IN THE UNITED STATES DISTRICT COURT FOR
THE MIDDLE DISTRICT OF NORTH CAROLINA

MAXWELL KADEL, et al.	)	
	)	
Plaintiffs	)	
	)	Cause No.
vs.	)	1:19-cv-00272-
	)	LCB-LPA
DALE FOLWELL, et al.	)	
	)	
Defendants	)	

VIDEO ZOOM DEPOSITION OF DR. PAUL W. HRUZ

Taken on behalf of the Plaintiffs

September 29, 2021

Sheryl A. Pautler, RPR,

MO-CCR 871, IL-CSR 084-004585

(The proceedings began at 9:31 a.m. Eastern.)

Pl. Trial Ex. 094

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VIDEO ZOOM DEPOSITION OF WITNESS, DR. PAUL W. HRUZ, produced, sworn, and examined on the 29th day of September, 2021, between the hours of nine o'clock in the forenoon and eight o'clock in the afternoon of that day, via Veritext Zoom, before SHERYL A. PAUTLER, RPR, Certified Shorthand Reporter within and for the State of Illinois and Certified Court Reporter within and for the State of Missouri, in a certain cause now pending before the United States District Court for the Middle District of North Carolina, wherein MAXWELL KADEL, et al. are the Plaintiffs, and DALE FOLWELL, et al. are the Defendants.

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Q. Okay. What is a wet lab?

A. A wet lab is really designating somebody that does hands-on research usually with either in-vitro or in-vivo studies, as opposed to a dry lab which mostly does literature searches or computer programming or things that do not involve experimentation with -- the reason the term comes, from wet reagents like buffers and solutions and bodily fluids.

Q. Is your research primarily conducted in a wet lab?

A. My -- until recently the vast majority of my research has been conducted in a wet lab. I have participated on a few occasions in clinical trials and have served as an adviser and consultant for colleagues in those types of studies.

Q. On how many occasions have you participated in clinical trials?

A. I never direct -- well, there was one trial at Washington University where I was more directly involved. But all of -- as far as principal investigator, all of my NIH funded research and service as a principal investigator has been done with my basic science research.

Q. Would you agree that clinical trials is

not your area of expertise?

MR. KNEPPER: Objection, form.

A. I would not agree with that statement. I would say that I -- in the course of the last decade that -- as I've been required to investigate the literature surrounding this particular issue of treatment of gender dysphoria, I have developed considerable expertise in clinical trials. And I also have previously served on institutional review boards. I did that while I was a medical student, where I reviewed the ethics of clinical trials and -- and in other ways as well. So I would say that covers my -- is included in my expertise as a physician scientist.

Q. (By Mr. Gonzalez-Pagan) Earlier you stated that the testimony you provided in the Bruce deposition was truthful; is that right?

A. To the best of my knowledge.

Q. In the Bruce deposition, you were asked: So clinical trials is in your area of expertise?

And you answered: That is correct.

MR. KNEPPER: Objection, form.

A. Can you please read that statement again? And it might even be helpful if we went to the area of that deposition so I can see the entire context.

But for now maybe you can just reread that just so I understand what that statement said.

Q. (By Mr. Gonzalez-Pagan) Well, let's -- my computer is not going to survive today. I apologize. It's on Page 39 of Exhibit 3.

A. Is there an easy way to navigate directly to a page without just scrolling down?

Q. Unfortunately I don't believe so. It's limitation of the medium. I apologize for that.

MR. KNEPPER: I will confirm that. Yeah. I haven't found one either.

A. Okay. So which line are you -- I'm on Page 39 right now.

Q. (By Mr. Gonzalez-Pagan) All right. So on line -- beginning on Line 23.

A. Okay.

Q. It says, Question: I see. So clinical trials isn't your area of expertise?

Answer: That is correct.

Did I read that correctly?

A. Well, if you read the preceding lines, it immediately followed a question about my direct participation in clinical trials where I clearly stated that there was only one clinical trial. That was the one I just mentioned to you at Washington

University. And similar to what I had in this deposition, my role in that project was relatively minor.

So in that sense, that does not mean that I do not have knowledge and experience in the context of clinical trials. It only means I have not directly participated in those clinical trials. Context is important.

Q. What is primary research?

A. I'm sorry. Primary research?

Q. Yeah.

A. Oh, so you're -- you're talking about the difference between conducting experimental -- directly conducting experiments versus systematic reviews and literature reviews of that nature. Is that the distinction you're trying to get at?

Q. Is that what you understand the distinction between primary and secondary research to be?

MR. KNEPPER: Objection, form.

A. That would be one definition that I would agree with, yes.

Q. (By Mr. Gonzalez-Pagan) Okay. Would it be okay if I were to adopt that definition, that primary research refers to conducting experiments --

experiments, etc. and not literature review or metanalysis of existing data?

A. For the purposes of this deposition, yes, that is fine.

Q. With that understanding, have you conducted any primary research relating to gender dysphoria?

MR. KNEPPER: Objection, form.

A. So if you're asking whether I have directly participated in clinical trials on gender dysphoria, the answer is no.

Q. (By Mr. Gonzalez-Pagan) Have you participated in cross-sectional studies related to gender dysphoria?

A. Again, I have not -- cross-sectional studies, you're meaning retrospective reviews?

Q. It could be longitudinal observational. It could be cohort studies. I guess my question is -- let me back up. Have you conducted any direct research relating to gender dysphoria that is not based on a literature review?

MR. KNEPPER: Objection, form.

A. It would depend on what your definition of conduct. I have not physically myself done those chart reviews or participated in the clinical

setting. My experience to what you had described as primary research is limited to my role as associate or assistant fellowship program director in supervising my fellows, two of whom are doing what we would -- what you would define as primary research.

I'm not the primary investigator, but I do have a role in directing my fellows in doing that research to make sure it's of the highest quality and standards that we expect of all of our fellows.

Q. (By Mr. Gonzalez-Pagan) When did you resume supervision of the fellowship program?

A. The official designation has happened since the time I filed my initial curriculum vitae. However, I have continually throughout my career been involved in the fellowship program.

One of the reasons I was reappointed as the assistant program director was that it was recognized that the area of scholarly research needed somebody with my background to be able to help the fellows to be able to select projects, select mentors and conduct research in the most rigorous manner. And that was a shortcoming that had developed since I had formally stepped away from

A. Okay.

Q. Well, actually, let me -- let me check. We've been going about an hour. Would you like to take a break right now or I can do this line of questioning? And we can --

A. I'm actually doing quite well. I'd be fine to keep pressing on.

MR. GONZALEZ-PAGAN: Sheryl, is that okay?

THE COURT REPORTER: That's fine.

Q. (By Mr. Gonzalez-Pagan) Okay. So if we go to the list of publications in your CV. Are you with me?

A. I am.

Q. In the category of journal articles, No. 48 is titled Deficiencies in Scientific Evidence for Medical Management of Gender Dysphoria. Did I read that correctly?

A. Yes. And I do see it here.

Q. Is that one of your publications relating to gender dysphoria?

A. Yes, it is. And it's probably one of the most highly cited of the papers that I provided.

Q. Sure. Is that a publication based on any primary research that you conducted?

MR. KNEPPER: Objection, form.

A. As which have defined it, no. It's a review of the literature and critical appraisal of the evidence.

Q. (By Mr. Gonzalez-Pagan) And that publication is -- that -- sorry. That -- that article was published in the Linacre Quarterly; is that right?

A. That is correct.

Q. Is the Linacre Quarterly a scientific publication?

A. It is an ethics journal. In fact, it's the longest standing continuously published ethics journal in the United States.

Q. Who publishes the Linacre Quarterly?

A. The NCBC.

Q. What does the NCBC stand for?

A. The National Catholic Bioethics Center.

Q. Turn to 50. Is this one of the other publications you have relating to gender dysphoria?

A. It's a letter to the editor.

Q. So it's not -- this is not a publication based on any primary research or scientific study you have conducted?

MR. KNEPPER: Objection, form.

A. As we have defined primary research, it is

merely a presentation of -- of concerns about the literature that has already been published.

Q. (By Mr. Gonzalez-Pagan) And as I understand this letter to the editor is a commentary on another publication, on another article; is that right?

MR. KNEPPER: Objection, form.

A. It includes more information than just the article itself. But, yes.

Q. (By Mr. Gonzalez-Pagan) And just pure curiosity, I don't know the answer to this, but are letters to the editor peer reviewed?

A. This particular one was. I recall when we were submitting this, that we were asked to make changes. And I interpret that as being peer reviewed.

Q. Well, I just want to clarify. There's peer review and then there's editorial review; is that right?

MR. KNEPPER: Objection, form.

A. There are numbers of different types of review; that's correct.

Q. (By Mr. Gonzalez-Pagan) Okay. As I understand peer review to mean, it is a process of objecting and circulating an author's work to the

scrutiny of others who are experts in the same field; is that right?

MR. KNEPPER: Objection.

A. That's how it's generally defined yes.

Q. Are you saying that the letter to the editor was circulated to experts in the field before it was published?

A. I don't know the details of how the letter was handled. I only can say that when we submitted it, we were asked to make revisions. It was reviewed by individuals with understanding of the area that was covered. I don't know any more details. And that's the way generally peer review occurs. One is not usually told who actually reviews the submission.

Q. The next publication, it's -- it's No. 2 under book chapter. It's titled Medical Approaches to Alleviating Gender Dysphoria. And it's a chapter in the book Transgender Issues in Catholic Healthcare; is that right?

A. That is correct.

Q. Who publishes the book, Transgender Issues in Catholic Healthcare?

A. That was also the NCBC.

Q. Is the book a peer-reviewed publication?

A. No.

Q. Going to the next page, there's a list of invited publications; is that right?

A. Yes.

Q. No. 6 is your article titled Growing Pains, Problems With Pubertal Supression in Treating Gender Dysphoria.

Did I read that correctly?

A. Yes, you did read it correctly.

Q. Is this a peer-reviewed publication?

A. It is not peer reviewed. It was editorially reviewed.

Q. The growing pains article was published in the New Atlantis; is that right?

A. That is correct.

Q. Is the New Atlantis a scientific journal?

A. It is not considered a scientific journal in the definition that we normally designate it. It was -- it's a journal that provides more broad readership to be able to distill topics of relevance at an understandable level to the lay public.

Q. At the time of the publication of the article, who published the New Atlantis?

A. Well, the New Atlantis.

Q. Was the new Atlantis a publication of the

ethics and public policy center?

MR. KNEPPER: Objection, form.

A. I believe that may be true. I didn't pay much attention to that.

Q. (By Mr. Gonzalez-Pagan) Let's turn to Exhibit No. 3, Page 44 -- sorry -- Page 46.

A. I went too far.

Q. You know what, it could probably be me. It's a few later. It's Page 49. I do apologize. Page 49.

A. I'm still scrolling, so. Okay. I'm there.

Q. Okay. Beginning on Line 13, it reads; Question: Okay. And the New Atlantis was founded by the Ethics and Public Policy Center; is that right?

Answer: I believe that that is correct.

Question: Okay. And that's a center dedicated to applying the Judeo-Christian moral tradition to critical issues of public policy; is that your understanding?

