Jane Doe

vs.

Joseph Ladapo

Taped Transcription

October 28, 2022

Doe Pls' Trial Ex.
24

JANE DOE,

Plaintiff,

vs.

JOSEPH LADAPO,

Defendant.

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CASE NO. 423CV114RHMAF

TRANSCRIPTION OF AUDIO RECORDING

FLORIDA BOARDS OF MEDICINE AND OSTEOPATHIC MEDICINE

JOINT RULES/LEGISLATIVE COMMITTEE RULE WORKSHOP

OCTOBER 28, 2022

TRANSCRIBED AUDIO RECORDING BY:

Julie Thompson, CET

Job No.: 322529

Thereupon,
The following proceeding was transcribed from an audio recording:

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CHAIRMAN ZACHARIAH: The Board of Medicine and -- let's call the meeting to order. The Florida Board of Medicine and Osteopathic Medicine Joint Rules and Legislative Committee Rule Workshop. Let the record reflect that the time now is 8:09. At this time, let's have the roll call.

MS. STRICKLAND: Thank you. Dr. Zachariah is present.

CHAIRMAN ZACHARIAH: Yes.

MS. STRICKLAND: Ms. Garcia has been excused.

Dr. Diamond.

DR. DIAMOND: Present.

MS. STRICKAND: Dr. Ackerman.

DR. ACKERMAN: Present.

MS. STRICKLAND: Dr. Barsoum and Dr. Cairns have been excused.

Dr. Derick.

DR. DERICK: Present.

MS. STRICKLAND: Dr. Di Pietro.

DR. DI PIETRO: Present.

MS. STRICKLAND: Dr. Gadea has been excused.

Dr. Hunter.

DR. HUNTER: Present.

MS. STRICKLAND: Ms. Justice has not arrived yet.

Dr. Pages.

MS. STRICKLAND: Mr. Romanello.

MR. ROMANELLO: Here.

MS. STRICKLAND: Dr. Schwemmer.

DR. SCHWIMMER: Present.

MS. STRICKLAND: Okay. Also present are staff, Janet Hartman, bureau chief; John Wilson, general counsel; Paul Vazquez, Executive Director Board of Medicine; Danielle Tarrell, Executive Director Board of Osteopathic Medicine; Ed Tellechea, board counsel, Donna McNulty, board counsel; myself, Cherise Strickland, program operations administrator; Carol Taylor, program operations administrator; Ms. Shaila Washington, regulatory supervisor; Cyra Williams, regulatory specialist III; and Mr. Derek Nieves, regulatory specialist III.

Chair, you have a quorum.

CHAIRMAN ZACHARIAH: Well, thank you so

much. Before we start, I want to thank -- it's an honor to work with Dr. Sandra Schwemmer, who I've worked with many, many, many moons ago on the Board of Osteopathic Medicine. I'm honored that you're here.

Now, let's have Mr. Paul Vazquez give the opening advice. Paul.

EXECUTIVE DIRECTOR VAZQUEZ: Thank you, Dr. Zachariah.

Good morning. It's Friday, October 28, 2022, at 8:11 a.m. My name is Paul Vazquez; I'm the executive director of the Florida Board of Medicine. This is a duly noticed meeting of the boards. This is a public meeting and it's being recorded. The audio will be available on the boards' websites next week.

I'll now go over some instructions, so this meeting will be successful, and the board members will be able to take care of the matters that are before them today. There is a court reporter in the meeting. If you speak to the committee, it's important that you state your name for the record. When appropriate, the chair will ask for public comments. Therefore, please refrain from speaking during the meeting until the appointed time.

Please remember this is a public meeting and is being recorded. Any side conversations may be recorded and become part of the public record. At this time, please silence all electronic devices.

The Board of Medicine invites and encourages all interested parties to provide comment on matters before the board. The following guidelines will apply to public comments: interested parties will be given an opportunity to provide comment on matters before the board after an agenda item is introduced. Interested parties may provide comments on the record during the meeting, or they can waive speaking and indicate their position on the issue, which will also become part of the record. Appearance forms have been provided to facilitate this process.

Interested parties will be limited to three minutes to provide comment which may only be extended by the chair if time permits based on the number of proposed speakers. If an interested party is part of a larger group of persons, you're requested to identify one individual who will speak on behalf of the group if possible. Interested parties may use pseudonyms if they do not wish to identify themselves on the record.

The Boards of Medicine and Osteopathic Medicine are apolitical bodies that have the primary mission of protecting the people of the state of Florida. As with any issue before the boards, this committee intends to look at the available science and appropriate standard of care while putting aside any personal feelings on the issues before it today.

In terms of how the meeting will be conducted, the committee's expectation is that we will have a civil discourse while discussing the issues on today's agenda. We require that everyone refrain from making any disruptive comments or taking any disruptive actions during the duration of the meeting. The committee reserves the right to remove any individual who chooses to disrupt the progress of the meeting. Please conduct yourselves accordingly.

This meeting will end no later than 1:00 p.m. Public comment will last no longer than two hours in total, and may last significantly less than that depending on the progress of the meeting. The public comment process will be as equitable as possible. However, it is evident that not everyone who wishes to speak will be able to speak given the time constraints of the meeting.

As stated in the public notice of this meeting, there is an email address set up to receive written statements from the public. That email address is BOMpubliccomment@FLhealth.gov. The email address will be active for 24 hours following the end of this meeting. All comments received are public comments and will become part of the rulemaking record.

The agenda for the meeting has been published. We will begin with a discussion with subject matter experts who will make presentations, and then there will be a period of time for questions and answers and discussion with the committee. That will be followed by discussion and development of rule language. A public comment section will follow, and closing remarks and administrative matters will follow the public comment portion of the meeting and followed by adjournment. Just so everyone is aware, there will be administrative matters that will have to happen after public comments, before the 1 o'clock deadline.

Subject matter experts present today are Michael Biggs -- Dr. Michael Biggs, Dr. Kristin Dayton, Dr. Aron Janssen, Dr. Riittakertu,

Dr. Michael Laidlaw, and Dr. Meredith McNamara. And we thank them for being willing to participate in this important endeavor of the boards.

Dr. Zachariah.

CHAIRMAN ZACHARIAH: Well, thank you so much. At this time, can we ask Dr. Michael Biggs to come forward and make his presentation. Dr. Biggs.

DR. BIGGS: Thank you. So I'm a sociologist at the University of Oxford where the students urged me to educate myself on transgender children. I read the literature on gender medicine. I was surprised by the poor quality of published research and very disturbed by the absence of literature. There are huge gaps in that literature.

One example, the world's largest pediatric gender clinic in London started research on puberty blockers in 2010. I discovered in 2018 that the results had been suppressed and I did a campaign to force the clinic to publish those results. I've now published my original research in journals like Archives of Sexual Behavior, Journal of Sex and Marital Therapy, and the Journal of Pediatric Endocrinology and Metabolism.

As time is limited, I'm going to focus on one intervention, the children experiencing gender

dysphoria, and that is puberty suppression. Full documentation is available in my written documentation -- written submission to the board.

So puberty blockers are a class of drugs (indiscernible), such as Lupron. These GnRHa drugs stop the production of sex hormones. For males, these drugs achieve chemical castration. The drugs are licensed for a few medical conditions, such as prostate cancer in men, and precocious puberty in children. They have never been licensed to treat gender dysphoria, not in the United States, not in the United Kingdom, nor any other country in the world.

Puberty suppression is intended for juvenile transsexuals, and that is the phrase that is in the title of the article that was first published advocating their use published in 1996. So keep that phrase in mind, juvenile transsexuals.

GnRHa drugs can be administered from Tanner Stage 2, which is the beginning of puberty. So in Britian, the youngest child to have been given this intervention was nine years old.

Advocates for puberty blockers claim that this is analogous to treating precocious puberty. For example, when a girl of five starts developing

breasts. But that treatment for precocious puberty involves delaying a puberty that arrives abnormally early, so the child can undergo puberty at the normal age. By contrast, puberty suppression for gender dysphoria is now stopping normal puberty in order to prepare the child to take cross-sex hormones for the rest of their life.

About 96 percent to 98 percent of children who start on puberty blockers continue to cross-sex hormones. Usually around the age of 16, or the ages going down 15 and 14 more recently.

The only plausible scientific evidence favoring this intervention comes from a longitudinal study of an early cohort of 70 teenagers. De Vries et al., in 2014 published outcomes shortly after surgery when the patients were in their early 20s. Several psychological measures showed improvement, but these measures were taken for only a small subset of the patients as there was 32 individuals.

Gender dysphoria also appeared to decline, but the latter finding on gender dysphoria was likely an artifact of the measures of gender dysphoria being switched halfway through the research study. De Vries et al., acknowledged that one patient was killed by necrotizing fasciitis

during vaginoplasty. Out of 70 patients, that's a death rate exceeding 1 percent. Remarkably high for a group of teenagers. De Vries et al. didn't mention that the death was actually a consequence of puberty suppression, as I'll explain in a moment.

The Dutch researchers have recently followed up this patient cohort of 70 people, but they have not published the result, so the long outcomes are still unknown.

The only attempt to replicate the Dutch study came from the gender clinic in London, which you might know as the Tavistock. They administer GnRHa drugs to 44 teenagers. Because the results of puberty suppression were not positive, the researchers decided not to publish them. I led a campaign to force them to publish, which took a couple of years and a high court decision in the (indiscernible) Bell case. Eventually, the clinic admitted that puberty suppression did not improve the psychological function of teenagers and did not reduce their gender dysphoria.

There is now a handful of American longitudinal studies more recent which are much worse in quality. Instead of replicating the methods pioneered by the Dutch and repeated by the

British, each research team used a different set of psychological measures, they have tiny samples, they have high rates or attrition which is never explained, and they use dubious statistical methods.

So what then do we know about puberty blockers? Well, it's certainly true that early puberty suppression produces a closer resemblance to the opposite sex. Patients are more likely to pass superficially. However, this benefit must be weighed against several serious costs.

There are some known costs. So for males, early puberty suppression makes subsequent genital surgery more risky and less satisfactory. The penis is so undeveloped that a normal vaginoplasty is usually impossible, and then so instead a portion of the patient's intestine has to be used. Leakage from the intestines after surgery is what killed the early Dutch patient at the age of 18. So that patient died as an indirect consequence of puberty suppression.

Second, puberty suppression hinders the normal accumulation of bone mass. Up to one-third of teenagers who take GnRHa for two years end up with abnormally low bone density which puts them at risk of osteoporosis in later life. Frieden

(phonetic) drastically could tell the use of puberty suppression because one of their patients developed severe osteoporosis at the age of 15 years old.

More serious are the costs that are unknown. So we have fragmentary evidence, but all the evidence points that in fact early puberty suppression followed by cross-sex hormones prevents the development of normal sexual functioning. There will be no libido and no capacity to orgasm. What's astonishing is that clinicians who prescribe puberty blockers haven't bothered to study their effect on sexuality. So the lead Dutch researcher, de Vries, recently said that orgasm was an interesting but not so far studied question, and that's after her clinic had been using this intervention for 25 years.

Finally, the most serious unknown consequence is their affect on emotional and cognitive development, which is particularly important given of course we're concerned about the capacity to consent to further interventions.

So a recent randomized control trial on mice showed the GnRHa drugs cause males to manifest high levels of stress, females to display increased anxiety and despair like behavior. Again, it's remarkable that researchers have never studied the

effect of puberty suppression on measures like, for example, acute.

Given the accumulating negative evidence and the continuing failure of clinicians to collect pertinent data, the English National Health Service just last week released a draft specification for gender services. In a complete reversal of existing policy, "it will only commission GnRHa in the context of a formal research protocol."

I recommend that the Florida Board of Medicine should adopt the same policy. Puberty suppression should be offered only in a proper randomized controlled trial. Obviously, it can't be blind. And most randomized control trials aren't blind. But with a treatment -- so with a treatment group and a control group. Any trial must ensure that follow up continues into adulthood and must guarantee to publish all clinical data. Thank you.

CHAIRMAN ZACHARIAH: Does the board members have any questions for the doctor?

Go ahead, Dave.

DR. DIAMOND: Dr. Biggs, thank you so much for being with us this morning. I have a question for you --

DR. BIGGS: I'm finding it very difficult

to hear your one --

DR. DIAMOND: Can you hear me now? Is that better? Is that better, Dr. Biggs? Can you hear me?

DR. BIGGS: Sort of. Yeah. Go ahead.

DR. DIAMOND: Okay. Could you please elaborate a little bit more on the last item that you mentioned, that last week the National Health Service issued a directive regarding a formal research protocol for the use of GHRH agonist, and could you tell us a little bit more about what that protocol involves?

DR. BIGGS: I'm afraid I can't because that's still under -- there's no further details that's been released by the NHS.

DR. DIAMOND: Okay. Because I was not aware of that; so this is breaking news. I would be very curious to know what the details of that protocol might be.

DR. BIGGS: Yes. I can send you the link. That wasn't in my documentation -- in my submission because it came so recently. I'll send you the link right away. But essentially, what they are -- this draft specification -- I should emphasize it's only a draft so far, but it just says that the emphasis

has got to be on psychological care, helping children to reconcile with their own body and their own social circumstances, and that GnRHa will only be offered in the case of a clinical trial. So that's as much as we know.

DR. DIAMOND: Thank you.

CHAIRMAN ZACHARIAH: Any other board members?

Yes, Dr. Hunter.

DR. HUNTER: I can clarify what the NHS guidance is because I have it with me. This is quoting from them. "Because of the uncertainties surrounding the use of hormone treatments, NHS England is in the process of forming proposals for prospectively enrolling children and young people into formal research program with adequate follow up into adulthood. NHS England will only commission GNRH analogs in the context of a formal research protocol. This research protocol" --

Dr. Diamond, and this addresses your questions.

-- "this research protocol will set out eligibility criteria for participation." They're still creating their criteria in their research.

DR. DIAMOND: Thank you, Dr. Hunter.

CHAIRMAN ZACHARIAH: Any other board members?

If not, Dr. Biggs, thank you so much for addressing -- taking time off from your busy schedule and talking to us. I really appreciate that.

Next is Dr. Kristin Dayton.

DR. DAYTON: Yes. Good morning, Board of Medicine and Board of Osteopathic Medicine members. Thank you for inviting me to be a part of this discussion on the development of practice standards for the treatment of gender dysphoria in Florida. Please note that my --

CHAIRMAN ZACHARIAH: Dr. Dayton, hold on one second.

UNIDENTIFIED SPEAKER: Mr. Chair, can we ask staff to maybe tweak the volume, so that we can better hear?

DR. DAYTON: Do you need me to speak more loudly?

CHAIRMAN ZACHARIAH: Let's ask our audio/visual people if there's something they can do to make the sound system better.

DR. DAYTON: I'm sorry, I'm having a very difficult time understanding you. I can try and

speak more loudly if that would help.

UNIDENTIFIED SPEAKER: Yes, that would help. Speak louder.

DR. DAYTON: Yes, absolutely. Good morning, Board of Medicine and Board of Osteopathic Medicine members. Thank you for inviting me to be a part of the discussion on the development of practice standards for the treatment of gender dysphoria in Florida. Please note my testimony reflects my own personal judgment and is not the official position of my employer.

My name is Dr. Kristin Dayton, and I am a board-certified pediatrician, a board-certified pediatric endocrinologist, and a member of the Florida chapter of the American Academy of Pediatrics, which represents more than 2600 pediatricians across our state.

I received my medical degree from Wake Forest University and completed pediatric residency and a pediatric endocrinology fellowship at the University of Florida Shands Children's Hospital. I am the medical director of the University of Florida's Shands Children's Hospital Youth Transgender Program. I am an assistant professor for the Division of Endocrinology Department of

Pediatrics at (indiscernible).

