the risks associated with chest masculinization surgery?

A. I do agree.

Q. And you mentioned vaginoplasty. What are the risks associated with vaginoplasty?

A. So, as with any procedure, bleeding, infection, flow accumulations, wound disruptions, delayed healing, blood clots, stenosis of the vaginal canal, fistula, rectovaginal fistula, meaning a hole or abnormal communication between the rectum and the vagina, urinary stream abnormalities, unsatisfactory cosmetic outcome, loss of sensation.

Q. Is that it?

A. That may not be all inclusive, but representative.

Q. Thank you.

What are some of the risks associated with phalloplasty?

A. Similar: Bleeding, infection, tissue loss, blood clots, urethral stream abnormalities, urethral fistula, urethral

stricture, delayed healing, unsatisfactory outcome, appearance, sensory, injury to nerves, including sensory nerves.

Q. What are some of the risks associated with gonadectomy?

A. Well, orchiectomy, removal of the testicles, fairly low risk. Like any procedure, there are risks of bleeding or infection or wound disruption.

Q. And what about penectomy?

A. Similar.

MR. PERKO: I have nothing further, Your Honor.

THE COURT: Redirect?

REDIRECT EXAMINATION

BY MS. McKEE:

Q. Dr. Schechter, my friend asked you about the risks associated with various gender-affirming surgical procedures. Are those risks the same when a procedure is performed to treat gender dysphoria and when it's performed to treat another condition?

A. Yes.

MS. McKEE: No further questions.

THE COURT: Dr. Schechter, you talked about a time when care wasn't available; insurers didn't pay for it. What's the situation now? Do all the major insurers pay for this?

THE WITNESS: Much better than it was. Of course, it varies state to state. It varies by insurer. I would estimate now -- so in 2000, if it was 5 percent of cases that were

covered by insurance that would probably be a lot. I could say now 80-plus percent of my practice is covered by insurance.

THE COURT: You draw patients from all around the Midwest or nationally? What's your patient mix?

THE WITNESS: 38 -- as of this last year, 38 states and Canada.

THE COURT: Heavily centered, I take it, in the Midwest?

THE WITNESS: Primarily Midwest, but including Alaska, Hawaii, Florida, Southeast as well.

THE COURT: The lawyers will have evidence of this other places.

You see Medicaid patients?

THE WITNESS: I do.

THE COURT: And that gets reimbursed from many of those 38 states, I take it?

THE WITNESS: I can't speak on each state of reimbursement. In Illinois, yes.

And I don't want to speculate exactly on the back end, but to my knowledge we treat people -- Indiana, the surrounding states where it is covered, and we do receive reimbursement. But I don't want to -- I know they are not paying out of pocket, let me say that.

THE COURT: You are not the financial guy, I get it?

THE WITNESS: I'm not.

THE COURT: All right. Thank you.

Questions just to follow up on mine?

MR. PERKO: No, Your Honor.

MS. McKEE: No, Your Honor.

Thank you.

THE COURT: Thank you, Dr. Schechter. You may step down.

THE WITNESS: Thank you.

(Dr. Schechter exited the courtroom.)

THE COURT: Please call your next witness.

MR. GONZALEZ-PAGAN: Your Honor, if we could have a couple of minutes. He's going through security right now.

THE COURT: All right. If he's going through security, he'll be here in just a minute. Let's just be at ease for just a minute.

MR. GONZALEZ-PAGAN: Thank you, Your Honor.

Mr. Charles will call him.

THE COURT: Who is the witness?

MR. CHARLES: Dr. Armand Antommaria.

THE COURT: Let me say this to the lawyers: The court reporter will be grateful if you provide a glossary. You've probably provided and she would have on her own some of the terms that are particularly related to this, but there have been times when the doctor has talked about procedures having nothing to do with gender-affirming care. If somebody on each side

would just make a note as those words come up, and then at the break provide it to the court reporter, she'd be grateful.

I do think DEXA, the DEXA studies, was D-E-X-A. That one we had.

Doctor, right up here.

(Dr. Antommaria entered the courtroom.)

THE COURTROOM DEPUTY: Please remain standing and raise your right hand.

DR. ARMAND ANTOMMARIA, PLAINTIFFS WITNESS, DULY SWORN

THE COURTROOM DEPUTY: Please be seated.

Please state your full name and spell your last name for the record.

THE WITNESS: My full name is Armand Herbert Matheny Antommaria. Antommaria is spelled A-n-t-o-m-m-a-r-i-a.

Matheny is spelled M-a-t-h-e-n-y.

DIRECT EXAMINATION

BY MR. CHARLES:

Q. Good morning, Dr. Antommaria.

What is your profession?

A. I'm a pediatrician, a pediatric hospitalist and bioethicist.

Q. Please describe for the Court your formal education and training.

A. I hold a medical degree from Washington University in St. Louis, and completed my pediatric residency training at the

University of Utah. And I hold a Ph.D. in religious ethics from the University of Chicago Divinity School.

Q. Are you licensed to practice medicine?

A. I am licensed to practice medicine. I'm currently licensed in the state of Ohio.

Q. And are you board certified in any particular fields of medicine?

A. I'm board certified as a general pediatrician and also as a pediatric hospitalist.

Q. What does bioethics entail?

A. Bioethics entails an investigation of the ethical issues in medicine in the biological sciences.

Q. What professional positions do you currently hold?

A. I'm currently the director of the ethics center at Cincinnati Children's Hospital Medical Center. I hold the Leal Carter Chair in pediatric ethics. I'm an attending physician in the division of hospital medicine. And I'm a professional in the departments of pediatrics and surgery at the University of Cincinnati College of Medicine.

Q. What do you do as a professor of pediatrics in surgery?

A. So my primary academic appointment is in the Department of Pediatrics. My work in both bioethics and in hospital medicine is within the department of pediatrics, but my work in bioethics also addresses other departments within Cincinnati Children's. And I work extensively with our surgical colleagues, and in

recognition of that work I have a secondary appointment in the department of surgery.

Q. And what do you do as director of the ethics center?

A. So I oversee the activities of the ethics center, which has activities related to research, clinical and organizational ethics.

Q. How often are you involved with clinical ethics consults with patients?

A. So Cincinnati Children's has a relatively large volume for a children's hospital in clinical ethics consults, and we conduct 40 to 50 clinical ethics consults a year.

I share responsibility for conducting clinical ethics consults with my colleagues and take call for clinical ethics consultation approximately two weeks per month.

Q. When ethicists are involved in clinical practice decision-making, what expertise do they offer?

A. The expertise that we offer is to help identify ethical issues, and help the principal parties involved in medical decision-making think through those issues, potentially identifying risks and benefits of procedures or other considerations that should inform decision-making.

Q. In your role as director of the ethics center, do you work with transgender patients?

A. I do. I started at Cincinnati Children concurrently with the development of our transgender health program and have been

involved with the clinic through its duration of its existence. I help both at the program and policy level, for example, assisting the clinic in the development and in the revision of its informed consent documents. And then I'll consult on individual cases that raise unique ethical issues and participate in the clinic's monthly multidisciplinary team meetings.

Q. Have you taught classes on the subject of bioethics?

A. During my time at the University of Utah, I taught classes in medical ethics. In my current position I predominantly will guest lecture in courses in medical ethics, but frequently provide lectures in courses on medical ethics.

THE COURT: Dr. Antommaria, it will help us if you keep your volume up so that somebody even against the back wall would be able to hear you.

THE WITNESS: My apologies. I will try, sir.

THE COURT: Thank you.

BY MR. CHARLES:

Q. Dr. Antommaria, are you involved in any professional associations?

A. I'm a member of the American Academy of Pediatrics, the American Society of Bioethics and Humanities, the Association of Bioethics Program Directors, and the Society of Pediatric Research.

Q. And can you tell me briefly, please, what does the

committee of bioethics for the American Academy of Pediatrics do?

A. The Committee on Bioethics for the American Academy of Pediatrics contributes to the Academy's work through writing of policy statements and technical reports to address ethical issues in pediatrics.

Q. Dr. Antommaria, you mentioned that in your role as director of the ethics center, you work with transgender patients. Do you recall that?

A. Yes.

Q. In this role, do you keep up with the research and scholarly work on the treatment of gender dysphoria?

A. Yes, I do.

Q. Are you being compensated for your testimony today, Dr. Antommaria?

A. Yes, I am.

Q. Does your compensation depend on the content of your testimony?

A. No, it does not.

MR. CHARLES: Your Honor, at this time I move to have Dr. Antommaria qualified as an expert in bioethics and pediatrics.

MR. PERKO: No questions.

THE COURT: No questions at this time?

You may proceed.

MR. CHARLES: Thank you, Your Honor.

BY MR. CHARLES:

Q. Dr. Antommaria, what is the goal of medical research?

A. The goal of medical research is to contribute to generalizable knowledge.

Q. And how is medical research conducted?

A. Medical research is conducted according to protocols which describe the steps in a study.

Q. Are there different types of research studies?

A. Yes, there are a variety of different types of research studies.

Q. What are some of those types?

A. Within clinical research, two of the main categories would be observational studies and randomized controlled trials.

Q. What are observational studies?

A. Observational studies look at a group of individuals either at a single point in time or over a period of time.

Q. What is the meaning of the distinction longitudinal?

A. So longitudinal would be in distinction to cross-sectional. So cross-sectional would be a study that looked at a group of individuals at a single point in time, and longitudinal would be a study that looked at individuals over a period of time.

Q. What are randomized controlled trials?

A. A randomized controlled trial would be a trial in which the group of participants were separated into generally two, but

potentially multiple, groups through a process of randomization which is frequently analogized to flipping a coin. And frequently there is an intervention group that receives the intervention that's being studied and a control group which might be a placebo, an ineffective treatment, or the current standards of care.

Q. What are some of the factors that go into determining which type of study to utilize for a particular intervention?

A. So there would be multiple factors that go into choosing a study design. Some of those factors include what the objective of the study is. So if one was doing an epidemiologic study looking at the demographic characteristics of people with a particular condition, a cross-sectional study might be the best design to do so. Other factors would have to do with the available evidence that already exists. The resources that the investigator has available would all contribute to the choices in terms of study design.

Q. Is there a study design that is generally considered the best quality?

A. Within clinical research of interventions or tests, randomized controlled trials would generally be referred to colloquially as the gold standard.

Q. And why would that be?

A. There are certain benefits of randomized controlled trials, particularly in terms of the ability to have a higher certainty

that the intervention was responsible for the observed effects.
Q. Are randomized controlled trials always appropriate for medical research?
A. No, randomized controlled trials are not always appropriate. There might be either ethical limitations in which a randomized controlled trial would not be appropriate or methodological limitations restricting the use of randomized controlled trials.
Q. When might there be ethical reasons not to conduct a randomized controlled trial?
A. So in order for a randomized controlled trial to be ethical, the individuals must have what's referred to as clinical equipoise, meaning that they must have reason to have uncertainty about whether the intervention or the control is better. If there was reason to believe that one was superior to the other, it would be unethical to conduct that type of randomized controlled trial.
Q. Can you just clarify what you mean when you say if one is superior to the other, what you are referring to there?
A. That either the intervention or the control is superior to the other. So, for example, in asthma research there is evidence that individuals with more severe asthma do better if they are on a daily medication called an inhaled corticosteroid. So it would currently be unethical to conduct asthma research that took people off inhaled corticosteroids as part of a study

design because there is evidence that they are preferable in the treatment of those patients.

Q. And so is that an example of a study that might not have clinical equipoise?

A. Yes.

Q. When might there be logistical reasons that a randomized controlled study would not be possible?

A. So in designing the study, investigators would do something called a power analysis in order to determine how many individuals they would need to enroll in this study in order for it to be informative. If there was good reason for investigators to believe that they are not going to be able to recruit a sufficient number of participants, then it would be inappropriate to conduct that trial.

Q. Any other logistical reasons that might limit the ability to use a randomized controlled trial?

A. So inadequate staff in order to conduct the trial appropriately and other limitations in terms of resources. So there are a variety of different logistical potential barriers.

Q. Dr. Antommaria, what does it mean for a study to be double-blinded or double-masked?

A. So for a study to be double-masked would be that neither the investigators nor the participants know into which group they are assigned, whether they are in the intervention group or the control group.

Q. Why is masking important?
A. Masking is important because if there was a lack of masking and individuals had background beliefs about whether the intervention or the control was more effective, that might influence their interpretation of the results or their participation in the study.

So, for example, if a participant thought that the intervention was much more desirable than the control, and they were -- and they knew they were assigned to the intervention group, and they were filling out surveys about the effect of the intervention, they might inadvertently inflate the quality of the intervention in their reports.

Q. Are there times when it is impossible to mask a study?
A. Yes. There's ongoing debate, particularly in the surgical literature, about the appropriateness of controls and, in particular, sham surgeries in order to try to provide appropriate controls for surgical interventions. And there the concerns are about what is sufficient to try to mask the surgery to a participant as well as whether, in trying to mask a surgery, it's unethical in exposing someone to harm.
Q. Does -- backing up just a little bit, Dr. Antommaria, does -- do the individuals conducting the study -- does it -- does the ability to get participants affect whether or not a randomized controlled trial is appropriate?
A. So, as I said, it's necessary in order to have a sufficient

number of participants for a study to move forward. There would certainly be situations in which there would be a concern of -- in one's ability to recruit an adequate number of participants, whether that's an individual institution seeing enough patients with that condition or participants potentially not having equipoise between the intervention and the control and, therefore, being unwilling to enroll in the study.

Q. Dr. Antommaria, you mentioned that in some situations it would not be ethical or logistically possible to do a randomized controlled trial.

Are there additional barriers to using randomized controlled trials?

A. So conducting randomized controlled trials is less common in pediatrics than in adult medicine, and there are a variety of different reasons for that, including generally the lower frequency of illness in the pediatric population. Certain outcomes such as death or serious disability are less common in the pediatric population. There are reasons why both NIH funding and pharmaceutical company funding for randomized controlled trials in pediatrics are lesser.

And, again, you've asked questions about recruiting participants. It is more difficult to recruit participants into pediatric trials.

Q. Are there ethical concerns about utilizing randomized controlled trials in pediatrics in particular?

A. I think that the ethical concerns are fairly similar in adult and pediatric medicine in terms of needing to have clinical equipoise in conducting a trial.

Q. You stated earlier, Dr. Antommaria, that randomized controlled trials are generally considered the best quality clinical research.

Does that mean that observational studies should not be relied upon to evaluate medical treatments?

A. No, that would not be true. There are times in which an observational study is the optimal type of study in order to investigate a particular question in situations in which observational studies may provide what's referred to as high-quality evidence.

Q. Are all medical treatments supported by research utilizing randomized controlled trials?

A. No.

Q. And so do clinicians make treatment decisions that have not been researched using randomized controlled trials?

A. Unfortunately, that is the case, that clinicians frequently must make medical decisions without the benefit of randomized controlled trials.

Q. How common is that?

A. I don't know that I'm able to provide a particular percentage to you, but I would say that it's certainly not uncommon.

Q. Is that common in pediatrics as well as in adult medicine?
A. I would describe that it's more common in pediatrics than it is in adult medicine. The example that I would give you is during the COVID -- during the COVID pandemic, although children were less frequently affected with COVID than adults, there are children who were seriously ill with COVID either due to hyperinflammatory responses or to a specific condition in pediatrics called MISC, Multisystem Inflammatory Syndrome, in children. And, whereas, there were multiple or numerous randomized controlled trials which guided treatment of patients with COVID in adults, there were -- there are, unfortunately, no randomized controlled trials of treatments in the pediatric population.
Q. Does the absence of a certain type of study researching a treatment mean that there is not sufficient evidence to support the use of that treatment?
A. Can you repeat your question, please?
Q. Sure. Does the absence of a certain type of study for a particular treatment mean that there is not sufficient evidence to support the clinical use of that treatment?
A. So in making recommendations, the type or level of evidence is only one factor that's considered in making recommendations and so, no, there is not a requirement for an individual particular type of evidence to make a treatment recommendation.
Q. Dr. Antommaria, what would happen if in the medical field

treatment was limited to only those treatments that have been studied by randomized controlled trials?

MR. PERKO: Objection; speculation, Your Honor.

THE COURT: It's probably argumentive.

Overruled.

THE WITNESS: Many of the treatments that I use as a pediatric hospitalist would not be available to me and my patients would be harmed as a result.

BY MR. CHARLES:

Q. And would limiting treatments to only those treatments studied by randomized controlled trials have an impact on patient welfare?

A. Yes, it would.

Q. What do you think that effect would be?

A. I think that would be a negative effect that treatments that are effective would be unavailable to them.

Q. Dr. Antommaria, we've been discussing medical research. How do doctors use -- I think you've referred to it as clinical research, so I'll use that term.

How do doctors use clinical research to inform their clinical practice?

A. Clinicians should make their clinical decisions based on the best available research. Given the volume of the medical literature, clinicians frequently rely on Clinical Practice Guidelines to summarize the evidence for them and support them

in making clinical decisions.
Q. You just mentioned Clinical Practice Guidelines.
What are those?
A. Clinical Practice Guidelines generally are guidelines related to particular topics, generally particular disease states, that are frequently developed by medical -- professional medical associations that review the available evidence and make recommendations to guide clinical practice.
Q. Could you provide some examples of medical professional associations that publish Clinical Practice Guidelines?
A. So in my field the American Academy of Pediatrics publishes Clinical Practice Guidelines, as well as other medical professional associations, including NASPGHAN, which is the national organization for gastroenterologists, publishes Clinical Practice Guidelines relevant to their area of practice.
Q. How are Clinical Practice Guidelines generally developed?
A. So there would be the identification of an area in which a Clinical Practice Guideline would be beneficial. An organization would then seek to establish a group of individuals to develop the guideline. They would utilize processes to evaluate potential expert -- individuals who have appropriate expertise and exclude individuals who had inappropriate conflicts of interest. Those individuals would then review the literature, ideally developing systematic reviews of the literature to review relevant literature and then make

recommendations based on that evidence base.
Q. Are there other factors considered in developing Clinical Practice Guidelines?
A. Factors other than what?
Q. Than some of what you just described.
A. It's not a comprehensive description, so yes, I would imagine there would be other factors.
Q. Is the quality of the evidence the only factor involved in making a recommendation in a Clinical Practice Guideline?
A. No. The quality of the evidence is only one of the factors involved in making a recommendation. So a recommendation would be -- a recommendation for or against an intervention is an evaluation of the potential benefits compared to the risks of the intervention. So it would be based, in part, on that balance as well as information about patients' preferences that inform that. And then as a secondary consideration, recommendations are also at times based on resource utilization.
Q. Dr. Antommaria, what is a systematic review of the literature?
A. A systematic review of the literature is a process through which all of the evidence relevant to a particular topic is ascertained through a search of, ideally, multiple databases. The relevant articles are identified initially by examining titles in abstracts and then the full text of articles. Data is then abstracted from each of the individual articles and

summarized, and ideally then the quality of the evidence is evaluated.

Q. What is the difference between a systematic review of the literature and a Clinical Practice Guideline?

A. So a systematic review of the literature will rate the quality of the evidence, whereas, a Clinical Practice Guideline will make recommendations and both ideally rate the quality of the evidence and the strength of the recommendations.

Q. Do systematic reviews of the literature make clinical recommendations?

A. They do not.

Q. Why is it generally useful for clinicians to have recommendations in Clinical Practice Guidelines?

A. The volume of the medical literature is enormous and continues to increase over time. The amount of effort that's required to conduct a single systematic review of the literature would be, you know, hundreds of person hours. And so for practicing clinicians, it's exceptionally beneficial to have that literature summarized for them in a useful manner in order to not have to go through that process themselves for each clinical decision that they're making.

Q. Are there specific methodologies used in developing Clinical Practice Guidelines?

A. There are, in particular, methodologies for grading the quality of the evidence and the strength of recommendations.

Q. Are you familiar, Dr. Antommaria, with the GRADE methodology?
A. I am.
Q. Do you know what GRADE stands for?
A. Yes. GRADE stands for Grading of Recommendations Assessment, Development and Evaluation. And it's a widely used method for grading the quality of evidence and the strength of recommendations.
Q. And I just want to make sure you said this. Is it widely -- is it a widely used methodology in Clinical Practice Guidelines?
A. Yes, it is.
Q. And what does the GRADE methodology do?
A. So it provides recommendations about how one describes the quality of the evidence and then -- and how one goes through a process of grading the quality of the evidence, including what factors should be considered in doing so.

And then in terms of recommendations, it has suggestions about how the strength of a recommendation should be described and the factors that should be considered in characterizing the strength of a recommendation.
Q. Why is it important to know the strength of a recommendation?
A. The -- as a -- for me, as a clinician, the strength of the recommendation is likely to influence how I approach the

informed consent process. I may have a longer or a more detailed conversation with a patient about what's referred to as a weak recommendation than a strong recommendation.

Q. And why is it important to know the quality of the evidence?

A. So the quality of the evidence is related to the certainty of an effect, so that the intervention will have a particular effect. And so, again, in counseling a patient, I'm -- knowing the quality of evidence will inform how I describe that certainty.

Q. In using the GRADE methodology, is an entire Clinical Practice Guideline given a single grade?

A. No. Individual recommendations are given -- the evidence supporting them is given a grade and the individual recommendation is given a particular strength.

Q. And so do guidelines typically have multiple recommendations?

A. They do.

Q. Within the GRADE system, what are the quality levels of evidence?

A. They would be high, moderate, low, or very low.

Q. You said that --

THE WITNESS: Your Honor, am I loud enough?

THE COURT: I'm sorry?

THE WITNESS: Am I loud enough?

THE COURT: Yes, yes, you are doing well. Thank you. All except the question whether you were loud enough.

BY MR. CHARLES:

Q. Dr. Antommaria, how does the study design inform the quality of the evidence grade?

A. So, in general, randomized controlled trials are initially assigned to the category of high-quality evidence, and observational studies are initially assigned to the category of low-quality evidence.