Answer: I believe that question came up at the last deposition. And I believe that that's an accurate statement.

Did I read that correctly?

A. You did read it correctly, yes.

Q. And you stand by that testimony?

A. Yes. I have no reason -- it's not something that I consider all that important. And I don't usually retain that. I've got so many other pieces of information for me to retain. But, yes.

Q. Going back to your CV, under invited publications.

A. I'm there.

Q. Okay. The next publication is an article titled The Use of Cross-Sex Steroids in Treating Gender Dysphoria; is that right?

A. That is correct.

Q. It was published in the National Catholic Bioethics Quarterly; is that right?

A. That is correct.

Q. Is this article, The Use of Cross-Sex Steroids, a peer-reviewed publication?

A. No, it is not.

Q. Is the National Catholic Bioethics Quarterly a peer-reviewed journal?

A. No.

Q. Is the National Catholic Bioethics Quarterly a scientific journal?

A. No. It is an ethics journal.

Q. All right. And the next publication, 8, under publications in your CV is Experimental Approaches to Alleviating Gender Dysphoria in Children; is that right?

A. Yes.

Q. And this is another one of your publications that relates to gender dysphoria?

A. Yes.

Q. Is this a peer-reviewed article?

A. It is published in the same journal as No. 7. And it is not a peer-reviewed journal.

Q. Okay. Do you have any other publications besides the ones that we just went through that relate to gender dysphoria?

MR. KNEPPER: Objection, form.

A. So there are -- I have no publications that have been added since the time I submitted this CV and it reflects my publications to date.

Q. (By Mr. Gonzalez-Pagan) Do you have any other publications besides the ones that we've discussed today relating to transgender people?

A. Not that I recall.

MR. GONZALEZ-PAGAN: All right. I actually do need to break. So if we can go off

scientific understanding of this condition. To my understanding, the transition from this definition as gender identity disorder to gender dysphoria was not based upon new scientific information.

It was more of a desire to alleviate the discomfort that one has in that label. So how we classify that really rests on the premises that one has about the underlying etiology. And I think that there are -- are more than one valid hypothesis or I should say premises that can be put forward, not necessarily all of equal weight.

Q. (By Mr. Gonzalez-Pagan) Okay. But what is your understanding of the condition of gender incongruent?

MR. KNEPPER: Objection, form, scope.

A. It's a very broad question. Could you narrow it down a little bit?

MR. GONZALEZ-PAGAN: John, what's the objection of the scope? I thought Dr. Hruz is here to testify about gender-affirming treatment for the condition of gender dysphoria and gender incongruent.

MR. KNEPPER: Hold on, Omar. You're free to ask the questions. I think the question I'm trying to understand is: Are you trying to ask

him to testify about -- as a psychiatrist or a psychologist? And it's not clear to me, you know, what the definition of gender incongruence -- are you -- it's not clear to me when you use that term, are you trying to say it's the ICD-11 definition or are you using something else?

I'm happy -- happy to let you continue to pursue this. I'm just as interested as you are. But I want to make sure that as you go through this, we don't end up -- we don't end up down a path where you're trying to say, now, ah-ha, he's coming here pretending to be a psychologist which is outside the scope of what he said he's going to testify to.

MR. GONZALEZ-PAGAN: Well, I mean, we have a 90-page report that I'm happy to go through.

MR. KNEPPER: Please do.

Q. (By Mr. Gonzalez-Pagan) Dr. Hruz, in your report, you state a number of opinions about the validity of the diagnosis of gender dysphoria contained within the DSM; is that right?

MR. KNEPPER: Objection, form.

A. I would be much more comfortable looking at the specific areas that you're referring to.

Because I present many things in my report as hypotheses. And without making definitive statements. So it would be most helpful if we can look at specific areas that you're referring to.

Q. (By Mr. Gonzalez-Pagan) Okay. So I guess what I'm curious about is, do you have a particular as a physician scientist, do you have a particular belief as to whether gender dysphoria is a disorder?

A. I have multiple scientific premises that I have and continue to consider. Again not of equal weight or validity. One of those premises is that this condition arises from a disconnect between neuronal biology and the bodily from -- sex -- bodily form of the body.

Another scientific premise is that this condition is due to the number of environmental, social, hormonal and neuronal components. So how we understand this condition is markedly influenced by the premise that we come to address the hypotheses that we're going to need to consider to develop clinical trials to establish safety and efficacy of treatment that provides the greatest benefit to the affected patients.

Q. Would you agree there are transgender people in this world?

A. Again, we have to be very careful about the terminology that we're using, to acknowledge that the condition of sex discordant gender identity, and there are individuals that -- that express an identity that is not in agreement with their biology is a true statement. That's undeniable that these -- there are individuals that have this experience of discordance between their gender identity and their sex.

Q. Do you believe that the experience of discordance between their identity and what you term their biology, is a disorder?

MR. KNEPPER: Objection, form.

A. So, again, it depends on what premise you're operating under. As far as whether this is a normal experience of -- of a human condition or whether it falls outside of -- of the norm for us as sexed beings. And, again, as a physician scientist I'm obligated to be able to consider all possibilities to be able to do the proper science to get at the ultimate question here as to what we can do to alleviate the suffering.

Q. (By Mr. Gonzalez-Pagan) Dr. Hruz, I guess I'm a little confused as to what it is that is your opinion here. Can you briefly summarize for me what

more cautious approach by the recognition that the studies that have been done up to this point in time do not give us an answer as to whether this is the best or the only course of intervention to alleviate that suffering. Is that -- is that what you're looking for?

Q. Thank you. I appreciate that. In your -- as part of your opinions, do you provide -- let me back up.

Do you express an opinion as to which modality of care should be provided to people diagnosed with gender dysphoria?

A. I believe that it's an ongoing scientific question about what the most efficacious approach is to provide the greatest benefit with the least amount of risk. And that is why I'm participating as an expert witness in this case, to bring to light for the benefit of the court that this is something that needs to be very much investigated to be able to get an answer to that question.

Q. Do you express an opinion as to which modality of care should be provided to people experiencing gender dysphoria?

MR. KNEPPER: Objection, form.

A. I would say because it's an unsettled

scientific question, that I don't have a firm opinion as to which is the best approach. Yet as time has gone on, more and more information is being generated that calls into question the affirmation-only approach.

Q. (By Mr. Gonzalez-Pagan) And I don't want -- what I'm trying to do is get clarity here. So would it be fair to say that you do not provide an opinion as to which modality of care should be provided for people experiencing gender dysphoria?

MR. KNEPPER: Objection, form.

A. My opinion is that based upon the lack of evidence for the gender -- gender-affirmation approach, that if we are going to provide interventions for this population that it is best done under a carefully controlled clinical experimental setting.

Q. (By Mr. Gonzalez-Pagan) You express that there are ongoing questions as to the efficacy of the gender-affirmation approach; is that right?

A. That is correct.

Q. Again for clarity's sake, are you -- you're not expressing an opinion with -- with medical certainty as to whether the gender-affirmation approach is effective or not; is

anxiety?

A. I would say that the answer is yes.

Q. So for people who experience gender dysphoria and do not have any other co-morbidity, what would you do to address their gender dysphoria while the clinical trials are being conducted?

MR. KNEPPER: Objection, form.

A. That's a broad question. And it depends upon the individual characteristics of the patient, including their age and including all of the other factors that are associated with that gender dysphoria. Was it a child who is prepubertal? Is it a child who is an adolescent? Is it an adult? Is it a child or an adult that, you know, all of the social situations or circumstances that they're involved in?

Again, without having a formal diagnosis of depression or anxiety or these other co-morbidities, all of that is going to impact how one approaches that particular patient.

Q. (By Mr. Gonzalez-Pagan) I guess here we're talking about this case, you said it's a provision of coverage for treatment for gender dysphoria; is that right?

A. That is the nature of this case, correct.

had a new chairman that came on board from the one that recruited me to that position. We disagreed in more than one area.

There was also my research program had been rapidly expanding and was getting into the area of drug development. I would say that the role of chief of any division is a thankless job. It requires a tremendous amount of time and effort. And so, you know, the decision to -- to step down from that position was actually very advantageous to my further career development. But, you know, it was one of the -- the gender center was one among many disagreements that I had at that time.

Q. Does the Washington University Transgender Center offer pediatric and adolescent gender-affirming care?

A. Yes. In the definition that we're talking about here meaning the GnRH agonist or puberty blockers, cross-sex hormones.

Q. Does the Wash --

A. In addition to --

Q. Does the Washington University Transgender Center offer hormone therapy as treatment for gender dysphoria in adults?

A. Does the pediatric center -- your question

is does the pediatric center provide care for adults?

Q. Well, my -- the transgender center offers both care to pediatric and adult patients; is that right?

A. So in general, the care that's delivered at St. Louis Children's Hospital spans birth to the low -- early 20s. There are individuals that are adults that are cared for by the adult endocrine division. And there's a separate team of doctors that participate in that care.

Q. Are you a member of the Endocrine Society?

A. Yes.

Q. The Endocrine Society publishes clinical practice guidelines regarding the treatment of gender dysphoria; is that right?

A. That's correct. Their initial document came out in 2009 with lead author Hembree and then they had a revision that was done in 2017.

Q. Showing you what's been marked as Exhibit 5.

(Whereupon Exhibit 5 was introduced for identification.)

A. Okay. I see it.

Q. (By Mr. Gonzalez-Pagan) Do you recognize

THE COURT REPORTER: Thank you.

MR. GONZALEZ-PAGAN: Borrowing a word from you, John.

Q. (By Mr. Gonzalez-Pagan) What is WPATH?

A. It's an organization known as the World Association of Professional Transgender Health. It is -- again, this is the organization that came out with their version seven of the guidelines quite a long time ago to provide their perspective on what should be done for people that experience sex discordant gender identity.

Q. Does the Washington University Transgender Center follow the WPATH guidelines?

A. Again, I will say that I'm not directly involved in the gender center. My understanding based on conversations with the director of that center, he claims that they do.

Q. Do you, yourself, provide treatment for gender dysphoria?

A. I will state that I'm a pediatric endocrinologist charged with treating hormonal diseases. And because I have not seen the evidence that supports the proper risk/benefit to that intervention, I do not provide that care, as I don't in any other area where I have not determined

appropriate benefit versus risk.

Q. Have you ever diagnosed a person with gender dysphoria?

MR. KNEPPER: Objection, form.

A. I'm a pediatric endocrinologist and my charge is to treat hormone related diseases. And therefore, I've not been called upon to make that diagnosis.

Q. (By Mr. Gonzalez-Pagan) Would you agree you do not have any clinical experience providing care for people for gender dysphoria?

A. I would not agree with that.

Q. Do you provide treatment for people?

A. I provide -- I provide treatment for hormone-related conditions that includes people with gender dysphoria.

Q. But specifically in treating gender dysphoria, do you have any clinical experience with regards to the treatment of that condition?

A. Since I'm a pediatric endocrinologist, my experience is limited to the treating of hormone-related diseases.

Q. Is that a no?

A. I have not treated with hormones for the purpose of alleviating gender dysphoria. I have

however treated patients that have experienced side effects related to that hormonal treatment including obesity, diabetes, dyslipidemia. So in that respect I have treated them, but not to address dysphoria. But, rather, the complications that have occurred in association with that treatment.