Today, as the practice standards for gender-affirming care are considered, I will speak about my expertise and knowledge on the standards of care for the use of pubertal suppression and (indiscernible) therapy.

UFC's gender program launched in 2016 and I have been involved as a clinician in that program since its inception. Our program serves transgender and gender diverse children and adolescents from throughout Florida and provides education to youth and their families about gender identity development, gender nonconformity, psychosocial support, and (indiscernible) medical affirmation.

The program's multidisciplinary team, which includes two board certified pediatric endocrinologists, one board certified pediatrician, a psychologist, a psychiatrist, two patient advocates, and a medical-legal partnership, provides developmentally appropriate, evidence-based gender-affirming care to children, adolescents, and young adults diagnosed with gender dysphoria and their families in a safe, inclusive environment.

Gender-affirming care interventions fall along a continuum and the risks and benefits of

potential interventions are discussed in an open, respectful manner with each patient and family with no end goal in mind other than providing the best care for each individual patient. The program utilizes national and internationally recognized standards of care developed by the World Professional Association for Transgender Health, and the Endocrine Society.

I have years of clinical experience in this area and have cared for over 300 patients during this time. And my recommendations are based on evidence-based standards combined with practices gleaned from my experience in this area. My primary goal as a physician is to provide clinical care, and I have the most clinical experience of anyone in this room in providing evidence-based hormonal care for youth and young adults with gender dysphoria.

I was initially drawn to working at this clinic after experiencing the joy it brought to people's lives to be affirmed and respected for who they are. Throughout my time with this clinic, I have seen the struggles that our patients face but I also have witnessed them (indiscernible) when they are able to be affirmed.

I always think of one of our patients who

would hide their face every day in online classes during the COVID pandemic, since he did not feel that how he looked on the outside matched how he felt on the inside. Fast forward two years later with the addition of testosterone therapy, as well as affirming mental health support, he is happily back to in person school and is considered the class clown.

Our patients report reduced suicidal ideation and improved satisfaction with their life after being able to access gender-affirming hormone therapy. Parents talk about how their children interact more at home and are finally more themselves after years of being closed off to the world.

Children and adolescents with gender dysphoria experience challenges such as bullying, discrimination, harassment, and a lack of social acceptance that increase their risk for experiencing depression, anxiety, and other mental health conditions. The high rates of discrimination experienced by transgender youth lead to a greater risk for suicidal ideation and attempts compared to their cis gender peers. A large-scale study of suicidality in adolescents found that up to 51

percent of transgender adolescents reported experiencing suicidal behavior, compared to just 10 to 18 precent of their cis gender peers.

In providing medical care for children and adolescents diagnosed with gender dysphoria, a specialized approach is recommended. Gender-affirming care is a model that includes assessments and customized care practices to meet the specific needs of each child or young adult experiencing gender dysphoria. There is no one size fits all model of care, nor are the (indiscernible) every child experiences gender dysphoria the same.

The guidelines and standards for gender-affirming care are set based on scientific data and evidence and are medical treatments necessary to treat the conditions of gender dysphoria. Gender-affirming care standards are endorsed and recommended by the American Academy of Pediatrics, the Florida chapter of the American Academy of Pediatrics, the American Medical Association, the American College of Obstetricians and Gynecologists, the American College of Physicians, the American Psychiatric Association, the America Psychological Association, the American Academy of Family Physicians, the American Academy of Child and

Adolescent Psychiatry, the Endocrine Society, the Society for Adolescent Health and Medicine, the Pediatric Endocrine Society, the World Professional for Transgender Health or WPATH, and many more organizations committed to providing the best, evidence-based care.

As stated previously, evidence-based standards of gender-affirming care recommend that each child and adolescent diagnosed with gender dysphoria is provided an individualized treatment plan that incorporates medical, mental health, and social services to provide care and support to the child or adolescent and their families.

In some cases, pubertal suppression and gender-affirming hormonal therapy are indicated treatments. Adolescents may be prescribed pubertal suppression or other hormone therapy to alleviate the stress that may occur with the development of secondary sex characteristics.

The decision to initiate puberty suppression is not automatic nor is it applied to every patient. Puberty suppression treatment occurs after the child experiences a prolonged and persistent gender dysphoria, and the decision to initiate treatment is made in concert with the

adolescent, their family, and the medical and mental health (indiscernible), after a careful discussion of risks, benefits, and alternatives to treatment.

Strong evidence support pubertal suppression for gender dysphoric adolescents. A study in the well-respected peer reviewed Journal of Adolescent Health examined adolescents who were referred to a gender clinic but had not yet begun undergoing gender-affirming medical care, including pubertal suppression, and adolescents who had already begun receiving gender-affirming care using pubertal suppression with cis gender adolescents.

The researchers found that adolescents with gender dysphoria had worse psychological health compared with their cis gender adolescent peers, and that after receiving pubertal suppression as part of gender-affirming care, the adolescents with gender dysphoria had similar or better psychological health when compared to their cis gender peers.

A study in the high impact Journal of Pediatrics found that transgender adults who wanted and were able to access pubertal suppression as adolescents were less likely to have lifetime suicidal ideation when compared to transgender adults who were not able to access pubertal

suppression as adolescents.

Overall, the studies that have examined the use of pubertal suppression as a component of gender-affirming care demonstrate that the use of these medications is evidence-based. Following the delay of puberty, adolescents may benefit from initiating gender-affirming hormonal therapy. This decision to treat is made with their parents or caregivers and is never made in isolation but is again made in the best interest of the patient at heart and in a team-based approach.

Just like the decision to initiate puberty suppression, the decision to initiate gender-affirming hormone therapy is highly individualized. Gender-affirming hormone therapy clearly lowers the chance that adolescents diagnosed with gender dysphoria will experience depression or suicidality. I'm happy to provide these references, as well.

In summary, children and adolescents diagnosed with gender dysphoria deserve the best evidence-based medical and mental healthcare available. The medical community has endorsed gender-affirming care as an evidence-based treatment for gender dysphoria. By proposing to develop an alternate standard of care for the treatment of

gender dysphoria Florida would ignore the broad consensus from the medical community and the weight of peer reviewed literature.

The role of the Board of Medicine is to ensure that every physician practicing in the state meets requirements for safe practice. To our knowledge, no other (indiscernible) has prohibited their fellow physicians from following evidence-based national and international guidelines.

The Florida Board of Medicine should reject the call for the development of new standards of care for the treatment of gender dysphoria and allow pediatricians, child and adolescent psychiatrists, psychologists, and other physicians and mental health providers to continue to provide gender-affirming care under the existing standards.

I'm happy to take any questions the board may have about the Youth Gender Program, the current standards of care for gender-affirming care, or the evidence supporting gender-affirming care. Additionally, my colleague, Dr. Brittany Bruggeman, who also provides care in our clinic, is present with me today and would be happy to answer any questions the board may have regarding our expertise. Thank you.

CHAIRMAN ZACHARIAH: Okay. Thank you, Dr. Dayton.

Any board members?

Okay. Go ahead, Dr. Hunter.

DR. HUNTER: Dr. Dayton, can you hear me?

DR. DAYTON: Yes, thank you.

DR. HUNTER: Do you all keep data on the patients in your clinic?

DR. DAYTON: The question was do we keep data on the patients in our clinic?

DR. HUNTER: Correct.

DR. DAYTON: We don't have an active registry of our patients currently.

DR. HUNTER: Okay. You had mentioned that one size does not fit all, correct?

DR. DAYTON: Absolutely.

DR. HUNTER: Okay. Can you just, off the top of your head, what percentage of kids who present to your clinic are placed on puberty blockers?

DR. DAYTON: I would say like probably 30 percent.

DR. BRUGGEMAN: Yeah. I would have said 20 to 30.

DR. HUNTER: And what percent --

DR. DAYTON: And there are ways to pull this data, so even though I'm not actively collecting data, we do have some -- you know, we use electronic medical records, and we have some ways that we could pull some more specific answers to your questions, so I'm happy to do so.

DR. HUNTER: And of those, what percent would you guess go on to cross-sex hormones? Dr. Biggs had mentioned, and I think most of the literature shows 96 to 98 percent of kids placed on puberty blockers go on to cross-sex hormones. So do you have a feel, since you don't keep data, what your --

DR. DAYTON: I would agree that the vast majority that start puberty blocking do progress to wanting to receive gender-affirming hormonal care, which would be a testosterone Estradiol, typically.

DR. HUNTER: And then could you just talk about the difference between suicidality and completed suicide?

DR. DAYTON: I think that that would probably be a better question for our mental health experts. But my general impression is that suicidality is a thought and feeling that someone has, and a suicide completion is clearly when

someone has died from suicide.

DR. HUNTER: And do we have data on those regarding children and youth with transgender identification?

DR. DAYTON: I'm sorry, I couldn't understand that.

DR. HUNTER: Do we have any data regarding the true suicidality risk and completed suicide risk?

DR. DAYTON: From our clinic?

DR. HUNTER: From the world, from anywhere.

DR. DAYTON: I think that there have been many studies looking at suicidality on a national and international scale in this population. Typically, these are population-based studies and survey-based studies. So as much as we can trust those types of studies, we do have data on that.

Chairman, I was wondering if we could bring Dr. Biggs back on because I think he has done research on the difference between suicidality and completed suicide.

CHAIRMAN ZACHARIAH: You know, let's finish our presentation and then we can bring him later, because otherwise we'll be out of order too many times.

DR. HUNTER: Okay.

CHAIRMAN ZACHARIAH: I think that --

Dr. Di Pietro.

DR. DI PIETRO: Thank you.

Dr. Dayton, can you hear me?

DR. DAYTON: Yes, I can.

DR. DI PIETRO: So I want to clarify one thing because I think one thing that you said is extraordinarily important and what I really want to get my point made today on this. Is from your perspective the current guidelines, research, the current perspectives we should all be taking on this is that it's a multidisciplinary team approach. Therefore, the pediatrician, the pediatric endocrinologist, psychiatry, and psychology should all be involved in a team approach when discussing hormone and gender therapy, correct?

DR. DAYTON: I would say this, in specific from the data that I've seen and from the guidelines we have it is in relation to youth that I would make that recommendation. But yes, for transgender youth it is recommended to use that sort of a team-based approach.

DR. DI PIETRO: Yeah. And I think personally, and in looking at most things in

medicine where you're -- and I'll use something as simple as bariatric surgery as an example. Even bariatric surgery transplant recipients all must have a team-based, multidisciplinary approach, because these are very big and important things that we are doing.

And so just as a reference, a patient cannot even get a transplant unless they have been deemed that they have a support system at home, that they're able to follow up on their care. And I think that this is very important, and I think when we're discussing this today, we need to keep in mind that this is really no different. This should be very much a multidisciplinary approach. Thank you.

DR. DAYTON: I would agree, and I would just also want to say that I don't know that those sort of procedures and surgeries have special rules from their boards, from their -- sorry, from like the Board of Medicine. And I think in the same way if we are to trust our doctors in our state, we are following those guidelines in that same way.

CHAIRMAN ZACHARIAH: Yeah, Dr. Hunter.

DR. HUNTER: Dr. Dayton, one more question. You mentioned quite a few studies. I was wondering, you're familiar with the systematic reviews out of

Sweden and out of England, and NICE reviews on puberty blockers, cross-sex hormones, and out of Sweden the SBU evidence review team there. And that they found all of these studies to be of low quality -- very low quality, low certainty of the evidence. I was wondering if you could comment on those reviews from those countries?

DR. DAYTON: Yeah. Thank you. I have familiarized myself with those reviews and I've looked through the base evidence that they are reviewing, and I think that there are also very good studies and there are also reviews saying that there is evidence to do this care. So I actually welcome you guys to listen a little bit more in Dr. McNamara's piece about the types of evidence and reviews and how we can interpret those.

CHAIRMAN ZACHARIAH: Thank you.

Are there any board members, any questions?

If not, Dr. Dayton, thank you so much for taking time away from your work and addressing this group on a very, very important matter. Thank you so much.

Next is Dr. Aron Janssen. Dr. Janssen.

UNIDENTIFIED SPEAKER: Oh, excuse me. I wonder if you could close the microphone in the hall

because that would help hearing the speakers when they speak. It's really difficult to hear because there's a lot of noise from the hall.

CHAIRMAN ZACHARIAH: I don't understand what they said.

UNIDENTIFIED SPEAKER: Can you mute the microphone in the actual room when the speakers are speaking because we're getting a lot of echo and can hear ourselves speaking across the room.

UNIDENTIFIED SPEAKER: I think they're asking all of our microphones to be off.

DR. JANSSEN: If not, no worries. I will plough through. All right. Thank you for allowing me to address the Joint Board of Medicine and Osteopathic Medicine. My name is Aron Janssen, and I am a board-certified child, adolescent, and adult psychiatrist. I'm an expert in the field of mental health and transgender youth.

I received my medical degree from the University of Colorado's School of Medicine, and I completed my residency in psychiatry and fellowship in child and adolescent psychiatry at New York University Langone Medical Center. In 2011 I founded the Gender and Sexuality Service at New York University, a clinical service (indiscernible). My

last (indiscernible) at NYU. That clinic served over 200 families with multiple referrals each week.

I'm currently the vice chair of the Bridge Care Department of Psychiatry and Behavioral Health and chief psychiatrist of the Gender Development Program at Ann and Robert H. Lurie Children's Hospital of Chicago. I am also an associate professor of child adolescent psychiatry at Northwestern University Feinberg School of Medicine. And I maintain a clinical practice in Illinois where I treat patients from Illinois and surrounding states.

I have treated children and adolescents with gender dysphoria for over 10 years. I have treated over 500 children and adolescents with gender dysphoria during my medical career, and approximately 90 percent of the patients in my clinical practice are transgender children and adolescents.

I am the chair of the American Academy of Children and Adolescent Psychiatry Sexual Orientation and Gender Identity Committee and have served on the Transgender Health Committee of the American Psychiatric Association. I'm also a contributing author to the child chapter and adult

mental health chapter of the Eighth Version of the World Professional of Association for Transgender Health Standards of Care, which I'll refer to as the WPATH SOC for the health of trans youth and gender diverse people.

The WPATH SOC first published in 1979 provides clinical guidelines for health professionals based upon the best available science and expert professional consensus after careful and robust discussion, review, and comment that took many years. The WPATH SOC has been recognized and adopted as the prevailing standard of care by the major professional associations of medical and mental health providers in the United States.

In addition, I've read numerous peer reviewed journal articles and chapters in professional textbooks about the treatment of gender dysphoria in children and adolescents. In 2018, I co-edited Affirmative Mental Healthcare for Transgender and Gender Diverse Youth. A clinical casebook which is the first clinical casebook on mental health treatment for children and adolescents with gender dysphoria.

I'm an associate veteran for the Journal of Transgender Health, and an ad hoc reviewer for

Journal of LGBT Health, and for the Journal of the American Academy of Children and Adolescent Psychiatry. Each of these is a peer reviewed medical journal.

I'm actively involved in training other medical and mental health professionals in treating children and adolescents with gender dysphoria. I've conducted trainings for over a thousand medical and mental health providers and have given dozens of public addresses, seminars, and lectures on the treatment of gender dysphoria in children and adolescents.

The widely accepted view of the professional medical community is that gender-affirming care is the appropriate treatment for gender dysphoria, and that, for some adolescents, gender-affirming medical interventions are necessary.

Gender dysphoria is a serious medical condition in which the patient experiences significant distress that can lead to impairment in peer and family relationships, school performance, or other aspects of life. Gender dysphoria is a formal diagnosis under the American Psychiatric Association's Diagnostic and Statistical Manual.

Treatments for gender dysphoria have the same or similar level of evidentiary support as many other well-established treatment protocols in psychiatry, and likely in every discipline of medicine. Treatments is individualized based upon the needs of the child and the family, and other psychosocial considerations, and is decided upon only after discussing possible benefits and risks of both the intervention as well as the possible benefits and risks to not proceed with the intervention.