Q. Then are there other factors utilized to give a grade to the quality of the evidence besides study design?

A. Yes. There are five additional factors that could decrease the quality and three additional factors that can increase the quality in terms of the final evaluation of the quality of the evidence.

Q. So is it possible that a randomized controlled trial could start as a high-quality grade but then be impacted by some of those other factors?

A. Yes, it's possible for a randomized controlled trial to, in the end, be low or very low-quality evidence.

Q. And, similarly, could an observational study be impacted in its ultimate grade by those other factors?

A. Yes. And in the end, then, an observational study might move from low- to high-quality evidence.

MR. CHARLES: Your Honor, I would like to show the

witness that's been marked as Plaintiffs' Exhibit 157.

THE COURT: Is this something that can be on the public board?

MR. CHARLES: It can, Your Honor.

THE COURT: All right.

BY MR. CHARLES:

Q. Dr. Antommaria, do you recognize this document?

A. Yes, I do.

MR. CHARLES: Right there. Actually, no -- I'm sorry -- keep going down.

Okay. Right there.

You got it.

BY MR. CHARLES:

Q. Okay. Dr. Antommaria, do you see on your screen page 404, Table 2?

A. I do.

Q. Looking at this table, how does GRADE define low-quality evidence?

A. So just to say that this paper -- so that the group who have developed the GRADE approach have published a variety of different descriptions of that approach as it has developed over time.

In this table in the far right-hand column, we see the definition from their initial publication, and in the left hand -- and in the middle column, the definition from the

current manuscript, which reflects this evolution. And so low-quality evidence in the current definition is that the confidence in the effect estimate is limited.

Q. And what do you understand that to mean?

A. So in reviewing the evidence, they're looking at the evidence -- looking for evidence that an intervention has a particular effect, and the quality evidence reflects the certainty or the level of confidence in that reported effect, and that a high-quality evidence provides a very high degree of confidence that the effect is accurate, and that other levels of quality provide less confidence in the effect. And for low-quality evidence, there may be a difference -- a substantial difference between the true effect and the effect that's currently reported in the literature.

Q. You mentioned in response to that question, Dr. Antommaria, what was reflected about high-quality evidence.

What do you understand the current definition to mean?

A. That there's a very high degree of confidence that the true effect is the effect that's currently represented in the evidence.

Q. So does low-quality evidence mean there is a likelihood that treatment will be determined to not be effective in the future?

A. Not necessarily.

Q. And does low-quality evidence mean there is a likelihood

that treatment will be determined to not be safe in the future?
A. It does not.
Q. What quality levels of evidence may a Clinical Practice Guideline base recommendations upon?
A. On any of those levels of quality.
Q. In general, Dr. Antommaria, does the GRADE system indicate the strength of the recommendations that are being made?
A. So a Clinical Practice Guideline makes recommendations, and the GRADE approach provides guidance for individuals creating the guidelines to rate the strength of the recommendations that they're making.
Q. How is the strength of a recommendation evaluated?
A. So the GRADE approach identifies recommendations as either being recommendations for or against an intervention as well as recommendations being strong or weak so that there is potentially a spectrum from strong recommendations for, weak recommendations for, weak recommendations against, and strong recommendations against a potential intervention.
Q. What are the levels of recommendations?
A. The levels of recommendation would be either a strong recommendation or a weak recommendation, although the GRADE group acknowledges that the term "weak recommendation" may have misleading connotations and uses other potential terminology, including "interim recommendations."
Q. What does it mean for a recommendation to be strong?

A. So the GRADE approach describes the difference between strong recommendations and weak recommendations in two different ways, one related to certainty. So a strong recommendation has a high degree of certainly that the benefits outweigh the risks, and a weak recommendation has a lesser degree of certainty.

And then the other way that they describe it is related to how many patients would agree with the recommendation. So in regard to any recommendations, that the majority of individuals would agree with the recommendation, but that with a strong recommendation, it would be the vast majority, whereas, with a weak recommendation, there might be a larger minority of individuals who would disagree with a recommendation, patients being those individuals.

Q. Are there other considerations in making a recommendation beside the quality of the evidence?

A. Yes. The balance between the risks and the benefits because those -- because patients might perceive those risks and benefits differently, the certainty of the knowledge of how patients would evaluate the risks and the benefits is a factor. And then in some circumstances resource utilization would also be considered in making recommendations.

Q. Is it common for Clinical Practice Guidelines to make recommendations based on evidence that is graded low?

A. Yes.

Q. And is it common for Clinical Practice Guidelines to make

recommendations based on evidence that is graded very low?
A. Yes, particularly in pediatrics.
Q. And why are recommendations made based on low or very low-quality evidence?
A. Clinicians are faced with treating patients based on the best available evidence, and sometimes the best available evidence is low or very low-quality evidence. But it's not possible for providers to tell patients to come back later in the future when better quality evidence is available. They have to make the best judgment possible at that particular point in time.
Q. Is it common for pediatric Clinical Practice Guidelines to make recommendations based on evidence that is graded low or very low quality?
A. It is.
Q. Why is it common?
A. Because of the lack of randomized controlled trials in pediatrics.
Q. Are there any other reasons why it is more common?
A. That would be the predominant reason.
Q. Does the Endocrine Society publish Clinical Practice Guideline in pediatrics?
A. It does.
Q. What are some that you are aware of?
A. There's a Clinical Practice Guideline for the treatment of

pediatric obesity, one for a condition called congenital adrenal hyperplasia, and one that includes pediatric patients related to the treatment of individuals with gender dysphoria.

Q. And what quality of evidence are the recommendations in those guidelines based upon?

A. In all three of those guidelines, the majority of the recommendations are based on low or very low-quality evidence.

Q. Do any of those recommendations utilize ungraded good practice statements?

A. In addition, there are ungraded good practice statements which account for across the guidelines, you know, approximately 20 percent of the recommendations.

Q. Do any of the Clinical Practice Guideline that you just listed have high-quality evidence supporting the recommendations?

A. To the best of my recall, they do, but only in a very small minority of the recommendations.

Q. Do Clinical Practice Guidelines require a threshold amount of evidence or a certain type of study to make a recommendation?

A. They do not.

Q. Dr. Antommaria, is not providing medical treatment an affirmative clinical decision?

A. Yes, it is.

So when -- in seeking informed consent, one discusses risks, benefits, and alternatives. One of the alternatives is

frequently not to undergo the procedure or the treatment, but that there would be particular risks or benefits of not receiving the intervention or the treatment.

Q. If a Clinical Practice Guideline were to recommend not providing medical treatment, would that recommendation need to rely on evidence?

A. It would.

So within the GRADE system we talked about recommendations for or recommendations against. Recommendations against are also graded in terms of their strength, and they would have a evidence -- ideally have a evidence quality assigned to them.

Q. Switching gears a little bit here, Dr. Antommaria.

Are there established ethical principles around medical decision-making?

A. There are.

Q. Under principles of medical ethics, how does decision-making around Medicare -- excuse me -- around medical care for adults generally work?

A. In general, adults informed consent would be required for treatment. There certainly are exemptions, but an adult who has medical decision-making capacity, their consent is generally required for medical treatment.

Q. Is there a term used to describe the process you were just discussing?

A. So historically the terminology would be the informed

consent process. Increasingly the language of shared decision-making is utilized. But both are common in the medical literature.

Q. Does the treatment decision ultimately lie with the doctor or with the patient?

A. With the patient.

Q. Under principles of medical ethics, how does decision-making around medical care for minors generally work?

A. So in general, for minors, parental or guardian consent is required and that pediatric patients should participate in medical decision-making to the extent that it is developmentally appropriate. So as children mature and are able to participate in decisions, they should participate in decisions. And that's described in the literature as seeking their assent. But in general, parental consent is still required.

Q. And with whom does the treatment decision ultimately lie for minors?

A. Generally their parents or legal guardians.

Q. What should a healthcare provider disclose to a patient, and for a minor their parent or guardian, to enable them to make an informed decision?

A. They should disclose the indications and the nature of the intervention, its potential risks and benefits, and the alternatives. And there are different standards for disclosure of the risks and benefits, because there are frequently more

risks and benefits than can be meaningfully conveyed. And frequently providers then will convey the common risks and benefits as well as the most serious risks and benefits.

Q. Should a healthcare provider disclose the risks and benefits of not undergoing an intervention?

A. As part of the description of the alternatives, yes.

Q. When the patient is an adolescent, does the patient have a role in the informed consent process?

A. Yes, they do. They should participate in the informed consent process, and their assent should generally be sought, although it's not necessarily determinative in decision-making.

Q. You've used the term "assent" when referencing minors and adolescents in the shared decision-making process.

What does it mean to assent to treatment?

A. It would be their verbal agreement to participate in treatment in contradiction to dissent or disagreement to participate.

Q. Can you describe the difference between assent and consent?

A. In some ways the distinction is a legal distinction, and in some ways it's a distinction about medical decision-making capacity.

So certainly there are older adolescents who have comparable medical decision-making capacity to adults but aren't legally authorized to provide informed consent. Whereas, substantially younger adolescents might have some degree of

understanding, and it's important for them to participate, but not a full understanding that's comparable to an adult's.

Q. In general, are adolescents who possess adequate decision-making capacity able to understand the benefits and risks of treatment?

A. Yes.

Q. Does adolescent decision-making capacity change over time?

A. So decision-making capacity is both relative to an individual's skills and abilities in making decisions, as well as the particular intervention. But, yes, as an individual's decision-making skills and abilities change over time, their decision-making capacity increases.

So an average 10-year-old has greater decision-making capacity than a 6-year-old but potentially less so than an 16-year-old.

Q. So, Dr. Antommaria, are you familiar with what the Rule of 7 is?

A. It's a rule of thumb that's used to help people understand an individual's decision-making capacity.

Q. Can you describe the general rule of thumb?

A. It would be that individuals who are less than 7 are incapable of assent; individuals between 7 and 14 are capable of assent, and individuals who are older than 14 are capable of consent.

Q. For adolescents who have the ability to assent to

treatment, must their parents or guardians still provide informed consent?
A. So in general, yes.
Q. In general, Dr. Antommaria, does having a mental health diagnosis impair medical decision-making capacity?
A. No, not in and of itself.
Q. Does the fact that a patient experiences depression mean they can't assent or consent to treatment?
A. Not intrinsically.
Q. Does the fact that a patient experiences anxiety mean that they cannot assent or consent to treatment?
A. Again, not intrinsically.
Q. Dr. Antommaria, have you read the regulation at issue in this case?
A. I have.
Q. And have you read the generally accepted medical standards determination on the treatment of gender dysphoria and all related attachments?
A. I have.
Q. The regulation and the document that I will refer to as the GAPMS memo refers to treatment for gender dysphoria. But if in my questions I refer to the range of care falling within that definition as gender-affirming medical care, will you understand what I mean?
A. Yes, I will.

Q. Is gender-affirming medical care as it is being used by doctors to treat gender dysphoria experimental?
A. No, it is not.
Q. Are there any Clinical Practice Guidelines regarding gender-affirming medical care?
A. Yes, there are.
Q. What are they?
A. There's a Clinical Practice Guideline produced by the Endocrine Society and one that's been produced by the World Professional Association for Transgender Health.
Q. If I refer to the World Professional Association for Transgender Health as WPATH, will you know what I'm referring to?
A. Yes, I will.
Q. And if I refer to those Standards of Care as SOC, will you know what I'm referring to?
A. Yes, I will.
Q. Dr. Antommaria, what is your understanding of what the Endocrine Society is?
A. The Endocrine Society is an international medical professional association of approximately 18,000 endocrinology clinicians and researchers.
Q. Does the Clinical Practice Guideline published by the Endocrine Society you just mentioned for the treatment of gender dysphoria make recommendations with regard to gender-affirming

medical care for adolescents?
A. Yes, it does.
MR. CHARLES: Your Honor, I'd like to show Dr. Antommaria an exhibit from the stipulated exhibits list, Defendants' Exhibit 24.
BY MR. CHARLES:
Q. Dr. Antommaria, if it's easier for access, there may be a copy in front of you of this document as well.
Do you recognize this document, Dr. Antommaria?
A. Yes, I do.
Q. And do you rely on it in your professional capacity?
A. I do.
MR. CHARLES: Your Honor, I believe this has previously been entered.
THE COURT: All the stipulated exhibits have been, yes.
MR. CHARLES: Okay. Thank you.
BY MR. CHARLES:
Q. Dr. Antommaria, what methodology does the Endocrine Society Guideline use?
A. They utilize the GRADE methodology.
Q. And so does the clinical guideline grade the quality of the evidence and the strength of the recommendations?
A. It does.
Q. So I'm now going to direct you to page 3872.

A. Yes.
Q. And looking at the bottom of page 3872.
What does the Endocrine Society guidelines say about strong recommendations?
It's going to be --
A. So they are utilizing the GRADE methodology. They describe that they are going to use the language of "we recommend," and the number 1 to indicate a strong recommendation.
Q. Does it define the meaning of "strong recommendation" in that section?
It's at the third-to-last sentence at the bottom of that section, beginning with "The task force has confidence..."
A. So they describe that if they've made a strong recommendation that they have confidence that an individual will derive, on average, more benefit than harm.
Q. Is that consistent with the GRADE concepts we discussed earlier?
A. It is.
Q. And looking at that same section, what does -- what does the Endocrine Society guidelines say a weak recommendation means?
A. They indicate that if a weak recommendation is given that there needs to be more careful consideration of the person's circumstances, values, and preferences in decision-making.
Q. And does that mean that a weak recommendation means that

the benefits of treatment do not outweigh the harms of treatment?
A. In general, no.
Q. Is the Endocrine Society guidelines supported by scientific evidence?
A. It is.
Q. What kind of evidence?
A. So depending on the individual recommendation, controlled trials, or, more commonly, observational studies.
Q. Do those include longitudinal observational studies?
A. They do.
Q. As you discussed before, does low quality in rating the evidence have a meaning under the GRADE system that is different from how that term is colloquially used?
A. I think that low quality might colloquially be interpreted as inadequate or insufficient, which is not the case, in that low-quality evidence may be sufficient to justify a recommendation.
Q. Dr. Antommaria, can I ask you to just speak up just a little bit, only because you're looking down?
A. I apologize.
Q. No, no, nothing to apologize for. Thank you.
Do the studies discussed in the Endocrine Society guideline demonstrate the safety and efficacy of gender-affirming medical care for adolescents?

A. They do.
Q. Would randomized controlled trials comparing the current treatment recommendation, that is, gender-affirming medical care and mental health care, to mental health care alone be ethical?
A. Not currently.
Q. Why would that be?
A. Because both investigators and participants are unlikely to have clinical equipoise between those two options, believing that gender-affirming medical care is superior to mental health care alone, based on the currently available evidence.
Q. Was there a time in the past where a randomized controlled trial comparing gender-affirming medical care to not receiving gender-affirming medical care would have had clinical equipoise?
A. Yes. There was likely to have been a time in the past when that was the case, but not currently.
Q. Can you think of other examples of treatments where the window of clinical equipoise closed before randomized controlled trials were able to be conducted?
A. So there are circumstances in which the observational studies are sufficient evidence that clinical equipoise no longer exists.
Q. Are there other challenges that a randomized controlled trial comparing gender-affirming medical care to not receiving gender-affirming medical care would be likely to face?
A. There would likely to be intrinsic methodological

limitation related to masking, in that if one is on a puberty blocker or is on gender-affirming hormone therapy, both the participant and the investigators would likely know if one was assigned to an intervention arm or a placebo arm based on physical changes in the participant over time. And that would likely create methodological limitations that decrease the quality of the study.

Q. Do you think such a study would be likely to collect sufficient participant numbers?

A. So that's returning to the issue of clinical equipoise because potential participants are unlikely to have clinical equipoise. They are unlikely to be willing to enroll, or they would enroll and if they realized that they were in the control arm would likely drop out of the study, so that there would be issues that were both about feasibility, and, in the long run, about ethics in terms of conducting that type of study.

MR. CHARLES: Your Honor, plaintiffs would request a recess for lunch break at this time if the Court is amenable.

I can also continue.

THE COURT: Are you not close to done, or you are just telling me this is a good breaking point, or somebody needs a break? What --

MR. CHARLES: I received a note.

MR. GONZALEZ-PAGAN: Your Honor, if I may? We think this may be a natural breaking point. I believe there may be

approximately 45 minutes --

MR. CHARLES: Half hour, 40 minutes.

THE COURT: Okay. All right. And we took an early morning break anyway.

Let's take an hour and we will start back at 1:15.

MR. CHARLES: Thank you, Your Honor.

THE COURT: Dr. Antommaria, if you would be back on that stand at 1:15, please.

Thank you.

(Recess taken at 12:14 PM.)

(Resumed at 1:15 PM.)

THE COURT: Please be seated.

Dr. Antommaria, you are still under oath.

You may proceed.

MR. CHARLES: Thank you, Your Honor.

BY MR. CHARLES:

Q. Dr. Antommaria, are you familiar with the WPATH Standards of Care?

A. Yes, I am.

Q. What are the WPATH Standards of Care?

A. They're a Clinical Practice Guideline for, among other things, the treatment of individuals with gender dysphoria.

Q. Do you know what the current version of the WPATH Standards of Care is?

A. It's currently in its 8th version.

Q. And if I refer to the WPATH -- I'm sorry. If I refer to WPATH SOC8, will you understand that I mean the 8th current version?
A. Yes, I will.
Q. Do the WPATH SOC8 recommendations for gender-affirming medical care for adolescents rely on scientific studies?
A. Yes, they do.
Q. What kinds?
A. Comparable studies to those relied on by the Endocrine Society, which are premeditatedly prospective observational studies or longitudinal observational studies.
Q. Are the WPATH SOC8 recommendations for gender-affirming medical care for adolescents consistent with the Endocrine Society guideline recommendations for the treatment of gender dysphoria?
A. Yes, they are generally comparable.
Q. Are you aware of any randomized controlled trials studying whether mental health services alone is effective to treat gender dysphoria?
A. No, I'm not.
Q. What about observational studies?
A. I'm aware of individual case reports, but no longitudinal observational studies.
Q. Some of defendants' experts rely on systematic reviews of the literature for some of their positions.

Do systematic reviews of the literature recommend banning gender-affirming medical care?
A. They do not, but as we noted earlier, systematic reviews do not make recommendations.
Q. And do those two Clinical Practice Guidelines we've discussed, the Endocrine Society guidelines and the WPATH SOC8, recommend gender-affirming care --
A. They do.
Q. -- for the treatment of gender dysphoria?
A. Yes.
Q. Dr. Antommaria, how does the evidence base supporting gender-affirming medical care for adolescents compare to the evidence base for other medical treatments for minors?
A. It is generally comparable. We discuss the Endocrine Society's guidelines for other pediatric conditions and the quality of the evidence that supports those recommendations are fairly similar to the quality of the evidence that supports the recommendations related to gender-affirming medical care.
Q. What are some of those Clinical Practice Guideline -- what are some of the recommendations within Clinical Practice Guidelines that are comparable?
A. The specific recommendations or that --
Q. I'm sorry. The Clinical Practice Guidelines.
A. Oh. The guidelines for pediatric obesity and for congenital adrenal hyperplasia.

Q. So do those Clinical Practice Guidelines include recommendations based on low or very low-quality evidence under the GRADE system?
A. They do.
Q. Are there any other pediatric Clinical Practice Guidelines that you can think of that are, again, similar in the reliance on low or very low-quality evidence?
A. Another specific one would be the American Heart Association's guidelines for cardiopulmonary resuscitation, which predominantly rely on low or very low-quality evidence in support of their recommendations.
Q. The defendants and some of their exerts raise the issue of potential risks associated with gender-affirming medical treatments.

Are you familiar with the risks associated with gender-affirming medical care?
A. I am.
Q. What are some of the more significant risks of which you are aware?
A. So the risks somewhat vary by the treatment, but for what are colloquially referred to as puberty blockers, the predominant risk would be the -- a decreased rate of development of bone mineral density while on treatment, which might be compensated for through the use of gender-affirming hormone therapy.

And then for testosterone, there would be cardiovascular risks, including the risk of heart attack, as well as potentially the risk of stroke, secondary to changes in lipids or in terms of having an increased production of red blood cells.

And for estrogen therapy, risks would include, again, the risks of blood clots, including clots in the veins and the legs, clots that go to the lungs, or clots that would cause heart attack or stroke.

And for any of the -- for the use of testosterone or estrogen, there would be risks of infertility.

Q. How do the risks of gender-affirming medical care compare to the risks associated with other medical treatments that adolescents may undergo?

A. There are other treatments that adolescents undergo that have comparable uncertainty or risk.

Q. Can you think of any examples?

A. So there are treatments for kidney diseases or blood diseases in adolescents that would also entail the risk of infertility.

Q. Are there chest surgeries that adolescents may undergo besides chest surgery for gender dysphoria?

A. There are.

Q. Can you think of any examples?

A. Chest surgeries that adolescents may undergo include

surgery for gynecomastia, which would be the proliferation of glandular ductal tissue in the chests of individuals who are assigned male at birth; chest surgeries for pectus excavatum or carinatum, which would be where the chest protrudes or goes inward; and individuals who are assigned female at birth might undergo either breast reduction or breast augmentation surgery.

Q. And are those surgeries you just mentioned premeditatedly about appearance or physiologic function?

A. Predominately about appearance.

Q. How do the surgical risks of breast reduction for cisgender girls and gynecomastia surgery for cisgender boys compare to the surgical risks of chest surgeries to treat gender dysphoria?

A. There would be comparable risks in kind.

Q. And specifically how do the surgical risks of pectus excavatum compare to chest surgery for gender dysphoria?

A. Pectus excavatum surgery potentially has greater risk in that there have been fatalities as a result of pectus excavatum surgery.

Q. You've talked some about the evidence supporting gender-affirming medical care for adolescents.

Is it unusual for adolescent patients and their parents or guardians to make decisions to undergo treatments supported by comparable levels of evidence?