Q. Clarify, you said association, yes?

A. That's correct.

Q. Do you have proof -- do you have proof that it was caused by the treatment for gender dysphoria?

A. If I thought I had enough evidence to say cause, I would have said caused. I said association.

Q. Thank you. You've given a number -- Strike that.

Have you given presentations regarding gender dysphoria?

A. Yes.

Q. Have any of these presentations been at medical conference -- conferences or settings?

A. Yes. I've -- well, I've delivered many lectures to major academic centers during medical grand rounds. And I'm happy to detail those for you. It includes University of Tennessee, Texas

Tech, Notre Dame, the University of Montevideo. And there are probably others. I can't remember. So -- and so as being a grand rounds presentation in major medical centers, yes.

Q. Aside from grand rounds, have you provided any presentations regarding gender dysphoria at any medical conferences or sites?

A. Well, I would consider grand rounds a conference.

Q. Grand rounds is when there's an invited lecturer at a particular hospital and everybody is invited to attend; is that right?

A. So you're asking about national meetings, like the Endocrine Society meetings or such?

Q. Well, let me just clarify what grand rounds are for the record. So what are grand rounds?

A. Grand rounds are usually a recurring series of talks given by experts in various fields to the relevant scientific community about topics of interest to those physicians. And generally, it involves the presentation of high quality scientific evidence for the conditions that those physicians in the audience would encounter.

Q. Okay. So you have not conducted any

studies for any gender dysphoria, right?

A. I believe we answered that question earlier when we went through my CV.

Q. Well, I'm just wondering what your presentation of the grand rounds are since you have not conducted any such study?

A. It was providing the same types of evidence that I presented in my expert declaration about the scientific studies that have been done or need to be done in this field. Presenting the various hypotheses for etiology and potential treatment. The various side effects that are known or potentially could occur. So it includes all of -- or very similar information regarding the scientific studies that I presented in my expert declaration.

Q. And now, to continue aside from grand rounds, have you provided any presentations regarding gender dysphoria in any other medical conferences or settings?

A. I would have to -- I'd have to think through my list. It's actually most of the major presentations that I've made are listed within my CV. So I'd have to look back as to what I listed there. But if you're asking about the Endocrine

Society or the pediatric Endocrine Society or those types of organizations, I have not presented at those conferences.

Q. Are you familiar with the gender and sex conference?

A. Yes. And are you referring to the one in Madrid.

Q. That was going to be my question. Did you participate in the gender and sex conference in Madrid in 2018?

A. I don't recall the exact date. But if it was 2018, yes, I did present there.

Q. Did you know that the conference was billed as, quote: A rebellion against the gender ideology and its freedom destroying damaging law, closed quote?

A. I -- I don't recall that language being presented to me when I agreed to present at that conference.

Q. Did you know that the conference was focused on opposing what it termed "gender ideology"?

A. You know, again, I was asked -- and this is true for -- if you're going to go through the list of all of the places that I've spoken at. When

I've been invited to present at any of these conferences, my desire is to provide the most accurate and up-to-date scientific information related to the condition of gender dysphoria.

I am willing to present to any audience that is willing to hear that information. I don't make judgment about what the motives are of the individuals organizing the conference. But merely serve with my area of expertise and my knowledge to be able to further that discussion in a productive manner. And that applies to that sex and gender conference in Madrid.

Q. Who organized the gender and sex conference in Madrid?

A. I do not recall the entity. I'm sure you'll tell me. But again that wasn't who invited me was not as important as whether I was going to be given the opportunity to present the information objectively on this particular condition within my area of expertise.

MR. GONZALEZ-PAGAN: Oh, shoot. John, I just published an exhibit without a label. Do you have any objection to me calling it Exhibit 6?

MR. KNEPPER: Having done that very same

thing, Omar, let me take a look at it. But, no, I -- I cannot imagine I will have an objection. Actually it labeled it as Exhibit 6 automatically, but there's no stamp.

MR. GONZALEZ-PAGAN: There's no stamp, yes.

MR. KNEPPER: Sheryl, you'll have to put the stamp on it. But I'm completely okay with calling that Exhibit 6.

MR. GONZALEZ-PAGAN: Thank you.

(Whereupon Exhibit 6 was introduced for identification.)

Q. (By Mr. Gonzalez-Pagan) Dr. Hruz, I'm showing you what's been marked as Exhibit 6.

A. I can see it.

Q. And I apologize for the formatting. Some pages don't print as well as others. This appears to be a press release following the conclusion of the gender and sex conference which you were talking about; is that right?

A. I've never seen this document before.

Q. Okay. If you go to the second page.

A. Okay. I think I'm there.

Q. It talks about the gender and sex -- in the paragraph beginning eight speakers, sort of --

A. Okay. I'm there. I've got it now.

Q. Okay. It speaks of the gender and sex conference as being organized by HazteOir.org and its international platform, CitizenGo; is that right?

A. That's what it says here, yes.

Q. And does that -- is that in keeping with your recollection about who organized the gender and sex conference?

A. Yes. I seem to recall now that you've jogged my memory. That is correct.

Q. Okay. And then on the third page in the middle, there's a paragraph beginning: The rest of the panel experts and lecturers was made up by Professor Glenn Stanton; Dr. Paul Hruz; the sociologist, Gabriella Kuby; and the former transsexual, Walt Heyer.

Did I read that correctly?

A. I see the paragraph that starts Stanton assured that and, in quotes, the gender theory is unscientific, is that what you're --

Q. Just above.

A. Oh.

Q. I skipped the links in reading those.

A. Ah, okay. I see that, yes.

Q. Okay. So it is your recollection then that you presented at this conference; is that right?

A. Oh, yes. I do recall the conference. I just didn't until you reminded me. I didn't know who organized it.

Q. You used the term "gender ideology" in your report; is that right?

A. I have used that term in the course of my investigation of this condition, yes.

Q. What is gender ideology?

A. I would define ideology is including statements that are made on a non -- a non-scientific basis with premises and goals that are outside of science.

Q. Do you consider any healthcare professional that subscribes to the gender-affirming treatment model to be a gender ideolog?

A. I think you're conflating different terms. You mentioned gender-affirming medical care and ideology; those are two separate --

Q. Well, that's my question. My question is, does somebody that provides or advocates for gender-affirming treatment, is that person a person who subscribes to the gender ideology?

turn to, to be able to define, you know, the condition and the treatment approach. And I --

Q. Isn't that true for many psychiatric conditions?

A. Absolutely. I would -- absolutely. It is not unique to the area of gender dysphoria. In fact, in talking, you know, to those that are engaged more in the field of psychiatry, they will acknowledge that the rudimentary nature of the discipline in comparison to the rest of the medical -- medical enterprise, it is a very known and serious shortcoming. And there is a desire certainly to -- to fill in those gaps.

And there's actually hope that as time moves forward with the advance in tools that one has, to study neurobiology and address some of these questions. But there will be an opportunity to provide clearer answers that are more evidenced based.

Q. Sure. But, I mean, isn't that the nature of science and medicine; we don't know everything, period?

A. We know far less of the psychiatric conditions that are listed in -- or many of the psychiatric conditions -- I wouldn't say all -- that

Q. But your practice is in the field of endocrinology, not psychiatry; is that right?

A. I think we've touched upon this earlier, but I'm happy to expound upon that. Is --

Q. Well, it's a yes or no.

A. I'm a physician scientist. So I'm very qualified to talk about deficiencies in scientific evidence that are present in this particular area.

Q. So you're not a psychiatrist?

A. I covered that earlier. That I'm a pediatric endocrinologist. Yes, that's correct.

Q. Are you aware that the revision of the DSM involves the establishment of a scientific review committee that evaluated and provided guidance on the strength of evidence of any proposed changes?

A. You know, that is how they describe the process. I again have asked for the evidence, scientific evidence for the change between gender identity disorder and gender dysphoria and then even the move to shift toward the ICD code of gender incongruence, that is based upon a scientific evidence, rather than something other than that.

Q. You also make reference in your report with statements by Thomas Insel, the then director of the National Institute of Mental Health, that it

field forward. So I think that's entirely consistent with my interpretation of the whole question.

Q. Were you aware that two weeks after the statement that you reference from Dr. Insel, Dr. Insel issued a joint statement with the American Psychiatric Association stating that, quote: The American Psychiatric Association Diagnostic and Statistical Manual of Mental Disorders, along with the International Classification of Diseases represents the best information currently available for clinical diagnosis of mental disorders.

Were you aware of that statement?

A. Yes. And that is completely in agreement with my opinion that I put forward here as well.

(Whereupon Exhibit 7 was introduced for identification.)

Q. (By Mr. Gonzalez-Pagan) Showing you what's been marked as Exhibit 7.

A. I have it.

Q. Okay. This is a statement issued by Thomas Insel, the then director of the National Institute of Mental Health, and Jeffrey Lieberman, the then president elect of the American Psychiatric Association; is that right?

A. Yes. I believe -- well, I don't know for sure, but I agree.

Q. Okay. Right below DSM-5 and RDoC, colon, shared interests, it states: The authors of this statement.

Do you see that?

A. I see the two authors, Thomas Insel and Jeffrey Lieberman, correct.

Q. All right. Going to the second paragraph, it reads: Today the American Psychiatric Association Diagnostic and Statistical Manual of Mental Disorders, along with the International Classification of Diseases represents the best information currently available for clinical diagnosis of mental disorders. Patients, families and insurers can be confident that effective treatments are available, and that the DSM is the key resource for delivering the best available care. The National Institute of Mental Health has not changed its position on DSM-5. As the National Institute of Mental Health research domain criteria project website states, the diagnostic categories represent that in the DSM-IV and the International Classification of Diseases 10, the main contemporary consensus standard for how mental disorders are

diagnosed and treated.

Did I read that correctly?

A. You read it correctly. Yet what follows in the next paragraph is more pertinent to the statement that I made in the declaration acknowledging the fact that the DSM is not sufficient for researchers and the statement was related to the basis for research funding. So, you know, taken in context, this document is completely in line with the statement that I made about the limitations of the DSM.

Q. But the DS -- the DSM -- this is a case about the treatment of gender dysphoria; is that right?

MR. KNEPPER: Objection form.

A. So as we've been talking about all morning, okay, the ability to have effective treatments is based upon quality research. And if the DSM is not sufficient for researchers to be able to conduct their scientific study, because of how the DSM generates their diagnostic codes, I think that that understanding is completely relevant to why one needs to be aware of that.

Q. (By Mr. Gonzalez-Pagan) All right. Going to what is the fifth paragraph, the second to last

sentence. It states: As research findings begin to emerge from the RDoC effort, this finding may be incorporated into future DSM revisions and clinical practice guidelines. But this is a long-term undertaking. It will take years to fulfill the promise that this research effort represents for transforming the diagnosis and treatment of mental disorders.

Did I read that correctly?

A. You did read it correctly.

Q. Is there a reason why you did not include this follow-up statement from Dr. Insel regarding the DSM views and reliability in your report?