Appropriate medical care, including mental health services, hormone therapy, and surgical treatment can help alleviate gender dysphoria. Like non-transgender people, transgender people do not have a choice in their gender identity. Every person has a gender identity which is not a personal decision or preference. A transgender boy cannot simply turn off his gender identity like a switch any more than a non-transgender boy or anyone else could.

Increasing research, including perspective cohort studies have pointed to the enduring and innate nature of one's gender identity. Living consistently with one's gender identity is critical

to the health and well-being of any person including transgender people. And efforts to alter one's gender identity to match gender assigned at birth has been proven ineffective and psychologically harmful. There is a reason every major mainstream medical or association in the United States has spoken against conversion efforts, including the American Medical Association, American Psychiatric Association, and others, calling such efforts unhelpful, unethical, and harmful.

The steps that make up a transgender's person transition into better alignment with their gender identity will depend upon that individual's medical and mental health needs. There's no specific step or series of steps a transgender person must undertake to complete their transition.

Typically, transgender people start their transition with a series of steps commonly referred to as a social transition. These steps include changing their name, using different pronouns, wearing clothing, adopting grooming habits typically associated with their gender identity, and using the corresponding sex specific facilities. Making these changes enable transgender folks to being living their lives consistent with their gender identity

and helps ensure that they are treated as such by family, peers, and others in the community.

At the onset of puberty, some transgender young people also start taking puberty delaying medication, known as puberty blockers, to prevent their bodies from developing unwanted and psychologically distressing secondary sex characteristics that conflict with their gender identity.

Delaying any of these treatments when they are indicated will not only exacerbate a young transgender person's gender dysphoria but could also lead to the development or worsening of other co-occurring mental health conditions, including depression, anxiety, and disordered eating. And importantly, in longitudinal research studies, accessing these treatments when appropriate improves gender dysphoria, improves (indiscernible), improves quality of life and reduces depression and anxiety.

Research and clinical experience repeatedly affirm that transition significantly improves the mental and physical health of transgender young people. This is true of each stage of a young person's transition and transition can and often does alleviate co-occurring mental health issues

that transgender young person experience prior to transition. Following transition, transgender young people are often able to see significant improvements in functioning and quality of life.

Mental health professionals use well-established, measurable, and objective criteria to diagnose and treat gender dysphoria. These criteria have been incorporated into the DSM-5 diagnostic criteria and are further honed by the ever-growing body of research.

The standard of care for mental health treatment of gender dysphoria also commonly referred to as the gender-affirming model of treatment, or gender-affirming treatment, requires a careful and thorough assessment of a patient's mental health including co-occurring conditions, history of trauma, substance use, among many other factors.

Therapists practicing consistently within the standard of care will create a space where the patient can explore their gender identity knowing that being transgender and not being transgender are both equally acceptable outcomes.

It is imperative that all individuals, including those with gender dysphoria, receive the optimal medical and mental healthcare they need and

deserve. Denying the provision of such care for Florida residents who meet the requisite medical criteria puts them at risk for significant harm. Further, mischaracterizing the professionally accepted medical guidelines for treating gender dysphoria and the guidelines supporting evidence leads to confusion and a possible delay in needed care.

If not treated or treated improperly, gender dysphoria can result in debilitating anxiety, depression, and self-harm. Further, eliminating access to evidence-based mental healthcare will make it even more difficult to retain and recruit child and adolescent psychiatrists who provide highly specialized medical care to Florida youth, including vulnerable infants, children, adolescents, and transitional aged youth across the state with a variety of symptoms and diagnoses.

Abandoning evidence-based mental healthcare is an overstep into the physician-patient relationship by interfering with the personal medical decisions and individualized treatment plans best left developed between the treating physicians, patients, and families. Again, thank you for the opportunity to address you today and I look forward

to answering any questions you may have.

CHAIRMAN ZACHARIAH: Well, Dr. Janssen, thank you so much.

Board members, any questions?

DR. JANSSEN: The meeting is still muted, so I don't know if you're speaking now.

CHAIRMAN ZACHARIAH: Yes. So Dr. David.

DR. DIAMOND: Dr. Janssen, thank you so much for being with us this morning. Can you hear me?

DR. JANSSEN: It's quiet. So maybe if somebody is in front of the mic can repeat the question, so I can --

DR. DIAMOND: Let's try again. There we go. Dr. Janssen, good morning. Can you hear me, sir?

DR. JANSSEN: I can hear you. Yes.

DR. DIAMOND: Very good. Thank you so much for being with us today. We appreciate it very much. I have a couple questions for you, so that I can better understand your position, and it does not necessarily belie my own. My chief question to you is this. As you well know, our colleagues in Europe were really the leaders in interventions in the treatment of minors with gender dysphoria decades

ago. And as you may know, our colleagues in Europe now have seemed to take a change whereby in England, and Sweden, and Finland, they are now taking a more -- I'm not sure what the correct term is -- a more cautious or conservative approach.

And I'm curious as to what this appears to me to be a paradox whilst our colleagues in Europe are now becoming perhaps more conservative, here in the United States we're taking a different approach. I'm curious to your thoughts on that, sir.

DR. JANSSEN: It's a great question, and you know, I can't speak to what the environment and the entirety of Europe is. But the part that I would emphasize is that the best data that we have, and the best longitudinal data that we have on transgender youth comes primarily out of the Dutch clinic. Dr. Biggs even referred to a lot of the Dutch studies and the Dutch model of care, and that's the prevailing model that most of the American clinics have based their care upon.

There's no effort in the Netherlands to reduce access to care. And similarly, in the adult world, Belgium is really the place where there's the most longitudinal care and the most longitudinal studies around transgender health and transgender

mental health. And similarly, in Belgium, there's been no effort to divert or discern a different standard of care than the one that was put forth by both the Endocrine Society and the World Professional Association for Transgender Health.

DR. DIAMOND: Over the last couple nights, Dr. Janssen, I was reading Dr. Hilary --

DR. JANSSEN: It's muted again.

DR. DIAMOND: Let's try again. Over the last several nights, I had the opportunity to review the interim findings from Dr. Hilary Cass, and I'm sure you know Dr. Cass is a world-recognized authority on this subject and she has been appointed as the chair of the Independent Review of Gender Identity Services for Children and Young People for England's National Health Service. And it's actually very interesting when I read the reports, they're actually very beautifully written. The language is beautiful in terms of the subtly and the nuances of the language.

And in the interim reports of the different items that we're discussing today, really the area that her team has focused on as the most problematic is that of pubertal blockers. And it's remarkable how humble they are in their admission of how little

we know. In other words, Doctor, many folks tell us how confident they are of their opinions but there's concern after concern mentioned.

So for example, in the most recent letter dated July 19, 2022, to Dr. Stewart, the National Director of NHS England, she mentioned how most of the data with the use of GHRH agonist in children were really focused on biologic males who had dysphoria, but she pointed out that this data does not necessarily reflect what we are seeing primarily today which is the later presenting young people, particular biologic females. So I'm just impressed how much more nuanced or perhaps how much more cautious they may be and I'm curious as to your opinion on that.

DR. JANSSEN: Sure. I think it's important to know that there are a lot of ongoing research studies in today's context in the United States. There's an NIH study that's been perspective for the last two years, including four different sites, that includes the proportion of assigned females at birth and assigned males at birth that you are referring to. And there has been data released from those studies that has clearly implicated the value of puberty blockers.

As an example, in one of the cohorts, the kids who had access to puberty blockers and were able to access them appropriately after an evaluation and assessment with that individualized treatment plan in place had diminished depression, anxiety, compared to their transgender peers when accessing gender-affirming hormones. They had a higher quality of life and significant improvements in functioning and body congruence.

So we have this data in the U.S. in the context, in the past decade, in the past several years that we've been following. So I think that that data is there. And I think it's important to know that the folks who are participating in this call today, that it's easy for us to talk about the studies, it's easy for us to talk about the policies, but it's also important just to recognize that the clinical work is very valuable. And the data that we have from our families and our patients who are telling us what is helping, what is working, how this has impacted our lives is also really important to recognize.

DR. DIAMOND: Thank you.

CHAIRMAN ZACHARIAH: Well, thank you, Dr. Janssen.

Next, we have Dr. Kaltiala. I hope I am pronouncing properly. Probably I'm not. Is Dr. Kaltiala here? Hey, Doctor. Thank you so much for coming and we appreciate your time talking to us about this very, very important topic. Thank you. Now you may proceed.

DR. KALTIALA: Good afternoon from my point of view. Good morning to you, dear audience. And I thank you for the opportunity to participate in this important discussion. And I feel a little bit underhand because I seem to be the only one here who is not native English speaker but hopefully, I'll manage.

I'm Ritta Kaltiala. I work in town for a university in Finland in Northern Europe as a professor of adolescent psychiatry and I'm also the chief psychiatrist in Tampere University Hospital Department of Adolescent Psychiatry, where we have one of the two nationally centralized gender identity teams for minors.

They have been seeing gender identity patients since 2011 and I have been participating in the clinical work meeting practically all adolescents who have in Finland ever proceeded to hormonal interventions with gender identity

indication. Because I'm not only seeing all the patients in our unit, but I also see all those patients who have been referred to hormonal treatments in the so-called second opinion visits they need to make to our unit. My research work also nowadays primarily centers around gender identity. I have published extensively since we started to do the gender identity assessment with minors.

In Finland -- and I also have to notice -- observe here that my opinion about the quality of evidence and as well the best interest of minors in this issue is rather different than some of the other opinions we have already heard today.

So in Finland, the regulation is as follows: diagnostic assessment that may result in medical gender reassignment is in Finland centralized by a code of law two of the five university hospitals in the country, and they are considered third level services. The whole population is, by the way, only 5.3 million, so you may wonder why so small numbers, but we are not such a huge nation.

Both of these centers have a unit for adults and another unit for minors. And in these

gender identity teams, mental health teams perform the diagnostic assessment and behavior. Endocrinology team, or hormone (indiscernible) clinic based on the gynecology as appropriate, bear the responsibility for initiating and balancing hormonal interventions. When hormonal interventions have been balanced, this mainly concerns those patients who are cross-sex hormones, the hormonal long-term care, hormonal care is transferred to local services.

Surgeries with gender dysphoria indication are available only for legal adults. This is from age 18 and by referral from the adolescent assessment teams. Genital surgery is centralized to one center in the country.

Legislation level can never give actual practical clinical guidelines, and so national guidelines for treatment were issued 2020 by the COHERE of Finland. It is body under Ministry of Health and Welfare that has the responsibility of outlining what kind of services are available in publicly funded services or reimbursed by national health insurance in Finland.

We also have another system of service guidelines which is by the Scientific Society

(indiscernible), and they give guidelines inline, for example, (indiscernible) parameters. But here we have a bit more official level given guidelines by COHERE of Finland.

And the national guidelines for the treatment of gender dysphoria in children and adolescents define that with children, they only provide possible interventions to associate with difficulties. So it is well known that 80 percent, even up to 85 percent of children who experience gender dysphoria and cross-sex identification feel differently when they reach puberty, after the various phases of puberty. And therefore, any medical interventions are not recommended to prepubertal children.

Also, you cannot make the identity and assessment and kind of prepare for possible medical interventions before the puberty has started because the onset of puberty is such an important phase in the gender identity experience and in consolidation of the gender identity for those who have gender identity issues from childhood.

With adolescents, the first line of treatment of gender dysphoria is exploratory psychotherapy with intervention in local services,

and this has to be provided in the level of care that is otherwise appropriate given that adolescent's possible associated difficulties. If the adolescent is thriving and doing well and does not have any psychiatric treatment needs, then it has to be the primary care level services, such as student health who provides the exploratory intervention. And if the adolescent is experience psychiatric symptoms or mental disorders, then this intervention can be intertwined with the appropriate psychiatric treatment according to their needs.

Appropriate treatment of possible psychiatric comorbidities and management of associated needs, such as for example, (indiscernible) needs or child welfare needs have to be before considering actual gender identity assessment is also included in the guidelines.

If considering medical gender reassignment after the first line interventions appear appropriate and timely, the referral to the nationally centralized gender identity services can be issued. Then the actual gender identity assessment and diagnostics that may result in medical gender reassignment interventions is taking place in the nationally centralized services.

These assessments take place in a multidisciplinary assessment with the young person and their guardians. The professionals who participate this multidisciplinary assessment include children and adolescent psychiatrist, psychologists, social worker, and a psychiatric nurse. And these assessments comprise multiple meetings over a period of 6 to 12 months in practice (indiscernible) and very rarely they can do it in 6 months. And they cover the next -- the following phases, excluding contraindication such as, for example, they nevertheless find that there are (indiscernible) psychiatric comorbidities that warrant treatment more urgently, then the adolescent is first referred to appropriate psychiatric treatments.

The next step is the assessment of gender identity in the context of identity development at large and evaluation of how well the developmental tasks of adolescents are progressing.

And next there will be the assessment of readiness, so they explore the expectations and -- what the expectations of the young person and the family and how realistically they see the possible interventions and outcome of the interventions. And

whether they have the appropriate resources and psychological strength for the possible medical interventions that are not an easy step for an adolescent. And also require appropriate level of mental support and psychological resilience.

And then based on all those previous steps, then follow appropriate (indiscernible) and follow up of the young person. If the young people proceed to hormonal interventions, they remain in our follow up until they have completed the treatments they currently desire.

We first prepare to follow up then until the end of all treatment, but it has turned out that this impractical because many adolescents after initiating hormonal treatments, they do not proceed to surgical interventions, particularly not to genital surgery so quickly that it would be appropriate to keep the follow up in the adolescent mental health team. Therefore, they nowadays discharge the young people from our follow up individually in a (indiscernible) phase of the course of the treatment, and absolutely before it's (indiscernible) and they are transferred to adult services if they further continue going further in treatment.

During the assessment period, a transfer to more appropriate or more timely interventions can take place at any stage of the assessment if they appear -- those needs appear. If medical interventions are initiated based on gender identity indication, then assessed further.

For childhood onset of gender dysphoria that intensifies in puberty, if there are no severe psychiatric comorbidities and there is appropriate development of (indiscernible). And this would be the patient group originally described as the model patients for the support (indiscernible) model of care.

CHAIRMAN ZACHARIAH: Doctor, we are passed the 10-minute mark, so I really appreciate it if you can wrap it up quickly. You have already spent 10 minutes, so I appreciate if you can wrap it up quickly.

DR. KALTIALA: Sorry, I really don't hear but you ask me to be quicker.

CHAIRMAN ZACHARIAH: Yeah.

DR. KALTIALA: So for this, we can offer our analogs to help pubertal development from early stages of puberty and cross-sex hormones from about 16 --

CHAIRMAN ZACHARIAH: Okay. Doctor, you know, thank you so much. Let me have the board members ask any questions of the good doctor.

Yeah, Dr. Hunter?

DR. HUNTER: Dr. Kaltiala, can you hear me?

DR. KALTIALA: Very poorly. I hope that a discussion could be --

DR. HUNTER: Right when you were finishing, you were mentioning that children or youth could not have -- I think, if I understood you correctly, could not have mental health issues at the time of transition. Then we're hearing from Dr. Janssen that transition helps with mental health issues, comorbid mental health issues. Could you clarify what you understand there about the comorbid mental health issues and if transition helps or does not?

DR. KALTIALA: Yes. Mental health comorbidities are often discussed in the light that they would be secondary to gender dysphoria, but actually, they have observed, and I have also published this finding, that many of the adolescents who are referred to our service suffer from long-term mental health issue which are similarly impairing their adolescent development and functional capacities and that have had the onset

well before the onset of gender dysphoria. So that the gender dysphoria has first emerged in the context of severe and functionally impairing mental health problems.