A. No, it is not.

Q. Why is it not uncommon?

A. Because there are multiple other medical conditions for which adolescents are treated that have comparable risks, benefits, and levels of uncertainty or levels of evidence related to those treatments.
Q. Is it unusual for adolescent patients and their parents or legal guardians to make decisions to undergo treatments with greater risks than those associated with gender-affirming medical care?
A. There are certainly medical conditions whose treatment entails greater risk.
Q. For medical treatments where there is evidence of safety and efficacy, how should the medical community respond to concerns about limitations of the evidence?
A. In general, it's preferable to generate additional evidence on which to base decisions through further research.
Q. In response to concerns about limitations of the evidence, should the medical community refuse to provide a particular treatment?
A. If there is available evidence that supports safety and efficacy, no.
Q. If Florida Medicaid does not provide coverage for gender-affirming medical care for transgender beneficiaries, is it possible to conduct more research on this treatment for this population?
A. It would be possible, but it would likely impede the

development of additional evidence.
Q. Why?
A. One of the potential ways to gather that evidence is through prospective observational trials of individuals who are receiving treatment, and if fewer individuals are receiving treatment because of restrictions on funding, that would impede the development of that type of evidence.
Q. Do research trials typically cover the cost of the treatment in addition to the cost of conducting the research?
A. If there is evidence of safety and efficacy, then the treatment itself is generally covered in whatever way the treatment would be covered, and the trial itself would only cover the additional expenses entailed in the research.
Q. So if the cost of the medical treatment is not covered and patients cannot access it, would the research trial typically cover the cost of the treatment for those patients involved in the research?
A. It might be very difficult to identify funders who were willing to cover both the research expenditures as well as the cost of the treatment.
Q. Why might it be difficult?
A. Because of the significant incremental additional expense.
Q. Dr. Antommaria, what does it mean to say that a medication is FDA approved?
A. That the FDA has reviewed evidence demonstrating that the

treatment -- the medication is safe and effective for a particular indication.

Q. I apologize. Let me back up.

Can you tell me what FDA stands for?

A. The U.S. Food and Drug Administration.

Q. And if I use FDA, will you understand what I'm referring to?

A. Yes, I will.

Q. And, Dr. Antommaria, what is meant by an indication as you just mentioned in the context of FDA approval?

A. When the FDA grants approval for a medication, it is for a particular indication, which would be a particular disease, whether it is being used for diagnosis, curative treatment, or palliative treatment, and for a particular population, frequently specified in terms of an age group.

Q. And if a medication receives FDA approval for an indication, is that medication only allowed to be used for that indication?

A. No. The FDA does not regulate the practice of medicine, and so healthcare providers are generally free to use that medication for other indications. The primary restriction would be that the pharmaceutical company can't advertise that medication for what are referred to as off-label uses.

Q. So what does it mean for -- I'm sorry.

What does it mean to use an FDA-approved medication

off-label?
A. That it's used for an indication other than the indication for which it was approved.
Q. So we've been discussing all the terms that comprise several sentences I've been asking you about related to indication.
Can you explain what it could look like to use an FDA medication off-label?
A. So using a medication off-label would be for another purpose other than what it's approved for, which might be simply using it for an age group in which it's unapproved. So, for example, as a pediatric hospitalist, I take care of children with bone and joint infections. Frequently I -- I frequently would utilize an antibiotic called nafcillin. It's not FDA approved for use in individuals under the age of 18, and so my using it to treat a 6-year-old would be an off-label use of that antibiotic.
Q. And as you said, indication can mean treating for a different condition?
A. Yes, it can.
Q. Or a different age group?
A. Yes. So an example of a different condition would be magnesium, for example, is FDA approved for preventing seizures in women with high blood pressure in pregnancy, but, again, as a pediatric hospitalist, I use it in children with severe asthma,

and there is evidence of safety and efficacy in those children, although its use is off-label.

Q. And does using a medication off-label mean that there is not evidence supporting that use?

A. No, it does not intrinsically mean that there is a lack of evidence.

Q. Could there be substantial evidence for the safety and efficacy of a medication when used off-label?

A. Yes, and in many cases there is. There are reasons why the manufacturer might not seek to have an additional indication added in spite of that evidence, but frequently there is evidence of safety and efficacy for off-label uses.

Q. Does using medication off-label mean that treatment is experimental?

A. No, it does not.

Q. Why not?

A. As I've stated, there may be evidence of safety and efficacy supporting the use of that medication.

Q. Is it unusual for a medication to be prescribed for indications other than the one it was approved for in pediatrics?

A. No. In fact, it's very common for medications to be used off-label in pediatrics. So there's a study that looked at off-label uses using a very restrictive definition of off-label for children that had encounters in children's hospitals, and

approximately 30 percent of encounters involved an off-label use. And in particular populations or settings, the rate of off-label use may go up significantly. So, for example, in a cardiac intensive care unit, the vast majority of medications may be used off-label in that setting.

Q. And if there's evidence that an off-label use of a medication is safe and effective, are there reasons a manufacturer might not seek additional approval for additional indications?

A. Yes, there are. Because of the time and expenditure that it takes to get an additional indication added, it might not be in a manufacturer's economic interest to seek to have that indication added to the label.

Q. Dr. Antommaria, can adolescents assent to gender-affirming medical care?

A. Yes, in general adolescents have sufficient medical decision-making capacity to assent to gender-affirming medical care.

Q. Why do you believe that?

A. So both based on my individual experience as a clinician, as well as evidence in the literature. So there's general evidence related to individual adolescents' medical decision-making capacity, as well as at least one study that's looked at adolescents' ability to assent to the use of what's colloquially referred to as puberty-blocking medications which

show that adolescents in general have adequate medical decision-making capacity to assent.

Q. And can parents and legal guardians provide informed consent for gender-affirming medical care?

A. Yes, they can.

Q. And why do you believe that?

A. Based on adults' general decision-making capacity and the comparable nature of decisions about gender-affirming medical care compared to the other types of medical care to which they're asked to consent on behalf of their adolescent children.

Q. Can you describe for me, please, the process at Cincinnati Children's Hospital of establishing informed consent?

A. So informed consent generally refers to a process of decision-making, although some individuals may have that misapprehension that it is about the signing of a form, and that there are multiple conversations held over time to discuss the potential benefits, risks, and alternatives to gender-affirming medical care, and to be able to answer parents' and their adolescent children's questions before they consent to treatment.

Q. Is there anything inherent to gender-affirming medical care that present -- prevents assent by minors and informed consent by their parents and legal guardians?

A. No, there is not.

Q. And why not?

A. So the requirements for having medical decision-making capacity are that you understand the risk benefits, alternatives; that you appreciate what those mean in your individual circumstance, and that you're able to evaluate and weigh the risks and the benefits.

And adolescents and their parents are generally capable -- or the average adult or adolescent is capable of understanding the risks, benefits, and alternatives of gender-affirming medical care, contextualizing that information in their own individual circumstance, and then weighing the potential risks and benefits in order to reach a decision; and that the risks, benefits and alternatives of gender-affirming medical care are not categorically different than the risks, benefits, and alternatives of other treatments to which parents and adolescents consent and assent.

Q. Are there other medical interventions in pediatrics that have similar levels of uncertainty or outcomes to which minor parents -- minor patients -- excuse me -- and their parents can provide assent and informed consent?

A. Yes, there are.

Q. Can you think of any examples?

A. So I had the occasion to perform an ethics consult for a 12- or 13-year-old young woman who had Turner syndrome, which is a genetic condition, and she had premature ovarian failure, meaning that her ovaries were not functioning properly, and they

were considering starting her on estrogen therapy to replace the estrogen that her ovaries were not making.

She also had a bleeding disorder and had multiple episodes of gastrointestinal bleeding which were severe, and they were contemplating performing a hysterectomy prior to estrogen therapy because of the potential risk of serious, if not life-threatening, bleeding from menses.

Because she was a minor and they were considering a hysterectomy, they requested an ethics consult. I met with the patient and her mother. The patient understood what a hysterectomy was and the implications it had in her life. She planned to go to college and to get married and to have children. She understood that as a result of having a hysterectomy, she wouldn't be able to become pregnant. She had family members who had adopted children, and she very much wanted to have children and saw adoption as a way to have her own children and believed that the benefits of having the hysterectomy outweighed the risks and assented to that procedure.

And so I think that in that clinical situation there were, you know, comparable benefits and risks, and even at 12 she had sufficient medical decision-making capacity to assent to that course of treatment.

Q. And so that -- is that a treatment, other than gender-affirming medical care, which would have impacted the

patient's fertility?
A. Yes. She was assigned female at birth, and her gender identity was female.
Q. Is the current standard of care for treating gender dysphoria consistent with general ethical principles instantiated in the practice of informed consent and shared decision-making?
A. Yes, it is. The Clinical Practice Guidelines, including the Endocrine Society's, are particularly attentive to informed consent and emphasize, for example, the importance of making individuals who are considering undergoing gender-affirming medical care aware of options for fertility preservation and make in general recommendations about the timing of different forms of gender-affirming medical care related to the development of medical decision-making capacity as individuals grow older.
Q. We've talked today about the Endocrine Society guideline for treatment of gender dysphoric persons and the WPATH SOC8.
Do these Clinical Practice Guidelines provide that doctors inform families of the potential risks and benefits of treatment?
A. Yes, they do.
Q. And in particular, do the guidelines emphasize the importance of adequate informed consent as related to fertility?
A. Yes, they do, specifically making recommendations that

individuals considering gender-affirming medical care are advised of the opportunities for fertility preservation.

Q. Dr. Antommaria, you testified earlier that generally in the practice of medicine the decision of whether to undergo treatment ultimately rests with the patient and in the instance of an adolescent with the parent or guardian.

Are the Endocrine Society guidelines and the WPATH SOC8 consistent with that?

A. Yes, they are.

Q. In your view, is there anything about gender-affirming medical care that makes the informed consent process inadequate to enable patients to make decisions about medical treatment?

A. No, there's nothing about gender-affirming medical care that makes the general principles of informed consent inapplicable or the process of informed consent inadequate.

Q. Dr. Antommaria, in your review, does the regulation at issue in this case have implications for clinicians' ability to comply with their ethical obligations as physicians?

A. It does.

Q. How so?

A. It would -- although they may still be able to recommend what they see as medically indicated treatment, it would significantly limit some patients' access to that medically indicated treatment.

Q. Some of the defendants' experts have asserted that some

doctors are providing gender-affirming medical care to adolescents without appropriate psychological assessments and without properly informing families of risks.

If an individual doctor provides treatment in an inappropriate manner or without informed consent, how might that be addressed?

A. There are multiple levels of oversight within the healthcare system to address inadequate performance, be that at the individual hospital level, at the individual patient level, or at the state level. So at my institution, there is what is called the PPEC, Professional Practice Evaluation Committee, and if there are complaints about inadequate practice or inappropriate practice, the PPEC committee would evaluate those concerns, might recommend remediation, and if that was ineffective, the provider could lose their privileges at our institution in providing care.

There's certainly mechanisms to address inadequate performance through the malpractice system, as well as at the licensing level. So state licensing boards would consider, again, concerns about unprofessional conduct and might effect remediation plans or remove a provider's license to practice.

Q. And as you understand it, those are all systems that are currently in place to regulate medical providers to ensure appropriate care, including gender-affirming care?

A. Yes.

Q. Dr. Antommaria, are you aware of any empirical studies showing that providers are providing gender-affirming medical care without appropriately informed consent?
A. No, I am not.
Q. Dr. Antommaria, are you familiar with utilization rates of gender-affirming medical care?
A. I am.
Q. What do you know about the utilization trends of gender-affirming care in the last 30 years?
A. That, in general, the utilization rates have increased over that period of time.
Q. How would you account for the increased utilization of those treatments over time?
A. So there would be a variety of potential reasons for that increased utilization over time. In part the increase in the available treatment, in terms of the numbers of centers that are available that provide that care, has increased over time.

And then there have been broader social changes which have decreased the stigma of identifying as transgender or seeking a diagnosis of gender dysphoria, which may increase individual's willingness to seek treatment.
Q. Have utilization rates for treatments for other medical conditions also seen increases over the last 30 years?
A. So in the way that there have been increases in the diagnosis of gender dysphoria, there have also been increases in

other diagnoses including autism as well as Type 1 diabetes over comparable time periods.

Q. And are increased utilization rates inherently a bad thing?

A. No. If there are increasing numbers of individuals who have a particular diagnosis having increased utilization rates as a result of them seeking and obtaining treatment would be intrinsically a good thing.

Q. Where utilization rates increase over time, is it a common response for the medical community's use of those treatments to diminish?

A. No. There might be questions -- so I'll use an example from my area of practice in hospital medicine.

So I treat children with bronchiolitis, which is a respiratory infection in children under two. There has been the development of a new technology called high-flow nasal cannula which is an alternative way to provide ventilatory support to help them get rid of carbon dioxide.

The utilization rates of high-flow nasal cannula have significantly increased in the last ten years. That's been a good thing because, in part, it allows us to treat these patients without having to intubate them -- put a breathing tube in them -- and over time allow them to be treated on the general hospital floor instead of the Intensive Care Unit.

So the increase in utilization has, in general, been a very positive thing for patients and their families.

There is a minor concern, potentially, now that high-flow nasal cannula is being over-utilized. And so wanting to make sure that the utilization is correct, but that's at the margins of the overall utilization being a positive thing for patients and their families.

Q. Dr. Antommaria, some of the states -- some of defendants' experts have attempted to discredit WPATH by asserting that they are not a scientific organization because their membership includes members of the patient community who are not medical professionals.

Is the inclusion of other stakeholder groups atypical for research or the development of Clinical Practice Guidelines?

A. So it is my general understanding that WPATH requires professional credentials in order to be a full member of the organization.

In developing of its standards of care, it incorporated stakeholder groups who were a minority of the participants who developed the standards of care, but that would be consistent with general trends in the development of Clinical Practice Guidelines.

So as we talked about in the development of recommendations it's important in considering the risks -- the balance of the risks and benefits that that balance reflects the evaluation of the risks and benefits of the patient groups. And so incorporating them in guideline development is a beneficial

change that has occurred over time rather than being problematic.

Q. Some of defendants' experts point to systematic reviews of the literature that describe the evidence base for gender-affirming medical care as being limited. What's your response to that?

A. That those systematic reviews are not Clinical Practice Guidelines. They do not make recommendations. And so the fact that they are evaluating the quality of the evidence has implications for recommendations, but do not intrinsically entail a specific recommendation.

Q. Dr. Antommaria, some of defendants' experts reference a systematic review of Clinical Practice Guidelines by Dolan, et al, in support of claim that the Endocrine Society Guidelines and the WPATH Standards of Care are of low quality.

What's your response to that?

A. The methodology that's used by Dolan, et al does not provide cut offs for assigning a quality grade to Clinical Practice Guidelines.

Q. Do you know what methodology that review used?

A. I apologize. I don't recall off the top of my head.

Q. Some of defendants' experts cite to treatment recommendations from government authorities in other countries.

Are you familiar with that reference?

A. I'm familiar with some decisions of some European

countries. Yes.
Q. What's your response to the assertion that countries in Europe are banning access to gender-affirming medical care, in particular for adolescents?
A. I'm not aware of any European country that has either banned or withdrawn coverage for gender-affirming medical care.
My general understanding of the recommendations are that the United Kingdom, Finland and Sweden are moving to providing gender-affirming medical care in the setting of multidisciplinary clinics, which is the type of care that is typically provided in the United States. And that those countries are also emphasizing the importance of ongoing research in the field. But, in particular, Sweden disclaims that that research will necessarily involve randomized controlled trials.
Q. And so to your knowledge, do the Sweden or Finland treatment recommendations evaluate the strength of the underlying evidence?
A. To the -- so the difficulty with the Swedish and Finnish guidelines are that I don't read Swedish or Finnish and that very limited parts of their reports are available in official English translation. So to the best of my knowledge, based on the limited information available, none of those reports constitute what I would consider a Clinical Practice Guideline that both grades the quality of the evidence and the strength of

recommendations.

Q. Are you familiar with the report from the UK known as the Cass Interim Report?

A. I am.

Q. Can you briefly describe with that is?

A. So a group that is chaired by Dr. Cass, who is an imminent British pediatrician, has been chartered to review the provision of gender-affirming medical care in the United Kingdom.

They have commissioned systematic reviews of the literature and have issued an interim report in the process of issuing a final report.

The interim report has recommended the development of regional multidisciplinary teams to provide gender-affirming medical care and building an infrastructure in order to provide research in the field. But the interim report makes no specific recommendations relative to the use of medications relative to gender-affirming medical care.

Q. Some people have characterized that report as shutting down gender-affirming care for adolescents in the UK. Is that a correct assertion?

A. That would not be my characterization. The Cass Commission has recommended the closure of a clinic that historically had provided evaluation for individuals with gender dysphoria, but rather than closing down the provision of gender-affirming medical care it is trying to address a substantial problem with

a large wait list and make evaluation and treatment more readily available to adolescents in the United Kingdom.

Q. Dr. Antommaria, some of defendants' experts rely on other organizations' views about gender-affirming medical care, such as the Society for Evidence-Based Gender Medicine, rather than the Endocrine Society and WPATH.

What's your reaction to that?

A. I'm not aware that the Society for Evidence-Based Gender Medicine has produced a Clinical Practice Guideline for gender-affirming medical care.

Q. And to your knowledge -- sorry. Strike that.

Dr. Antommaria, defendants claim that patients with gender dysphoria engage in self-diagnosis. Is that accurate in your view?

A. I would not consider it accurate, or to the extent that it is accurate it's not dissimilar to other medical conditions. So it's not uncommon when I see patients for them, based on their symptoms, to have a sense of what they have.

If they have a fever and a cough and shortness of breath they might reasonably suspect that they have pneumonia. It would, however, be up to the healthcare provider to confirm that diagnosis and make a treatment recommendation.

I would say that individuals with gender dysphoria might have reason to believe that they have gender dysphoria, but it would be up to their healthcare providers to appropriately

evaluate and diagnose them as to whether they, in fact, have gender dysphoria.

Q. So in your view, do medical diagnoses commonly rely on patient's self-report of their symptoms to medical providers?

A. Yes. When I see a patient the process that we undergo would be obtaining a history performing a physical exam. The history is about obtaining the report of their symptoms.

There are other medical conditions that rely on individual's self-report of their symptoms. Many other -- the one nonmental health condition that readily comes to mind would be migraine headaches.

Migraine headaches are exclusively diagnosed based on patient's report of their symptoms; the duration, frequency, characteristics of their headaches. And there are, in fact, no laboratory or radiographic studies that allow one to confirm a diagnosis of a migraine headache. Laboratory and radiographic studies are only used in those instances in which one is attempting to exclude other diagnoses.

Q. Dr. Antommaria, are clinicians who perform research in their clinical specialty inherently biased?

A. No, they are not.

Q. Why not?

A. So having heard that claim in the past, it's hard for me to understand who individuals making that claim envision doing that research, if not individuals within their own medical specialty

because they're the individuals who have the knowledge and expertise to frame the research questions and the access to the patients, or potential participants, in order to conduct the studies. And that there are multiple mechanisms in the profession to review potential conflicts of interest and to appropriately address them, including at the level of grant submission, so that if there was a particular individual who had a specific conflict of interest, that would be addressed either in not funding that individual to perform the research, or potentially not publishing the results of their research.

Q. And similarly are clinicians who develop Clinical Practice Guidelines in their clinical specialty inherently biased?

A. They are not.

And medical professional associations generally have robust mechanisms to screen candidates for guideline development committees for potential conflicts of interest and exclude them from potentially participating in the development of such guidelines.

Q. So are clinicians who prescribe treatment for gender-affirming medical care inherently biased, or do they have an inherent conflict of interest in performing research or developing guidelines about that care?

A. No, they are not. They do not have intrinsic conflicts of interest.

Q. And why would that be?

A. Their recommendations are generally based on their knowledge of evidence in the literature and their clinical experience. And that knowledge and experience in and of itself doesn't constitute bias in the negative or pejorative sense of the term. It is, in fact, what patients would be seeking their care for.

Q. Dr. Antommaria, does a condition's cause being unknown mean that there can be no established treatments for it?

A. No. It's not necessary to know the cause of a condition in order to have effective treatments.

Again, I'll rely on my experience as a pediatric hospitalist. So there is a condition called Kawasaki disease which is common to me as a pediatric hospitalist and not uncommon in the general population. And it's an inflammatory disease in younger children. And we do not know what causes it. But we have effective treatments that have been demonstrated to be effective, based on studies. And so our lack of knowledge of what causes the condition does not prevent us from having effective treatments for that condition.

Q. Do the adverse effects of a treatment not being fully elucidated make the treatment experimental?

A. No, it does not.

Q. Why is that?

A. It is not uncommon for the potential side effects of the treatment to not fully be elucidated, say, for example at the

time the FDA approves a medication.

So the FDA reviews evidence of safety and efficacy typically to trials, which may have several hundred individuals, and that that is adequate evidence of safety and efficacy, that there might be uncommon side effects that are identified when that treatment is used in a larger population, or side effects that only become apparent over a longer time frame.

Again, I'll use a COVID example. So the COVID vaccines were approved, but there was post-marketing surveillance, as there are with other approved treatments, in order to potentially identify side effects in larger groups or over longer periods of time. But the FDA, none the less, approved those vaccines as safe and effective.

Q. And has -- excuse me. Has medicine identified a definitive cause of gender dysphoria that you are aware of?

A. It's my understanding that medicine has identified contributing factors of gender dysphoria, including potential genetic influences, but not a definitive cause.

Q. And does that undermine the existence of well-established evidence-based treatments for gender dysphoria?

A. No, it does not.

MR. CHARLES: Your Honor, I'd like to show the witness a stipulated exhibit labeled Defendants' Exhibit 28.