A. You know, I could have put the entire document that you have here into the report. The point being made, I think, is one that I fully agree with. I think that as we be able to -- are able to incorporate science into the DSM, it is going to increase in its validity and its usefulness. But in its current state there is acknowledged in this statement itself by the fact that this research is needed. It acknowledges the deficiencies that currently exist. So there's a whole host of other things that I could have included in my declaration. The point that was intended, I think, was

sufficiently made and supported even by this document that you put forward as a new exhibit.

Q. Sure. But in clinical qualification to your statement is that that doesn't exist yet, and that the DSM is the best current available tool that we have according to this statement?

MR. KNEPPER: Objection, form.

A. The point I made is that there are deficiencies in how it was -- or limitations how the DSM has been put together. And that is relevant to the understanding of how we put forward hypotheses for efficacious treatments. And so I would say that, you know, that's -- the state of knowledge in this area is -- is what is of concern and how we are using the DSM beyond its capabilities without knowledge of molecular or physiologic mechanisms for most of the psychiatric diseases is a major limitation which is acknowledged by the authors of this document. That is what I believe is important for the court to recognize and to understand as we move forward in this conversation.

Q. (By Mr. Gonzalez-Pagan) In your report you speak of three modalities of treatment for gender dysphoria; is that right?

A. I would say three different categories

based upon different underlying scientific premises. I think the reality of interventions are much broader than that and not as easily demarcated into three categories. But indeed, I do present those in my declaration.

Q. And these modalities, are they reparative therapy, watchful waiting and the affirming approach?

A. That is how I presented it, correct. And, again, if it would be helpful, if we're going to talk about it, if we can direct ourselves to that part of my declaration.

Q. We'll get there. Are you familiar with Ken Zucker's work?

A. Yes, I am.

Q. In fact, you repeatedly cite Dr. Zucker throughout your report; is that right?

A. Yes, I do, among other people, yes.

Q. What do you understand to be the model of care that Dr. Zucker employed?

A. Broadly speaking prior to his clinic being shut down was to approach care in a way to understand the underlying basis for the sex discordant gender identity in that era was referred to as gender identity disorder.

And to -- one of the approaches that he used was to help facilitate an individual to realign their gender identity with their sex. And if that was not possible, would then advocate for moving forward with affirmative approaches.

Q. So under Dr. Zucker's model, affirming care would be provided if there was persistence of cross-gender identification into adolescence and adulthood?

A. Based upon the information that Dr. Zucker had at the time that he was engaged in that care, that was how he proceeded, yes. He was not privy to the information that has come forward in the last several years about outcomes with that affirmative approach.

Q. What is the watchful waiting model?

A. Again, all of these approaches are based upon different scientific premises and it is based upon the experience that the majority of prepubertal children that experience sex discordant gender identity, if merely left alone, will have spontaneous realignment of their gender identity with their sex.

And it is again, whether it's intended or not, perceived as to be a desirable

outcome. And that those individuals that have that experience will not be exposed to gender-affirming medical interventions with all the associated risks and questionable benefits that we -- that I mentioned already. And I certainly can share more information if you would like.

Q. Let me introduce you to what's been marked as Exhibit 8.

(Whereupon Exhibit 8 was introduced for identification.)

Q. (By Mr. Gonzalez-Pagan) Do you have access to the exhibit?

A. Yeah. I'm seeing it now, correct.

Q. This is a publication on -- it's an article on adolescent health medicine and therapeutics; is that right?

A. I'm seeing that here. Is this a peer-reviewed journal -- a peer-reviewed article, just so I know?

Q. I'll answer that question for you then. The answer is yes, but it's the next exhibit.

A. Okay. I'm sorry. Did you have a question for me?

Q. Not yet.

A. Okay.

Q. I will represent to you that this is a peer-reviewed journal, but -- and I'll come back to -- to another exhibit to discuss that with you. But turning --

A. The reason I ask that was because it's a review article. And even in peer-reviewed journals, not all reviewed articles are reviewed with the same rigor. So that's -- but thank you.

Q. Let's exit out of that exhibit. And if my computer will cooperate.

(Whereupon Exhibit 9 was introduced for identification.)

Q. (By Mr. Gonzalez-Pagan) All right. I'm introducing what's been marked as Exhibit 9.

A. I have the document, just so you know.

Q. Great. Do you see where it describes the journal as an international peer-reviewed, open access journal focusing on health, pathology and treatment issues specific to the adolescent age group?

A. That's true. Just below the ISSN number.

Q. Correct.

A. Yes, I see that.

Q. Okay. So you would agree that it is a peer-reviewed journal?

A. Yes. They're claiming it is. I would have no reason to doubt that.

Q. Okay. So going back to Exhibit 8. If you can turn to Page 61 of the document.

A. Okay. Are you referring to the highlighted area?

Q. Well, we're going to go to the bottom of the right-hand -- right-hand column.

A. Okay.

Q. Under the watchful waiting model.

MR. KNEPPER: And, Omar, let's identify on the record the highlighting is not in the underlying document, but it's been added.

MR. GONZALEZ-PAGAN: For the record, the highlighting in the exhibit has been added by me. Otherwise the document is unaltered.

Q. (By Mr. Gonzalez-Pagan) The highlighted portion states -- reads: In contrast to live in your own skin approach, a young child's demonstration of gender nonconformity, be it gender identity, expressions or both, is not to be manipulated in any way, but observed over time. If a child's cross-gender identification and affirmations are persistent over time, interventions are made available for a child to consolidate a

transgender identity, once it is assessed, through therapeutic intervention and psychometric assessment as in the best interest of the child. These interventions include social transition (the shift from one gender to another, including possible name change, gender marker change and gender pronoun changes), puberty blockers and, later, hormone and possible gender-affirming surgeries.

Did I read that correctly?

A. Yes.

Q. So under the watchful waiting model, gender-affirming care is provided for adolescents and adults if they persist in the cross-gender identification; is that right?

MR. KNEPPER: Objection to form.

A. That's correct according to this use of the model, yes.

Q. (By Mr. Gonzalez-Pagan) Well, the watchful waiting model was developed by -- it's the Dutch model. It was developed in the Amsterdam Center of Expertise on Gender Dysphoria; is that right?

A. That's my understanding.

Q. Under the gender-affirmative model, medical and -- no medical and surgical interventions are initiated until after the onset of puberty; is

that right?

A. If you're talking about there's no reason to block puberty that hasn't started yet or to intervene with cross-sex hormones until that age; that is correct.

Q. Did you disclose to the -- in your report that under Dr. Zucker's model, under the watchful waiting model, and under the gender-affirmative model, gender-affirming medical treatment is indicated if cross-gender identification persists into adolescence and adulthood?

A. I would challenge you on the assertion that it's indicated. I would say that the model itself bases itself on the next step of intervention. Whether there's a prudent approach is really what is of concern with the literature that we have available. So the models itself indeed -- and they actually differ in not only in the timing of when one engages.

The affirmative model actually begins earlier with social affirmation, not just medical intervention. And there's different scientific premises that are underlying -- underlie these two different approaches.

Q. But under each of the models of the three

models that we've discussed, medical and surgical care is provided as a mode of treatment?

MR. KNEPPER: Objection, form.

A. Under the model. So let me be clear. Okay. So the reason for the watch and wait approach is to know that in prepubertal children that present with gender dysphoria, that the vast majority of them will have that spontaneous realignment, other gender identity with their sex, by varying estimates ranging from 50 to 98 percent. I think 88 -- 85 percent is a good average based upon the published literature.

That means that this would apply to 15 -- at most 15 percent, maybe even less, that would have persistence. It also makes the assumption -- and this is certainly one that one considers with the current social environment as to whether the influence of the social affirmation component, you know, is -- is provided.

So the underlying premises are different in the two models. One has a premise that there are a number of factors that led to the gender dysphoria. And the vast majority of individuals, that they may differ from one patient to another. There is no biological test that one can do to

determine which of these individuals are going to have persistence or have that spontaneous realignment. And the safest course of action is to do nothing until things are sorted out.

The gender-affirmative model makes a scientific premise that when one experiences sex discordant gender identity, it reflects something that is innate and immutable. And, therefore, a prudent approach would be to immediately engage in social affirmation followed by these hormonal interventions. I hope that I've stated that clearly enough for you and for the court.

Q. (By Mr. Gonzalez-Pagan) Sure. But ultimately as to the question for transgender people who persist in their cross-gender identification by definition into adolescence and adulthood, medical care and surgical care if indicated under any of the three models, that being Zucker's model, the watchful waiting model or the gender-affirming model?

A. I don't know that I would distinguish what we were talking about earlier with the Zucker model being -- I think you're doing that more as the reparative therapy.

And this is based upon again the

issue at hand of the emerging scientific evidence that leads one to question whether this provides a long-term solution to the problem of dysphoria. And, again, I will state again that there are many concerns about the presumption in proceeding with affirmative care that can be challenged by the outcomes that one is observing about how well these individuals are doing after receiving the gender-affirmative care.

So this is -- these are statements in this particular paper by Dr. Ehrensaft that is based upon the presumption that those are -- who receive the affirmative approach are going to be completely cured of their difficulties that they experience. And my point is that when you say indicated, it fails to recognize the -- the challenges that are emerging for that outcome.

Q. Sure. But my last question wasn't whether it was indicated. My last question is whether under each of the three models -- and let me clarify something. You discuss a reparative therapy model in your report; is that right?

A. Yes. Can we again go to that part just so you can direct me just so we can be looking exactly at what I wrote.

Q. Sure. It's Page 49 going into Page 50.
A. Thank you very much. Okay. Very good.
Q. My point is --
A. I do remember what I wrote. I just want to make sure we're talking about the same thing.
Q. My point is that -- that I'm trying to distinguish actually there are four models, if you will. The Ken Zucker model is distinguished from reparative therapy in that -- in a significant way.

And let's go to Page 61 of Exhibit 8, the highlighted portion above the watchful waiting model. It states: If by the arrival of puberty a child is still exhibiting cross-gender identification and expressing a cross-gender identity, that child should be supported in transitioning to the affirmed gender including receiving puberty blockers and hormones once it is assessed from clinical interviews and psychometric testing that the affirmed gender identity is authentic.

Did I read that correctly?

A. Yes.
Q. Okay. So my question was whether you disclose in your report that under the watchful waiting model and/or Ken Zucker's approach,

gender-affirming medical care is provided after the onset of puberty?

A. I'm trying to -- let's go back again to my report and the context of the discussion that I'm putting forward. You said that was -- we were on page -- page or bullet point No. 59, I think you said.

Q. Page 49, going into 50.

A. 49. Okay. That's where I -- that's where I lost you. I was on 59. Sorry. So I would also add that the presentation of three broad categories -- and you've mentioned a variation of one of those categories saying there are four approaches. I would -- I would posit it that there's a number of other hypotheses that have been put forward about treatment approaches that --

Q. Did you disclose any of those other approaches in your report beyond the three that you listed in this paragraph?

A. Let me explain what I mean by that. Okay? As I repeatedly said in my declaration that there are multiple hypoth -- alternative hypotheses that can be put forward about the most prudent approach to care. These broad categories provide the foundation for understanding the design and

implementation of these various applications of these broad categories.