In this case, I think it is not possible to conclude a persistent identity because so severe mental disorders impair the identity development and there are great risks in concluding that gender identity would be so fundamental and stabilized that it would be safe to proceed to hormonal interventions, not to mention surgical interventions based on gender identity. So I consider it of utmost importance and severe psychiatric disorders first be treated into remission.

Very seldom we see patients where you could think that the mental health comorbidities would only be secondary and mild. It is often stated in the literature. There is no basis for such statements. I have also myself reviewed the literature and the evidence for -- because it is often stated that the gender reassignment will also help in the mental health difficulties and the functional impairments. This is not the case. There is no evidence base for such claims.

Literature and the research on the impact

of gender reassignment of mental health is lousy at best and I cannot conclude based on my own reviews and the reviews by COHERE Finland, and also the Cass review and some other experts, that there is evidence to say that mental health difficulties, psychiatric disorders (indiscernible) if an adolescent experiencing gender dysphoria is given gender reassignment, for instance. These are separate problems and if the psychiatric problems seem to be more fundamental, they have to be treated first.

DR. HUNTER: Speaking to what you said at the beginning about you had some other opinions about the evidence in general, could you share about that? Not just the mental health but the overall evidence in general.

DR. KALTIALA: (Indiscernible), you may be wondering why I seem to have a different evidence from the American speakers. Yes, this is an interesting question, but I have myself reviewed the evidence for the impact of medical gender reassignment on the mental health in children and adolescents for a webinar of WPATH and Society of Sexual Medicine. And also, this was presented in the Congress of European Professional Association

for Transgender Health, and also invited to be repeated in the European Society of Pediatric Endocrinology. And this is really my sincere understanding that the evidence is lousy.

Research on the impact of child and adolescent gender reassignment -- medical reassignment in children and adolescents is mainly comprising the one Dutch study which can be criticized because they didn't have a comparable comparison group and it only included some 70 patients and we are now treating tens of thousands of patients all around the world. So 70 patients as the model for treatment for tens of thousands of patients, I find it really lousy. And it is not in the same level as is usually expected for evidence-based medicine in any field of medicine nowadays.

And the other treatment studies after the Dutch study have been even worse. They only have a handful of patients; the follow up times is up to one or two years only; they have been using a variety of instruments; and they mainly have not been able to demonstrate any improvement of mental health or functional capacity -- functional abilities; and they have also not reported who were

the patients who were not included in the study. So there is no basis for critical (indiscernible) what kind of group is the treatment group representative of.

So evidence is lousy in general regarding mental health and adolescent progress and adolescent development in particular. I am convinced in the light of current evidence that there is evidence that modifies secondary sex characteristics, clearly modified secondary sex characteristic. There as almost all of the other claims of their effectiveness is questionable, based on questionable quality studies.

DR. HUNTER: One last question. I understand there's been significant changes in the way Finland does things, Sweden, and the NHS in that -- this is a difficult maybe but why are they making those changes? What's driving that?

DR. KALTIALA: Why?

DR. HUNTER: Why are these changes happening in Europe? That may be too big of a question.

DR. KALTIALA: Oh, why have in Europe going to go more conservative? Because of the observations that the treatment -- the impact of

treatment on the adolescents' mental health functioning and thriving in every way in the society are not that great. So they have been increasing concerns about the assessment -- quality of the assessments and also the impact of the treatments and the miserable results on mental health and functioning.

And therefore -- and also, it's the matter of that the patient mix has changed totally. And the literature based -- also, the Dutch literature was based mainly on patient groups where they had childhood onset gender dysphoria cases in children with male sex. Now we are seeing increasing numbers of adolescent onset cases in young people with female sex. And about this condition, the natural course of this condition and the optimal treatments for these conditions, we know nothing about. There is no literature about what is the natural cause of adolescent onset gender dysphoria.

And therefore, even the literature in favor of the Dutch model of care was modest at its best when we consider optimal patients for the Dutch model of care which I defined earlier. But now we are treating totally different patient mix and there is no evidence what should be the treatment options

for this patient group. Therefore, I personally think that actually hormonal treatments on gender dysphoria indication for children and adolescents should preferably be limited into the context of formal research studies at the moment.

CHAIRMAN ZACHARIAH: Well, thank you Dr. Kaltiala. Let's move on to our next expert. Again, thank you so much, Doctor, for coming all the way from Finland. We really appreciate it.

Now let's have Dr. Michael Laidlaw. Thank you.

DR. LAIDLAW: Can you hear me now?

UNIDENTIFIED SPEAKER: A little bit better.

DR. LAIDLAW: Okay. Thank you, Dr. Zachariah. Thank you, Board, for having me. I have slides.

DR. ACKERMAN: Can you just make him a little bit louder?

DR. LAIDLAW: Is that better?

DR. ACKERMAN: Oh, much. Yeah.

DR. LAIDLAW: Okay. Sorry about that.

Okay. Thank you for having me. I'm Dr. Michael Laidlaw; I'm a board-certified endocrinologist practicing in private practice for the last 16 years in Rockland, California. Trained

at University of Southern California primarily. Did internal medicine residency and a fellowship at that location. I've been studying and publishing in this area for the last five years, including a peer reviewed journal such as Journal of Clinical Endocrinology and Metabolism, and others. I also serve as an expert witness on subject matter in this area on a number of cases. I also have a patient who is a de-transitioner.

So start with some definitions. Some of this has been gone over but the gender identity is an internal feeling of being a boy, or a girl, or some variation. Gender dysphoria is a distress that arises from an incongruence between that identity and the physical body, leading to impairment. I think it's important to note that desistance, or growing out of this condition of children by adulthood is very high, some 50 to 98 percent. And these are studies done primarily on 12 years old and younger.

Now, as an endocrinologist, I treat, for example, diabetes. I want to be sure before I give someone a very powerful hormone like insulin that they in fact have diabetes. I want to test to show that the glucose levels are high, or I could

possibly injure or even kill the person. What about cancer? Before we give any powerful agent such as chemotherapeutics or surgeries, we certainly want to have physical evidence of this problem, such as biopsies or imaging.

Now, the gender affirmative therapy treatment proposed by WPATH and in place with WPATH gives very powerful hormones and surgeries on what basis? Where can we find the gender identity to be certain that these children will not desist by adulthood? Can we use imaging of the brain, or blood tests, genetic testing? Are there other biomarkers to ensure that we are correct? There is no such thing.

Starting with basic -- just go back a bit to basic biology. There are two human sexes, male and female. Males produce sperm, females produce eggs. An embryo is conceived in such a process. When we move on to sexual development and differentiation of the embryo, there are two pathways based on two ductal systems, the wolffian ducts become male associated organs, such a epididymis, seminal vesicles. The malarian ducts develop into fallopian tubes, uterus portion of the vagina.

It's important to note that this bifurcation or splitting down pathways occurs and one cannot switch from one pathway to the other. In other words, the actual ductal systems that produce these are destroyed in the process. And so this process is complete by around 12 weeks of embryologic development.

Moving on to puberty, the next development in sexual maturity occurs during this time. The purpose of puberty is to achieve full adult sexual function and reproductive capacity. It's not optional. One cannot switch from one pathway to another. A testicle cannot be induced to produce eggs and ovaries cannot be induced to produce sperm.

I think it's important to note that around what you see there, Tanner Stage 4 or 3, is when fertility is established. And so blocking puberty at Tanner Stage 2, which is what's advised by Endocrine Society WPATH, will necessarily lead to infertility. Cross-sex hormones given over a prolonged period of time may lead to sterility. And certainly surgeries to remove sex organs will ensure sterility.

The basic problem with this treatment as I see it is what happens when you force a square peg

into a round hole? You end up injuring or destroying the peg in the process.

So what is gender affirmative therapy? There's really four stages. Social transition, puberty blockers, cross-sex hormones, and then surgical modifications.

What do we know about this? The biggest study showing data over 30 years and looking at the entire medical databases of the entire population of Sweden found 324 individuals who had such hormones and surgeries and tracked them out. Here you can see at around -- this is showing survival, and at around 10 years, the bottom two dotted lines show a rapid increase in mortality starting around year 10. And you can see by the end the survival rate is much lower. They also found increased risks of all causes of mortality of three times and in patient psychiatric care. And there was 19 times completed suicide rate compared to the general population.

Dr. Biggs covered puberty blockers very well and I just want to add a couple of things. Here is showing normal pituitary function where you have signals sent out by the pituitary. In this case to tell the testicles to make testosterone, or in the case of females, the ovaries to make

estrogen. What happens when you give puberty blockers? You actually cause a medical condition that endocrinologists would try to treat. It's called hypogonadotropic hypogonadism. This is an iatrogenic injury from this type of treatment. And to emphasize the idea from the guidelines is to stop at Tanner Stage 2 there will be no further pubertal development even when giving cross-sex or opposite sex hormones.

Just quickly, here's a look at bone density, the male and female over time. You can see where there's a rapid increase. Should be a rapid increase in bone density somewhere in the teen years. You can see the red and blue lines rising very quickly, an increase in bone density. Then you can see the flatlining that I've shown which occurs with puberty blockers, which will lead to adulthood lower bone density potential for osteoporosis and fractures.

Moving onto cross-sex hormones or opposite sex hormones. I want to give you an idea of what sort of doses we're talking about. Now, I have here in blue is a normal adult female testosterone range is somewhere from 10 to 50. Conditions that we treat which are called hyperandrogenism, or high

testosterone conditions such as PCOS may have levels from 50 to 150. With endocrine tumors, such as with adrenal carcinoma, for example, you might have much higher, 150 to 1000, which is the red box you see there. And what are they advising in their guidelines for females for transition? Somewhere from 300 to 1000, which is exceedingly high. If you calculate, it's about 6 to 100 times higher than androgynous female testosterone levels.

What are the sorts of problems when giving high dose hormones to males or females? Well, in both you have an increased risk of myocardial fraction and death due to cardiovascular disease. You also have sexual dysfunction and infertility.

Sticking with a female born person who is taking high doses of testosterone, erythrocytosis, or high red blood cell counts. Severe liver disfunction is a possibility. Hypertension. Increased risks of breast/ovarian cancer. Hirsutism or permanent hair growth of the face, chest, abdomen. Permanent deepening of the voice.

How about male bodied persons taking estrogen? There's a five times increased risk of thromboembolism, or deadly blood clots. Gallstones, high triglycerides. Breast cancer risk has been

shown to be increased 46 times above normal. Gynecomastia or abnormal breast tissue growth, which if the person desists is a big problem as far as removal.

I'd like to move on to surgeries. This is a person born as a female who identifies as a trans male. You can see here evidence of the hyperandrogen state with hair growth on abdomen and face. Now, the types of problems you can have with this surgery are significant scarring, 7 to 10 inches. Problems with normal nipple sensation. I think I read a study where one nipple fell off, it did not adhere afterwards. Difficulties with wound healing.

What sort of ages are we talking about here in the United States? You may hear that, well, surgeries aren't done on kids. But here's a study published 2018, JAMA Pediatrics, I believe. You can see age groups. There is a couple of 13-year-olds who had mastectomy. What five 14-year-olds, 15-year-olds, 16-year-olds. Very young ages. It's important to --

CHAIRMAN ZACHARIAH: Dr. Laidlaw, you have already surpassed your 10 minutes.

DR. LAIDLAW: Darn, okay.

CHAIRMAN ZACHARIAH: I appreciate your presence, so if you can wrap it in the next 30 seconds, or 40, I really appreciate it.

DR. LAIDLAW: Sure. Let me just jump to -- I want to emphasize the Endocrine Society guidelines are written in 2017. 9 out of the 10 of these folks were all part of WPATH. WPATH is an activist advocacy organization. In the disclaimer it says very clearly, page 3895 that "They do not establish a standard of care." This is not standard of care. There's already a community standard of care. All of the evidence is of low or very low quality or absent evidence. It's right there in their document.

The WPATH has actually created standards of care eight and has removed all of the age minimums they had. They had 15-year-old for mastectomy, hysterectomy, orchiectomy, 17 years old. They've removed all these ages restrictions against the advice of their own experts. They've also done a very poor job with grading the evidence. They've invalidated it. They have a chapter on how to make men into Unix.

This is an extreme document and presents a grave danger to minors. I would advise

investigating children with autism, depression, anxiety. Help them with their psychological comorbidities, psychotherapy, cognitive behavioral therapy, individual counseling, and family support. Thank you.

CHAIRMAN ZACHARIAH: Thank you, Dr. Laidlaw.

Board members have any questions?

You know, I have one question, Doctor. Not a question, a comment.

DR. LAIDLAW: Yes.

CHAIRMAN ZACHARIAH: You made a very good presentation. From what I understand, the complications, the short-term, the long-term complications I believe are irreversible and significant. Is that what your message was?

DR. LAIDLAW: Yes. I'm making the case that they are -- well, certainly surgery is irreversible. Removing testicles and ovaries is permanent sterilization. Some of these other problems will be permanent. Like being on puberty blockers for a couple of years will cause permanent loss of bone density. There's brain development which occurs under the influence of sex hormones which will be altered permanently. And other such

effects, like I said, hirsutism, changes in voice will be permanent. Yeah. And fertility and such. Sexual dysfunction, also.

CHAIRMAN ZACHARIAH: Thank you.

Board members?

DR. HUNTER: I hear from you that there's a 50 to 90 percent natural desistance rate, and I've seen that in the literature, but then we hear from Dr. Janssen that this identity cannot change. There's a clear conflict there. What are we to believe?

DR. LAIDLAW: Well, you can believe the studies. It's there in black and white. I have it -- I have references to look at. I mean, the reason why they're saying it's a permanent identity is because they're -- a lot of the studies doing now, they kids have already socially transitioned, they're on puberty blockers, which you've heard there's very high rates of kids continuing on to cross-sex hormones. So they're doing the interventions and then they're saying, "Look, they don't desist." But they've already undergone the treatments, so it's not a fair comparison in anyway.

DR. HUNTER: And then we hear that the -- you're saying that the evidence is low quality,

Endocrine Society and their guidelines, say that it's low quality. But then we're hearing that the quality is -- the evidence quality is there. Again, we're hearing conflicting -- what are we to believe?

DR. LAIDLAW: Well, if you look at quality of evidence, we're talking about are there any randomized controlled studies that look at -- let's take a group -- two groups of kids with gender dysphoria. One we give psychological support, the other we give hormones and other therapies, and compare those. Those studies don't exist. Those would be called high quality studies. They don't exist. Even the NIH study that he referenced doesn't do such a thing. So we don't have high quality evidence based on that.

CHAIRMAN ZACHARIAH: Any other board members?

DR. DERICK: I have a question.

CHAIRMAN ZACHARIAH: Dr. Amy.

DR. DERICK: Your slide number 10 on the long-term mortality with using cross-sex hormones, what is the age of the transition of the participants that are being studied? Is it people who have been transitioned as youth or at all times?

DR. LAIDLAW: These -- yeah, here is it.

These are, to my knowledge, all -- well, they're adults, for the most part. Yeah. There is no such long-term study for children. But one would predict, based on what's happening to adults, it would be similar for children or worse.

CHAIRMAN ZACHARIAH: Hearing no other questions from the board, Dr. Laidlaw, thank you so much for coming from California and spending the time with us on such a very important matter.

DR. LAIDLAW: Appreciate it. Thank you.

CHAIRMAN ZACHARIAH: I really appreciate it.

Next is Dr. McNamara.

DR. MCNAMARA: Mr. Chairman and members of the Florida Boards of Medicine and Osteopathic Medicine, thank you all for your invitation to testify today. My testimony addresses the board's proposal to develop draft rule language related to practice standards for the treatment of gender dysphoria. I appreciate the opportunity to furnish the public record with a truthful account of the evidence regarding gender-affirming care. And I'm honored to testify alongside Doctors Dayton and Janssen whose expertise in gender-affirming care, gender dysphoria, and gender expansive identity I

hold in high regard.