BY MR. CHARLES:

Q. Dr. Antommaria, can you see this document on your screen?

A. I can.
Q. Are you familiar with it?
A. I am.
THE COURT: Is this -- this can be shown to the public, can it not?
MR. CHARLES: Oh, I'm sorry, Your Honor. Yes.
BY MR. CHARLES:
Q. Dr. Antommaria, what is this document?
A. It's a systematic review that was conducted, in part, to support -- I believe it was Swedish recommendations related to gender-affirming medical care, in this case specifically hormone treatment.
Q. I'm going to take you to a section here.
Can you just read that highlighted paragraph to yourself, please, Dr. Antommaria?
(Pause in proceedings.)
THE WITNESS: I've read it, sir.
BY MR. CHARLES:
Q. Okay. And can you -- I'm looking at the sentence that starts, "Given the current lack of..."
Do you see that about halfway through the paragraph?
A. I do.
Q. Okay. And it states: *Another ethically feasible option would be to randomize individuals to hormone therapy with all study participants, independent of intervention status,*

receiving psychological and psychosocial support.

Do you understand what kind of study design that is suggesting?

A. So I will note that this is an accepted article, which means that it is not in its final published form and has yet to undergo copy editing.

The sentence is hard for me to understand and appears in some ways to not be well formed. But in particular I would say it's hard for me to envision the study design, because they talk about randomizing individuals to hormone therapy, but they are suggesting that that would be the intervention. But they don't suggest in the sentence what they would be randomized in terms of what the control is.

So it would be at least incomplete in terms of the type of study design that they are envisioning.

Q. Based on what you can understand from that suggestion, would that be an ethical study design for gender-affirming medical care?

A. So I don't -- so their claim about it being ethically feasible is simply an assertion. They don't -- so I'll say this as an ethicist, they don't provide an argument for why it would be ethically feasible. So I have both difficulty understanding what design they envision and why they think it would be ethically feasible because they don't provide specific reasons to justify that assertion.

I would have concerns about their subsequent sentence that said: *Controlled trials do not necessarily require placebo treatment, but could for example build on the date or time of starting hormonal therapy to generate comparison groups*, which might suggest that they envision a study design that required -- that is dependent on there being a waiting list in randomizing people, for example, to initiate treatment versus continue on the waiting list. But that would strike me as ethically problematic, because it would seem that the primary ethical thing would be to decrease the waiting list as opposed to utilizing the waiting list as a mechanism to generate a clinical trial.

Q. Dr. Antommaria, we discussed earlier today the Florida Medicaid GAPMS memo.

Do you believe the GAPMS memo properly characteristics gender-affirming medical care and the evidence base for it?

A. I do not.

Q. Why is that?

A. Because I believe that there is evidence of the safety and efficacy of gender-affirming medical care and that there are appropriate mechanisms to obtain informed consent for gender-affirming medical care, and that it is a medically indicated treatment.

Q. And, Dr. Antommaria, is gender-affirming medical care experimental?

A. It is not.
Q. Or investigational?
A. So it is possible for gender-affirming medical care to be part of a trial or for research to be conducted on gender-affirming medical care. But as a broad category, as it is used in clinical practice, is it a medically indicated clinical treatment and is not experimental except in those specialized circumstances in which research is being conducted.
MR. CHARLES: Finished, Your Honor.
THE COURT: All right. Before we start cross, let me note, the last exhibit I think you used was Defendants' Exhibit 28. I think you said it was stipulated. I don't think it was. I don't know if you wanted it admitted.
MR. CHARLES: I'm sorry, Your Honor.
THE COURT: It doesn't matter. I'm just noting it -- I think it has not been admitted. If somebody wants it admitted, you need to offer it.
MR. PERKO: We'd like it to be admitted, Your Honor.
THE COURT: You would like it admitted?
MR. PERKO: Yes, sir.
THE COURT: Is there --
MR. CHARLES: No, we don't want it to be admitted, Your Honor.
THE COURT: All right. We'll wait until it's authenticated and a foundation is established.

CROSS-EXAMINATION

BY MR. PERKO:

Q. Good afternoon, Dr. Antommaria.

Dr. Antommaria, you're a pediatrician and a bioethicist; right?

A. Correct.

Q. You are not a psychiatrist?

A. No, I am not.

Q. And you're not an endocrinologist?

A. No, sir, I am not.

Q. And you are not a surgeon?

A. No, I am not.

Q. And you do not diagnose patients with gender dysphoria?

A. I do not provide the initial diagnosis of gender dysphoria to patients, no.

Q. And you talked at length about the GRADE methodology.

MR. PERKO: And if you could bring up Plaintiffs' 157, please.

IT STAFF: I'm sorry?

MR. PERKO: 157.

IT STAFF: Thank you.

BY MR. PERKO:

Q. Now, this is the article that you talked about in direct examination.

The last author listed here is Gordon H. Guyatt. Do you

understand him to be the father of the GRADE system?
A. Sir, you'd have to explain to me which what you mean by father --
MR. CHARLES: Objection.
BY MR. PERKO:
Q. Was he the original author of the GRADE system?
A. The GRADE approach was developed by a multi-author group. He was among the authors of the original paper and an author on the subsequent publications.
Q. You've never heard him acknowledged as the father of the GRADE system?
MR. CHARLES: Objection, Your Honor.
THE COURT: Overruled.
THE WITNESS: I'm to answer the question?
THE COURT: Yes, you are.
THE WITNESS: Not until you've used the term today, sir.
MR. PERKO: Okay. If we could turn to that Table 2 on Bates number 6349 that you previously testified about.
BY MR. PERKO:
Q. Now, Dr. Antommaria, you previously testified about the low evidence -- or quality of evidence in this table. And I believe you said it meant our confidence is the effect estimate -- in the effect estimate is limited. But you did not read the second sentence.

Can you tell me what that says?

A. The rest of the sentence after the colon states: *The true effect may be substantially different from the estimate of the effect.*

Q. And what is very low quality of evidence defined as?

A. Would you like me to read that sentence?

Q. Yes, sir.

A. *We have very little confidence in the effect estimate. The true effect is likely to be substantially different from the estimate of effect.*

Q. And you talk a lot about --

MR. PERKO: You can take that down now.

BY MR. PERKO:

Q. You talked a lot about the Endocrine Society's Clinical Practice Guidelines.

In your expert report, you state that the Endocrine Society Clinical Practice Guidelines make 28 recommendations, and that 10 are strong, 12 are weak, and 6 are ungraded good practice statements.

Do you recall that?

A. So I don't have a copy of the report in front of me, sir.

MR. PERKO: Could we bring up -- I'm sorry. I have too much paper here.

Bring up Plaintiffs' 5.

May I approach, Your Honor?

THE COURT: You may.

IT STAFF: Plaintiffs' 5?

MR. PERKO: If we could turn to page 11.

BY MR. PERKO:

Q. In the paragraph 23 that starts on page 11, you state: *The Society's clinical practice guideline for the endocrine treatment of gender-dysphoric/gender-incongruent persons makes 28 recommendations.*

Is that an accurate statement?

A. Yes, sir.

Q. You go on to say: *Ten are strong, 12 are weak, and six are ungraded good practice statements.*

Is that a correct statement?

A. Yes, sir.

Q. Now, you mentioned ungraded good practice statements on your direct. Can you tell me what that is?

A. Those are recommendations for which there is not substantial evidence available, and they are made as recommendations for practice without a specific grading of evidence in support of them.

Q. You are saying they are recommendations?

A. I'm sorry?

Q. You are saying that they are recommendations?

A. They are not recommendations in the sense of strong or weak recommendations, but I would say that I think that they're

broadly understood as recommendations in the sense of directing provider performance.

MR. PERKO: Can we bring up page 39?

Which is exhibit C to your expert report.

It's the very last page. It's Appendix C to his report -- Exhibit C. It's the very last page. It should be, at least.

There we go.

BY MR. PERKO:

Q. So this is Exhibit C to your expert report, and it does -- in footnote 3 it says: *Upgraded Good Practice Statement.* And then, quote: *Direct evidence for these statements was either unavailable or not systemically appraised and considered out of the scope of this guideline. The intention of these statements is to draw attention to these principles.*

Is that a correct understanding of what ungraded good practice statements are?

A. Yes, sir.

Q. Going back to -- on page 11, again, paragraph 23. Page 11.

After you say that: *Ten are strong, 12 are weak, and six are ungraded good practice statements,* you say that: *Three are based on moderate, 14 on low, and five on very low-quality evidence.*

Is that a correct statement?

A. Yes, sir.

Q. You also mention that the Endocrine Society has guidelines on pediatric obesity. Do you recall that?
A. Yes, sir.
Q. Those guidelines don't recommend the use of hormone therapy for pediatric obesity, do they?
A. I don't believe that they do, sir.
Q. You'd agree with me that there is no confirmatory laboratory or radiographic study for the diagnosis of gender dysphoria, wouldn't you?
A. Can you repeat your question, sir?
Q. Yes.
There is no confirmatory laboratory or radiologic -- radiographic study for the diagnosis of gender dysphoria?
A. That's correct, sir.
Q. You talked about migraine headaches as having similar quality evidence to support it as gender dysphoria.
What's the treatment for migraine headaches?
A. So, sir, I don't believe that I talked about the quality of the evidence related to migraine headaches. I believe that I discussed that migraine headaches are diagnosed based on patients' reports of their symptoms.
Q. Thank you for that clarification.
What's the treatment for migraine headache?
A. This is a pharmacotherapy for migraine headaches, sir.
Q. There is what?

A. There are medications that are used to either prevent or treat migraine headaches, sir.
Q. Is hormone therapy used to treat migraines?
A. Not to the best of my knowledge, sir.
Q. And you're a member of the American Academy of Pediatricians; right?
A. The American Academy of Pediatrics.
Q. Pediatrics.
A. Yes, sir.
Q. Are you aware that -- and I'll refer to it as the APA; is that all right?
A. The AAP, sir.
Q. I'm sorry. The AAP.
Are you aware that the AAP endorsed WPATH's Standards of Care?
A. So the AAP endorsing another medical professional organization's Clinical Practice Guideline has a very specific meaning. And no, I'm not aware that the AAP has endorsed WPATH's SOC 8.
Q. Has the AAP taken a position on the WPATH Standards of Care?
A. The AAP has taken positions on gender-affirming medical care.
Q. Have they taken a position on the WPATH's Standards of Care?

A. On the recently published 8th version?
Q. I believe it was the 7th.
A. So I don't recall a specific statement by the Academy on SOC 7 or SOC 8.
Q. But you did say that the Academy did endorse gender-affirming care? Did I hear you correctly?
A. So the American Academy of Pediatrics has not published a Clinical Practice Guideline on gender-affirming medical care, but has published other documents in support of gender-affirming medical care.
Q. Okay. Were you and your fellow members asked to vote on the AAP's endorse -- or position on gender-affirming care?
A. No, sir, I wasn't. But I was also not asked as a member of the Academy to vote on its Clinical Practice Guideline for the treatment of febrile infants.
Q. So it's possible that not all members of the AAP agreed with the AAP's position on gender-affirming care, isn't it?
A. Yes, that is possible, sir.
Q. It's possible that the majority of the members didn't agree with that position statement, isn't it?
A. As a theoretical possibility, sir?
Q. Is it possible that a majority of the members did not agree with that position statement?
A. It would theoretically be possible, but I would believe it to be highly unlikely.

Q. You talked about the Swedish -- I don't know if you used the phrase, but the Swedish National Board of Health and Welfare coming out with a new position.

Do you recall that testimony?

A. Yes, sir.

MR. PERKO: Could we bring up Defendants' 8?

BY MR. PERKO:

Q. Do you see it on your screen?

A. I do, sir.

Q. Is this the official translation that you're referring to about the Swedish physician paper?

MR. CHARLES: Objection, Your Honor.

THE COURT: What's the objection?

MR. CHARLES: It lacks an authentication certificate -- an official translation certificate.

THE COURT: Well, he's asking. Let's find out if Dr. Antommaria knows what it is.

THE WITNESS: Can you scroll through several of the pages, sir?

BY MR. PERKO:

Q. Sure.

A. Can you keep going, please?

To the best of my understanding, this is the official translation of the summary of their document. It is not an official translation of the entire guideline.

Q. You referred to official translation (indiscernible) --

(Reporter requested clarification.)

THE COURT: Slow down.

Look, here -- everybody speak up, speak one at a time. It's getting late in the afternoon. Everybody is slowing down, but we need to keep going. So speak up and make it clear.

We're going to be reading some papers back and forth. When you're reading, read slowly and loudly. We can all read faster than we need to read in the courtroom.

So let's get back on track.

You had an objection?

MR. CHARLES: Yes, Your Honor. Lacks authentication.

THE COURT: He just authenticated it. The objection is overruled.

MR. PERKO: Can we go to page 3, the first paragraph under "Caution in the use of hormonal and surgical treatment"?

THE COURT: And I guess, before you ask the question, I can ask: Do you think this is not what it purports to be?

MR. CHARLES: Your Honor, it appears to be a document online. We don't know anything else about it.

THE COURT: Well, your witness just said what it is, so I overrule the objection.

MR. PERKO: Thank you, Your Honor.

BY MR. PERKO:

Q. Do you see this paragraph? It says: *At group level (i.e.*

for the group of adolescents with gender dysphoria, as a whole) the National Board of Health and Welfare currently assesses that the risks of puberty blockers and gender-affirming treatment are likely to outweigh the expected benefits of these treatments. The National Board of Health and Welfare therefore gives the following weak, negative recommendations as guidance to the healthcare system.

And those include *treatment with GnRH analogues, gender-affirming hormones, and mastectomy can be administered in exceptional cases.*

Is that your understanding of what the Swedish National Board of Health and Welfare concluded?

A. So, sir, this is a different document than the one with which I am familiar.

THE COURT: All right. Let's back up.

Where did this come from?

MR. PERKO: It came from the Internet, Your Honor.

THE COURT: I sustain the objection.

If you find somebody that knows what this is, you can put it in, but I take what the doctor has just told me to be that when he first said this is what he thought he had seen, now having seen more of it, he does not think it is what he has seen.

So if all you've done is pull some document off the Internet without anybody who can say what it is, it's not coming

in.

MR. PERKO: Fair enough, Your Honor.

THE COURT: You've got an expert -- I assume you've got experts on your side, and somebody will know what this is.

But, look, you -- on both sides, don't go pulling preliminary drafts and bringing them in here as if they're some official document. So I assume that this is really the official document and you have somebody that's going to say it is, and when you do that, I'll admit it.

MR. PERKO: Fair enough, Your Honor.

Thank you, Your Honor. I think that's all I have.

THE COURT: Redirect?

MR. CHARLES: Nothing further, Your Honor.

THE COURT: There was some discussion, I think on your direct examination, about the increase in the number of -- I think it was adolescents seeking treatment, and you said if -- in effect, as I grasped it, you said, in effect, if these are people who need treatment, the increase in people seeking treatment is a good thing. I get it.

Is there any way to know whether the increase in the number of people seeking treatment is an increase in the number of people seeking treatment out of a population of people who need treatment that's unchanged or instead is reflective of an increase in the number of people who need treatment?

I asked that very badly. I hope it came across. The

idea is are we looking at an increase in the number of people with gender dysphoria, or are we looking at a situation where it's the same percentage of people who have gender dysphoria, it's just that more of them are seeking treatment?

THE WITNESS: I don't think that we have that information available to us. I think going forward -- but even know there are not broad in the U.S. population-based estimates of the measures of the number of individuals with gender dysphoria, and certainly that information wasn't available in the past. So we don't -- we are not able to make those comparisons.

THE COURT: I take it it would be very difficult even now to find out what percentage of people in the population are trans.

THE WITNESS: So there are people who are working in order to be able to do that, both in terms of developing robust questions in surveys in order to do that, as well as being able to field those surveys to a representative group of people. But those are still barriers to being able to answer the question that you are asking, sir.

THE COURT: Very hard survey to get honest answers to, I take it?

THE WITNESS: Well --

THE COURT: Sociological research is always difficult. This one has got to be one of the harder problems, isn't it?

THE WITNESS: Somewhat outside of my field, sir. I might not say -- certainly there might be individuals who, again, because of the social stigma, might have hesitance to answer honestly, but some of the issue is just how do you ask the question at all and in a way that people respond consistently.

THE COURT: One of the other discussions that you had, I think on the direct examination, was about this assertion that the people who are providing care in this field are biased. And, frankly, I understand the concern. There's the old statement when the only tool you have is a hammer, everything looks like a nail. On the other hand, if we're going to study a cardiology problem, we're not going to get pediatricians to do the research. We're going to get the cardiologists to do the research. That's why you'd do it.

So I've heard from you and the other experts about clinics where this kind of work is done, so, for example, the University of Michigan clinic where people come.

Are there any successful practices treating gender identity in other ways, under other paradigms, successful practices that -- by "successful" I mean that have attracted people who wind up satisfied with the outcomes. Is that going on anywhere?

THE WITNESS: I'm not aware of what you refer to as successful practices using a different paradigm for postpubertal

children, sir.

THE COURT: Thank you.

Questions just to follow up on mine?

MR. CHARLES: No, Your Honor.

MR. PERKO: No, Your Honor.

THE COURT: Thank you, Doctor. You may step down.

(Dr. Antommaria exited the courtroom.)

THE COURT: Please call your next witness.

MR. GONZALEZ-PAGAN: Thank you, Your Honor. I believe Ms. Altman will be calling our next witness, but we're wondering if we could take a brief afternoon break for just --

THE COURT: I mean, if someone needs a break, we can take it, but, look, what I'd like to do is take one more break this afternoon. If we take it now, it's going to be a long afternoon.

MR. GONZALEZ-PAGAN: I understand. It's been requested of me, so I defer.

We're okay.

THE COURT: So let's keep going.

Who is the next witness?

MS. ALTMAN: Your Honor, the plaintiffs call Jeffrey English.

(Mr. English entered the courtroom.)

THE COURTROOM DEPUTY: Please remain standing and raise your right hand.

JEFFREY ENGLISH, **PLAINTIFFS WITNESS, DULY SWORN**

THE COURTROOM DEPUTY: Please be seated.

Please state your full name and spell your last name for the record.

THE WITNESS: My name is Jeffrey A. English. My last name is spelled E-n-g-l-i-s-h.

MS. ALTMAN: Your Honor, may I approach?

THE COURT: You may.

MS. ALTMAN: I have put the exhibits -- we're going to call them up electronically, but I also have paper copies here, and I have a copy for the Court.

THE COURT: I've got the one electronically and the one you're going to call up, so thank you.

MS. ALTMAN: All right.

DIRECT EXAMINATION

BY MS. ALTMAN:

Q. Good afternoon, sir.

We've met before?

A. We have.

Q. And can you introduce yourself to the Court, please?

A. My name is Jeff English.

Q. Were you previously employed by the Agency for Health Care Administration?

A. Yes.

Q. And if I say AHCA, will you agree with me that that's going

to refer to the Agency of Health Care Administration?
A. Yes.
Q. For what period of time were you employed by AHCA?
A. I believe I started in September of 2019, and -- until February of 2023, so --
Q. And --
A. Yeah.
Q. -- what positions did you hold while employed there?
A. I was a Government Analyst II. Initially in that role I was responsible for the generally accepted medical standards process, and then ultimately I transferred out of that position and into the position as the Medicaid state planning coordinator.
Q. In the Government Analyst II position -- the Generally Accepted Professional Medical Standards --
A. Uh-huh.
Q. -- we can call that GAPMS; is that correct?
A. Correct.
Q. And you were the GAPMS guy?
A. Yes, I was.
Q. And how long did you hold that position?
A. Three years.
Q. How long did you hold the state planning coordinator position?
A. Several months.

Q. When did you leave AHCA?
A. I left in February of 2023.
Q. Did you leave voluntarily?
A. I did.
Q. When you decided to leave AHCA, did you have another job?
A. I did not.
Q. But you chose to leave anyway?
A. I did.
Q. Are you working today?
A. I am not.
Q. Are you being compensated for your time?
A. I am not.
Q. Why did you choose to leave AHCA?
A. It was a combination of personal reasons and professional reasons, some family considerations, and just the direction that the agency seemed to be going. There were a lot of morale problems, and I just didn't feel like -- I no longer wanted to be associated with a position that I didn't feel had any more integrity.
Q. Is the position that you're referring to your position as the GAPMS guy?
A. It is.
Q. And is that the position for which you felt the GAPMS no longer had any integrity?
A. It is.

Q. Can you describe for the Court what you did while you held the title of Government Analyst II, the GAPMS guy, meaning what were your specific roles and responsibilities?
A. Any GAPMS request that came in, I was responsible for researching and writing those reports and routing them through leadership. I also worked quite a bit with regards to things going on with session. I was the liaison with the agency for the Centers for Medicaid & Medicare Services, the National Association of Medicaid Directors, and some other organizations that pertain to the work we did.
Q. Who was your supervisor when you were in the GAPMS role?
A. When I was hired, it was a woman named Christina Vracar, and ultimately it was Jesse Bottcher.
Q. Who is Jesse Bottcher's supervisor?
A. The bureau chief, which would be Ann Dalton.
Q. Why did you transition to the state planning coordinator position?
A. I had -- I had wanted to switch positions. I didn't want to be involved in the GAPMS position anymore. I had tried to leave, and Jesse explained to me that he really wanted to keep me and offered me my choice of a couple of different Government Analyst II positions in order to try and get me to stay.
Q. And the period you're talking about where you no longer wanted to be associated with the GAPMS role, was that after the June 2, 2022, GAPMS report on gender dysphoria was issued?

A. It was.
Q. And prior to that, you were not looking to leave that role, were you?
A. No.
Q. Did you resign after the June 2, 2022, GAPMS report on gender dysphoria was issued?
A. I did. I sent a two-week notice to the bureau chief and my supervisor.
Q. The bureau chief being Ann Dalton?
A. Yes.
Q. Did you end up resigning?
A. No. That was when Jessie came to me and convinced me to stick around a little longer.
Q. And you stuck along, I guess, about six more months; is that fair?
A. That's fair.
Q. When you tendered your resignation in the summer of 2022, did you explain to them why -- why you were resigning?
A. I didn't lay that out in the email to Ann, but Jesse was well aware of the circumstances of why I wanted to leave the position.
Q. And when you say the circumstances of why you wanted to leave the position, did it relate to the June 2, 2022, GAPMS report?
A. And its impact on the process as a whole.