The point of dividing it up into three categories is to really -- and I think that that is still valid -- that the starting underlying scientific hypotheses or the scientific premise, I should say, varies in these three different approaches. How that scientific premise is translated into hypotheses that lead to care approaches is -- is at issue here. And that I think is the important point that I wanted to illustrate for the court. And make it very clear that what is put forward by the plaintiff experts, and they said this repeatedly, is that the affirmation-only approach is the only accepted intervention in the care of gender dysphoria youth. And in this paper here and in my declaration, you know, challenge that as far as the most prudent approach. And that's the point of why it was included in a benefit for the court.

The affirmation approach is not the sole approach. And there are alternative approaches that haven't been adequately investigated and that need to be investigated. And this is an area of unsettled controversial treatment that is going on

currently.

Q. Sure. But ultimately there's a distinction that they are different, right? Under all three of these models, gender medical care and surgical care is provided after the onset of puberty?

MR. KNEPPER: Objection, form.

A. I would say that is an important distinction because if the underlying --

Q. (By Mr. Gonzalez-Pagan) The modalities of treatment, are they different?

A. If the outcome of the affirmation approach is proven to be not effective it would change the way that one applies that model to the effected patients.

Q. But on the altering model, you're providing medical care after the onset of puberty. So the real difference has to do with prepubertal children and how they're treated; is that right?

A. Well, let's talk a little bit about the emerging demographic of what we are experiencing right now. Many of the people --

Q. But that's not my question, though. Like --

A. Okay. I don't think it applies

exclusively to the prepub -- medical care -- I would say the hormonal interventions apply only to people that have progressed at least to stage two puberty. Social affirmation applies across the board and would be relevant whether one presented during adolescence or in childhood.

Q. But social affirmation is not a medical or surgical treatment.

A. Many would argue that. And I would say in a technical sense, that is true. However, there are many concerns that are evidenced in the literature, that that influences the trajectory of the children as to whether they go on to medical care. So many can and have argued that it is the first step that is leading them on to the subsequent hormonal interventions. So I think it is relevant.

Q. In Paragraph 50 in discussing -- in describing the watchful waiting approach, you note that this approach may include the use of scientifically validated treatment, e.g., CBT, for the patient's anxiety, depression, social skill deficits or other issues.

But you do not note that gender-affirming medical care and surgical care are provided under this approach. I'm just wondering

why you did not provide that context in your report?

A. Because that's under the premise that the affirmative approach actually provides benefit, and throughout my declaration I have raised multiple concerns with existing published data that lead to a presumptive or tentative conclusion that at best we should have more caution to that approach.

Q. So at best your description of the watchful waiting approach in this paragraph is incomplete?

MR. KNEPPER: Objection.

A. Let's read through and we can even read it into the record if you'd like, the way that I present that. Because that's where I think it's important to look at this in context.

Q. (By Mr. Gonzalez-Pagan) Actually let's just -- let's just go to Paragraph 53 of your declaration. It states: Another controversy --

A. Hold on. I'm not there yet.

Q. Okay. I'll wait for you.

A. It's a long paragraph.

Q. Well, I'm right at the beginning of Paragraph 53.

A. It starts with "assistance"?

Q. Paragraph 53.

A. Paragraph 53 talking about another controversy, the watchful waiting treatment; is that what you're talking about?

Q. Sure.

A. Okay.

Q. I'll just read the heading: Another Controversy, the watchful waiting treatment modality involves no medical treatment and is currently the best specifically -- sorry -- is currently the best scientifically supported intervention for young children reporting gender dysphoria.

But the watchful waiting model does involve medical treatment; isn't that right?

A. Perhaps to clarify that statement when I say young children when we're referring to prepubertal children, that is true, and it is actually included in the Endocrine Society guidelines. As far as the concerns about intervening and the caution that should be expressed precisely because of the high rates of desistence.

So that statement, again, when we're talking about social affirmation and your contention as I'm hearing it as you're stating it is social affirmation is not technically a medical intervention. And I think we've already discussed

that. That it is relevant as far as the first step in influencing the trajectory of these individuals.

Q. This case --

A. And there's also --

Q. So this case involves gender-affirming care, right?

MR. KNEPPER: Object to form.

MR. GONZALEZ-PAGAN: I apologize, Sheryl.

A. So -- so -- okay. Let's -- let's also move on. So if -- if you then look at the first stage of medical intervention which involves the administration of an GnRH agonist or also known as a puberty blocker, significant concerns that that normal trajectory where you see the majority 50 to 98, I would say 85 percent have the desistence. That demographic or that statistic changes drastically in those individuals that have received that first step of pubertal blockade and that actually most of the studies that have been published thus far says the vast majority of -- it's not 100 percent. It's very close to that -- will go on cross-sex hormones. So again that is not -- that is more the affirmative model.

The watch and wait model would posit that as a child begins into their puberty, that

acknowledging that the bodily changes that occur may heighten the level of dysphoria that they experience. But as they go through that developmental process, that experience of puberty is actually critically important in the overall integration of one's identity with their sex. And that would be consistent with the watch and wait model. So that again, as being presented in this one review article by Dr. Ehrensaft -- much more I could say about that -- I think there's much more to be said about the way that these models are being presented.

Q. The study that you -- the study to which you refer regarding persistent cross-gender identification following the provision of GnRH analogue, is that the de Vries study?

A. That's the one that shows a hundred percent persistence or a hundred percent moving that across sex hormones. There's been subsequent ones where it's not been a hundred percent, but it's been the 90 percent range.

Q. You say that those studies pertain to the application of the gender-affirmation model, but the de Vries study is actually speaking to the watchful waiting model. It is the Dutch model.

A. We need to say a lot more about that if we want to flesh that out for you. I don't know that you've adequately characterized the Dutch model. And I will add that the Dutch model was presented a decade ago with a different patient population that is currently presenting at the gender clinics across the world. And even --

Q. But that's a different point than -- than the one that we're talking about, right? You indicated that the affirmation model -- studies show that the affirmation model leads into persistence, but you're relying on a study based on the Dutch model.

A. Well, I would qualify that statement. I didn't say that it leads to that model, because the way the study was conducted, you know, causal effect cannot be inferred. Okay? So I would moderate that. But I would say it's certainly of concern that that number is drastically different than the prior studies that have shown that rate of spontaneously -- spontaneous realignment with gender identity with sex.

Q. But those are different populations, right? I mean, we're talking about prepubertal and pubertal youth versus prepubertal youth?

A. Not necessary -- so, again, you know, it would be much more helpful to talk about specific studies. In the de Vries study, the whole basis of giving pubertal blockers applied only to pubertal patients.

Q. That's by definition any person who's receiving puberty blockers.

A. No necessarily.

Q. It has to happen at the onset of puberty.

A. Well, yes, onset of puberty, that would be the only indication for giving it in the area of pediatrics.

MR. GONZALEZ-PAGAN: All right. How about we break now for lunch?

MR. KNEPPER: Dr. Hruz?

MR. GONZALEZ-PAGAN: Well, I'm -- I'm hungry, so.

MR. KNEPPER: I know. This works with your diet?

THE WITNESS: Yeah. I think as we go through this, I'm going to be happy just plowing through. So it's going to have to come from your end if you want to take a break.

MR. GONZALEZ-PAGAN: Well, it's coming from my end. Because I -- I'm running on a

have to demonstrate a concept of what we call non-inferiority. So if that's the natural outcome, so if there's a realignment with gender identity with sex and that obviates the need for them to go on to receive hormonal treatment of any sort at all, that would be a desired outcome.

The challenge is that in those individuals, there is no reliable diagnostic test to predict which of those children are in the category of 85 percent, like we go to this realignment versus the subset that's going to persist in that sex discordant gender identity.

So that's the challenge. So I would say I wouldn't be so firm to make an absolute determination of the best course of action, but I wouldn't say that any alternate approach would have to prove that non-inferiority outcome.

Q. (By Mr. Gonzalez-Pagan) Okay. And the desistence study speaks to prepubertal youth who were diagnosed with gender identity disorder under the DSM-III or the DSM-IV; is that right?

A. So this is -- I'm very much aware of that critique, and the way that people have attempted to dismiss that desistence literature based upon that difference of gender identity disorder versus gender

dysphoria. It's very interesting that if you look in detail for example at that same paper the number of people based upon the criteria --

Q. I'm sorry, Doctor. I apologize for interrupting. But I guess -- I'm happy to go into a conversation about this. But I guess I have a predicate question, which is I want to establish whether it's true or not that the desistence studies are based on prepubertal children diagnosed with gender identity disorder as opposed to gender dysphoria under the DSM-5?

A. Well, older studies would certainly necessitate that they use the diagnostic criteria that was available at the time the study was conducted. And some of them -- and most of those studies were the era prior to the revision of the DSM-5 giving the gender dysphoria diagnosis.

Q. Are you aware of any studies looking into the desistence in prepubertal youth using the DSM-5 criteria?

A. You know, that is an outstanding question and I'm very happy to share with you the problems with that question. In the fact that because of what has happened in the approach to the care of these individuals, the opportunity because of the

widespread adoption of the affirmation only approach and the early adoption of social affirmation makes it very challenging to be able to even put forward as a hypothesis a study that would be able to operate under the current diagnosis of gender dysphoria.

And I think that's very problematic as we seek to understand the natural history of this disease, and we seek to find ways to alleviate the suffering that will be sustained long-term in these individuals. I think it's the fact that the discussion is not allowed to occur and the studies have not been proposed and conducted. And even if they were, there would be challenges in the current environment of really encouraging that social affirmation approach.

So the answer to the question is that there are many problems that currently exist as to why those studies have not been reported and would be very difficult to perform at this point in time, yet would be essential to providing the best care for these individuals.

Q. Okay. But you do not know of any studies documenting an 85 percent desistance rate for kids diagnosed -- prepubertal kids diagnosed with gender

dysphoria mode in the DSM-5?

A. I'm not aware the question has actually been investigated by a scientific trial. Not that there's data that says it doesn't exist, but that it has not been investigated. The only data that's available right now are people that have received that social affirmation which clearly shows that that demographic has changed. And, you know, if you ask this as a hypothesis --

Q. I appreciate that, Dr. Hruz. We'll get to the demographic changes later on. But I want to stay focused. So going back, the studies have to do -- the studies in desistance that you reference have to do with prepubertal children; is that right?

A. The ones that were done previously that I'm referring to dealt with prepubertal children. Now, there's another component of this, that of -- you divided this between prepubertal and adults. And it's very necessary if we're going to adequately address this question to consider what happens during the period of puberty.

Q. Okay. Are there studies that document desistence during the period of puberty?

A. There are case reports. There are not -- and there's a growing -- this gets at the --

Q. In your report you state that case reports are not valid scientific evidence.

A. They are useful for hypothesis generation. They're not useful for making definitive causal conclusions. That is correct.

Q. So are there any studies showing high desistence among adolescence diagnoses with gender identity disorder?

A. There are not. And the reason for that, again, is because in many of the studies where one looks at this, there's a very, very high dropout rate in many of the subjects where one can't conclude at all what the outcomes were. Based upon the available evidence, more by case reports of growing number of people experiencing this desistence, that did occur when it's experienced post pubertally would lead one to raise hypotheses to be investigated in a rigorous scientific manner to address that question.