Please note that my testimony just reflects my professional judgement. It is not the official position of my employer which is Yale University.

A bit about my qualifications. I'm a board-certified adolescent medicine physician and pediatrician with an MD and a master of science in clinical research from Emory University, and I am an assistant professor at the Yale School of Medicine. I provide clinical care for youth aged 12 to 25, which includes transgender and gender expansive youth.

I join you from Connecticut to address health policy matters in Florida because misinformation about gender-affirming care poses a threat to the wellbeing of youth everywhere, and the use of misinformation to set legal standards will degrade medical authority.

On June 2, 2022, the Florida Agency for Healthcare Administration, the AHCA, issued a purported scientific report, which I'll refer to as the June 2nd report, concluding that standard medical care for gender dysphoria does not meet generally accepted medical standards and is experimental. I'm concerned that the board may rely

on this flawed report in crafting its own standard of care for gender dysphoria.

I'm part of an interdisciplinary cohort of subject matter experts who have performed the most in-depth analysis of Florida's AHCA report to my knowledge. My testimony today summarizes portions of our analysis, but I urge the board to read our report in its entirety and reject the conclusions that the June 2nd report reaches.

To state the matter firmly and positively, standard medical care for gender dysphoria does meet generally accepted medical standards. It is not experimental or investigational. Gender-affirming care for youth is supported by every relevant major medical organization, and this consensus is based on a solid body of evidence with more than 16 studies confirming that standard medical treatments for gender dysphoria are safe and effective.

The deeply flawed June 2nd report was commissioned by the state of Florida to provide cover for the deprivation of healthcare of 9000 transgender Floridians who are insured by Medicaid. The misinformation and flawed methodologies of this report are grave. The report reaches an incorrect conclusion based on the misuse of the scientific

method and poor insight into the nuances of clinical research. Its veneer hides the flawed analysis that ignores the truth and relies instead on pseudoscience particularly purported expert reports that are biased, actually inexpert, and filled with errors.

After a line-by-line examination of the June 2nd report, including all 142 pages of its contents and appendices, I testify today that its conclusions are incorrect and scientifically unfounded.

The lynchpin of the report is a so-called systematic review that is deeply flawed and violates basic standards of research integrity. Its design and execution raise several red flags for bias. Neither of the authors of the state's review was a subject matter expert. One individual is a dentist, the other is a post-doctoral fellow in biostatistics. At a bare minimum, a systematic review should be conducted by those who are qualified to critically assess the literature. I would trust a dermatologist's review of the literature on a neurosurgical procedure, for instance.

The authors also make no effort to engage

with peers or subject matter experts, which violates foundational aspects of the scientific method and standards established by the National Academy of Medicine for Systematic Reviews. And also, finally, the authors uncritically assign equal weight to peer reviewed studies and gray literature. I personally vetted the gray literature sources included and found them to be politically biased and from an anti-transgender website.

Also, the state only examines an arbitrarily truncated sample of the literature on gender-affirming care sourcing only from 2020 to early 2022. The authors don't justify this. This also spans the worse public health emergency in a century which likely stalled the production and publication of non-COVID research.

Moving on, the state claims that the absence of randomized control trials negates all evidence for the benefits of gender-affirming care. First, an RCT, or randomized control trial for gender-affirming care would never pass an institutional review board's safety or ethical standards.

Second, if the board feels strongly that RCTs offer the only acceptable evidence and that

medical care not backed by RCTs should be restricted, the board would have to consider banning statins, mammography, insulin for diabetes, penicillin, and some minimally invasive surgeries, just to name a few. All of these types of medical care derive their evidence base from robust observational studies, not RCTs, and yet, there are no calls to limit this care. This raises concerns about the exceptionalist standards that gender-affirming care are being held to.

The June 2nd report repeatedly and erroneously dismisses solid studies and clinical practice guidelines as "low quality." We've just heard this. The misuse of technical language is confusing to nonexperts. Low quality evidence is a technical designation rather than terminology that should be viewed in lay terms. Low quality evidence does indeed inform strong recommendations for clinical practice.

For instance, the Endocrine Society's guidelines in obesity recommend that children consume fruits and vegetables rather than sweetened beverages such as juice. This is based on "low quality evidence," but it's been adopted widely in the counseling and treatment of pediatric obesity.

Reye's Syndrome is a mysterious neurodegenerative disorder that may be associated with Aspirin in febrile children. Evidence strongly recommends against Aspirin for the treatment of pediatric fever, but this is low quality and yet, resoundingly supported by the medical community. An RCT in this case would be absolutely inappropriate.

The technical rating system that identifies studies as high or low quality specifically states that low quality studies can and do provide a sound basis for clinical recommendations.

The June 2nd report also reiterates that puberty blockers are used off-label for the treatment of dysphoria -- or gender dysphoria, and falsely supposes that this should prompt safety concerns and tight regulation. Actually, off-label use is so common in pediatrics that off-label drugs are prescribed in 30 percent of patient visits. In palliative care, neonatology, addition medicine, psychiatry, gynecology, and general pediatrics, off-label medication use is the cornerstone of essential treatments.

In our report we review key examples spanning from the use of steroids for croup, ondansetron for nausea, vomiting, dehydration; birth

control pills for heavy menstrual bleeding; and sertraline for depression. The key message here is that off-label does not equal off evidence. Again, the exceptionally high burden of proof that gender-affirming care faces is unfair in the context of other accepted treatments that do not face such scrutiny. Off-label use does not denote experimental treatment but use of that term by the state risks stoking public fear.

Throughout the June 2nd report, individual studies are misused, misquoted, and distorted, and the entire body of research that establishes the benefits of gender-affirming care is seriously mishandled. Leading researchers have come forward to describe how the state of Florida mischaracterized their work. They were not contacted to verify that the state was correctly summarizing the results of their research.

One study on the impact of gender-affirming care is criticized because it did not have a control group of youth without gender dysphoria. This is ignorant to the norms of clinical research. Control groups are not necessary to study the effect of an intervention. Thousands of published studies have advanced medical care with observational research

protocols. I myself have performed statistical analysis on and reviewed several observational studies where the independent effect of an intervention on an outcome was detected with a single cohort of participants. Either the June 2nd report's authors are not qualified to conduct such an influential literature review, or their baseless claims are purposeful.

Perhaps the most glaring, and repeated, and troubling error in this report is the singling out and thoughtless dissection of single studies rather than engaging with the entire body of evidence. As I said, at least 16 studies show that puberty blockers and hormones benefit patients with gender dysphoria, but none appear in the June 2nd report and are treated fairly. This is likely an effective way to dismiss consensus and throw fog up around the issues at hand, but it should not and cannot guide healthcare.

Before legal interference a year ago, the United States was not out of step with practice in other countries. No other country in the world has prohibited the provision of gender-affirming care for youth. Despite the picture painted by some, in Sweden, Finland, the United Kingdom, Canada, and

others, gender-affirming healthcare is available to any adolescent whose clinician recommends it as long as the required consents are obtained. I submit to the board an amicus free from Stonewall U.K. et al., which details an accurate account of gender-affirming care in other countries from those who provide it.

In conclusion, I emphasize that standard medical care for gender dysphoria does need generally accepted medical standards and it is not experimental or investigational. Nothing in the state of Florida's June 2nd report calls into question the solid medical evidence that underlies consensus recommendations of WPATH, the Endocrine Society, the AAP, and many others.

I urge the board to read out report, not rely on the June 2nd, which is full of misinformation and errors. And as physicians and scientists, the members of the board can give the June 2nd report the critical scrutiny it deserves and make the right decision for Floridians. Thank you so much for your time.

CHAIRMAN ZACHARIAH: Well, Dr. McNamara, thank you for the very eloquent presentation.

Now, the board members, any question for

Dr. McNamara?

I think Dr. Derick first and then Dr. Hunter.

DR. DERICK: Certainly a percentage of non-gender conforming children with gender dysphoria will not have persistence and will be post pubertal homosexuals. What is the way that these children are identified in clinic in your clinical experience?

DR. MCNAMARA: I heard you here and there, in and out, so I'm going to repeat your question and you'll tell me if I have it right. You're asking about younger children who present with gender dysphoria and you're asking about their chances of persistence into their adolescent years?

DR. DERICK: What I'm asking is, there are a certain percentage, which is debatable, of kids who have nongender conforming behavior and have gender dysphoria that does not persist.

DR. MCNAMARA: Yeah.

DR. DERICK: And so my question is what are the discussions and what are the mechanisms to determine these children? Because those children might have a different course of action than children who will ultimately have persistent gender

dysphoria.

DR. MCNAMARA: Yeah. I mean, I think one of the prevailing themes of all of our testimony today is that it's highly individualized. These children and their families meet with therapists, with experts on gender dysphoria, a range of options to help this child live authentically and comfortably are offered. For prepubertal children though this does not include medications of any kind, and I really want to state that clearly. That is stated emphatically in clinical practice guidelines from WPATH and the Endocrine Society.

CHAIRMAN ZACHARIAH: I think Dr. Hunter, I think you were next.

DR. HUNTER: This is going to be more of a statement but then I would like Dr. McNamara to comment. The concern seems to be with the June 2nd report, and I just wanted to clarify that this -- my reading of the June 2nd report, my understanding of the June 2nd report, this is not a Florida report, this is a report from McMaster University in Ottawa, Canada, okay.

And I agree those people who wrote the report are not physicians, they are not involved in gender medicine, but they are experts in evidence

reviewed. McMaster University being the home of the term "evidence-based medicine." Gordan Guiette coined that term, and these are all trainees of Dr. Guiette. And I think there was some concern in the literature that if evidence is not reviewed in a systematic fashion and it is reviewed by people heavily involved in the field that the conclusions may in fact be biased.

So I don't think there's a bigger name in evidence-based medicine than McMaster University and the experts who reviewed the literature in this area. I just wanted that clear and for the record, and if Dr. McNamara would like to comment on that.

DR. MCNAMARA: I'm not sure if you'd like me to comment but I really couldn't hear much of what you said. I apologize if I've missed --

DR. HUNTER: Should I try to say it again?

DR. ACKERMAN: Yeah. Speak louder.

DR. HUNTER: I think to describe the evidence reviewers as inexpert and not qualified when it's coming from McMaster University where the term evidence-based medicine and they have an entire program in reviewing the quality of evidence, I think that's --

DR. MCNAMARA: I see. Yeah, I actually can

respond to that if you would like, quickly. The National Academy of Medicine stipulates that systematic reviews must be conducted by people who have specific clinical and research expertise in the area at hand. The National Academy of Medicine, about 10 to 15 years ago, I believe developed standards (indiscernible), and those are viable by a system used from outside of the United States in this report.

CHAIRMAN ZACHARIAH: Next, Dr. Pages, and Dr. David.

DR. PAGES: Can you hear me? So the first gender clinic was established in 2007 in this country, and now we see there are over, I believe around 50 gender clinics. So my question to Dr. McNamara, as an adolescent medicine expert, why in your opinion are we seeing this significant increase in gender dysphoria in children, especially in the adolescent population?

DR. MCNAMARA: I have so much to say about that and I really value this question. First of all, we're not seeing much larger numbers. I think that that has been blown out of proportion and discourse, but if you look at the absolute numbers, it's not exponential by any means. The fact of the

matter is that we live in a more forgiving and nurturing environment than we did 20 years ago for gender expansive identities. I believe that there are -- there are trans and nonbinary role models. There are people that are trailblazing and showing young people that it's safe to be who they are. That's my simplest answer.

The data do not back up the social contagion claim at all. If social contagion was indeed driving these "spread" of gender dysphoria -- I really dislike even saying that -- the numbers of young people identifying as trans or gender expansive would be much higher. Another way to think about it is this is a predominantly, overwhelmingly cis gender society and young people are far more exposed to cis gender social norms, social contagion would work in the reverse if that were the case.

So I appreciate this question, I appreciate the opportunity to speak to it. I want to just pushback substantively that we're seeing much larger numbers and that represents a change. I think merely young people feel safe to be who they are.

CHAIRMAN ZACHARIAH: Well, thank you. Dr. Pages, one of the reports that I read said that

in 2007 there was 1 and now in 2020 there's over 300 in the United States. That's what I read.

Dr. David.

DR. DIAMOND: Dr. McNamara, good morning. Thank you for joining us from scenic New Haven, Connecticut. I'd like to ask you the same question as I asked Dr. Janssen, which is that our colleagues in Europe, who I'm sure you would agree are of goodwill, are trying to do the best for their patients, clearly are not bigots. How do you explain this obvious paradox that these individuals who had been the leaders in a more permissive approach to the treatment of minors with gender dysphoria, how do you explain the paradox of their institutions taking a more conservative approach whilst we in the United States have moved to a more permissive approach? How do you address that, ma'am?

DR. MCNAMARA: I suppose that I disagree with the assessment that international guidelines are more conservative. In my experience, in my professional collaborations across the country, I have observed gender-affirming care being practiced according to clinical practice guidelines. I don't really see any substantive differences in other

countries. And I do believe --

DR. DIAMOND: But Dr. McNamara, I must interrupt you.

DR. MCNAMARA: -- put a thorough primer on some of these issues.

DR. DIAMOND: Doctor, I must interrupt you though. You just mentioned that you don't see any substantive difference. However, we just heard experts telling us that for example in NHS, going forward, the use of some of the medical interventions will be on a clinical trial, so I'm not sure why you say there's no substantive difference.

DR. MCNAMARA: That's a wonderful question. Thank you for highlighting that. The word trial does not appear at all in that document. They're not proposing clinical trials, they're simply proposing to gather data. So I think the distinction between a trial and an observational study is really important. There will be no randomization to different types of treatment. And also, those are bulleted guidelines. There's really nothing specific in there yet. What they want to do is gather evidence moving forward, just roll out more perspective studies.

DR. DIAMOND: Understood. And just as an aside, in our August meeting, the one item that I think everyone agreed upon is that there is a pressing need for better data, so I could concur on that. I would also like to ask you --

DR. MCNAMARA: Yeah. There's always a need for better data. Sorry, I didn't mean to interrupt.

DR. DIAMOND: I'd also like to ask you at Yale New Haven what are your policies of treatment with respect to age cutoffs for referrals of individuals for so-called bottom surgery and so-called top surgery? Do you have any hard and fast age cutoffs or is it an individualized assessment?

DR. MCNAMARA: Individualized based on pubertal stage which follows the WPATH and Endocrine Society guidelines.

DR. DIAMOND: So for example, are patients being referred at Yale New Haven at age 17 or 16 for bottom surgery? I'm just curious.

DR. MCNAMARA: No.

DR. DIAMOND: What age would that be?

DR. MCNAMARA: I -- what do I think of what?

DR. DIAMOND: What age would it be that --

you seem to have a cutoff that you just put discrimination for referrals, and I'm asking for bottom surgery is it age 18? Is it age 17?

DR. MCNAMARA: So to be honest, it's so rare. I've never referred a patient for bottom surgery. I don't know of a recent case in which it's been done here. I think what we're dealing with is extremely rare cases in which that's done. And to my knowledge, it has not been done under the age of legal majority in my institution.

DR. DIAMOND: And I believe that's the policy at University of Florida and other institutions here in the state. What about for so-called top surgery or mastectomy?

DR. MCNAMARA: The exact same thing. To be honest, I've never referred a patient for a surgery. I've never had a patient express that they desire top surgery. And I've never had to explore that because, again, it's quite rare.

DR. DIAMOND: I'm a little surprised because --

DR. MCNAMARA: I think they're (indiscernible) cases in the past year that have been reported.

DR. DIAMOND: I'm a little surprised

because I believe at some of our institutions, we are seeing biologic females being referred at age 16 for a mastectomy. But that's not your experience, ma'am; is that correct?

DR. MCNAMARA: No. It's not my experience.

DR. DIAMOND: Thank you.

DR. ACKERMAN: I have a question. Zach, over here to your left.