Q. What do you mean by that?
A. Part of the process -- when you get a request, you end up kind of having a working relationship, so to speak, with the requester. They trust you to see the report through. There were multiple reports that had been written that were lying around that had not been reviewed. There were people who mistakenly believed that I had written the June 2 report. There were a host of reasons why I didn't want to stay in that position.
Q. Did you write the June 2, 2022, GAPMS report on gender dysphoria?
A. I did not.
Q. What is the purpose of a GAPMS report?
A. It's a request for coverage. It's a coverage determination document that's prepared in response to a request for coverage for something that Florida Medicaid doesn't already provide coverage for.
Q. Does it also determine medical necessity?
A. It does.
Q. So it determines both coverage and medical necessity; is that correct?
A. Yes.
Q. While you held the title of Government Analyst II, did anyone else work on GAPMS reports with you?
A. Yes. And you'll have to forgive me. There was a woman

that worked in Medicaid policy briefly who was brought in to help take some longer form -- some longer reports and condense them down to something called a short form GAPMS. And there was a gentleman named Nick who we -- when I accepted the job there was a big backlog, a big queue of requests that had not been addressed, and we had Nick -- we tasked Nick with going through those requests and applying the GAPMS checklist to make sure that every request that was in the queue was truly a GAPMS.

Q. Sir, if you could turn to Tab 1 in your binder.

MS. ALTMAN: For the Court's indulgence, it's Exhibit 18.

THE WITNESS: Okay.

MS. ALTMAN: Plaintiffs' Trial Exhibit 18.

BY MS. ALTMAN:

Q. Do you recognize this document, sir?

A. I do.

Q. What is it?

A. It's the Florida Medicaid GAPMS report on gender dysphoria.

Q. Who created this document?

A. Matt Brackett.

Q. Did you have any involvement in the preparation of this document?

A. None whatsoever.

Q. Does this GAPMS report set out the basis for AHCA's determination to not cover treatments for those diagnosed with

gender dysphoria, including treatment such as puberty-suppressing medications and cross-sex hormones?
A. It does.
Q. Is the June 2nd, 2022 GAPMS report the basis for AHCA to establish Florida Administrative Code Rule 59G-1.050, which bans medical treatments for gender-affirming care?
A. Yes.
Q. Was this GAPMS report created while you were still employed by AHCA as a Government Analyst II, as the GAPMS guy?
A. Yes.
Q. And is this a business record of AHCA maintained in the ordinary course of business that you had access to while you were employed by AHCA?
A. Yes.
Q. Where was this record maintained?
A. On AHCA's website.
Q. Was there a slogan associated with it?
A. I believe it was Let Kids be Kids.
Q. And at the time this GAPMS report was created, who was responsible for preparing GAPMS reports?
A. Myself.
Q. Did you have any role in drafting this report?
A. I did not.
Q. Were you asked to participate in the drafting of this GAPMS report?

A. I was not.
Q. Other than this GAPMS report, meaning what's been marked as Plaintiffs' Trial Exhibit 18 for identification, are you aware of any other GAPMS report while you were employed there that was created by someone other than you while you were in the Government Analyst II position handling the drafting of GAPMS reports?
A. I am not.
Q. Prior to the June 2022 GAPMS report, are you aware of any other instance where a GAPMS report was drafted and issued without your direct involvement?
A. I am not.
Q. At the time of the June 2022 GAPMS report, were there other GAPMS reports in queue?
A. Yes.
MS. ALTMAN: And, Your Honor, we'd ask that Plaintiffs' Trial Exhibit 18 be moved into evidence.
MR. PERKO: Your Honor, our only objection is it's not complete. It doesn't have the attachments to it. We'd offered that into evidence.
THE COURT: The one in this book has some attachments. Is that not all of them?
MR. PERKO: I don't believe it does, Your Honor.
MS. ALTMAN: Your Honor, Plaintiffs' Trial Exhibit 18 is just the report, which is what we are using with Mr. English.

The attachments are the -- I'll use air quotes -- assessments of the experts, for lack of a better word, that they attached to the report.

THE COURT: Does the whole thing have a different number? Is there a defense number?

MR. PERKO: DX6.

THE COURT: DX6?

MR. PERKO: 6.

THE COURT: DX6 is admitted.

(DEFENDANT EXHIBIT DX6: Received in evidence.)

THE COURT: And I'll admit Plaintiffs' 18 as well. It won't hurt to have the two versions.

MS. ALTMAN: Thank you, Your Honor.

THE COURT: And if you are going to work with him on this one, I don't want to have to worry about whether the page numbers are the same or whatever, so I'll admit both exhibits.

(PLAINTIFFS EXHIBIT 18: Received in evidence.)

MS. ALTMAN: Thank you, Your Honor.

And just for the Court's edification, we are not going to go through the attachments with this witness.

Thank you.

BY MS. ALTMAN:

Q. Why was the June 2022 GAPMS report pushed in front of other GAPMS reports that were in process before this one?

A. Because the request for it came in from the executive.
Q. And who is that?
A. The Governor.
Q. What type of information is in a GAPMS report?
A. Everything from recognized relevant Clinical Practice Guidelines.

There's usually -- there is always a literature section pertaining to the most relevant studies on the subject.

There's coverage considerations, both from other state Medicaid programs and major insurance companies.

There is -- and if need be for a particular report, there can be a fiscal analysis included as well.

Q. Is there more than one type of GAPMS report?
A. There's what I call a traditional GAPMS report, which is a traditional request that comes in and goes through the normal process and routing process. And then there is something that's called an expedited GAPMS that is an internal memo between a health plan and Medicaid policy when the health plan denies coverage for something as experimental and investigational.
Q. Is a request from the Governor a traditional request for a GAPMS report? Is that how they traditionally come in?
A. That's what this report would most closely -- would most closely resemble.
Q. And I'm sorry. My question probably wasn't clear.

When you talk about the requests for how a GAPMS is

requested, do they usually come from the Governor? The request?
A. No, they come in through an email address called Health Service Research, and it's typically either providers who are seeking treatment for a patient, or, say, a manufacturer who has invented a new medical device or some type of company that has treatment that they want Florida Medicaid to cover.
Q. While you were the GAPMS guy, were there any requests that came in to you from the Governor?
A. No.
Q. Just this one?
A. Well, this one didn't come to me, but, yes, just this request, as far as I know.
Q. And do you know who it came to, meaning the request from the Governor?
A. Ultimately it went to Matt Brackett.
Q. Is the GAPMS process used to ask for treatment or service to be excluded?
A. No, it's a request for coverage; it's not a request for exclusion.
Q. Sir, if you could turn to tab 2.
Do you recognize this email exchange?
A. I do.
Q. And what is it?
A. That is an exchange between myself and DeDe Pickle pertaining to, I believe, an expedited GAPMS.

Q. And you said DeDe Pickle. This says Devona. Does Devona go by DeDe?
A. Yeah. I knew her as DeDe.
Q. Who is she?
A. She is, I believe, now the -- I believe she's the head or senior person on the Canadian drug import team. And at the time of this email, she was -- in situations where Ann Dalton, the bureau chief, was unavailable in the office, then DeDe would frequently be put in place to cover for her while Ann was gone.
Q. At the time of this email exchange, were both you and Ms. Pickle employees of AHCA?
A. We were.
Q. Was this written and exchanged while you were performing your role as Government Analyst II, meaning while you were the GAPMS guy?
A. I was.
Q. When you were employed by AHCA, was it part of your regularly conducted business to write emails to other employees of AHCA about the business and affairs of AHCA, and, in particular, matters within the scope of your employment related to GAPMS?
A. It was.
Q. And was this email retained as a business record of AHCA?
A. Yes.
MS. ALTMAN: Your Honor, we would ask that Plaintiffs'

Trial Exhibit 30 be moved into evidence.

MR. PERKO: No objection, Your Honor.

THE COURT: Plaintiffs' 30 is admitted.

(PLAINTIFFS EXHIBIT 30: Received in evidence.)

BY MS. ALTMAN:

Q. Sir, in this email, Ms. Pickle says to you: *Interesting. I went back to read the GAPMS rule. It's for requesting coverage -- not disputing it.*

Did I read that right?

A. You did.

Q. And Ms. Pickle is telling you -- she's citing to a rule there; is that correct?

A. Yes.

Q. What rule is that?

A. That's the GAPMS rule.

Q. And she's indicating that that GAPMS rule provides only for coverage requests, not disputing or excluding coverage; correct?

A. Correct.

Q. The exhibit we were looking at, the June 2022 GAPMS for gender dysphoria, is that a GAPMS for coverage or a GAPMS to exclude coverage?

A. It reads like a document to exclude coverage.

Q. And that's not what the GAPMS rule was designed to do, according to Ms. Pickle and yourself; is that correct?

A. That's correct.

Q. Sir, if you can turn to Tab 3 in your binder.

MS. ALTMAN: And, Your Honor, this is a stipulated exhibit, Exhibit 23. Plaintiffs' Exhibit 23.

BY MS. ALTMAN:

Q. Do you recognize this document, sir?

A. I do. That's the GAPMS rule.

Q. And that's what Ms. Pickle was discussing with you in the email we were just talking about?

A. It is.

Q. Now, sir, looking at (4), (4) seems to outline the areas that AHCA must consider when determining whether something meets with Generally Accepted Professional Medical Standards; is that correct?

A. It is.

Q. When you held the position of Government Analyst II, did you rely on this rule when preparing GAPMS reports?

A. It was the foundation for every report.

Q. Under the rule, one of the things that AHCA must consider is whether there are evidence-based Clinical Practice Guidelines; is that correct?

A. Correct.

Q. And did you do that when you held that position?

A. I did.

Q. And the rule, 59G-1.035, also requires AHCA to consider the effectiveness of the health service in improving the

individual's health prognosis or health outcomes; is that right?
A. Yes.
Q. And AHCA is also required to consider the recommendations of clinical or technical experts in the field; is that right?
A. Correct.
Q. And these are some of the criteria that AHCA is required to look at as part of the GAPMS process; correct?
A. Correct.
Q. And, again, the purpose of this rule and the GAPMS rule is to establish coverage and medical necessity; correct?
A. Correct.
Q. Not to exclude it; correct?
A. Correct.
Q. Sir, based on your review of the June 2022 GAPMS report on the treatment of gender dysphoria, do you believe AHCA considered the factors outlined in this rule, which is Plaintiffs' Trial Exhibit 23?
A. Not adequately.
Q. What factors do you believe that AHCA failed to consider?
A. I believe they just outright dismissed the evidence-based Clinical Practice Guideline. Quite a bit of the literature that's included and referenced in the work cited is not peer-reviewed scientific literature; it's opinion pieces.
There is no inclusion in the report of coverage policies by major insurance companies, which is a standard part of the

report.

They're dismissive of the effectiveness of the health service in improving health outcomes. And -- yeah -- not well.

Q. Are those things that you would have considered if you had been asked to write the GAPMS report on gender dysphoria?

A. Those are things that my duties and my job required to me to consider.

Q. And the rule requires; correct?

A. Correct.

Q. Are there any examples of evidence-based Clinical Practice Guidelines that AHCA disregarded?

A. Sure. You know, everything from the Endocrine Society to the American Academy of Pediatrics, the American Psychological Association, and there are a host of them, actually.

Q. Okay. Can you describe for the Court the normal timing of the process for the preparations of a GAPMS memo? So, by example, how long would you normally take to research and draft a report from the point at which a request comes in?

A. It can vary depending on the topic and the context of when the request is received. I was generally working on about a six-to-eight-month turnaround time. But I inherited a very large queue when I started, so it was a lot of backtracking to begin with.

Q. And just to make sure I understood you, six to eight months just for the drafting process; is that right?

A. The research and drafting.
Q. Sir, can you look at (4) and just briefly talk through for the Court's edification what you would look at for subparts (a), (b), (c), (d), (e) and (f). What kinds of evidence and information you would look at and just identify the subpart and then some examples for the Court?
A. Well, for instance, with evidence-based Clinical Practice Guidelines, if I was reviewing a treatment for wound healing, there are organizations like the Wound Healing Society and other professional organizations, that have released Clinical Practice Guidelines for the treatment of those types of wounds that might be considered in the report.

The published reports and articles and the authoritative medical and scientific literature published in peer-reviewed scientific literature, it's -- the way we regard it, if it wasn't peer-reviewed, it was opinion and opinion didn't go in the reports.

Utilization trends; we would look at, you know, how many patients have a particular diagnosis or, you know, that would obviously factor into a cost analysis if we were to add the service for coverage.

Coverage policies by other credible insurance payor sources; we look at what other state Medicaid programs cover. And we also look at what the major insurance companies cover.

And then recommendations or assessments by clinical or

technical experts on the subject or field; that could be a subject matter expert that I consult within AHCA, or it could be something like maybe a well-respected researcher or related person to the subject, to the topic, who maybe has written -- is engaged in like a journal letter discussion or something like that. But we didn't typically hire people from outside the agency.

Q. A couple of follow-up questions.

On subsection (f), recommendations or assessments by clinical or technical experts that you were just discussing, would you rely on a practitioner that doesn't treat the area of medicine that was at issue? So, by example, in the area of gender dysphoria, would you rely on or would they be considered subject matter experts if they didn't practice in that area or treat patients of that nature?

A. I don't believe it would occur to me to do so.

Q. And under -- I think you skipped subsection (c).

A. Yes. The effectiveness of the health service; you know, is there a -- does this treatment produce an improvement? And that's -- that's essential to coverage.

Q. Did AHCA consider these factors in issuing the June 2022 GAPMS report?

A. It's a mixed bag. I would describe it as inconsistent. So no.

Q. Did AHCA, while you were the GAPMS guy, hire outside

consultants for this process?
A. No.
Q. Did AHCA ever contract with non-AHCA employees to write assessments in support of a GAPMS report while you held that position?
A. No.
Q. Did AHCA ever pay experts to consult with you and give you a list of sources?
A. Absolutely not.
Q. Sir, if you can turn to Tab 4.
MS. ALTMAN: For the Court, it's Plaintiffs' Trial Exhibit 238. And I believe this is stipulated, Your Honor.
BY MS. ALTMAN:
Q. Can you identify this document, sir?
A. That's the GAPMS checklist.
Q. What is this?
A. That's a required element of the position. When a request comes in, as stipulated in the requirements for the position, the job description, whenever a request would come in, I would have five days to have -- to apply this to the request and then to review it with my supervisor.
Q. Did this document exist before you worked at AHCA?
A. Not that I'm aware of. My -- my initial supervisor, Christina Vracar, and I made this.
Q. You made it together, yourself with your supervisor; is

that correct?
A. Yes.
Q. Why was it prepared?
A. Well, for a couple of reasons. One, as I said, when I started the position there were anywhere from 40 to 50 requests that had come in, most of which had not even been looked at.
What we started to understand when we were looking through the queue was that some of those weren't actual GAPMS requests; they were other types of coverage requests. And so we fashioned this checklist to weed out -- both to weed out non-GAPMS assignments in the queue and also to apply to all the requests, new requests, that came in going forward so that we made sure -- to make things more efficient and to get things into the GAPMS process, when they belong there, as quickly as possible.
Q. Did you utilize this checklist when you issued GAPMS reports?
A. I had to.
Q. Was this part of the basis on which your annual reviews would be conducted? Were you sort of graded, for lack of a better word, on how well and how often you use this document?
A. I was. It's stipulated five days from the request.
Q. Was another thing that you did when you came on as the GAPMS guy -- was part of what you understood AHCA required was to shorten the actual reports?
A. Initially they were -- they were traditional long-form

reports, the ones I wrote. And then -- I kind of outran the coverage, so to speak, and there were more reports than management was able to -- basically I was told we were moving to the short-form reports in order to provide shorter documents for management to read in the hopes of speeding up the process.

So I took long-form reports and condensed them down into, quote/unquote, short-form reports.

Q. How long were those short-form reports supposed to be?

A. They were supposed to be four pages, but a page and a half of that four pages is nonnegotiable template. So what they ended up getting were -- primarily were six- to seven-page reports.

Q. And the June 2022 GAPMS report doesn't comport with the short-form report; correct?

A. That's a 45-page report that was written at a time when I was being asked to submit six- to seven-page reports.

Q. Are there multiple checklists used in connection with preparing GAPMS reports?

A. There are not.

Q. If someone said that there were, would that be truthful?

A. No.

Q. If you could look at the top of the checklist and explain to the Court -- and I'll read the language I'm referring to at the very top of the document. And it says: *If any item on the list is yes, discuss with your manager for the potential to move*

towards a coverage determination (decision point) instead of a GAPMS report.

Did I read that right?

A. You did.

Q. What does that mean?

A. It's basically -- one of the purposes, as I said, of this checklist is to weed out the requests that come in. Some of them are not actual GAPMS reports, but they are just more simplified coverage determination reports, which we referred to as decision points. So we would run the request through this checklist, and depending on what and how many of these things they checked off, it was highly likely that it would not be a GAPMS report.

Q. So, by example, sir, if you look at No. 5, it says: *Does any Medicaid state cover the service?*

If the answer was yes, what would you do?

A. Well, that would be -- you know, it can vary. If it's a situation where, you know, I look it up and I find four states that cover, then that's -- that's something. If I find, you know, 40 states or, you know, a whole lot of states that cover something, then that's going to be a big feather in the cap for the requester, and that will be a clue that perhaps this isn't considered experimental/investigational.

Q. And the same for No. 6, would it be the same analysis: Does any private insurance cover the service?

A. Yes.
Q. And what about No. 7: Does the agency cover a similar device, service, or product?
A. Yes.
Q. The same analysis? So, by example, if AHCA already covered the procedure or service or treatment at issue -- if they were already covering it, what would you do?
A. If AHCA already covered the service, then it wouldn't be a GAPMS. It would just go back -- the requester would be notified that, Hey, this is on our fee schedule. This is what we pay for it, and that's that, and move on to the next project.
Q. So there would be no need for a GAPMS report?
A. No.
Q. To your knowledge, did Medicaid cover puberty-suppressing medications prior to the June 2022 GAPMS report?
A. Yes.
Q. To your knowledge, were puberty-suppressing medications covered for the treatment of gender dysphoria prior to the issuance of the June 2022 GAPMS report?
A. Yes.
Q. To your knowledge, did Medicaid cover cross-sex hormones prior to the June 2022 GAPMS report?
A. Yes.
Q. To your knowledge, were cross-sex hormones covered for the treatment of gender dysphoria prior to the issuance of the

June 2nd, 2022, GAPMS report?
A. Yes.
Q. And the same question, sir: To your knowledge, was gender-affirming medical care covered by Medicaid prior to the June 2022 GAPMS report?
A. Yes.
Q. And to your knowledge, were gender-affirming care -- surgeries, rather, covered for the treatment of gender dysphoria prior to the issuance of the June 2022 GAPMS report?
A. Yes.
Q. So since the three subject matters that are covered in the June 2022 GAPMS report -- puberty-suppressing medications, gender-affirming surgeries, and cross-sex hormones -- were already being covered by the agency, would a GAPMS report have been issued?
A. No. I would have completed the checklist, would have determined that it was already on the fee schedule, would have gone and spoken to my supervisor. And traditionally, because this has happened before, we would have got requests for things we already covered; we would just reach out to them, give them the billing code, the price that Florida Medicaid pays for it, and then we would move on to the next project.
Q. Now, sir, we were talking about the GAPMS report that's behind Tab 1, if you want to look at it.
If I understood your testimony, because all of these things

were covered, the report that's behind Tab 1 would not have been issued; correct?

A. Correct.

Q. And there would have been no need for it, correct, because all of these services were already being covered?

A. Correct.

Q. And was there actually a GAPMS report for puberty-suppressing medications already in existence before this report was issued?

A. I believe so, yes.

Q. And that's true for gender dysphoria; correct? There was a GAPMS report already issued for puberty-suppressing medications in 2016 --

A. Yes.

Q. -- for gender dysphoria?

A. Prior to my approval with AHCA; correct.

Q. Why would AHCA have issued another one then?

A. It's highly unusual. We don't typically re-review things.

Let me fix that. It is -- I've never seen an example where it was something that we had decided to cover through GAPMS and then later did another GAPMS to not cover it. That doesn't exist.

What does happen quite often is that a request comes in; we write the report; the report is denial of coverage for a whole host of different reasons, and then the requester accepts that

and then just turns around and reapplies for coverage again.
Q. Do you know why that was done here?
A. I do not.
Q. Now, the June 2, 2022 GAPMS report covers multiple treatments or procedures; correct?
A. Correct.
Q. Puberty-suppressing medications, cross-sex hormones, and gender-affirming surgeries; correct?
A. Correct.
Q. Is that typical to have a GAPMS report that covers multiple areas, multiple treatments, or multiple services?
A. Not at all.
I was told very, very specifically, one treatment, one GAPMS.
Q. While you were the GAPMS guy, was there anytime where you wrote a GAPMS report that covered multiple treatments, surgeries, or procedures?
A. No.
Q. And if I understood you earlier, the request for this GAPMS report did not come through traditional -- traditional channels; correct?
A. Correct.
Q. It came from the Governor; is that correct?
A. Yes.
Q. Do you know why you were not asked to prepare this report?

A. I only know what I was told by my supervisor.
Q. What were you told?
MR. PERKO: Objection, hearsay.
THE COURT: Overruled.
THE WITNESS: Jessie Bottcher explained to me that he was in a meeting with the bureau chief, and Jason Weida came in and inquired with Jessie if I would be willing to write the report. Jessie said I would not be willing to write the report. And Jessie and Ann recommended that Matt write the report, because Jessie said that he told Jason that Matt would complete any assignment that he was given.
BY MS. ALTMAN:
Q. You said Jason Weida came in; is that correct?
A. To the meeting with Ann and Jessie.
Q. Who is Jason Weida?
A. He's now the secretary of the agency.
Q. Was he at the time?
A. No. He was Medicaid director of policy and quality or something along those lines, I believe, at the time.
Q. And the other two people in the meeting, one was Ann Dalton?
A. The bureau chief. And the other was my direct supervisor, Jessie Bottcher.
Q. Did you at some point learn that this report was being prepared?