Q. You believe that all medical treatment needs to be subjected to randomized clinical trial?

A. It depends on -- so every medical decision that is made is based upon consideration of the overall risk and the overall benefit. And I think that the greater the risk, the greater the scrutiny

are certainly --

Q. But that's just a hypothesis; is that right?

A. You know, all along here, I've been tell -- I've been stating, and I hope very clearly, that much of my opinion is based upon hypotheses and alternative hypotheses, because there is no definitive answer to this question. But the prevailing current hypothesis that's not presented as a hypothesis, it's presented as an established fact, is that gender-affirming interventions are the solution to gender dysphoria. And that is what I challenge. And that is what, I think, is very important for this court to understand, is that the scientific evidence does not support that as being a cure for all of the difficulties that these individuals are experiencing.

Q. Going back to the desistence studies. What is the error rate for the desistence studies that you rely on?

A. So the error rate is -- there's a number of factors. I'm glad that you brought this up as far as, you know, how we think about the reliability of studies. So this is a problem throughout the literature. And I've addressed this in my

Q. (By Mr. Gonzalez-Pagan) Are you aware that the American Psychiatric Association opposes reparative therapy efforts regarding gender identity?

A. Now we're into a new line of questioning about medical societies. But I'm aware of -- of the general recommendations for affirmation only. That is entirely consistent with what has been put forward by WPATH, American Psychological Association. There's a little bit more caveat in the Endocrine Society guidelines. I think they're a little bit more cautious in the prepubertal children, at least in the 2009 document cautioned against social affirmation in recognition of the same desistence literature that I'm referring to. Again, not just my opinion. This is the professional societies in the 2009 guidelines acknowledged those studies of being relevant to that consideration of treatment.

Q. Sorry. I just don't want us to go down a different path. I'm not talking about the general position statement about gender-affirming care. I am talking about the physician statements regarding conversion therapy. Are you aware that the American Psychiatric Association opposes conversion therapy

eff -- conversion therapy efforts?

A. The reason I answered in the way I did to your previous question was not to evade the question. It was merely to -- you began with a professional association. And so it's necessary to acknowledge what the basis of those statements are. The APA recommends the affirmative approach to care.

Q. Okay. But that's not my question. That is a different position statement. And I'm glad -- yeah, the APA does do that. But does the American Psychiatric Association also have a position statement regarding conversion therapy?

A. Okay. Thank you. Because you used the word "conversion therapy" for the first time. I think it's very important for us to acknowledge when we're talking about reparative therapy and what people talk about as far as conversion therapy. That's actually a pejorative term that actually is trying to equate these efforts to realign gender identify with sex to a completely different condition related to same sex attraction with methods that virtually everyone would recognize as being unethical.

And so I think it's an injustice to -- and the statements are often made in the

literature published talking about conversion therapy.

Q. All right. One second. Let's just go -- let's just go to Page 49 of your report, Paragraph 52.

A. Sorry. Paragraph 52?

Q. Yeah. So very last sentence going into the next page of your report states: The first approach often referred to as conversion or reparative -- reparative therapy --

A. Correct.

Q. -- is directed to or actively supporting and encouraging children to identify with their biological sex.

Did I read that correctly?

A. I could add often incorrectly referred to as conversion therapy. I think that's probably something I could have added to my declaration to indicate that. I think it's incorrect and an injustice to use that term to describe the approach to -- to addressing gender dysphoria.

Q. Are you aware that the American -- you know what, let's -- I apologize. I forgot the stamp again. It is marked Exhibit 10. Do you see that?

(Whereupon Exhibit 10 was

introduced for identification.)

A. Correct. I see this.

Q. (By Mr. Gonzalez-Pagan) Okay. Under the position heading at the bottom of the page, in Paragraph 2, it states: APA recommends that ethical practitioners respect the identity for those with gender diverse expression.

Did I read that correctly?

A. I'm in the wrong paragraph. You said the second paragraph?

Q. Under -- under the heading position at the bottom of the page?

MR. KNEPPER: Omar, I think you made -- I think you swapped gender and diverse. But it's just -- in other words, I think you read gender diverse expression and it's diverse gender expression.

Q. (By Mr. Gonzalez-Pagan) Sure. Let me just read that again. Are you there?

A. I'm here. Okay. I'm sorry. I was reading the introductory paragraph. Sorry.

Q. Okay. It states, Paragraph 2, quote: APA recommends that ethical practitioners respect the identity for those with diverse gender expressions.

Did I read that correctly?

A. Yes.

Q. Then just below that on Paragraph 3 on the next page, it states, quote: APA encourages psycho -- psychotherapies which affirm individual's sexual orientations and gender identities.

Did I read that correctly?

A. Yes.

(Whereupon Exhibit 11 was introduced for identification.)

Q. (By Mr. Knepper) Showing you what's been marked as Exhibit 11.

A. I see it.

Q. Okay. This is a resolution by the American Psychological Association on gender identity change efforts. Is that right?

A. That's the title of this document, correct.

Q. It's dated February 2021; is that correct?

A. That's correct.

Q. Go to the second page, third to last paragraph on the right-hand side column. And it's use of GICE as an acronym for gender identity change effort; is that right?

A. I see that, yes.

Q. It reads: Whereas, GICE has not been

shown to alleviate or resolve gender dysphoria (Bradley and Zucker, 1997; Cohen-Kettenis & Kuiper, 1984; Gelder and Marks, 1969; Greenson, 1964; Pauly, 1965; and SAMHSA, 2015).

Did I read that right?

A. You did.

Q. If you go to Page 3, the last two paragraphs, on the right-hand side column, it states: Be it therefore resolved, that consistent with the APA definition of evidenced-based practice (APA 2005), the APA affirms that scientific evidence and clinical experience indicates that GICE put individuals at significant risk of harm.

Be it further resolved that the APA opposes GICE because such efforts put individuals at significant risk of harm and encourages individuals, families, health professionals, organizations to avoid GICE.

Did I read that correctly?

A. You did.

Q. Okay. So the American Psychiatric Association and the American Psychological Association both oppose reparative therapy as a form of treatment; is that right?

A. Gender identity change efforts as stated

in the document, which again is different than what people generally equate with conversion therapy, in quotes.

Q. And the American Psychiatric Association and the American Psychological Association consider gender identity change efforts to be unethical and harmful; is that right?

A. That's what's stated in these documents.

Q. All right. I will apologize in advance, that exhibit is large and will make navigating it a little difficult. Hopefully it will take a little bit longer to upload.

(Whereupon Exhibit 12 was introduced for identification.)

Q. (By Mr. Gonzalez-Pagan) Showing you what's been marked as Exhibit 12. It's a document entitled Understanding the Well Being of LGBTQI Plus Population. Is that right?

A. That's the title in the document that I'm looking at, yes.

Q. It appears to have been published in 2010; is that right?

A. It says 2020.

Q. Sorry. 2020.

A. Okay.

correctly. And that many of the studies that are referenced here have major methodologic weaknesses and the strength of the statement based upon that evidence in light of the emerging evidence that is coming forward, for example, in the other studies that we've discussed already today --

Q. Well, let's --

A. -- this conclusion can be scrutinized.

Q. Let's move to the next page. The highlighted statement reads: The available evidence suggests that sexual orientation and gender identity conversion efforts were ineffective and dangerously detrimental to the health of SGD population, especially for minors who are unable to give informed consent.

Did I read that correctly?

A. I'll say again, you read it correctly. And the meaning of that statement and context of the whole paper is something that we can discuss later.

Q. Would you agree that it is the position of the National Academies of Sciences, Engineering and Medicine that conversion therapy is harmful?

MR. KNEPPER: Objection, form.

A. I don't know whether the small panel of people that were included in generating this

consensus statement represents the entire views of the entire membership of that society. I know from my own experience that for the other societies that I'm involved with these types of consensus statements are not brought to the entire membership of the organization. I can only conclude that the members that were present on this panel made those conclusions. I would not go as far as to say that it was supported by every member or even majority or even substantial number of the rest of that group.

Q. (By Mr. Gonzalez-Pagan) If you go to the fourth page of the PDF.

A. Back up to the top now? Okay.

Q. On the last sentence, the second clause, it states: It represents the position of the National Academies on the statement of facts; is that right?

A. That is what is stated here, and that is also stated by other organizations that have put forward similar statements. The same concern applies, that just because they put it forward, it does not mean that -- that the entire membership has been able to weigh into this question or those that wish to do so.

Q. Was the review that you referenced in

A. You know, again I don't have the answer. I don't know.

Q. Okay. Are you aware that in the United Kingdom, medical and surgical care is provided for transgender adolescents post puberty and for transgender adults?

MR. KNEPPER: Objection to form.

A. I guess I didn't understand the question there.

Q. (By Mr. Gonzalez-Pagan) Sure.

(Simultaneous speakers.)

Q. (By Mr. Gonzalez-Pagan) You talk about -- you talk about the reviews in the United Kingdom, in Finland and in Sweden. So I'm curious, are you aware -- are you aware whether in the national health system in the United Kingdom, they provide coverage and treatment for gender dysphoria in post prepubertal adolescents and adults?

A. So I think it's reflected in the recent Tavistock versus Bell decision. It is recognized that this is an area of controversy and that is an unsettled question about --

Q. Well, the Tavistock decision has to do with minors. I'm talking about adults and cross-sex hormones and surgery. Are you aware whether in the

United Kingdom they provide coverage and treatment of cross-sex hormones and surgery as a modality of treatment for gender dysphoria?

A. Yes, I do.

Q. Okay. Same question with regards to Sweden?

A. Sweden -- again, I'm a pediatric endocrinologist. And I think that the caution that is put forward in relegating this care to the setting of -- of an experimental setting is where it's been pulled back with concerns based upon the --

Q. The restrictions to which you speak all relate to the provision of puberty blockers; is that right?

A. No. I think it's more extensive than that. But it -- it acknowledges that based upon the literature that there's not very stong evidence and then instructs that this care be delivered with the safeguards exactly as I'm saying, you know, it should be done here in the United States. Recognizing that this is --

Q. That's in the context of minors, though; is that right?

MR. KNEPPER: Objection, form.

A. Again, that's what I've addressed in my declaration. And that is my --

Q. (By Mr. Gonzalez-Pagan) But with regards to transgender adults in Sweden, does the nationalized healthcare system in Sweden provide coverage and treatment for gender dysphoria in the form of hormones and surgical care?

A. You know, I would say this is outside the scope if we're getting into a discussion about insurance coverage. My expertise is in looking at the scientific data about the affirmation and other --

Q. Well, you rely on the national reviews of Sweden, Finland, and the United Kingdom. So --

A. Correct.

Q. -- I'm wondering if you rely on the national reviews, I think it's pertinent and relevant whether you disclose in your report that these countries provide for the treatment and coverage of this care?

MR. KNEPPER: Objection, form, scope.

A. As a pediatric endocrinologist and physician scientist, my service to this court is not to opine upon -- I know it's a big part about this case about insurance coverage. My role in this

gender-affirming treatment for adults?