CHAIRMAN ZACHARIAH: Yeah. Go ahead, please.

DR. ACKERMAN: So I'm confused, Dr. McNamara. You really are an advocate for gender-affirming care and what I'm hearing from you and other speakers is this is healthy for people, it's healthy for mental health, it's healthy for them in general. So why would you not refer a minor for surgical sex affirming surgery?

DR. MCNAMARA: You know, I -- I also appreciate this question because it lends insight into the shared decision-making process. I've never referred a patient for surgery because a patient has never desired surgery who I've cared for. It's all about what the patients want, how that fits into the informed consent model, and how that is -- and how that goes along with clinical practice guidelines.

DR. ACKERMAN: I'm sorry, so what age group are you seeing? I think up to 25 or something?

DR. MCNAMARA: 10 to 25.

DR. ACKERMAN: Yeah. So at no age has any of your patients desired to have surgery for their mastectomy, a phalloplasty, a phallectomy, none of that?

DR. MCNAMARA: Right. None of my patients have desired that surgery at that moment in time. We discuss openly --

DR. ACKERMAN: So again, if gender-affirming care is what's proper, why have you not recommended that surgery?

DR. MCNAMARA: I don't -- I think what -- what I'm trying to say is that I haven't recommended that surgery, I haven't helped facilitate it because none of my patients have expressed a desire for it. That's my --

DR. ACKERMAN: Right. So I'm an oncologist. Patients don't come to me requesting desire for chemotherapy, but I recommend chemotherapy because that's what's best for them. So as a physician, if you think that gender-affirming care is best for your patients why have you not recommended surgery on any of your patients?

DR. MCNAMARA: Gender-affirming care does not equal surgery.

DR. ACKERMAN: I understand. There's a continuum --

DR. MCNAMARA: You know, I think they're a little bit different.

UNIDENTIFIED SPEAKER: That behavior is inappropriate, please.

CHAIRMAN ZACHARIAH: We need to have some quorum here, so we would appreciate it if you do not do those actions at this point in time. Let's have an intelligent and cohesive conversation, please.

DR. ACKERMAN: Dr. McNamara, I understand there's a continuum of puberty blockers, sex hormones to change the sex, and surgery. And what we've heard from all the other experts is that there's this whole continuum is part of gender-affirming healthcare. So do you think that the surgery is part of gender-affirming healthcare or not?

DR. MCNAMARA: I do think it's part of gender-affirming healthcare for some individuals.

DR. ACKERMAN: Okay. So but you don't recommend it to anybody is what you just said?

DR. MCNAMARA: That is not an appropriate

characterization of what I said. I have not had a patient who has expressed a desire for it in my experience.

DR. ACKERMAN: Again, they may not express the desire but you as a physician make recommendations to patients based on what you think is best for their overall care. So you have never made the recommendation? Just want to get that on the record. Did you hear me?

DR. MCNAMARA: Yeah, I have. I can hear you.

DR. ACKERMAN: So are you going to answer my question or just not?

DR. MCNAMARA: Oh, I'm sorry. Did you ask another question? I promise I can only hear about 50 percent of what you're saying.

DR. ACKERMAN: So my question was, have you ever -- you know, as a physician, we recommend treatment to patients based on our judgement of what's best for their care. And so in the continuum of gender-affirming healthcare, surgery is part of that.

DR. MCNAMARA: Yeah.

DR. ACKERMAN: And so I'm asking you have you ever recommended surgery to your patients?

DR. MCNAMARA: I don't tell anybody, "You need surgery. You should get surgery." That's not how gender-affirming care works. Physicians don't tell patients what they should do with their bodies or their gender expression.

DR. ACKERMAN: I understand. Again, as an oncologist, I give my recommendation as to what they need. So again, just answer the question yes or no. Have you ever recommended surgery for your patients?

DR. MCNAMARA: I have -- I wonder if maybe we're disagreeing on the definition of recommendation.

DR. ACKERMAN: Okay. I'm done. Thank you.

DR. MCNAMARA: Is there a --

CHAIRMAN ZACHARIAH: Dr. McNamara, I have one question. Just one question that as a board member. My only question is that if tomorrow a patient comes to your office and that person says he or she believes that they need a top or bottom surgery, would you recommend the surgery? The patient really wants the surgery done. He or she believes that they must have the surgery done. Would you recommend the surgery, yes or no?

DR. MCNAMARA: At what stage of the patient's care are we in?

CHAIRMAN ZACHARIAH: What's that?

DR. MCNAMARA: At what stage are we at in this patient's care?

CHAIRMAN ZACHARIAH: No. The patients that you see for gender dysphoria. If the patient comes to you and the patient believes that he or she needs the surgery, would you recommend surgery? Please answer yes or no.

DR. MCNAMARA: I can't do that. How old is this patient?

CHAIRMAN ZACHARIAH: Let's say 17.

DR. MCNAMARA: 17, okay. And how long has this patient been in my care for?

CHAIRMAN ZACHARIAH: Well, I didn't talk to the patient. Let's assume the patient had it for several years and now the patient believes that he or she must have the surgery.

DR. MCNAMARA: Must have the surgery.

CHAIRMAN ZACHARIAH: Yes.

DR. MCNAMARA: And what kind of surgery are we talking about specifically?

CHAIRMAN ZACHARIAH: Either the top or the bottom surgery.

DR. MCNAMARA: Either surgery, okay. So if a patient came to me after they had been in my care

for several years and they expressed a strong desire for a gender-affirming surgery and they were 17, the WPATH guidelines state that this patient should be referred for an informed consent discussion with a qualified surgeon who can discuss the risks and the benefits of that surgery with them. I would facilitate that referral and refer that person to an expert in the surgery that they desire.

CHAIRMAN ZACHARIAH: You would recommend the surgery?

DR. MCNAMARA: I would allow the surgeon to discuss the options, the risks, and the benefits, because that is not my specific area of expertise as somebody who does not practice any surgery.

CHAIRMAN ZACHARIAH: Thank you, Dr. McNamara. Next is Dr. Pages and Dr. David.

DR. PAGES: I have another question for you, Dr. McNamara. Can you please walk us through the assessment that gets done in your clinic when a patient presents with issues on possible gender dysphoria before they get referred to an endocrinologist for further treatment?

DR. MCNAMARA: I'm actually wondering if I could refer that question to Dr. Dayton who is an endocrinologist who practices in your state? I feel

like she would be the more appropriate person to answer.

DR. PAGES: No, but I'm sorry. I want your opinion as an adolescent medicine expert, because when they get to the endocrinologist they are already affirmed. Am I correct?

DR. MCNAMARA: Say that again.

DR. PAGES: I want your opinion as an adolescent medicine expert because they go to see you or a psychologist before. Once they get to the endocrinologist, they usually go there for treatment, so they're pretty much affirmed when they get there.

DR. MCNAMARA: I don't think that that's true. I apologize this is so hard, I can hear about 50 percent of what you're saying again and very limited. It's not quite a yes or no because --

DR. PAGES: I'm sorry?

DR. MCNAMARA: -- we all follow the same guidelines.

DR. PAGES: I was just curious about what's the assessment done in your clinic before they get referred to an endocrinologist? You as an adolescent medicine patient. You see a teenage girl that is going through issues with sexual identity,

gender dysphoria. How do you approach these patients? Who do you send them to when you come to see you, referred by their pediatrician?

DR. MCNAMARA: I believe what you're asking is how do we approach these patients in their adolescent years. We approach them initially with an interdisciplinary team. So for all intents and purposes, in the provision of gender-affirming care, Dr. Dayton, for instance, and I, practice the exact same type of clinical care. She is an endocrinologist, I am an adolescent medicine specialist. We're both physicians. We're both totally capable of providing this care in the same way. And Dr. Dayton is able to provide youth friendly, developmentally appropriate care for adolescents. The initial approach is just with a team of supportive clinicians. They work with psychiatry, psychology, social work, and others as we've discussed.

DR. PAGES: So how long does a patient get seen by a psychologist, psychiatrist before they move forward is my question? How in depth is this evaluation of an adolescent? Especially females, we're seeing more in the female population that are having this issue before they move to

endocrinologist. Because a lot of the times they go to the endocrinologist and these kids are already affirmed by somebody. So who is doing the affirmation of these children is my question?

DR. MCNAMARA: It's all individualized. It truly depends on the individual. It does take quite some time for people to move from the initial assessment, the first visit, to any sort of medication, things along those lines. But people are ready for different things at different stages in their life and their journey. It's a really tough question to answer with an absolute. It's impossible, actually.

CHAIRMAN ZACHARIAH: And Dr. David, you will ask the last question because we've been going on for 40 minutes.

DR. DIAMOND: Thanks. Dr. McNamara, we are regulators. That's why we're trying to ask some of these questions. Cases come in front of us. We see terrible things happening every day. So when we're asking some of these questions it's because this is what's going to come in front of us. I think what Dr. Ackerman was trying to get a sense of was how do we respond when we see cases of 14- or 15-year-old biologic females having mastectomies? Is that in

the public interest of the great state of Florida, or is it not? That's what we're really trying to get at. We're asking for your help.

So for example, as a -- I'm asking your personal opinion now. At age, let's say 15, is it an appropriate consideration in your professional experience that mastectomy be a consideration for an individual whom, in your opinion, has gone through all of the requisite antecedent steps?

DR. MCNAMARA: I'm wondering if I could give this question to Dr. Janssen, one of our additional experts who is really, truly an expert on that process?

CHAIRMAN ZACHARIAH: David, if she cannot answer the question, I need to stop the meeting and take a 10-minute adjournment.

DR. DIAMOND: Yes, sir.

CHAIRMAN ZACHARIAH: Let the meeting adjourn for the next 10 minutes. Thank you so much, Doctor.

(Recess taken)

CHAIRMAN ZACHARIAH: Can we get started? Okay. Let's get started. At this time we will have some discussion about what will happen to the rule language. Can we all have some attention? Can you

please stop talking in the back if you don't mind. Hello? Okay. Let's start the discussion about the rules, board members.

Dr. Diamond, do you want to start? Just kidding.

DR. DIAMOND: I believe Romanello had some comments.

MR. ROMANELLO: So Mr. Chair, let me start the discussion on the development of a potential rule.

Am I on?

Mr. Chair, let me start the discussion with the development of a potential rule by reminding the board that we historically have prescribed and regulated standards of care. In fact, one of the rules in the Florida Administrative Code that this board submits rules to is chapter 64B8-9, which is entitled, "The Standards of Practice of Medicine." And in that chapter, this board -- and there's a parallel rule for our osteopathic physicians.

That rule historically has created registries and standards for such practice areas as prescription drugs to treat obesity, office surgery standards, opioid dispensing and prescription, electrolysis, use of laser and light-based devices,

medical marijuana, including a consent form. And by extension, this board regulates the standard of care of a physician when they are supervising a PA or an anesthesia assistant. And most recently, we took up the issue of the Brazilian butt lifts. So we have a -- and Mr. Tellechea, who has been board counsel for a long time, could probably think of other areas where the board has weighed in on standard of care issues.

So this morning, it was certainly helpful to hear from the subject matter experts, as well as to review the materials in the portal that we were provided, and to hear the questions of my much more learned colleagues.

Mr. Chair, I believe that based upon the testimony that we heard this morning and the materials in the portal that the risks of puberty suppressing therapies, cross hormonal therapy, and surgery, those risks outweigh the possible benefits and that there is a lack of consistent, reliable, scientific peer-reviewed evidence concerning the efficacy and safety of such treatment.

And with that in mind, for discussion purposes, I would propose a rule that would prohibit such therapies. And again, I'm talking about

puberty blocking therapies, such as GRH, and I'll look to my colleagues to better define what that looks like, as well as kind of cross hormonal therapies and surgery to treat gender-affirming care or gender dysphoria for patients under the chronological age of 18.

CHAIRMAN ZACHARIAH: Do you make this in the form of a motion?

MR. ROMANELLO: I do.

CHAIRMAN ZACHARIAH: Well, we have a motion on the floor. Do I hear a second?

DR. ACKERMAN: I'll second that.

CHAIRMAN ZACHARIAH: There is a motion and a second. Is there any further discussion regarding that?

DR. ACKERMAN: Yes. I think we --

CHAIRMAN ZACHARIAH: Yeah, go ahead.

DR. ACKERMAN: I think we should have some further discussion regarding that. I think there's more to it. It was a simple motion. I assume Mr. Romanello put that motion in a fairly simple way right now, so we can discuss this, but I think that there's more to it than that that we need to get through and regarding young Floridians that are already in the process, regarding children that

might have other disorders in where those medications would be appropriate in children that have genetic chromosomal aberrations that need to be addressed.

So I just want to -- I don't know how to -- I don't want to necessarily incorporate that into the motion but I'm just putting that out there as a point of information and I'm looking for some guidance of how we encompass that in there, as well.

DR. DIAMOND: Dr. Ackerman, I think what you're saying is that this is specifically limited to individuals with gender dysphoria. It has no application to individuals with disorders of sexual development. Is that correct?

DR. ACKERMAN: That's part of, Dr. Diamond. I think there's some other medical disorders where these children would benefit from some of these drugs. I just would want to make sure that we flush through that and make those drugs still available for the --

DR. DIAMOND: Precocious puberty, for example.

DR. ACKERMAN: Exactly. Exactly.

MR. ROMANELLO: So to that point, Dr. Ackerman and Dr. Diamond, right, the motion I

had talked specifically about the treatment of gender affirmation care or gender dysphoria. Certainly open to expanding that or contracting it and creating -- you know, and I would look to add. I mean, if it's pretty --

DR. ACKERMAN: I guess my input is just I want to make it clear that that's what it's for and that these drugs remain available for those that need it that have other disorders. And just saying that in there as part of the motion is a healthy thing to do.

MR. ROMANELLO: Yeah.

CHAIRMAN ZACHARIAH: See, we have a motion on the floor but we're not going to vote on it until we have full discussion by the board --

DR. ACKERMAN: By the board or by the committee?

CHAIRMAN ZACHARIAH: By this committee -- with this committee. And we can have some public hearing before we actually vote on the issue. But right now, I just wanted to make sure we had a motion, and we can hear from the rest of the board members. Then I will have to allow the public to speak on either side of the issue and then we can vote on the issue.

Other board members?

Dr. Hunter.

DR. HUNTER: I think we should -- and I'm not sure how this would be done but to include that the standard of care would involve availability of psychotherapy to address the gender dysphoria, distress associated with gender dysphoria, and as we've learned, any other comorbid mental health issues, anxiety, depression.

Also, there's -- that I don't believe was brought up, the concern about the high rate of children with neurodevelopmental disorders, such as autism, and ADHD, and others, that are involved in this, that those also have to be addressed. That this isn't just a moratorium but that this is -- the standard involves psychotherapy.

DR. DERICK: I'll --

CHAIRMAN ZACHARIAH: Yeah, please.

MS. JUSTICE: I'll try to say I have some hesitation. I just -- I haven't heard enough about, from my perspective, perhaps the unintended consequences of pulling the guidance around this treatment out from the medical community and into this realm. Not to say that we are not part of that community, right. But I just want to make sure that

we're thinking about potential unintended consequences for the population that would be served by this treatment. In particular, mental health as we've heard from many of the experts today.

I recognize from the work that I do that that is a service that is in dire shortage. And so I do think we have an obligation to consider potentially the unintended consequences of any work that we might do here, and consider buffers for that, however that might go. I don't know.

UNIDENTIFIED SPEAKER: You folks are the physicians. I think that's something that you're going to have to consider and address through your motions.

CHAIRMAN ZACHARIAH: Dr. Diamond.

DR. DIAMOND: So Mr. Romanello, to help develop this it's your intent that this motion is limited to individuals with gender dysphoria, and specifically excludes individuals with disorders of sexual development and other types of medical issues as Dr. Ackerman referenced.