A. I did.
Q. How did you learn about that?
A. A member of the Canadian import drug team, Nai Chen, informed me that the project was underway.
Q. Was Nai Chen also working on the project?
A. That's my understanding.
Q. With Matt Brackett?
A. Yes.
Q. And do you -- other than what you just testified, that Jessie Bottcher told you as to why Matt Brackett was chosen, do you have any other understanding as to why Matt Brackett was chosen to write this report since he wasn't in the GAPMS department?
A. Only what Jessie told me. And I know that prior to my arrival at AHCA Matt had been responsible for the GAPMS process for a period of time.
Q. What was your reaction when you learned that Matt Brackett was asked to and was preparing this GAPMS report?
A. The project was explained to me, and as I understood it, I was actually concerned for him.
Q. Why?
A. Well, you know, when you are given an assignment like that coming from someplace like that, there's a lot of pressure to perform and to comply with what the assignment is made to be.
Q. What do you mean by that, what the assignment -- you mean

to reach a specific conclusion?
A. That, and, you know, Matt has a background in academics, and if he had wanted to continue to write or publish or anything like that going forward, I was concerned that, you know, his involvement in this process might do damage to that down the road.
Q. Now, you mentioned earlier that typically it would take six to eight months to prepare the research, the report itself. This report, according to testimony -- and I'd like you to assume that this is what's been testified, that they started on April 20th of 2022, and it was issued by June 2nd of 2022. Is that typical?
A. No.
Q. Is it unusual?
A. Highly.
Q. Would you be able to write a thorough, comprehensive report in that period of time following the rule?
A. I was never blessed with the assistance of experts.
Q. Well, the -- I'm assuming you are referring to the assessments that were attached to the report; is that correct?
A. Uh-huh.
Q. Do any of those experts, for lack of a better word, actually treat individuals with gender dysphoria?
A. Not that I'm aware of.
Q. Would you have reached out to treaters in an area --

individuals who don't treat people in the specific area that you were analyzing?
A. I mean, really, I was a one-man gang, so I wouldn't have reached out to anybody. I would have just sat down and researched and written the report.
Q. Well, for example, if you are looking at a pharmaceutical, do you have resources within the agency?
A. I could go and speak to the pharmacy team about that. Or if it were a piece of durable medical equipment, I could go and speak to the durable medical folks at AHCA.
Q. And what else would you do in order to thoroughly research and analyze whatever subject you were looking at?
A. Extensive, extensive literature reviews. You know, you scour -- research is half the job. So it's just going out and knowing where to find high-quality research and what the best available resources are for the subject matter that you're considering.
Q. Are news articles research that you would have relied on?
A. No.
Q. Are news articles something that's included within the June 2022 GAPMS report as a source?
A. There's probably about a half a dozen of them, yes.
Q. Did anyone ask you whether or not you had the time to evaluate the three procedures or treatments outlined in the June 2022 GAPMS report?

A. No.
Q. Sir, can you look at what's behind Tab No. 5?
MS. ALTMAN: And for the Court and Counsel, it's plaintiffs' trial Exhibit 302.
BY MS. ALTMAN:
Q. We can start at the back if you want. And it starts with an email from Dr. Cogle.
Who is Dr. Cogle?
A. The chief medical officer of Florida Medicaid.
Q. And this was an email exchange between yourself and Dr. Cogle; correct?
A. Correct.
Q. And it looks like the initial email came from Dr. Cogle on June 25th, 2022; is that right?
A. Yes.
Q. And that's about two -- two to three weeks after the GAPMS report was issued that we're discussing about earlier?
A. It is.
Q. And it says: *Hello, Jeff. Good talking with you this past Friday. Are there standard operating procedures* --
MR. PERKO: Objection, Your Honor. She's reading hearsay into the record.
THE COURT: I overruled the earlier hearsay objection under 801(d)(2)(D). Why isn't the same thing true here? This is a statement by a party opponent, is it not?

MR. PERKO: It hasn't been established it was within the scope of his duties.

MS. ALTMAN: I'm happy to --

THE COURT: I can read it and tell it's within the scope of his duty, can't I?

MR. PERKO: Your Honor --

THE COURT: Can you stand up when you are speaking?

MR. PERKO: I'm sorry, your Honor.

It wasn't part of his responsibilities at the time.

THE COURT: Let me make two statements about it.

First, I overrule the objection. I think on the face of it it indicates that it is within the scope of his duties.

Second, when you have to run away from the statements that your own medical director made, you -- when we get to closing argument, you need to explain why it is that I should ignore what your medical director said. That's a heads-up for closing.

Just when you have to run away from what your own people say, you ought to be concerned about how you are going to explain it.

I think it's admissible.

MR. PERKO: Yes, Your Honor.

And I apologize for not standing up. I meant no offense.

THE COURT: Well, I certainly take no offense.

As you've all figured out, I'm a dinosaur. I pretty much lost this battle in the judiciary. I still make people stand up. So -- but there aren't many of us left, and I take no offense.

BY MS. ALTMAN:

Q. Mr. English, at the time of this email exchange, you were still the GAPMS guy; right?

A. I was.

Q. Okay. So Dr. Cogle is asking you whether or not there are standard operating procedures for GAPMS; correct?

A. Correct.

Q. And if you turn back to the first page and then the next two pages, you give him a very lengthy explanation as to what the standards are; is that right?

A. I do.

Q. And that's what you've testified here today to the Court contemporaneously to Dr. Cogle back in June of 2022?

A. Correct.

Q. And in June of 2022, you went through a lengthy process -- and feel free to look at the email to see if you left anything out. But would you agree with me that the process you described to the Court today is akin to one you described to Dr. Cogle in your email on June 27th, 2022, at 2:30 p.m.?

A. It is.

Q. And I note just in the very first sentence, after you say,

"Good afternoon, Dr. Cogle," there is an SOP for GAPMS.

Did I read that right?

A. Yes.

Q. And SOP is short for standard operating procedure?

A. Correct.

Q. And you go on to say: *Typically the requests for consideration of coverage come in through a health service research email or from leadership (less often)*; correct?

A. Correct.

Q. That's consistent with what we discussed earlier, that these are determinations of coverage, not to try and exclude coverage?

A. They're seeking coverage.

Q. Okay. And you go on in the next paragraph -- and I'm certainly not going to make you read this entire document single spaced. But you go on to talk about the checklist.

A. Yes.

Q. And you say it's attached. It says: *The request gets run through the attached checklist, and once it is determined to be an actual GAPMS (rather than a decision point or 'simple' determination) I reach out to the requester and schedule a time to gently walk through the process.*

Did I read that right?

A. Correct.

Q. And I just want to confirm, is the checklist that you are

referring to in this email the one that we spoke about earlier?
A. The one I'm required to use.
Q. Okay.
You then go through a lengthy expression of the process --
A. I apologize.
Q. -- that you discussed with the Court earlier today.
And then you go down -- and I'm going to read from the paragraph that starts with "All of that..." And it says: *All of that is the ideal. The reality is that the reviews get done, the reports get written, and then they all bottleneck with leadership because GAPMS are fairly low on the totem pole of priorities, particularly since the pandemic began.*
Did I read that correctly?
A. Yes.
Q. And what were you trying to explain to Dr. Cogle when you said that?
A. There were at that point somewhere between five and ten completed reports, all of which had been completed for approximately two years. Something I was having to do with each of those reports -- it had been written, but, you know, it's -- a GAPMS report is kind of a snapshot in time, and coverage considerations can change, and the evidence can change.
So while I was awaiting those reports that had been written to be reviewed, I was having to periodically go through and update the coverage considerations and things; maybe another

major insurance company had added coverage or some additional states had added coverage. Everything had to be current for when it was presented to leadership.

Prior to the pandemic and when I was hired for the job, it was explained to me that the GAPMS aren't always a priority, and so you really have to try and stay on top of people to get them to route. When the pandemic started, not just GAPMS, a whole lot of things became less priority, and understandably so in some cases. So I kept a grease board in my office with a list of the completed reports as kind of an effort to shame people into taking a look at them so that we could reach out to the requesters and move forward.

Q. And I'm just going to flip down one paragraph, and it says -- because you mentioned five or six. I think you were short one. It says: *I believe there are currently about seven completed that are still awaiting review and approval from leadership. Some of them have been written for over two years. I have re-reviewed them and made any necessary updates concerning coverage, research, etc. I typically do that twice a year.*

A. Yes.

Q. And is that what you were just explaining to the Court?

A. Precisely.

Q. And so if there was approximately seven -- when you say they were two years, meaning they had been drafted and ready to

be signed for two years?
A. Yes.
Q. So would it be unusual if a GAPMS report was --
A. Well, I mean, something else -- to be fair, something else to consider was that there was a great amount of turnover at the agency, and so -- you know, I had multiple supervisors. We had multiple bureau chiefs. We had multiple secretaries. We had multiple Medicaid directors. And the bureau chief -- my supervisor, the bureau chief, and the Medicaid director are the three spots on my routing form that I need to get the report to.

And there's a big learning curve whenever anyone moves into a new position, and I don't think GAPMS was, quote/unquote, sexy enough for that to be an immediate priority when someone is trying to, you know, acquire the skills and the experience in their new positions.

Q. But in June of 2022 when the gender dysphoria GAPMS report was completed, there were seven in queue that needed to be finalized; correct?
A. Correct.
Q. And was the typical practice to go in the order in which they were received?
A. Ideally.
Q. Well, would it be unusual that a GAPMS report was completed and then signed and executed the next day, as was the case with the -- Plaintiffs' Exhibit 18, the gender dysphoria GAPMS

report?
A. Yes.
Q. Is that unusual?
A. Yes. I mean, there's not a lot of, quote/unquote, queue jumping, so to speak, with the reports. It might be a situation where hypothetically, you know, one topic is No. 4 in the queue and another topic is No. 6, but maybe we're waiting on the results of a clinical trial to finish on No. 4. So I can't go further with that report, so I'll go down to the next one. So there is some out of order, but not typically.
Q. The gender dysphoria GAPMS report, that was written in just over a month and signed the very next day.
A. That entire project was conceived, completed in an extremely accelerated time frame.
Q. Did it follow the GAPMS process, the standard operating procedures that you outlined to Dr. Cogle?
A. No.
Q. And I want to go to the last paragraph on the second page.
THE COURT: Tell me where we stand. We do need to get to a break here at some point. Are you --
MS. ALTMAN: We can break. That's fine. I only have a --
THE COURT: Now is as good as any?
MS. ALTMAN: Yeah.
THE COURT: Let's take 15 minutes, and we'll start

back at ten till 4:00.

(Recess taken at 3:34 PM.)

(Resumed at 3:50 PM.)

THE COURT: Please be seated.

Mr. English, you are still oath.

And, Ms. Altman, you may proceed.

MS. ALTMAN: Thank you, Your Honor.

BY MS. ALTMAN:

Q. Just a few more question, Mr. English.

Earlier you mentioned a conversation with Jesse Bottcher where he told you -- he discussed with you the meeting that he attended with Jason Weida, Ms. Dalton, and himself where he indicated that you would not write the GAPMS report that was being requested.

Do you recall that testimony?

A. I do.

Q. Did he say why he told them you would not write the report?

A. Yes. He did not think that I would be willing to write it. His perception of it was that it was either predetermined or political, and he said that he did not want to supervise the person who did write the report either.

Q. So I have one final question on your email to Dr. Cogle, and if you could turn to the second page at the bottom, and I'm just going to read something and ask you what you meant by that.

A. Okay.

Q. Starting at the last -- at the bottom of the page, it says: *If you will excuse me, I feel obligated to include this information: I was not informed or consulted, did not in any way participate, and did not write the GAPMS concerning gender dysphoria treatment. That particular GAPMS did not come through the traditional channels and was not handled through the traditional GAPMS process. Every report I have written represents my best effort at determining the most timely and accurate information available on the subject under consideration. I do not cherry-pick data or studies and would never agree to if I were so asked. All I can say about that report, as I have read it, is that it does not present an honest and accurate assessment of the status of the current evidence and practice guidelines as I understand them to be in the existing literature. I sincerely apologize if I come across as a bit agitated about it, but as the 'GAPMS guy' around here, lots of assumptions have been made by those who do not know me well. I'm a different sort of person than the author of that report. I can't speak for them. I conduct myself and my work with integrity, and I do not play favorites, yay or nay. Full stop, period.*

What did you mean by that?

A. Dr. Cogle is someone that I have a lot of respect for. He is -- he has very extensive knowledge of research and the type of work that I was doing. My interpretation of his initial

inquiry to me regarding a standard operating procedure for GAPMS was that he had looked at the June 2nd report and did not believe that it -- and this is me. My impression was that he was asking sort of, you know, like, Jeff, do we have an actual SOP for GAPMS? Because that one was a radical departure from the normal process.

And at the same time, shortly before I responded to this email, I had multiple employees that very day ask me about the report and whether or not I had written or participated, and that had been starting to wear on me a little bit.

And so it was important to me that Dr. Cogle understand that I have integrity.

MS. ALTMAN: I have no further questions.

THE COURT: Cross-examine?

MS. ALTMAN: Thank you, sir.

MR. PERKO: Thank you, Your Honor.

CROSS-EXAMINATION

BY MR. PERKO:

Q. Good morning, Mr. English.

A. Good morning.

Q. Or afternoon.

A. Or afternoon, yeah.

Q. You said that the request for the June 2022 GAPMS report came from the Governor?

A. Uh-huh.

Q. Did you talk with the Governor?
A. I did not.
Q. Did you talk with anybody in the executive -- in the Executive Office of the Governor?
A. I did not.
Q. Did you talk to the Secretary about the June 2022 report?
A. I did not.
Q. And in your three years working at the -- as the GAPMS guy at AHCA, how many times did you meet with the AHCA Secretary?
A. Maybe a couple of times.
Q. How many times have you met with the Governor's office?
A. I have not.
Q. Were you involved in any rulemaking while you were at the agency?
A. I was.
Q. Which one was that?
A. You know, it was shortly after I started as the state planning coordinator. Some of them had to do with, I think, reimbursements and some other things that were rules that had to be done in conjunction with some of the state plan movements, but the particulars -- I think one had to do with the iBudget program or something like that, but that wasn't really my area of expertise.
MR. PERKO: Can we pull up Plaintiffs' 23, please. It's a copy of the GAPMS rule.

We can -- there we go.

BY MR. PERKO:

Q. In paragraph 3, it says: *Health services that are covered under Florida Medicaid program are described in the respective coverage and limitations handbooks, policies, and fee schedules, which are incorporated by reference in the F.A.C.*

Then it goes on to say: *The public may request a health service be considered for coverage under the Florida Medicaid program by submitting a written request via email to* -- and it gives the email address.

Now, I see that it says that the public may request, but is there anything that prohibits GAPMS from being initiated by some other means?

A. No. I mean, technically, John Doe could send in an email requesting coverage for something. It's typically, like, a manufacturer or provider.

Q. You're familiar with the expedited GAPMS process, right?

A. I am.

Q. And those can get turned around in a matter of days, right?

A. They're required to be.

Q. I'd like to talk a little about your experience.

You worked for AHCA from September 2019 until -- did you say --

A. February of this year?

Q. -- February of 2023?

And from September 2019 to September '22, you were the GAPMS -- you wrote the GAPMS reports?

A. I did.

Q. Did you have other responsibilities during that time period?

A. I did.

Q. For most of those three years, you worked from home because of COVID; is that right?

A. You know, it all kind of runs together. It's probably -- it might be on the side of more months I was home than I was in the office. I'm not, honestly, sure. But there was a stretch where we were all working from home.

Q. In those three years, you had one GAPMS report make it all the way to the final approval; is that correct?

A. That's correct, one traditional GAPMS.

Q. Okay.

A. There were multiple expediteds.

Q. And in those three years, you never supervised anyone, did you?

A. I did not. When I was hired, I was told I would be supervising two people, but those hires were never made.

MR. PERKO: If we could pull the GAPMS rule up again, Plaintiffs' 23.

BY MR. PERKO:

Q. I wanted to talk a little bit about your interactions with

Dr. Cogle.
A. Okay.
MR. PERKO: If we could blow that up a little bit.
BY MR. PERKO:
Q. Is there anything in this GAPMS rule that provides a role for the chief medical officer of the agency?
A. Specifically the chief medical officer? No.
Q. Yes, sir.
A. But I -- in the process, I would have considered him a technical expert or a clinical expert on some of the subjects that were under consideration, and he's a well-established expert on research, publication, and study types, and that sort of thing.
Q. Had you ever consulted him before on a GAPMS report?
A. I had.
Q. How long has Dr. Cogle had his job?
A. I couldn't say. You mean at AHCA?
Q. Yes, sir.
A. I couldn't say exactly. Maybe -- by now maybe a couple years. He started after me, I know that.
Q. Are you familiar with Dr. Cogle's responsibilities at the agency?
A. I am.
Q. And do those include review of GAPMS reports?
A. It does not, but he is always available for discussion, and

he has participated in some of the meetings regarding GAPMS.
Q. You don't know whether every GAPMS report has a checklist, do you? Right?
A. I know that every one that I was responsible for was, and I know that every one from the creation of the checklist going forward does.
Q. Is the checklist a rule?
A. It's required in my annual performance review. It's stated in there that the checklist has to be performed within five days of receipt of the request.
Q. It hasn't been adopted as a rule by the agency, has it?
A. It's adopted insofar as my annual reviews are concerned, and I'm graded on that, literally.
Q. But my question is: It has not been adopted as an agency rule, correct?
A. I'm not sure what that means.
Q. You've been involved in the rulemaking process before?
A. Well, the rulemaking process and what pertains to employee behavior are two different things.
Q. Right. So has the checklist been adopted as a rule?
A. No. It's just internally part of the process that I was required to perform.
Q. Do you recall a draft GAPMS report that you prepared regarding total knee arthroplasty?
A. I sure do.

Q. And isn't it true that you took -- you cut and paste from a Blue Cross Blue Shield publication for an entire section of this report?
A. I did, and then I cited it.
MR. PERKO: Thank you, Your Honor. I have nothing further.
THE COURT: Redirect?

REDIRECT EXAMINATION

BY MS. ALTMAN:
Q. I'll be brief, Mr. English.
Very quickly, counsel mentioned an expedited GAPMS.
A. Uh-huh.
Q. Is an expedited GAPMS a public-facing document?
A. No, it's an internal document. It's like an internal memo between the health plan and the agency, or Medicaid policy really.
Q. So it's not like the GAPMS report that was issued in June of 2022 that was a public-facing document; correct?
A. Correct.
Q. And so when you're talking about an expedited GAPMS that could be prepared in one or two days or a week, that's not what the June 2022 GAPMS report is; right?
A. No. An expedited GAPMS comes in -- it's when a health plan is denying coverage for something as, quote/unquote, experimental and investigational, and we're required -- we have

three days to turn around a response to that, to either confirm or deny their claim for that.

And regarding the one that he was specifically speaking to, it wasn't three days; it was approximately seven hours.

Q. And just very quickly, have you ever -- because I'm not sure of the implication of counsel. Have you ever plagiarized anything?

A. No. And, I mean, plagiarism is, I guess, utilizing someone else's words or ideas and trying to pass them off as your own.

But the final copy of that expedited GAPMS report that was sent for routing -- it was emailed to Ann Dalton for Tom's signature -- included citations. There was no plagiarism.

Q. And I know you mentioned that the checklist was part of your performance reviews. Do you recall that?

A. Yes.

Q. Did you get good performance reviews while you at AHCA?

A. I believe so. I was the only -- I'm the only employee in Medicaid policy for whom GAPMS was a portion of my annual performance review. I routinely scored very highly. I believe on the last one I got a 5 of 5, and they don't typically like to give out 5s. It's normal you'll get a 4 or a 4.5. And I believe the comment actually referenced both my performance on the traditional GAPMS and praised for my performance on the expedited GAPMS.

MS. ALTMAN: I have no further questions.

Thank you for your time, Mr. English.

THE COURT: Mr. English, you've told us about your work at AHCA. Give me some background before that. What did -- give me the 30-second version of your career up until the time you came to work for AHCA.

THE WITNESS: History major. I love research and writing. I did about ten years in child welfare. I wrote reports and performance reports and things like that. In my spare time, I research and write about baseball history, and I accepted the job at AHCA because I love the research and writing. It's my hobby and what I prefer to do for a living.

THE COURT: If I understood what you told Mr. Perko, there was one GAPMS report that made it all the way to the end --

THE WITNESS: Yes.

THE COURT: -- during your tenure?

THE WITNESS: Correct.

THE COURT: Were there other full reports that you prepared that you got into the queue for approval?

THE WITNESS: There were approximately seven that were ready to go, and we had -- we had a handful of meetings with the bureau chief. I was in this unique situation where between the pandemic and then turnover among the leadership at the agency, I was -- you know, those reports stretched across multiple bureau chiefs, multiple Medicaid directors, and multiple supervisors.

So when someone new came in, they had to catch up.

THE COURT: But there were seven reports that you were responsible for preparing and then got sent up?

THE WITNESS: (Nods head up and down.)

THE COURT: Okay. There was some reference to Let kids be kids. Do you know where that came from?

THE WITNESS: That was a motto that was -- came along with the gender dysphoria GAPMS. It was something that was -- we had never had a GAPMS report that came with its own motto, but that was --

THE COURT: You don't know where it came from?

THE WITNESS: I do not.

THE COURT: Questions just to follow up on my questions?

MR. PERKO: No, Your Honor.

MS. ALTMAN: Nothing from me, Your Honor.

THE COURT: Thank you, Mr. English. You may step down.

(Mr. English exited the courtroom.)

THE COURT: Please call your next witness.

MR. GONZALEZ-PAGAN: Thank you, Your Honor. Ms. Dunn is going to call our next witness.