A. Again, I would have to say for me to comment specifically about that, we would need to have the document in front of me to be able to look through all of the papers. It was a very extensive study. And there are a number of papers there.

And so I would have to look through the papers to specifically look at the inclusion criteria, whether it was exclusively in kids or included adults and, again, how he defined, you know, adulthood, whether it's post prepubertal, post 18, early 20s. You know, many people have different definitions of that. And so --

Q. All right. Same line of questioning with regards to Finland. Did you disclose that Finland provides through its national -- nationalized health care system gender-affirming treatment for gender dysphoria for adults?

MR. KNEPPER: Objection, form, scope.

A. I'm going to state again that for me to opine on that, I would need to look at, in those studies, what the inclusion -- inclusion criteria and whether it extended into adulthood.

Q. (By Mr. Gonzalez-Pagan) My -- my -- my question is not pertinent to the report. It's not a

question of whether they reviewed it. It's a question whether that care is provided in Finland.

MR. KNEPPER: Objection, form.

A. I will say again that this is a question related to insurance coverage. And I'm a pediatric endocrinologist, physician scientist opining on issues of science, not on medical coverage.

Q. (By Mr. Gonzalez-Pagan) One moment, please. Let's take a -- well, actually no. We'll come back. In your report you disclose the Bell v. Tavistock position; is that right?

A. That's correct.

Q. That was a decision from December 2020 in the United Kingdom?

A. Correct. And it was before the appeals court decision came out recently.

Q. And you submitted an expert report in Tavistock; is that right?

A. In that Bell versus Tavistock case, I did.

Q. Are you aware that the Bell v. Tavistock case dealt solely with the ability of a minor to provide informed consent on their own?

MR. KNEPPER: Objection to form.

A. So the decision was based on that. But that was not what I was opined [sic] to comment on.

there's no indication here that this was a peer-reviewed document. It wasn't published in a journal in the typical way that we do it. So it's a Council for Choices -- recommendations of the Council for Choices in Healthcare in Finland. So this is -- the council itself came to this conclusion to answer your question.

Q. Let's go back to Exhibit 12.

A. I'm there.

Q. All right. We're going to go to Page 12-10. It is Page 311 of the PDF.

A. I wish there was a way you could just type in the number and get to it.

Q. Don't we all.

A. Okay. This is with the section that's titled Guidelines and Policies Related to Gender-Affirmation?

Q. That's right.

A. Very good.

Q. The highlighted statement states: Clinicians who provide gender-affirming psychosocial and medical services in the United States are informed by expert evidence-based guidelines. In 2012, the World Professional Association for Transgender Health, WPATH, published Version 7 of

the Standards of Care for the Health of Transgender, Transsexual, and Gender-Nonconforming People, which have been continuously maintained since 1979, and revisions for Version 8 are currently underway (Coleman, et al., 2012). Two newer guidelines have also published -- have also been published by the Endocrine Society (Hembree, et al., 2017), and the Center of Excellence for Transgender Health (UCSF Transgender Care, 2016). Each set of guidelines is informed by the best available data and is intended to be flexible and holistic in application to individual people. All of the guidelines recommend psychosocial support in tandem with physical interventions and suggest timing interventions to optimize an individual's ability to give informed consent. Mental and physical health problems need not be resolved before a person can begin a process of medical gender-affirmation, but they should be managed sufficiently such that they do not interfere with treatment.

Did I read that correctly?

A. You indeed read that correctly.

Q. Okay. This is a consensus study report by the National Academies of Sciences, Engineering and Medicine of the United States; is that right?

record. This is Media Unit No. 5. The time is 4:05 Eastern time.

Q. (By Mr. Gonzalez-Pagan) Dr. Hruz, one of the critiques in your report is that puberty blockers have not been approved by the FDA as a treatment for gender dysphoria; is that right?

A. That is correct. Although it's important to understand why that is a relevant piece of information.

Q. Well, let's go to page 50 of your report.

A. I'm there.

Q. Okay. On the -- there's a number of statements that you bold and italicize, but on the third -- the sentence involving the third bold and italics.

A. Okay.

Q. It's like in the middle of the page. It states: The off-label prescription of this drug is legal but unethical outside the setting of a carefully controlled and supervised clinical trial.

Did I read that correctly?

A. You did.

Q. And why is that?

A. So, again, this relates to the statements that are made that these drugs are known to be safe

in this patient population. And we really don't have the scientific evidence to make that statement. Because it's unknown what the -- some of the effects are known, but many of the effects are unknown, to be able to expose people to this intervention, not only to expose them to that, but to make the statement that it is known to be safe with that absence of evidence, it really finds itself outside of what I'd consider ethical.

Q. Just for clarify, what do you understand "off-label" use to mean?

A. Oh, it's actually very common in the area of pediatrics. It's to prescribe a medication for something that it has not been FDA approved. So it could be for another -- a drug that's approved for one purpose and using it for another purpose. Most often that's how it's used.

Q. Have you personally ever prescribed any drugs on an off-label basis?

A. Very frequently do.

Q. Do you do so even in the absence of randomized clinical control trials?

A. Usually when I prescribe them off-label, there are randomized controlled trials in different populations that I turn to. I look at the relative

risk and -- but I don't make the statement that we know with definity [sic] about the safety of a medication in a way that we don't have that information.

Q. And you said usually. So there are times when you prescribe off-label drugs even in the absence of clinical controlled randomized trials?

MR. KNEPPER: Objection, form.

A. Usually when I'm prescribing it, what we would consider off-label most often, it is for a condition that is not markedly different for the use that it is being given only that it had been approved most often for adults rather than children.

Q. (By Mr. Gonzalez-Pagan) And clinical control trials are actually relatively rare in the pediatric population?

A. No. I would say that -- I mean, that's the standard that's accepted especially for medication use. The reason why they're not done in pediatrics is that usually there's a substantial cost associated with that. People are looking at market share and, you know, how much it's going to cost to be able to study that drug in that patient population. Yet it's already been studied in a randomized control trial in a similar population

without the same caveats that we consider when we look at this question of pubertal blockade.

Q. What is the FDA?

A. The Food and Drug Administration.

Q. Does the FDA regulate prescription drugs?

A. Yes.

Q. What is the FDA's decision with regards to a prescription of off-label use of drugs?

MR. KNEPPER: Objection, form, scope.

A. You know, I don't know that they have a statement that there is an ethical responsibility that all physicians who are prescribing off-label. It also applies both to the prescribing physician and it also applies to the pharmaceutical company that's making the medication.

If it's off-label, they cannot market it to a group of people that it wasn't approved for. Physicians that prescribe off-label medications accept the responsibility, you know, for the risks and benefits. And they're obligated to inform their patients of the evidence that they have, where it comes from, and the basis for recommending that medication.

That's true for all medications, but certainly when you're using it off-label, you know,

it involves consideration of the indication, how applicable the randomized control studies that have been done to approve the drug are applicable to the population that you're going to use it for.

(Whereupon Exhibit 14 was introduced for identification.)

Q. (By Mr. Gonzalez-Pagan) Showing you what's been marked as Exhibit 14. Do you have that in front of you?

A. I do.

Q. This appears to be a notice by the Food and Drug Administration in the Federal Register dated November 18, 1994, pertaining to a citizen petition regarding the Food and Drug Administration's policy on promotion of unapproved uses of approved drugs and devices, request for comments.

A. I see that.

Q. Did I -- did I describe the document correctly?

A. I've not read the entire document. But that section that you read was read correctly.

Q. Okay. Going on to the second page. It's a highlighted portion. I will represent any highlights in the document were done by me. And

there are no other alterations to the document.

The highlighted portion reads: Over a decade ago, the FDA Drug Bulletin informed the medical community that once a drug product has been approved for marketing, a physician may prescribe it for uses or in treatment regimens of patient populations that are not included in approved labeling.

The publication further stated unapproved, or more precisely unlabeled uses may be appropriate and rational in certain circumstances and may, in fact, reflect approaches to the drug therapy that have been extensively reported in medical literature. Valid new uses of drugs already on the market are often first discovered through serendipitous observations and therapeutic innovations, subsequently confirmed by well-planned and executed clinical investigations.

Did I read that correctly?

A. You did, indeed.

Q. Your report doesn't acknowledge that the long-standing position of the FDA has -- with regards to off-label use of drugs?

MR. KNEPPER: Objection, form.

A. I would say that this paragraph that you

read does not directly apply for the reason for my consideration of this use of GnRH agonist in pubertal adolescence for gender dysphoria is the same. And it's important to note in this paragraph, it says the word "may." It doesn't guarantee that it is. And it reflects the nature of the application that one is providing.

(Whereupon Exhibit 15 was introduced for identification.)

Q. (By Mr. Gonzalez-Pagan) Introducing what has been marked as Exhibit 15. Noted below, the creator of the document is a printout of a web page from the Food and Drug Administration's website. It is titled Understanding and Approved Use of Approved Drugs Off-Label.

Did I read the title of this web page correctly?

A. Yes, you did.

Q. Okay. Moving on to the second page, there's a highlighted portion. I will stipulate for the record that any highlights in this document were inserted by me and that there are no other alterations to the document.

The highlighted portion of the document states: From the FDA perspective, once the

FDA approves a drug, healthcare providers generally may prescribe the drug for an unapproved use when they judge that it is medically appropriate for their patient?

Did I read that correctly?

A. You indeed read it correctly.

Q. Before opining as to whether the use of off-label puberty blockers should be considered unethical, did you review the positions of the FDA with regards to off-label use?

A. Again, I'm very, very familiar with that. Maybe perhaps not these specific documents, but I -- this is entirely consistent with my understanding of the off-label use of drugs.

(Whereupon Exhibit 16 was introduced for identification.)

Q. (By Mr. Gonzalez-Pagan) Showing you what's been marked as Exhibit 16. I'll represent this is a guidance for institutional review board for clinical investigators published by the Food and Drug Administration dated January 1998. It is titled Off-Label, an Investigational Use of Marketed Drugs, Biologics and Medical Devices.

Did I represent the document correctly?

A. You correctly read the title of this document.

Q. There is a highlighted portion in the first page of the exhibit. I'll represent that all the highlights were added by me to that exhibit. And there are no other alterations to the document.

The highlighted statement reads: If physicians use a product for an indication not in the approved labeling, they have the responsibility to be well-informed about the product, to base its use on firm scientific rationale and on sound medical evidence, and to maintain records of the product's use and effects. Use of the marketed product in this manner when the intent is the practice of medicine does not require the submission of an Investigational New Drug Application, Investigational Device Exception or review by an Institutional Review Board.

Did I read that correctly?

A. You read that section correctly.

Q. Do you acknowledge this guidance of the FDA in your report?

A. You mean the statement that I made about the ethics of prescribing the medication and the need does not require that, but it does not mean

that it's not the approach that should be done. So that one -- for example, it's not malpractice and one's not going to lose their license by prescribing a medication off-label in this manner.

However, when we look at the use of this -- the GnRH agonist with a reference that I made to the FDA off-label use involves product use that is not the same as what it is used in the treatment of prepubertal children and the risks require -- and because of the risks of the intervention and the lack of knowledge, it's very different than many of the other times that I myself have used off-labeled use of medications.