The second point would be, with your motion, is your intent that once this rule may be in effect, would it take -- would it have jurisdiction over all persons? Would it have jurisdiction only

over those individuals who have not yet begun treatment? Obviously, if a person is currently under hormonal therapy, that is an important item to consider.

MR. ROMANELLO: A potential unintended consequence that Ms. Justice had raised and aware of. Yes. So, you know, the answer to your first question is yes. It would exclude, my proposal or my thoughts would be to exclude those conditions that Dr. Ackerman had first spoke about. And certainly welcome the remainder of the board to add other conditions that would be excluded from the rule.

The second point, Dr. Diamond, is, you know, my rule would be a prospective rule to take effect, and I would look to board counsel to help on a prospective start date. And then recognize, though, that a potential consequence of a prospective rule would be that it would have an impact on minors who are currently somewhere in the continuum of care that we talked about earlier today.

And so for those patients I would propose that we continue that care but that we -- to ensure kind of the safety and ensure an educated and

well-informed patient that we enhance the consent process for those sorts of therapies. Very similar to the way that this board in the past has created specific consent forms for the use of and dispensary of medical marijuana. And so with respect to a potential consent, I would, again, for the board's consideration -- three, I think significant portions of the consent. Again, very similar to what we did with marijuana.

So the first, I think is that we need to create some sort of a multispecialty type of consent. We heard the witnesses today, specifically Doctors Dayton and McNamara, agree to a multidisciplinary approach when treating patients seeking gender-affirming or dysphoria type of treatment. So a multidisciplinary consent to include, you know, concurrence from pediatrics, endocrinology, psychiatry. And even I heard, you know, about social workers, licensed clinical social workers, for the importance of ensuring that patients who go through this treatment to have adequate support during the treatment and following the treatment. So I think that's the first thing that I would propose that we consider in creating a consent.

The second, similar to marijuana, would be highlighting and specifically documenting the patient's or the family's attempt with alternative treatments for gender dysphoria, or gender affirmation. You know, counseling -- and again, I don't know what's at the very beginning of the continuum, but before we get to puberty blockers and such, were there other alternative treatment options considered?

And then finally, a section where we would specifically require the identification of risks associated with such treatment. You know, the irreversibility or the permanency of, you know, surgery, the effects of puberty blockers. And again, I would look to my colleagues to weigh in on what the appropriate list of risks are. But it would seem that for the protection of patients, and for patients, minor patients and their parents or guardians to be fully and knowingly informed, that they would have that list of risks presented to them at the time of treatment.

CHAIRMAN ZACHARIAH: Other board members?

DR. SCHWEMMER: Dr. Zachariah?

CHAIRMAN ZACHARIAH: Go ahead, Sandra.

DR. SCHWEMMER: Mr. Romanello, you talk

about a consent but yet, we're talking -- who would be signing this consent?

MR. ROMANELLO: Yeah. So the parents or guardian of the minor patient.

CHAIRMAN ZACHARIAH: Any other comments from the board?

DR. DIAMOND: So again, Mr. Romanello, if I understand you correctly you are proposing a prospective rule and as an interim measure, are you stating that individuals currently receiving this therapy should receive this enhanced education and asked to go through an enhanced consent process? Am I understanding that correctly?

MR. ROMANELLO: Yes.

DR. DIAMOND: So if I understand correctly, if this rule were promulgated, there would be some time window that individuals who are currently receiving care would be asked and required to go through this enhanced consent process in order to be able to continue on this treatment; is that correct?

MR. ROMANELLO: Yes.

DR. DIAMOND: Thank you.

DR. ACKERMAN: So this is the end of October. If we put this rule forth at this committee, it then goes to the Board of Medicine and

the Board of Osteopathic Medicine for their next meetings, which is not next week's meeting -- is it next week's meeting that we're talking about? The joint meeting. So it would go to that meeting next week and then that joint committee can then decide when it would go into effect. Whether it would go in effect immediately, or 1st of the year, or 1st of December, or what. We would discuss that I guess next week.

MR. ROMANELLO: So can I just -- so Mr. Tellechea, if there's a rule that's acted upon today, procedurally, it would go to the Joint Committee next week and then to each respective board at their next regular meeting? Or does it just stop at the joint meeting?

EXECUTIVE DIRECTOR TELLECHEA: Well, is it going to be the full board that's going to be meeting jointly?

UNIDENTIFIED SPEAKER: Yes, Ed.

DR. ACKERMAN: Yes. Next Friday.

EXECUTIVE DIRECTOR TELLECHEA: Then if it's the full board that are meeting jointly, both of the full boards, then that could be the final stop if necessary.

CHAIRMAN ZACHARIAH: Does any of the other

board members want to make any comments before I allow the public hearing?

DR. DI PIETRO: So just to touch on what I mentioned earlier, I'm in full support of a multidisciplinary team. I think that's of the utmost importance in this to have a mental health counselor, a board-certified pediatric endocrinologist, a board-certified pediatrician -- not a nurse practitioner -- a board-certified physician, and part of a multidisciplinary team to ensure that we're doing this correctly.

Because it's very easy a lot of times, and I'll use an emotional support animal as a perfect example, to get a letter from someone stating that you need something. And I think the -- for the safety and welfare of these children who very well might need this, it is extremely important to have that multidisciplinary team to make sure that the pediatric endocrinologist is the one who is assisting with hormones, and that the social worker or the psychologist is making sure that there's a support system in place for these children.

But I do have a question. So if we're talking about this and the informed consent, sorry, this is for over the age of 18?

MR. ROMANELLO: No. Under the age of 18.

DR. DI PIETRO: Okay. That's where I was a little confused. So we're talking this informed consent process with this multidisciplinary team approach for under the age of 18, correct?

MR. ROMANELLO: Yes.

DR. DI PIETRO: Okay.

CHAIRMAN ZACHARIAH: Dr. Hunter.

DR. HUNTER: If this -- where this discussion is going, and I'm hearing what Ms. Justice had to say about there is not -- there's a concern about access to mental healthcare and I think mental healthcare should be part of the standard of care. I'm not sure what the role the board has in this area, but we've heard that the research is very conflicted in this area, very low quality. Would a board rule need to include the option of research in this area where these could be used in IRB protocols, IRB approved protocols, research protocols, what England, and Finland, and Sweden have in plan with the appropriate safety and ethical oversight?

DR. DIAMOND: Dr. Hunter, are you referring to psychologic care, or are you talking about hormonal care? Please be more specific.

DR. HUNTER: I would be talking about all of that. Yes.

DR. DIAMOND: So if I understand you correctly, you would prefer to have a rule in place that outside of participation in a clinical study, these actions that Mr. Romanello enunciated would be prohibited, but you would be willing to entertain them on a clinical study that meets certain specifications? Ala, the National Health Service approach?

DR. HUNTER: Yes. Yes. With certainty of safety and ethical oversight.

CHAIRMAN ZACHARIAH: Dr. Amy.

DR. DERICK: Yeah. I feel I would be supportive of that, too, in order to continue investigating the science.

DR. DIAMOND: Dr. Hunter, could you give us a little bit more of your sense as to the mechanics of these studies? Would this have to be an IRB approved study? Would it be limited to a university setting? Could it be in the office setting? What is your -- do you have any sense on this?

DR. HUNTER: No doubt it would have to be IRB approved, no doubt. And that hopefully would provide the safety and ethical oversight. I think

I'd prefer it being a center, like a university, a Florida based medical school. I would be even more grateful if it involved international experts, Dr. Cass and the NHS, and Dr. Kaltiala in Finland. And the partner in a way like that, so we do get good quality data, so we know what's the best thing for these kids.

DR. DIAMOND: And so Dr. Hunter, again, I'm trying to understand, you're proposing that there would be an allowance that minors who have given appropriate -- whose parents have given appropriate consent, and the child of course given assent, that there would be a mechanism for clinical trials to be conducted, ideally in the university setting, both with GRH agonist and with cross-sex hormones?

DR. HUNTER: No.

DR. DIAMOND: So please revise.

DR. HUNTER: That I think is to be determined, and I think that's what the NHS guidance is saying, that they are writing those now. So to be -- I think we cannot be that specific at this point.

DR. DIAMOND: So therefore, you would be supportive of a rule but include in that rule an exception that there could be a carve out for

appropriate research studies and not be more specific than that. Is that correct?

DR. HUNTER: Correct.

UNIDENTIFIED SPEAKER: So IRB approved --

EXECUTIVE DIRECTOR TELLECHEA: So this is something that's going -- this is a whole new area that you folks are entering into within the context of a standard of care rule, and it's going to have to be specific. You cannot be -- just provide these generalized terms for an IRB approved study in a university setting.

DR. DIAMOND: I agree with that. Because, Dr. Hunter, I understand what your intent is is to have flexibility to help further scientific research but it's going to make Ed's job impossible. It won't be -- there's going to be no way to enforce these provisions and it will lead to a lot of confusion.

EXECUTIVE DIRECTOR TELLECHEA: Yeah. I mean, it's something that's going to have to be clear, understandable, defendable, and it has to be written by next Friday.

ATTORNEY MCNULTY: Can I interject? Just one other option that I was thinking of as you were making this presentation and listening to this

discussion is the opportunity for maybe a registry, a Florida registry, which the state has done in other situations. And it would allow then for, you know, the families to optionally enter into a registry. You know, that could be a potential. But then the information about that individual and the therapies could be captured. And it could be -- you know, you could start a registry that could monitor and give data back to the boards to be able to have our specific Florida data to be able to review.

EXECUTIVE DIRECTOR TELLECHEA: I think the problem with that, that that goes beyond the standard of care rule.

ATTORNEY MCNULTY: Okay.

EXECUTIVE DIRECTOR TELLECHEA: So I don't really think you would have the authority to create that registry and to be able to enforce it and all that through the standard of care practice. I think that would be something that you would need to go to the legislature and ask the legislature to create.

ATTORNEY MCNULTY: Yeah. My thoughts around that were that, you know, certainly as we've heard with, you know, the testimonies this morning, the patient specific therapies would -- you know, it gives more of a general umbrella, I suppose, to

reporting on those case specific treatments, so -- and variation of age. You know, I still think that registries are very helpful. You know, so are -- of course, so are the studies, but when you have small participation in those studies. We know we're going to have a small participation in the registries, and so, you know, the conclusions may not be as direct in a registry as one would conclude in a study with an IRB, but I still think it opens an opportunity to be able to monitor this ongoing situation, therapies. Anyway --

CHAIRMAN ZACHARIAH: Any other comments from the board?

DR. ACKERMAN: I just want to make sure we're all on the same page here, or I understand what we're talking about here. Mr. Romanello proposed a rule which was seconded by me. Now I'm hearing discussion about a registry and is this registry a loophole to avoid the rule, or is this registry for those individuals that are already in care?

ATTORNEY MCNULTY: Collecting data.

DR. ACKERMAN: Collecting data on who? I mean --

ATTORNEY MCNULTY: Those individuals who

are already in care.

DR. ACKERMAN: I'm sorry, if we're having a rule, the rule is the rule, and you can't go around the rule by having a registry.

ATTORNEY MCNULTY: And Dr. Ackerman, my comments were only within the discussion of what we were talking about with IRB. My thoughts were about a registry, but I agree.

CHAIRMAN ZACHARIAH: See my concern with a registry is you can form all the registries you want, nobody is going to enroll. Why would you do it? What is in it for you? So you can get your records public. Nobody is going to register in the registry, it's not going to happen.

DR. ACKERMAN: Well, they're anatomized.

CHAIRMAN ZACHARIAH: Yeah.

DR. ACKERMAN: No, you would. A lot of my patients are in registry trials. It's all anatomized. They don't -- the records aren't public.

CHAIRMAN ZACHARIAH: I agree but, you know, treatment for a cancer, treatment for a heart disease is slightly different than what we're dealing with.

MR. ROMANELLO: So, Mr. Tellechea, so we

can make your job a little harder, right. So I think what you're hearing from the board though is kind of a coalescing around the idea of excluding from the rule clinical trials. Like IRB approved, academically sponsored. I don't know, I would look to Doctors Diamond, and Hunter, and Ackerman, and others to weigh in on how to define that. But we certainly don't want to impair progress. We want to promote the continued research in this area for the betterment of all patients. So how could be accomplish that? I mean, I wouldn't want a rule then to inhibit or chill clinical research.

EXECUTIVE DIRECTOR TELLECHEA: Well, you would write it in such a way that, as you stated earlier from the outset is that the current procedures are prohibited unless it is done under a -- you know, these particular circumstances. And I'm going to need from you, you know, clinical trials, you know, what type of language you would put in there to make it clear that these are the type of clinical -- that under these circumstances, that it would be approved. So it's a prohibition except for under these circumstances, and then you would have to outline what the particular circumstances are, in a clear, you know, enforceable

manner.

DR. ACKERMAN: And I think it's difficult to craft the language to allow for clinical trials, and I think it could easily be gamed.

DR. DIAMOND: Dr. Hunter, how would you respond to Dr. Ackerman's comment on that?

DR. HUNTER: I probably would agree with that but I -- we need to learn more in this area. We need to learn more.

DR. DIAMOND: So I think where we stand right now is there's a sense that if promulgate a rule, it should be a prospective rule. Number two, that those individuals who are currently receiving therapy, that those individuals be required to go through a process of more robust consent as was discussed. And then number three, that the rule, if we were to go and set a chronologic age of 18 for these different points of bifurcation, GHRH agonist, cross sex hormones, and surgical procedures, that there be an opportunity for exceptions to be made in the limited context of robust clinical studies conducted at the appropriate centers. Those are the different elements I'm trying to help synthesize here. Is that the sense of where we stand right now?

DR. ACKERMAN: I think it is but the last thing you said is the difficult thing to define what a robust clinical study is and define what those appropriate centers are. That's my reservation about that. And there's -- not to --

ATTORNEY MCNULTY: Where are they normally done?

DR. ACKERMAN: Well, I guess other rules that we have, we keep -- those rules are for Florida, and people may do things contrary to those rules in other states.

EXECUTIVE DIRECTOR TELLECHEA: Well, you only have jurisdiction in Florida, okay, so --

DR. ACKERMAN: I understand. I know but my point -- that's what I'm saying. We have jurisdiction in Florida but if we have a rule here and people do research in another state, similar to the fat transplant to the butt, if they do some research in the state that shows that our rule is not appropriate, then we change our rule. And so people can do research, just not in Florida.

ATTORNEY MCNULTY: So we would want them done in university centers?

DR. ACKERMAN: No. I don't think we need to make any comment about research. Just leave it

at that. I think it's too -- I think it's difficult for us to craft appropriate language for that. And so I think if there's a rule, there's a rule. And if there's research done, the research can be done in Yale.

UNIDENTIFIED SPEAKER: Right.

CHAIRMAN ZACHARIAH: Any other discussion?

DR. DERICK: Can someone re-read for me because -- can someone re-read the motion that's currently on, that's seconded?

DR. DIAMOND: I think where we are, we're trying to develop a sense of different elements --

DR. DERICK: I know. I'm still a little -- because whenever the motion was initially given, there was a specific age given, and so that's what I'm trying to clarify. So after the age of 18, the consent process we're speaking of is no longer applicable, correct?

DR. DIAMOND: Correct. So --

DR. DERICK: That's what I needed clarification on.

DR. DIAMOND: So for example, my sense would be that once we moved past this, I was also going to make a motion that for individuals who have passed the age of majority that there should be no

restrictions on hormonal therapy or restrictions regarding surgery. I think a person, for example, who is 25 years old, who is mentally competent, to go and tell that person no, I think that is inappropriate. I would like to see this limited just to minors. I think that the state perhaps overreached a little bit on its initial petition when it spoke to individuals who had passed the age of majority.

DR. DERICK: I agree with that.

DR. DI PIETRO: Will we have opportunity to discuss again after public comment?