MS. DUNN: Your Honor, I call Dr. Kellan Baker to the stand.

(Dr. Baker entered the courtroom.)

THE COURTROOM DEPUTY: Please remain standing and raise your right hand.

DR KELLAN BAKER, PLAINTIFFS WITNESS, DULY SWORN

THE COURTROOM DEPUTY: Please be seated.

Please state your full name and spell your last name for the record, including your first name.

THE WITNESS: Kellan Baker, K-e-l-l-a-n B-a-k-e-r.

DIRECT EXAMINATION

BY MS. DUNN:

Q. Good morning -- or good afternoon, Dr. Baker.

What is your current profession?

A. I am a health services researcher and health policy professional.

Q. And when you submitted your expert report in this case, you submitted a copy of your CV?

A. I did.

Q. Does that CV accurately reflect your professional qualifications?

A. It does.

MS. DUNN: Your Honor, that curriculum vitae is Plaintiffs' Exhibit 363 and was included on the parties' stipulated exhibit list.

THE COURT: Plaintiffs' 363 is admitted.

BY MS. DUNN:

Q. Dr. Baker, have you ever testified as an expert before?

A. Not in court.
Q. What are you being compensated for your time spent on this case?
A. I'm being compensated at a rate of $200 per hour.
Q. Does this compensation affect your opinions or testimony in any way?
A. It does not.
MS. DUNN: Your Honor, I ask that Dr. Baker be qualified as an expert on health services research and policy.
THE COURT: Questions at this time?
MR. BEATO: No, Your Honor.
THE COURT: You may proceed.
BY MS. DUNN:
Q. Dr. Baker, what health policy topics does your research focus on?
A. My research focuses on health insurance coverage, cost utilization, with a particular focus on sexual and gender minority populations, with a focus on transgender populations.
Q. And do you conduct any research on insurance coverage policies for certain populations?
A. I do.
Q. What populations are those?
A. I do a variety of research related to health equity and health disparities, but with a particular focus on sexual and gender minority populations, and especially transgender

populations.
Q. What is your current position of employment?
A. I'm currently the executive director and chief learning officer of Whitman-Walker Institute. The Institute is the research policy and education arm of Whitman-Walker, which is a community health system in Washington, D.C. that is affiliated with a federally qualified health center. That health center turned 50 this year and has a history of serving LGBTQ populations and people living with HIV.
Q. What is a federally qualified health center?
A. A federally qualified health center is a recipient of federal funds through the Health Resources and Services Administration that is intended to make it possible for the clinic, the health center, to serve all patients who need assistance, regardless of their ability to pay.
Q. What did you do before becoming executive director and chief learning officer of Whitman-Walker Institute?
A. I was previously at the Johns Hopkins Bloomberg School of Health where I worked in research. And before that I was a senior fellow at a think tank, the Center for American Progress, in Washington, D.C., where my work focused on health reform with a particular focus on the Affordable Care Act and coverage reforms that were associated with the law.
Q. What is a chief learning officer?
A. A chief learning officer is a person who is responsible for

coordinating educational and training opportunities across the entire organization. We provide, for example, clinical training to health professionals. We also do a variety of training and education activities with local community-based organizations with the D.C. Department of Health, with other community-based nonprofit and government entities across the country.

Q. How does your role at the Whitman-Walker Institute touch on health policy issues?

A. I am the executive director of the Institute which is specifically charged with three portfolios; research, policy, and education.

So policy is probably my primary role at this point. We have a very large research department that has a variety of research studies funded by the National Institutes of Health. And within our policy department we do a great deal of work at the local, regional, and federal levels related to access to care and issues of understanding barriers to good health for populations experiencing health disparities.

Q. And do you have any oversight over the clinicians or clinical management for quality assessment and practice assessment?

A. I do not.

Q. Do you work with clinicians on these issues?

A. Very closely.

Q. Can you explain that?

A. Whitman-Walker is a community health system, so it has several components, if you will. The federally qualified health --

(Reporter requested clarification.)

A. Federally qualified health center, and that is where the clinicians reside. It's also where our population health and quality department is responsible for conducting quality assurance and quality improvement initiatives per HRSA guidelines.

The Institute as an affiliation of Whitman-Walker Health is responsible for leveraging research policy, education, and that clinical experience and expertise to improve care for our patients and to contribute to the knowledge base for serving patients, both at FQHCs and across the entire health system.

Q. And have you been called upon to contribute to or consult on reports regarding LGBTQ populations and health disparities?

A. Yes, many times.

Q. Are you familiar with the National Academies of Sciences, Engineering and Medicine?

A. I am.

Q. What is the National Academies of Sciences, Engineering and Medicine?

A. The National Academies of Science, Engineering and Medicine are private, independent nongovernmental institutions that exist to bring scientific authority to questions of national

importance. They often take requests, for example, from the National Institutes of Health or other government entities to apply an independent expert, unbiased and authoritative assessment of a particular question.

Q. And have you worked with the National Academies of Sciences, Engineering and Medicine on issues related to sexual and gender minority populations?

A. Yes.

Q. Can you describe those interactions?

A. I have a substantial history with the National Academies. I worked with them beginning in 2016 on the development of an NIH-sponsored study -- that has a number of other sponsors as well, but NIH was one of the primary sponsors -- wanting to learn more about the health and well-being of sexual and gender-diverse populations, that is, LGBTQI populations. And I was responsible for all aspects of developing that study, convening the committee. I participated in every aspect of the creation of the report.

And I was then the lead on dissemination of that report, so I was responsible for presenting on its findings to a variety of stakeholders, government entities, for example, back to the sponsors, NIH, other government entities, the Department of Justice, for example, and as well as other private and public stakeholders who had an interest in what the report had found.

MS. DUNN: Your Honor, I would like to pull up what

has been marked as Plaintiffs' Exhibit 142.
BY MS. DUNN:
Q. Dr. Baker, do you recognize this report?
A. I do.
Q. What is it?
A. It is the 2020 report from the National Academies on understanding the well-being of LGBTQI+ populations.
Q. Is this the report that we were just discussing?
A. It is.
Q. And can you explain your contributions to this report?
A. I was a consultant on this report, so I supported the consensus study committee in the elements of the deliberation, the drafting, and finalizing of this report. And then, as I mentioned earlier, was responsible for leading dissemination efforts to ensure that the findings of this report were communicated back to the sponsors and to other interested parties.

MS. DUNN: Your Honor, I would like to introduce this exhibit as a learned treaties. And I'll have Dr. Baker read certain portions into the record.

THE COURT: A learned treaties is just hearsay.

Is there --

MR. BEATO: Yes, sir.

THE COURT: You object?

MR. BEATO: Yes, sir.

THE COURT: Isn't that right? Isn't it just hearsay?
BY MS. DUNN:
Q. Dr. Baker, would you rely on this report in the -- in your professional activities?
A. Yes, I do.
MS. DUNN: Your Honor, Rule 803, the exception for a learned treatise, where it can be read into the record. May I have Dr. Baker read --
THE COURT: You can cross-examine a witness with a learned treatise and read it into the record, but not introduce it. In a bench trial it doesn't make a lot of difference whether you just read it.
But I take it you are not cross-examining him saying he's going to testify inconsistently with this. You are trying to introduce this as affirmative evidence.
Am I missing something?
MS. DUNN: I do not have the text of Rule 803 in front of me. I understood that it allowed it to be read on direct as well.
THE COURT: Well, you can impeach your own witness on direct, so it's not a direct cross.
MS. DUNN: Understood.
THE COURT: But it's to impeach the witness.
MS. DUNN: I'll ask a different question.
Your Honor, the way the rule reads, that a statement

is called to the attention of an expert witness -- I'm sorry -- is relied on by the expert on direct examination.

THE COURT: Yeah. What is it you are trying to put in?

MS. DUNN: I can just ask Dr. Baker to explain the opinion from this report that he helped to -- or that he contributed to.

THE COURT: Let me tell you what will help me more, is if you ask him what he knows and he can tell me what he knows. That's why he is here. And if it's something he relies on in accordance with the rule, yeah.

But, look, this rule is really not a way to put in a treatise in lieu of a witness.

MS. DUNN: Thank you, Your Honor.

BY MS. DUNN:

Q. Dr. Baker, did this report draw any conclusions that are relevant to the case that you're -- to our case that you are testifying on?

A. Yes.

Q. And what were those conclusions?

A. The report examined a large body of evidence and concluded that gender-affirming care is safe, effective, and medically necessary for the treatment of gender dysphoria.

Q. Did the report make any conclusions with regard to whether gender-affirming care improves mental health outcomes for

transgender people?
A. Yes.
Q. What were those conclusions?
A. The report concluded that gender-affirming care supports the health, physical and mental health, of transgender people.
Q. Did the report make any conclusions about the evidence-based guidelines that clinicians use in providing gender-affirming care?
A. Yes.
We reviewed those guidelines and we found them to be authoritative. We are very strictly bound within the Academy's process to rely on existing evidence, which means that we looked at the existing evidence, which includes expert standards of care.
Q. Are you been involved in efforts to connect low and middle income LGBTQ+ people with health insurance coverage?
A. Yes.
Q. And what are those efforts that you have been involved in?
A. In 2013, I founded a initiative that we called Out2Enroll, and the purpose of that initiative was to connect low and middle income LGBT people with affordable health insurance coverage through the health insurance marketplaces. We had done research that showed that LGBT people, including transgender people -- actually, especially transgender people were less likely than the general population to have health insurance coverage. So we

treated the Affordable Care Act with its expansion of coverage, and particularly covered subsidies for low and middle income people, as an opportunity to reach those people who were uninsured.

Q. Have you held any other positions relevant to health insurance coverage?

A. I am currently an appointed consumer representative to the National Association of Insurance Commissioners.

Q. Dr. Baker, I'd like to turn to your -- the opinions you've come to share today.

What did you review in coming to the opinions that you offer today?

A. I reviewed the rule. I reviewed the GAPMS report and the materials cited, discussed therein. I reviewed the scientific literature in my field, which is health insurance coverage, health services research. I reviewed relevant policies related to health insurance coverage. And I reviewed documents such as the National Academies' report.

Q. Are these materials the same type of materials that experts in health and public policy regularly rely upon when forming opinions?

A. Yes.

Q. Dr. Baker, what does it mean to be transgender?

A. According to the National Academies, being transgender is when your gender does not align with the sex that you were

assigned at birth.
Q. And have you done research into the demographics of the transgender population in the United States?
A. Yes.
Q. How many transgender people are there in the United States?
A. There are an estimated 1.6 million transgender people in the United States. That's approximately .6 percent of the population.
Q. How have estimates of the number of transgender people in the United States changed over time?
A. The estimates have remained stable since -- for example, the 2023 numbers that I'm referring to, .6 percent, when those estimates were done in 2016, the estimate was the same, .6 percent of the population.
Q. Since 2016 the number of transgender people in the U.S. has not changed demonstrably, according to the data you reviewed?
A. Not according to the data that I reviewed, no.
Q. Where do those numbers that you cited to us come from?
A. The numbers come from a variety of sources. For example, the 2016 number came from an analysis of the Behavioral Risk Factor Surveillance System, which is a nationwide survey, system of surveys, really, that's done by state departments of health in partnership with the Federal Centers for Disease Control and Prevention. There's also, for example, the Gallup poll, which is a nationwide nationally representative poll that has

collected information about LGBT demographics since approximately 2012.

So those are the two most reliable numbers.

Q. What has your research in transgender health focused on?

A. It has focused both on overall health and well-being, as well as on experiences of access to care. My research is really focused on health disparities, which are avoidable gaps in, for example, outcomes, quality, access, that affect specific populations.

The National Institutes of Health has designated the transgender population as a health disparity population in recognition of gaps related to the overall health and well-being of that population.

Q. Specifically what disparities affect the transgender population?

A. There are a variety of disparities that have been documented in the transgender population. For example, transgender people are less likely to report good or excellent health compared to the cisgender population. Transgender people are less likely to have access to health insurance coverage. They are less likely to have access to health care. They are more likely to encounter barriers to care, such as financial barriers, that make it difficult to access health care services.

Q. Dr. Baker, I'd like to turn your attention specifically to health care coverage.

How long has the medical community been providing treatment for gender dysphoria?
A. Internationally speaking, treatment for gender dysphoria has been provided for 100 years -- more than 100 years. In the United States the initial provision of gender-affirming care in relation to gender dysphoria for transgender people was in the 1960s.
Q. And we've been using the term "gender-affirming care" or "gender-affirming medical care." What do you understand these terms to mean?
A. I understand gender-affirming care to encompass services and supports that affirm the gender of a person.
Q. And are there specific health services that are being referenced when the term "gender-affirming medical care" is used?
A. I generally understand that term to refer to puberty-delaying medications, hormone therapy, and gender-affirming surgeries.
Q. In your research regarding insurance coverage of gender-affirming medical care, what types of insurance carriers have you studied?
A. I've studied a variety of public and private health insurance carriers.
Q. With regard to private insurance, what are the major ways that private health care coverage is regulated in the U.S.?

A. In the United States we have both state regulation of insurance coverage as well as federal regulation.
Q. And describe to me what types of insurance policies or plans are state regulated.
A. The states are the traditional regulators of insurance coverage, so every state has an insurance commissioner, and they are responsible for regulating individual, small-group, and large-group coverage.
Q. And what plans are federally regulated?
A. Plans that are federally regulated fall under ERISA, and those are large self-insured employers that, rather than purchasing coverage for their employees, actually act as the insurance carrier themselves. So they pay the claims of their employee when they need health care, and those are the federally regulated plans.
Q. With regard to state-regulated plans, what trends have you observed regarding the coverage of gender-affirming medical care?
A. In state-regulated plans, there has been a substantial increase, particularly over the last ten years, in states that have required plans under their jurisdiction to remove exclusions for gender-affirming care and, in many cases, to offer affirmative coverage.
For example, in 2012, there was only one state where the insurance regulators had required plans to be inclusive of the

medical needs of transgender people, and as of 2023, I believe we're at 24 states, plus D.C., that have such a requirement in place.

Q. What position have state regulators collectively taken regarding transgender people's access to gender-affirming healthcare coverage?

A. Many state regulators have spoken individually, and a number of them have signed on to group statements. For example, most recently in fall 2022, 21 insurance regulators, so regulators from 21 different states, signed on to a letter to the U.S. Department of Health and Human Services affirming their interest in ensuring that transgender consumers in the markets that they regulate are able to access the health care that they need without facing discriminatory barriers and that that health care should include gender-affirming care that is provided in accordance with expert medical standards.

Q. Turning to ERISA-regulated plans, what trends in coverage policies for gender-affirming care has your research identified?

A. The trend in ERISA-regulated plans has been the same. If anything, it's been even faster, what I would call an exponential increase over the last decade in the number of self-insured employers that cover gender-affirming care for their employees. As of the most recent analysis, I believe approximately 86 percent of the more than 1,200 major employers that were assessed by the Corporate Equality Index offered

inclusive coverage to their transgender employees.
Q. Can you identify any major employers in the U.S. that offer fully inclusive plans to employees?
A. I mean, there are -- pretty much anybody that you can think of. I believe at the top of the list include companies such as Walmart, Amazon, and CVS, among many others.
Q. What position have insurance carriers collectively taken regarding ensuring transgender enrollees can access treatment for gender dysphoria?
A. We have really seen a sea change in the last decade with regard to the types of coverage protocols that private carriers are coming out with that affirm the availability of coverage, refer to expert medical standards, and looking at -- they've spoken -- individually a number of carriers, for example, put in comments on nondiscrimination rules through the U.S. Department of Health and Human Services.

Most recently, America's Health Insurance Plans, AHIP, which is the major professional trade association -- it includes about 1,300 different carriers that cover somewhere around 200 million people across the U.S. -- they put in a letter to the U.S. Department of Health and Human Services affirming their interest in ensuring that transgender enrollees can access gender-affirming care and reiterating their support for nondiscriminatory -- as they put it, nondiscriminatory benefit design and coverage designs that are based on expert medical

standards.
Q. We've been discussing private employer healthcare coverage.
What types of plans does the government offer as an employer -- do government entities offer as employers?
A. The government acts as an employer in a number of circumstances. For state governments, for example, the State acts as the employer and offers insurance coverage to its employees. The federal government also offers coverage to approximately 8 to 9 million federal employees and their dependents through the Federal Employees Health Benefits program, or FEHB.
Q. What trends in coverage for gender-affirming medical care in state employee benefit plans has your research identified?
A. The trend in state employee benefit plans has been the same as among self-insured employers, as well as among state-regulated plans. Over the last decades in particular we have seen a large number of states either removing explicit exclusions -- categorical exclusions of coverage for gender-affirming care and/or instituting affirmative coverage policies.
Q. How many states offer affirmative coverage policies for treatments for gender dysphoria?
A. I believe the number is approximately the same as the number of states that have regulation or guidance from their insurance commissioners, so 24 plus the District of Columbia.

Q. And how many jurisdictions offer employee benefit plans that do not categorically exclude treatments for gender dysphoria?
A. Over 40 different jurisdictions. So that includes states and territories. Over 40 jurisdictions offer plans that do not have categorical exclusions of gender-affirming care.
Q. With regard to the federal government -- and you mentioned the Federal Employees Health Benefits plan. How does the Federal Employees Health Benefits plan handle coverage for gender-affirming health services?
A. FEHB does not permit categorical exclusions of gender-affirming care. There is a requirement for this plan year that coverage be provided in a manner that is consistent with expert standards in the field.
Q. And what expert standards in the field are referenced in that affirmative requirement?
A. The WPATH standards and the Endocrine Society guidelines.
Q. What are the other major sources of insurance coverage in the United States?
A. The other major sources are what I tend to refer to as the three M's: Medicare, Medicaid, and the health insurance marketplaces.
Q. Let's turn first to the health insurance marketplace.
What is the health insurance marketplace?
A. The health insurance marketplaces were established under

the Affordable Care Act as the primary means by which people would access subsidies to purchase insurance coverage at a lower cost to make it more affordable.

There are two kinds of health insurance marketplaces at this point -- about 30, 33 states rely on -- as of this most recent year rely on healthcare.gov which is the federal platform, and the remainder of the states operate their own marketplaces.

Q. And have you researched the trends related to gender-affirming medical care coverage by the plans sold through healthcare.gov?

A. Yes.

Q. What has your research shown?

A. Out2Enroll has conducted research on the availability of coverage without exclusions through healthcare.gov. We have consistently seen a trend of a declining number of plans that have any exclusion at all, let alone a categorical exclusion of all care related to gender affirmation.

Q. And do you know approximately what percentage of those plans have no exclusions for treatments for gender dysphoria?

A. In the most recent analysis, over 90 percent of the plans for which we were able to access the plan documents and dig into the coverage -- over 90 percent do not have exclusions of care related to gender dysphoria.

Q. And how many of those plans that you were able to research

have affirmative coverage policies that cover treatments for gender dysphoria?

A. Roughly half, about 47 percent.

Q. How does Florida operate its marketplace?

A. Florida uses healthcare.gov.

Q. And what did your research show with regard to how the insurance carriers selling coverage through healthcare.gov in Florida handle coverage of gender-affirming medical care?

A. None of the plans that we reviewed in healthcare.gov in Florida had exclusions of gender-affirming care.

Q. And did any of those plans have affirmative coverage policies that explicitly provided for coverage of gender-affirming care?

A. Yes, the vast majority. I believe there was one that had unclear language, and one or two that didn't mention at all. But the vast majority had affirmative coverage.

Q. Turning now to Medicare, does Medicare currently cover gender-affirming medical care?

A. Yes, it does.

Q. Does that include gender-affirming surgeries?

A. Yes.

Q. And does that include hormone therapy?

A. Yes.

Q. Has Medicare always covered these treatments?

A. No. In 1981, HCFA, H-C-F-A, which is the precursor to the

Centers for Medicare & Medicaid Services, adopted an informal policy of no coverage, and that policy of no coverage was codified as a national coverage determination in 1989. That NCD, national coverage determination, was overturned in 2014.

Q. Dr. Baker, we're going to pull up on the screen what has been marked as Plaintiffs' Exhibit 71.

Do you recognize this document?

A. I do.

Q. What is it?

A. It is the Departmental Appeals Board decision in 2014 overturning the Medicare exclusion.

Q. Does this document reflect the Departmental Appeals Board's determination regarding whether gender-affirming surgeries are experimental?

A. Yes.

MS. DUNN: Your Honor, I ask that this be admitted as Plaintiffs' Exhibit 71.

THE COURT: Plaintiffs' 71 is admitted.

(PLAINTIFFS EXHIBIT 71: Received in evidence.)

BY MS. DUNN:

Q. Dr. Baker, can you explain the basis of the Departmental Appeals Board ruling?

A. The basis for the national coverage determination and the earlier informal policy from 1981 were that, quote/unquote, transsexual surgery was experimental and cosmetic.

The Departmental Appeals Board looked at the evidence in the 30 years since then and concluded that the characterization of coverage for gender-affirming care or the characterization of gender-affirming care itself as cosmetic and experimental was no longer reasonable.

Medicare uses a reasonableness test to determine whether or not something should be covered, and the Departmental Appeals Board found that the national coverage determination and that earlier informal policy did not meet the reasonableness standard and that the national coverage determination was thus no longer valid.

Q. What guidelines did this determination -- this appeals board ruling look to in determining whether gender-affirming medical interventions are reasonable and necessary pursuant to Medicare regulations?

A. The decision looks at the WPATH guidelines.

Q. Dr. Baker, has Medicare issued a national coverage determination with regard to any of the health services at issue to treat gender dysphoria?