So the statement itself is accurate. It is consistent with my understanding of the FDA guidelines for that. And I think my statement in my declaration fully reflects the reason why it is of ethical concern in this case.

(Whereupon Exhibit 17 was introduced for identification.)

Q. (By Mr. Gonzalez-Pagan) Showing you what's been marked as Exhibit 17. Are you familiar with the American Academy of Pediatrics?

A. I was a member of the American Academy of Pediatrics for over 20 years.

Q. This is a policy statement by that organization titled Off-Label Use of Drugs in Children; is that right?

A. That is the title of the statement, yes.

Q. I'll represent that there are highlights within this document. Those highlights have been added by me. And there are no other alterations in the document.

On the abstract in the highlighted portion, it states: However, off-label drug use remains an important public health issue for infants, children and adolescents, because an overwhelming number of drugs still have no information in the labeling for use in pediatrics. The purpose of off-label use is to benefit the individual patient. Practitioners use their professional judgment to determine these uses. As such, the term "off-label" does not imply an improper, illegal, contraindicated or investigational use. Therapeutic decision-making must always rely on best available evidence, the importance of the benefit for the individual patient.

Did I read that correctly?

A. You read it correctly. And I would

comment that the very last sentence is at the heart of my concern about how it's -- GnRH agonists are being used in the setting of gender dysphoria.

Q. So is your critique that the use of GnRH analogues [sic] for the treatment of gender dysphoria is unethical because it's not the best available evidence in your opinion?

A. There are many layers to the question. I would say that many of the people that are prescribing these drugs are not even aware of the emerging evidence that is coming forward about lack of efficacy and the risks of these medications. They're relying on their decision based upon statements made by many of the organizations that you mentioned earlier that -- that are not considering the relative risk-benefit analysis. And so a provider, unless they've had the opportunity like myself and others who have been familiar with the literature, are going to be misled with the assumption that this is the available evidence, supports its use.

Q. Well --

A. Many of the people that are prescribing these medications have not read those papers, not considered those papers, not considered the poor

Q. (By Mr. Gonzalez-Pagan) Dr. Hruz, how did you first come to be an expert in transgender litigation?

A. Well, I think it was a recognition of my knowledge of the -- of the subject area and -- that I had in a number of different settings including the grand rounds talks that I said previously and some of the things that I've been discussing for the last -- since almost ten years now.

Q. Do you know what the Alliance Defending Freedom is?

A. Yes.

Q. Have you met with staff from the Alliance Defending Freedom in order to discuss how to serve as an expert in cases involving transgender issues?

A. My involvement was mostly to tap into my knowledge and expertise in this area, to inform that organization of some of the relevant issues. I've never been coached on how to be an expert witness, nor have I necessarily been encouraged in any way. These requests have generally come from the litigating lawyers, how they received my name or to what extent and in what ways they became familiar with my knowledge and expertise in this area is not known to me.

Just like the other groups that I've spoken to, I've been more than willing to be -- to share the knowledge that I've accumulated over this last decade in this area.

Q. Did you attend a meeting at the Alliance Defending Freedom offices in Arizona in 2017?

A. I don't recall the exact date, but I did travel to Arizona to meet with other individuals that also had unique areas of expertise in the area, yes.

Q. Just to clarify, was that one or two meetings?

A. I think I've had two separate meetings. The first was much shorter. And the second one was much more of presentations with actual data.

Q. What was discussed in that first meeting?

A. Again, it was many years ago. But my recollection was just to understand what was going on. It was -- it was the same types of questions about the care that is being proposed and offered. But it was much less defined, I think, at that point in time. It was more of an informal type of meeting.

Q. Who was in attendance at that first meeting?

A. I suspected you were going to ask me. And, you know, honestly I don't remember the exact composition of the people that were there. If you happen to know, I can acknowledge or deny whether they were there or not. But I've met literally hundreds of people over the last ten years in various settings. I do know that at that first meeting, Allan Josephson was there. And I believe that Mark Ramirez was there as well.

Q. Was Jeff Shafer there?

A. Yes. He actually at that time was working for ADF.

Q. Was Gary McCaleb there?

A. Yes. And he was one of the first contacts I had from that group.

Q. When they invited you to this meeting, what was the invitation, what did they tell you it was going to be about?

A. They had desired to convene a group of people that had knowledge in this area and to be able to discuss that, is my recollection at that point in time.

Q. Was Ryan Anderson there?

A. He was at one of the meetings, the two meetings, I'm not sure which -- which one.

Q. About how many people were in that first meeting?

A. Probably about eight to ten if you include Jeff Shafer and Gary McCaleb. You know, no more than a dozen, probably less than that.

Q. And the second meeting, you indicated that it involved some presentations; is that right?

A. That's correct.

Q. Was it also in Arizona?

A. Yes.

Q. Who was present at the second meeting?

A. Similar to the first meeting. And, again, I may get mixed up, the first and second meetings. There were different people that were present. I know that Walt Heyer was at one of the meetings. Oxy Horvath was at one of the meetings as well. You'd have to give me the other names if there was any. I'm drawing a blank. It was a while ago.

Q. Was Mark Regnerus at the second meeting?

THE COURT REPORTER: I'm sorry. What was that name?

A. He was only at --

MR. GONZALEZ-PAGAN: Mark Regnerus, R-E-G-N-E-R-U-S.

A. I believe he was at one of the meetings.

I'm not sure which one.

Q. (By Mr. Gonzalez-Pagan) Was Patrick Lappert at one of these meetings?

A. He would have been likely at the second meeting.

Q. Was Paul McHugh at any of those meetings?

A. No.

Q. Was Michelle Cortella at any of these meetings?

A. I've encountered Michelle at a number of different settings. I'm trying to think back. I honestly -- I just can't remember. She may have been at one of them.

Q. Was Quinton Van Meter at any of these meetings?

A. I have met with him. I'm just trying to think of what the circumstances and when he was there. Again, you know, I've met so many people over many different years in many different venues. It's challenging for me to remember who was in what meeting.

Q. Did the ADF lawyers discuss the need to develop expert witnesses for litigation?

A. Again since it was several years ago, I'm trying to remember the exact content. I think the

main focus was -- was understanding what was going on to be able to understand from multiple different perspectives. One of the most helpful outcomes for myself was the opportunity to talk to the transitioners. These are adults that have had the experience of going through the affirmation approach only to discover eight to ten years after that, that it did not solve their problems.

It was similar to my efforts to connect with parents and -- that were experiencing this with their children as part of my understanding of the unique circumstances facing these individuals. That's what I walked away with more than anything else. Whether there was discussions about, you know, whether there were -- were litigation going on is -- I just don't recall.

Q. Were you aware that the Alliance Defending Freedom is a religious organization?

A. I think that's -- if you travel to their headquarters, that's hard to miss.

Q. Let's go back to your report, Exhibit 1. On the third page, Paragraph 7.

A. We're on my expert report. Okay.

Q. Page 3, Paragraph 7.

A. Thank you. I'm going to go to my clean

copy that I have printed out. Okay.

Q. Okay. It is mentioned that you also spoken with parents of children experiencing gender dysphoria and earlier you mentioned that you had spoken with Eli Coleman; is that right?

A. That is correct.

Q. And Eli Coleman is one the authors of the WPATH standards of the care; is that correct?

A. He's one of the lead authors, correct.

Q. In Paragraph 7 you state that you have met individually and consulted with several pediatric endocrinologists including Dr. Norman Spack, who had developed and led transgender programs in the United States; is that right?

A. That is correct.

Q. Who's Norman Spack?

A. Norman Spack was from Harvard. He was actually probably the first person to introduce the Dutch model of care to the United States. In the latter years of his career, he became a very outspoken advocate for that approach. In fact, Dr. Spack was invited to Washington University very early on when the question was being proposed to start the gender center at Washington University.

Q. And you discussed the treatment of gender

dysphoria and transgender people with Dr. Spack?

A. That's correct.

(Whereupon Exhibit 19 was introduced for identification.)

Q. (By Mr. Gonzalez-Pagan) Showing you what's been marked as Exhibit 19.

A. So this is the declaration for Norm Spack for the Drew Adams case, correct?

Q. That's correct, yes. Have you seen this document before?

A. I've heard of it. I believe I saw that during the -- my involvement in the Adams case.

Q. He mentions that on or about October 19, 2014 -- sorry. On Paragraph 8 of the declaration on Page 2, he mentions that on or about October 9, 2014, he gave a presentation at St. Louis Children's Hospital regarding the foundation of GeMS, the workings of a gender management program at a pediatric hospital, and in medical treatment and care of gender and nonconforming and transgender children and adolescents; is that right?

A. Other than the word "gender" is misspelled, yes.

Q. It goes on to say on Paragraph 9 on the next page that following the presentation, he met

privately with medical staff including endocrinologists at St. Louis Children's Hospital to answer their questions and share his knowledge and experience.

He then goes on to say that he also in that context met privately with you at St. Louis Children's Hospital when you approached him after the presentation.

Do you recall that?

A. I recall the meeting both with the faculty -- I don't specifically remember the private meeting afterwards. I do remember we had kind of a round table. We actually sat around a circle with other colleagues of mine and addressed questions. But I -- it certainly would be in agreement with where I was at that point in time in an understanding for the proposal for care involving affirmation.

Q. He goes on say that during his meeting with you, you directly expressed that you had, quote, a significant problem with the entire issue, closed quote, and, quote, whole idea of transgender, closed quote. He then states that you followed up these comments by stating, quote, for me it is a matter of my faith, closed quote.

Do you recall making these statements to Dr. Spack?

A. I do not.

Q. Do you deny making these statements to Dr. Spack?

A. I do not recall making those statements. And it really seems to be -- I'm not sure of the context of the conversation, where that came from. This was a time shortly after our institution was considering the adoption of the affirmative care model for starting their gender center. And very clearly at that point in time, I was very early in investigating the literature and I remember talking with my colleagues at that very same time about the questions that I had about the science, about some of the statements that were being made.

One of the questions that came up related to some of the assertions about more in the area of anthropology as far as a human being and whether it was possible for one to change one's sex. I recall that at that point in time, you know, the people were just starting to make the comments like in one of the other cases where Dr. Atkins would make the statements gender is sex. And I certainly challenged those assertions at that time.

So this is a period of discovery for me. And for me to make a definitive statement like that is not really even logical from where I was at that point in time.

Q. Are you familiar with the St. John Paul, II, Bioethics Center?

A. Yes.

Q. Is St. John Paul, II, Bioethics Center a religiously affiliated institution?

A. I believe it is, yes.

Q. Did you speak at the St. John Paul, II, Bioethics Center in November of 2017?

A. I'm not sure of the exact date. But I did deliver a talk to that group.

Q. During that talk, did you not state about being transgender that, quote, in fact, probably goes back to some of the early heresies in the church, closed quote?

MR. KNEPPER: Objection, form, scope.

A. You know, I'd have to see the context of when that statement was made and how it was being portrayed to that audience, whether it was in response to a question with context that is not included in your question.

Again, as you mentioned, this was a