A. No.

Q. Is this unusual?

A. No.

Q. Why not?

A. Most services and interventions covered by Medicare do not have a national coverage determination. They are provided under

the reasonableness standard.
Q. And in the absence of a national coverage determination, how does Medicare treat requests for coverage for treatments of -- of treatments for gender dysphoria?
A. It considers them on a case-by-case basis according to standards of medical necessity and expert medical guidelines in the relevant field.
Q. Turning now to Medicaid, how common are exclusions like Florida's for Medicaid coverage of gender-affirming medical care?
A. Extremely uncommon.
Q. Can you estimate how many states have similar categorical exclusions?
A. Roughly eight states at this point have some degree of exclusion of gender-affirming care, but the vast majority of those do not have the type of categorical exclusion that I understand to be under consideration here.
For example, some of them exclude some procedures and services but not others. Some have age limits, and some remain on the books, but according to Department of Health officials are not being enforced.
Q. How many jurisdictions do not explicitly exclude coverage for gender-affirming medical care?
A. Counting states and territories, since territories also have Medicaid programs, I believe 46 to 47. I don't remember

the exact number off the top of my head, but over 40, I guess I can say, do not have exclusions of gender-affirming care.

Q. And how many jurisdictions affirmatively provide coverage of gender-affirming health services?

A. 27 jurisdictions at most recent count did not have exclusions -- had, actually, affirmative coverage of gender-affirming care, which is where it's outlined in Medicaid regulations or a Medicaid handbook what procedures and services are covered.

Q. And just to clarify, we've been talking about affirmative coverage policies versus a lack of exclusions. Can you describe the difference?

A. A lack of exclusions means that -- well, so originally you would have the situation that you had in Medicare where you had an explicit, often categorical, exclusion that no coverage would be provided for gender-affirming care. Increasingly in response to medical consensus and the evolving scientific evidence in relation to gender-affirming care, those categorical exclusions began to go away.

In some cases, that simply means, as in the case of Medicare, that coverage decisions are made on a case-by-case basis according to a standard such as Medicare's reasonableness standard and with reference to the expert standards of care.

It is, however, possible to go one step further, if you will, which is a case for any medical condition to clarify

exactly what coverage is available, and so increasingly we have seen state Medicaid programs, private insurance carriers -- you know, this is the case with what a lot of the state regulators are doing is to say that it's important to spell out what coverage is available so that transgender enrollees and people who are administering coverage programs understand that coverage is available and are applying the correct rationale, criteria, and updated standards of care in making determinations of medical necessity for coverage.

Q. Have you reviewed the GAPMS report assessment of the status of Medicaid coverage in the U.S. for gender-affirming medical care?

A. Yes.

Q. Was there representation of the number of states that cover or don't cover this care accurate?

A. I did not agree with it on the basis of what I have already stated, that the type of categorical exclusion in Florida's Medicaid program is extremely rare, and for the states that do -- the relatively small handful of states that do explicitly exclude coverage, again, those types of exclusions are typically either for some procedures or services but not others, have some sort of age limit or are on the books but are not being enforced. So I did not agree with the way that the GAPMS memo characterized the status of Medicaid coverage for gender-affirming care.

Q. What does your research show with regard to the current trends among Medicaid programs with regard to coverage of gender-affirming medical care?
A. Those trends are following the same trend lines as every other type of public and private coverage. When you look at the state-regulated plans, you look at self-insured employers, you look at the state employee plans, you look at Medicare, you look at Medicaid, the trend, especially over the last decade, has been very strongly in the direction of coverage.
Q. What is the reason that every type of insurance carrier providing insurance coverage in the United States is moving towards coverage of gender-affirming medical care?
A. In response to the expert medical consensus acknowledging that gender dysphoria is a real and serious medical condition for which safe and effective treatments exist and that more than 20 major U.S. medical associations all affirm that gender-affirming care is important to the overall health and well-being of transgender people and is, thus, an important area of medicine and, thus, an important area of coverage for programs whose entire intent -- although we could argue about private insurance. But programs where coverage is being provided in order to make sure that people can access the health care services that they need.
Q. Dr. Baker, I'd like to ask you some questions about utilization trends of these health services for treating gender

dysphoria.

How has number of insurance claims for gender-affirming medical care changed in the past decade?

A. It has increased.

Q. What is this increase attributable to?

A. There are, I think, two main drivers of this increase.

One is the greater availability of coverage. This medical consensus that is causing more insurance carriers to provide coverage, so it's more accessible for transgender people.

And the other reason actually also relates to the medical consensus and the removal of these exclusions. Previously when a provider would code something with a code that was related to gender dysphoria, if there's an exclusion in place, then that plan -- that claim automatically gets denied. So there is now a trend in health care of providers who are providing gender-affirming care to transgender people to be more clear in actually using the codes that relate to gender dysphoria as a diagnosis, which allows us to see that information in, for example, a claims record much more easily.

One other thing that I would note is that there has been increasing data collected on transgender people, so there is an increasing understanding, I think, of -- back to one of your earlier questions -- the overall demographics, sort of who transgender people are and what kind of health care services they need.

Q. What does the increase in the number of insurance claims for treatments for gender dysphoria indicate?
A. It indicates both that coverage is more available and more providers can appropriately code for these services without feeling like they have to hide the care that they are providing in order to avoid triggering a coverage denial from a categorical exclusion.
Q. Turning now to the issue of cost effectiveness of these type of health services.
What is the overall impact of coverage on gender-affirming care on payor health insurance carrier budgets?
A. De minimis.
Q. Why is this?
A. There just aren't that many transgender people. So for an individual transgender person, the cost of care can be prohibitive. But when you are talking about health plan, whether that's a public plan, public program, or a private plan, it's simply -- when you are looking at sporadic claims from .6 percent of the population, you are just not talking about that much money.
Q. What evidence are the cost estimates that you've reviewed based on?
A. This are a number of estimates out there. Particularly in the last couple of years several states -- North Carolina, for example, looking at its state employee plan; Alaska Medicaid;

Oregon Medicaid; Wisconsin Medicaid. There is a number of states that have either performed or contracted out for an analysis of the cost, the actuarial cost of providing coverage for gender-affirming care.

Q. And generally what have these estimates shown?

A. That the costs of covering gender-affirming care are, again, de minimis; too small to matter, as I recall one state saying.

Q. And have any federal entities conducted analysis of the cost of covering gender-affirming care?

A. In the discussion about open service by transgender service members, the Department of Defense looked at the cost of providing coverage of gender-affirming care to trans service members.

Q. What was the result of that assessment?

A. He called it budget dust. Hardly even a rounding error.

Q. So we've been talking about the de minimis costs.

Have there been analyses looking at the costs in realization to the benefits of providing gender-affirming medical care coverage?

A. Yes.

Q. And what has the literature concluded about the costs and benefits of this type of care?

A. The literature demonstrates that the de minimis costs of providing this care are substantially outweighed by its

benefits.
Q. And how has that conclusion been quantified?
A. In a 2016 study, for example, which used standard cost utility analysis methodology, the incremental cost effectiveness ratio was calculated, which is where you quantify the amount of money in dollars that you are willing to -- that you are paying for some outcome, for example, quality of adjusted life years.
In this particular study the ICER, the incremental cost effectiveness ratio, for gender-affirming care was less than $10,000 per quality-adjusted life year, which, in comparison to in the United States and in many other countries, the standard willingness-to-pay threshold that we use, which is where you draw the cutoff of if I get a certain amount of benefit for a certain amount of money, I can consider it cost effective. If it costs me more money than this threshold -- willingness-to-pay threshold to get that benefit, I consider it not cost effective.
So the standard willingness-to-pay threshold in the United States is $150,000 per quality-adjusted life year.
Q. And, again, how much was the cost of coverage for gender-affirming health services?
A. Less than $10,000 for quality of adjusted life year.
Q. What procedures were assessed in making this conclusion regarding quality -- quality of adjusted life year?
A. The same definition of gender-affirming care that we have been --

Q. Including?
A. Hormone therapy and surgeries.
Q. Did that model also look at the cost of gender-affirming services on a per-member per-month basis?
A. Yes, it did. A per-member per-month basis is a standard measure in looking at costs of coverage. And that particular study found that the cost of providing coverage for gender-affirming care when spread across the U.S. population was .016 cents per-member per-month.
Q. Have you done any independent research regarding the cost effectiveness of gender-affirming care?
A. Yes.
Q. And can you describe your methodology in your research?
A. I accessed a proprietary commercial claims database that includes insurance claims from several hundred million people in the United States. I identified transgender people using codes that are associated with treatment for gender dysphoria. I identified the procedures that are related to gender-affirming care. And then I calculated how much -- added up over time, how much that care cost.
Q. And what did your own research indicate with regard to the cost effectiveness of gender-affirming medical treatments?
A. My research found that the cost of care for a transgender person on average in that database was less than $2,000 per year and considered on a per-member per-month basis, when spread

across that entire insured population. So a little bit more conservative than the other study that I was referencing. Rather than the U.S. population looking specifically at this insured population and this database, I found that the per-member per-month cost of coverage was 6 cents.

Q. How would you summarize the literature on cost and benefit for coverage for gender-affirming medical care?

A. The literature on the cost and benefits of gender-affirming care demonstrates that the de minimis costs of gender-affirming care are substantially outweighed by its benefits, financial and otherwise.

Q. Turning now to Florida's exclusion of coverage for gender-affirming medical services, the challenged exclusion. Have you reviewed that exclusion?

A. Yes.

Q. And what health services are excluded from coverage under the challenged exclusion?

A. I would call it a categorical exclusion that excludes coverage of puberty-delaying medications, hormone therapy, and surgeries.

Q. Is this coverage exclusion consistent with prevailing nationwide coverage trends?

A. No.

Q. Is this coverage exclusion consistent with expert medical standards used by health insurance programs?

A. No.
Q. And what expert medical standards are used by health insurance programs generally?
A. They refer to the WPATH standards, the Endocrine Society guidelines.
Q. Speaking of WPATH, Dr. Baker, are you a member of WPATH?
A. No. I have been in the past, but I'm not currently a member.
Q. Did you play any role in the formation of the WPATH Standards of Care 8?
A. Yes.
Q. What role did you play?
A. I was part of the research team at the Johns Hopkins Evidence-Based Practice Center, which is part of the Johns Hopkins medical institutions. It is an entity that is contracted to conduct evidence reviews. And it was contracted by WPATH while I was a staff member there to conduct reviews that would inform the development of the SOC 8.
Q. Are you still affiliated with the John Hopkins Evidence-Based Practice Center?
A. No.
Q. Were you the lead author on any published articles summarizing the results of those systematic reviews that you were a part of at the Johns Hopkins center for evidence-based medicine -- I'm sorry -- Evidence-Based Practice Center?

A. Yes.
Q. What systematic review -- what was the title of that systematic review that you published?
A. The one which I was the lead author was the Effects of Gender-Affirming Hormone Therapy on Mental Health and Quality of Life Among Transgender People.
Q. Dr. Baker, what is a systematic review? How would you define that?
A. A systematic review is a systematic review of a body of evidence that is intended to not cherry-pick, to ensure that the body of evidence is being fully scoped in order to answer a key question.
Q. And what was the purpose of the systematic review that you published with regard to hormone therapies?
A. It was to answer the key question, KQ11 -- I remember it very well -- the key question of what is the effect of gender-affirming hormone therapy on mental health --
(Reporter requested clarification.)
THE WITNESS: Gender-affirming hormone therapy on the mental health and quality of life of transgender people.
BY MS. DUNN:
Q. How did your systematic review do this?
A. We systematically searched the evidence. We searched PubMed, Embase -- you know, there is a whole range of scientific databases. So we developed a search strategy. We applied the

search strategy to these databases. We worked as a team. You don't really do anything alone in a systematic review; you are making sure that there's always someone else who is looking at the same studies and that you agree on your conclusions.

So we identified the studies that were relevant; we extracted data from those studies; we assessed the quality of evidence and risk of bias in those studies, and then we synthesized the findings, not quantitatively, but we synthesized the findings of what that body of evidence showed in relation to our key question.

Q. Was WPATH involved in the systematic review?

A. Yes.

Q. In what way?

A. They provided the key questions.

Q. Did they have any role in the study design?

A. No.

Q. Did they have any role -- or did WPATH have any role in the data collection?

A. No.

Q. Did WPATH have any role in the analysis or interpretation of the results?

A. No.

Q. And what were the results of that systematic review?

A. The systematic review found that gender-affirming hormone therapy supports the mental health and quality of life of

transgender people.
Q. What was the certainty of evidence supporting that conclusion?
A. The certainty of evidence, according to the specific rubric that we used, was low.
Q. And why was it considered low under your rubric?
A. Well, the GRADE methodology that we used automatically assigns a low certainty of evidence to any study that is not a randomized controlled trial. And the literature that we were looking at has very few randomized controlled trials. They are not very common in transgender health due to bioethical issues, as well as the difficulty of conducting a randomized controlled trial when you have a treatment that is well established to be effective.
Q. And what did your review of the entire body of the literature conclude?
A. We concluded that gender-affirming hormone therapy supports the mental health and quality of life of transgender people.
Q. You noted that your review accounted for potential flaws or bias. Is it unusual for a study to have potential flaws or bias?
A. No. All research has potential flaws and potential risks of bias.
Q. And how do you account for that when conducting a systematic review?

A. You look at the risk of bias. There are standard tools to do that. We used a standard tool that assesses different domains and looks at the overall degree to which the flaws of the studies outweigh their quality.
Q. What is the ultimate takeaway or conclusion of this article that you were the lead author on?
A. We concluded that gender-affirming hormone therapy is an important component of health care treatment for transgender people.
Q. And in the course of your review of the literature, did you identify any studies showing that hormone therapy harms the mental health or quality of life of transgender people?
A. No.
Q. As the author of this study, would you conclude that its findings support a categorical exclusion for gender-affirming care like Florida's?
A. Absolutely not.
MS. DUNN: I'm done. I have no further questions at this time.
THE COURT: Cross-examine?
MR. BEATO: Your Honor, considering it's after 5:00, would it be more appropriate to begin tomorrow morning?
THE COURT: If you wish. Up to you. You can do it in the morning or we can finish tonight, whichever you wish to do.
MR. BEATO: Let's do it in the morning. I can finesse

my answers -- or finesse my questions.

THE COURT: There you go. I knew you'd have it.

Very good. We'll start at 9:00 o'clock tomorrow morning.

How are we going on the overall schedule? Are you about where you thought?

MR. GONZALEZ-PAGAN: Yes, Your Honor.

Omar Gonzalez-Pagan, Your Honor.

We actually wanted to bring up -- I believe it is quite likely plaintiffs' case-in-chief would be done being presented morning or midday Friday. And so the question is how the Court would wish to proceed. I know there is some availability questions for some of the defendants' witnesses, and we were wondering --

THE COURT: Dr. Baker, thank you. You may step down.

And then if you'd be back on that witness stand, please, at 9:00 o'clock tomorrow morning.

THE WITNESS: Yes, sir.

THE COURT: And I'm not trying to run you off. You are welcome to stay or go.

THE WITNESS: I'm just sad I have to put it all back on again.

(Dr. Baker exited the courtroom.)

THE COURT: So you think you are going to finish midday Friday. What are you telling me about the schedule?

MR. JAZIL: Your Honor, my out-of-town experts won't be coming into town until Tuesday, which is when -- since we are not having court on Monday and Tuesday.

My two agency experts, one is testifying in a trial in the Southern District of Florida that's going on now. And the other's availability I'm just not sure of for the rest of the week.

So if we are going to finish midday Friday, perhaps we can pick back up Wednesday morning with our witnesses.

MR. GONZALEZ-PAGAN: Plaintiffs would have no objection to that if it is the amenable to the Court.

THE COURT: Not my first choice, but we can do that. If it works, we'll just plan on finishing the plaintiffs' case this week, and starting the defense case Wednesday.

MR. JAZIL: Yes, Your Honor.

And then I just have a conceptual question. I know we've been talking about the other cases being wrapped into this one.

Would the plaintiffs be closing their case or leaving it open so that if things are -- I just note the procedural hiccup.

THE COURT: Yeah, I didn't -- some of that was just kind of raising possibilities to discuss. And I haven't thought it all the way through. It does seem clear to me that the other case is the other case.

Anybody have any more information about when the Governor is likely to sign the law?

MR. JAZIL: I do not, Your Honor. However, I did go back and look to see when presentment happens, because there are two things that have to happen: The legislature has to present the bill to the Governor. Then there is a trigger for the Governor to either sign, veto, do nothing and it becomes law. Presentment goes on until June because laws usually don't become effective until July. So I don't have a good way to predict when it is the legislature will present the bill and the Governor will sign it. So we could be looking at possible presentment in June when this trial is done.

I'd just note that for the record.

I don't have perfect answers, Your Honor. I apologize.

THE COURT: All right. I'll give it some more thought.

Meanwhile, we'll have Dr. Baker back on the stand at 9:00 o'clock in the morning, cross-examine, and then call the rest of your people. We'll plan on the plaintiffs' case this week, the defense case starting Wednesday morning.

Is it Monday I'm getting your memo on the preliminary injunction?

MR. JAZIL: Yes, Your Honor. You'll get my memo on the preliminary injunction Monday. I'm done with the memo. I'm

just trying to get transcripts of the rulemaking hearings that the two boards had so I can make those available to the Court.

THE COURT: I guess it's the other case.

MR. GONZALEZ-PAGAN: That would be Ms. Levy and Ms. Chriss, Your Honor. And Ms. Dunn.

THE COURT: When are you going to be back in town? And if we -- Tuesday afternoon, can we do the preliminary injunction Tuesday afternoon? It makes more sense to put it back after we've had a couple of your experts. We can put it back on toward the end of the week.

MR. JAZIL: Your Honor, my understanding is we are not in trial Tuesday afternoon.

THE COURT: We're not.

MR. JAZIL: Okay.

THE COURT: But I can be available Tuesday afternoon. If I'm getting your memo Monday, depending on what time -- when you get it done; you get the attachments, go ahead and file it. Don't wait. So I can get to it. I'll need some time with it.

MR. JAZIL: Your Honor, I have a note saying that I have a hearing Monday at 6:00 p.m.

THE COURT: And I'm pleased to say that's not my case.

MR. JAZIL: No, it isn't, Your Honor.

MS. LEVI: We would just ask for some set time when the preliminary injunction would be heard.

THE COURT: Why don't we try to pick a time.

How long are your experts going to be in this trial?

MR. JAZIL: So we have four expert witnesses.

Your Honor, if we go half a day each with each expert, two days; plus Mr. Brackett will likely be on for half a day, Ms. Dalton; likely four days is what we are looking at.

No, I've got the math wrong.

THE COURT: That arithmetic doesn't work.

Would it help to have a set time to do the preliminary injunction, or do you want to do it first thing Friday morning?

MR. JAZIL: Next week?

THE COURT: Yeah.

MR. JAZIL: Fine with me, Your Honor, if it works for counsel.

MS. LEVI: We'll make it work.

MR. GONZALEZ-PAGAN: And, briefly, Your Honor, from this case's perspective, we have three rebuttal witnesses, two of which will be traveling, but we expect to present those.

THE COURT: I'm just curious, how do you know you have three rebuttal witnesses? You haven't even finished putting on your case. If it's somebody you already know is going to testify, how is that a rebuttal witness?

MR. GONZALEZ-PAGAN: Well, it's depending on who they call, Your Honor, and what the testimony is.

THE COURT: Well...

MR. GONZALEZ-PAGAN: We are happy to present them

earlier, if it pleases the Court.

THE COURT: Let me -- we probably all have different views about what rebuttal is. Let me tell you what I think rebuttal is.

I think rebuttal is something that you weren't planning on putting on unless there was something new and different than what you expected on the defense case.

This is not a case with a counterclaim or any of those complications. It's just your case. So what I would expect is your case and then their case and very limited rebuttal -- something new or unanticipated.

So just because you have, for example, an expert who is going to disagree with something they say, that doesn't make that a rebuttal witness. So you really ought to plan on putting on your whole case.

MR. GONZALEZ-PAGAN: Understood, Your Honor. We will reassess, and it may be then that we are not done by midday Friday, but we will then re-order our witnesses.

THE COURT: And that doesn't make a whole lot of difference in a bench trial. So if you've got somebody that you mistakenly thought I was more reasonable about rebuttal, and you just can't have them here until later, we can work with that, but try to put on your whole case the first time through.

MR. GONZALEZ-PAGAN: We will do that, Your Honor.

Thank you.

THE COURT: And, frankly, that's only fair to the defense. They want to meet your witnesses, too. So everybody gets -- if you hold back your real witness until rebuttal, they don't get a chance to put on their evidence.

MR. GONZALEZ-PAGAN: Sure, understood.

THE COURT: Put it all on. And they'll put it all on. And then if you have real rebuttal, you can put it on.

MR. GONZALEZ-PAGAN: Understood, Your Honor.

Thank you.

THE COURT: All right.

So Friday morning, maybe more like 8:30, and we'll do the preliminary injunction at 8:30 Friday morning and then finish up whatever we've got with the trial. And you should feel free to finish up on Thursday if you're done.

MS. LEVI: Just want to be clear, are we talking this Friday or next Friday?

THE COURT: Next Friday.

MS. LEVI: The 19th?

THE COURT: Yes, the 19th.

MS. LEVI: I just want to be clear.

Thank you.

THE COURT: That meets whatever emergencies you've got, right? I mean, the 19th is soon enough? Sooner is better, but the 19th can work?

MS. LEVI: We've made our case and the facts, and

we'll argue them in front of you of the serious urgency of the preliminary injunction.

THE COURT: All right.

I'll see you at 9:00 o'clock tomorrow morning.

(Proceedings recessed at 5:16 PM on Wednesday, May 10, 2023.)

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I certify that the foregoing is a correct transcript from the record of proceedings in the above-entitled matter. Any redaction of personal data identifiers pursuant to the Judicial Conference Policy on Privacy is noted within the transcript.

/s/ Megan A. Hague 5/10/2023

Megan A. Hague, RPR, FCRR, CSR Date
Official U.S. Court Reporter

I N D E X

E X H I B I T S

DEFENDANT'S EXHIBITS	OFFERED	RECEIVED
DX6	419	419
PLAINTIFFS' EXHIBITS	**OFFERED**	**RECEIVED**
18	419	419
30	423	423
71	482	482