CHAIRMAN ZACHARIAH: Yeah, sure.

DR. DIAMOND: Yes. Perhaps we have some comment now.

CHAIRMAN ZACHARIAH: Okay. So let's get the public comments. The comments are for a timeframe of three minutes. And again, if someone who came before you, if they have already stated their case, there's no reason to repeat it, for the interest of time.

The first speaker is Zoe Hawes -- am I saying it right? H-a-w-e-s. Zoe Hawes. Yeah. Please come forward.

ZOE HAWES: My name is Zoe Hawes. I'm a

23-year-old wife and expectant mother, who at the age of 16 believed I was a boy and that transitioning would bring me peace. Growing up, I experienced a lot of trauma. I was molested when I was 6. My parents divorced when I was 8. My mom attempted suicide when I was 13. I was diagnosed with depression and anxiety in middle school, and I couldn't accept my body and puberty. I just wanted to escape.

By the age of 16, I was very unstable and suicidal. I came to believe I was male in a female body after reading a memoir about someone who had transitioned. I came out to my mom who was scared I was going to kill myself if she didn't affirm me. I was immediately taken to a gender therapist who diagnosed me with gender dysphoria and wrote a letter recommending I start testosterone after only three months of therapy.

I started T 7 months after coming out at the age of 16, and I really thought transitioning was going to fix everything. My period stopped, facial hair grew. Pretty soon, I was passing as male. At first, I was elated, but my mental health did not improve. I became more suicidal, more unstable, and the anxiety became debilitated. The

testosterone was never questioned as a contributing factor to my increasing instability. I was in and out of mental hospitals six times while being affirmed as a male and supported in my decision to transition by my doctor, psychiatrist, immediate family, and even church. I was also diagnosed with complex PTSD and OCD during this time.

I desperately wanted top surgery and a hysterectomy but couldn't afford them. After a serious suicide attempt in February of 2018, I realized that just changing my appearance was not going to take away the pain, so I started working really hard in therapy, but I still believed I was a male.

A year later, in 2019, I had a life changing encounter with Jesus and begin to find deep heeling and peace within myself. After nearly four years of being on testosterone, I decided to detransition and accept my womanhood. My mental health improved exponentially. I'm no longer in therapy, nor even on mental health medication. I have not been suicidal or hospitalized since stopping testosterone.

Three years later, my menstrual cycle has still been irregular, I still have to shave my face

daily, and I struggle with hormonal acne. I'm truly grateful I never got surgery because now I'm happily married and 28 weeks pregnant. But if I had gotten the surgeries that I so desperately wanted as a teenager, that would have stolen this future from me. So I'm asking the board to create a rule that makes it unethical for doctors to prescribe these hormone treatments for people under the age of 18 and surgeries under the age of 21. Thank you.

CHAIRMAN ZACHARIAH: Thank you, Zoe, for the courage, and appreciate you coming before the board.

Next is Rachael Foster (phonetic).

RACHAEL FOSTER: Hello, my name is Rachael Foster, and I am a 32-year-old de-transitioned woman. At 21, I was diagnosed with gender identity disorder, as it was at the time, and spent the next five and a half years taking synthetic testosterone. I was told by my psychologist and by my general practitioner she referred me to that if I did not take this drug, I would kill myself.

Within a few weeks, I went from talking with my psychologist to being prescribed synthetic testosterones. I was discouraged from seeing an endocrinologist and was told all effects except hair

growth and hair loss were reversible. This was a lie. My provider failed to assess risks based on my medical history or in fact critically analyze whether I was fit to consent, or if there were more psychological reasons for my distress around my sex.

In addition, my therapist lied on documentation to say I had been her patient for far longer than I had been and that I had no preexisting conditions that might affect my gender identity disorder diagnosis.

There are many compounding factors for why I felt wrong in my body. At 17, I was diagnosed with schizophrenia with major depression, now diagnosed with schizoaffective disorder. I also have a history of sexual abuse and trauma. I disclosed these things to my psychologist and prescribing physician but was still told that I need to transition.

At the age of 26, I began to experience renal failure. I was jaundiced, vomiting, and urinating blood. The only drug I was on at this time was synthetic testosterone. I saw a new practitioner who suggested I stop the injectable synthetic testosterone in exchange for a topical version at a much lower dose. My symptoms improved.

At 27, I stopped all together.

Shortly after, I experienced the first of three transsystemic attacks, also called ministrokes. Then at 28, I was diagnosed with endometriosis and adenomyosis. At 29, I lost my uterus and my cervix to the disease and had a hysterectomy. After the operation I discovered that my vaginal tissue was excessively thinned and weekend by testosterone use. I had multiple tears which lead to infections. I also learned that my ovaries no longer function, and I am on supplemental estrogen.

Today, I implore you to consider the risks these medical experiments have and stop this method of treatment. We cannot consent to treatment as experimental as this. No one, child or adult, should have to go through the constant health battles I've been through. Instead of my mental health being taken care of, I was sold a medication that has left me with physical pain, emotional trauma, and the same mental illness I had before. Medical intervention should not be taken to effect emotional distress over one's body. Thank you.

CHAIRMAN ZACHARIAH: Thank you, Ms. Foster.

Next is Chloe Cole (phonetic).

CHLOE COLE: My name is Chloe Cole, and I am an 18-year-old de-transitioned female from the Central Valley of California. I was what some may refer to as a trans kid as I transitioned between the ages of 12 to 16. I began my social transition by cutting my hair, wearing boys' clothes, and asking my family and friends to refer to me using a new name.

At 13, I started taking puberty blockers and testosterone. And at 15, I underwent a double mastectomy in which my breasts were removed, and my nipples were grafted. And yet, at 16, after years of medically transitioning, I came to realize that I severely regretted my transition. It has been over a year since my last testosterone injection.

During my diagnosis for dysphoria and the consultations for my treatments, the overall picture of my life just went completely unaddressed. From a young age, I was actually quite a very feminine girl, although I did somewhat model myself after my older brothers. Up until my transition I had relatively normal levels of teen distress, but my early exposure to social media and the internet led to my body image worsening. I was introduced to inappropriate content and an echo chamber of

far-left ideology, such as that sex and gender are separate, women are inherently victims, men are inherently superius in every way, and that dysphoric children need hormones and surgeries in order to live. These reductive ideologies have crept their way into science, and by extension, medicine.

I knowingly gave my mind and eventually my body to an anti-science movement that reduces womanhood to long hair, Barbie dolls, dresses, and false self-perception. I actually developed more psychiatric issues the further I went into transition. I was on the verge of suicide for nearly all of high school. Some things went undiagnosed for years until after I stopped transitioning, like autism and body dysmorphia.

All that talk about mental health, self-perception, pronouns, and ideology leads me to the question why is the mental health epidemic not being addressed with mental health treatment to get at the root causes for why female adolescents like me want to reject their bodies? I was not suicidal before going on hormones, and yet, doctors asked my parents the question, "Would you rather have a dead daughter or a living son?" This is not how medical professionals are supposed to talk. This is how

activists talk.

What was the cost of treating mental health with barbaric surgeries? I have bandages on my chest today, over two years post op, because my nipples leak fluid and they stain my clothes. I have no breasts. I want to be a mother someday, and yet, I can never naturally feed my children, my future children. My breasts were beautiful and now they have been incinerated for nothing. Thank you, modern medicine.

CHAIRMAN ZACHARIAH: Well, thank you so much, Chloe, for coming here today.

Next is Camille Keifel (phonetic).

CAMILLE KEIFEL: My name is Camielle Keifel. I stand here before you today, Florida Board of Medicine, in hopes that you'll make the right decision regarding transitioning children and take greater consideration for adults.

Prior to my transition, I had spent 20 years of mental health therapy with conventional modalities. I didn't respond well to medication, saw a gender therapist, and had two rounds of transcranial magnetic stimulation therapy. I was diligent and wanting to heal, but nothing my doctors offered had healed me because they always saw my

issue strictly as a mental one.

I was 30 and at the end of my rope when I transitioned. At the time, I believed I was nonbinary. I struggled with severe mental illness and suicidal ideation. I had a trauma history. When I was in sixth grade, my best friend had been raped by her brother. Being a girl meant I was vulnerable. I started to present more masculine. This should have been a red flag, yet, within months of requesting top surgery, it was performed on me.

I developed complications after my surgery. There were many times I didn't know if I would make it through the night. If I made this mistake as an adult, a young girl could too. Not only did my surgery exacerbate my mental health issues, I now struggle with physical complications as well. Presenting and taking on another gender was a way for me to escape womanhood. Escape is not a valid way of dealing with trauma. You will have to deal with it eventually.

I was able to work through these difficult emotions and improve my mental health through a holistic approach. I had physical health issues that had been previously overlooked. Had that been managed, I would have never gotten the surgery. The

surgery was an abhorrent misdiagnosis. The goal of healthcare should always be to get to the root cause of the problem. Today I am more grounded than I have been in my entire life, but I am mutilated. Between my carved-up body and the physical complications, I often question if there's anything on the other side. Where my breasts were are hollow, I can never get them back. I can never fit a dress the same way again. I can never breastfeed. Who will love me? You know what keeps me going? Stopping this from happening to someone else. Thank you for your time. You will have a lot to consider, and I know you will make the right decision.

CHAIRMAN ZACHARIAH: Thank you, Ms. Keifel, for coming. I appreciate you spending time with us.

Next is Shay Scheffler (phonetic).

SHAY SCHEFFLER: Hi. My name is Shay. I started identifying as transgender at 22 while still in college. Before that, I was just a feminine gay man. Being asked about my pronouns led me to research transgender ideology, and pretty quickly I got convinced that I was transgender woman. I was able to get hormones really easy through Fenway Health (phonetic) and was only on them for a year before receiving facial feminization and breast

augmentation surgeries at 23.

Taking hormones actually worsened my mental health but therapists thought it was because I was stuck in the wrong body. They're clearing me for sex reassignment surgery by diagnosing me with gender identity disorder. Immediately after SRS I was super excited to start a new life. I was happy for a few months while recovering.

However, soon I realized that my new part wasn't what doctors promised me. My new vagina started constricting, despite reverse dilation which resulted in me developing vaginal stenosis. This left me unable to have penetrative sex, which adversely impacted my mental health. I also lost my sex drive, my motivation to achieve anything, and became brain fogged and lethargic. I had multiple unsuccessful revisions attempting to get a few inches of new vaginal tunnel. I even had colon vaginoplasty. The last revision was at the University of Miami by Dr. Christopher Salgado in 2018 and has left me with a colorectal fistula. I've been all over the country trying to seek help, but I have received none.

Earlier this year after hitting rock bottom with my depression, I reached out to a new

therapist. This therapist helped me realize that I have complex PTSD from a traumatic childhood and also pointed out that I have body dysmorphia, OCD, borderline personality, and bipolar disorders. I also realized I had internalized homophobia. I realize now that medical transition was sold to me as a hardware fix for software issues.

A few months ago, I started de-transitioning by taking testosterone. However, it is traumatic to be on testosterone without having functional genitals. Moreover, my back hurts every day due to a psoriasis and scoliosis that I developed post SRS. I'm now dependent on synthetic hormones for life.

I traded my perfectly healthy genitals for an artificial one-inch tunnel that is sexually nonfunctional. I realize that I'm never getting back a functional penis and full detransition is not really possible in my case. I feel stuck in surgically created body. I believe nobody under 18 should be allowed to medically transition. Sex reassignment surgery should only be allowed in very rare cases after full psych evaluations. Patients should be made aware that what they're really getting is a cosmetic surgery and it's a genital

approximation surgery that does not change biological sex. Thank you.

CHAIRMAN ZACHARIAH: Well, thank you so much.

Next is Billy Burley (phonetic).

BILLY BURLEY: Good morning, members of the board of medicine. My name is Billy Burley and I used to be transgender. When I was about five years old, I started having the reoccurring thought that God made a mistake, I'm a girl. I prayed before going to bed and always asked, "God, please make me a girl before I wake." If I could have, I would have chosen any path that would have transformed me into a girl.

In my early 20s, I sought help for the disconnect between my mind telling me I was a woman and my body telling me I was a man. In seeking help and doing my own research, the message I received was that I had to change my body to match my mind. I decided to follow the therapists' and medical researchers' encouragement to change my body. I started on testosterone blocker and estrogen. My emotions were up and down, and my body was changing, but I was supposedly on this new road to happiness, which made me happy.

In my first surgery, I had a penile inversion, an Adam's apple shave, and a brown shave. After the surgery, the doctors and nurses had difficulty stopping the bleeding from my new vagina. My artificial vagina was packed with gauze and a sandbag was placed on my lower abdomen, but the bleeding did not stop. I received a blood transfusion and plasma and eventually, the bleeding did stop. My two-week stay in the hospital turned into a three-week stay. But changing my penis to an artificial vagina required two surgeries, so about four months later, I was back for part two, labiaplasty.

I was desperate for the happiness I believe was ensured me. After this, I had additional feminization surgeries but no matter how many I had, every time I looked in the mirror, I saw a man looking back at me. I tried hard to resolve the conflict between my mind and my body but after seven years of trying, I had more problems at that point than when I started on the road of transition.

The bottom line is that the therapists and medical researchers were wrong. I have fully transitioned back to male. I am happily married. I have two beautiful stepdaughters. And I have peace

of mind and body. I was an adult when I made the horrible decision to transition. The therapists and doctors failed to help with my underlying problems. They identified me as transgender, and they were wrong. How often are they wrong? I urge you to create a rule that makes it unethical for doctors to prescribe gender converting treatments or puberty blockers for people under the age of 18. Thank you for hearing my testimony.

CHAIRMAN ZACHARIAH: Thank you, Mr. Burley, for coming and talking to us.

Next is Cat Cadison (phonetic).

CAT CADISON: I'm Cat, a de-transitioned woman, singer, and molecular biologist. As a child, I was artistic, nerdy, and socially awkward struggling to find my place in the world. I was subjected to both abuse and bullying beginning in toddlerhood. As a result, I felt alien in my body very early on. If I was a body, I thought I could protect myself.

At 5, I asked my mother if it was possible to change genders and she said no. For the next eight years, I disliked my sex but believed I was resigned to my fate until age 13 when I came across an online forum for transgender people. That day I

began believing that the reason I suffered from anxiety, depression, and anorexia nervosa was because I should have been born male. I read that if one had gender dysphoria it meant she was trans and that she was extremely likely to take her own life if she didn't transition. But back then in the mid-2000s, gender-affirming culture did not yet exist. My parents, peers, and pediatrician did not affirm me, for which I am now grateful.

My cross-sex identification persisted until age 17 when my parents took me to a gender therapist. They hoped he would take a holistic approach considering my many comorbid mental health issues, but he affirmed as a boy immediately. The therapist began using he/him pronouns for me, and my appointment three, he suggested I started testosterone. My parents were astounded and did not comply with his recommendations.

I was unable to pass as male without any medical interventions, and I temporarily desisted. But my unhealthy beliefs about gender such as you cannot be happy unless you transition, continued to fester in my mind. After years of rumination, this culminated in me deciding to medically transition. I obtained testosterone by calling Planned

Parenthood and was prescribed after just a 30-minute phone conversation.

Within months of starting testosterone, I experienced side effects such as liver and gall bladder damage, heart palpitations, and the permanent loss of my natural singing voice. This was what ultimately influenced me to detransition as I realized appearing as a man was not worth sacrificing my music. But if this hadn't been my tipping point, I might have pursued surgery and come to regret it as countless others have.

If I had been prescribed puberty blockers at age 13, I'd likely be suffering from infertility, osteoporosis, and/or stunted brain development. All gender-affirming care is experimental, lacking controlled studies, and sufficient data on its long-term outcomes, so I caution against treating patients of any age in this manner. However, patients younger than 25 when the brain is fully developed are particularly vulnerable.

Because puberty blockers stunt brain and bone maturation leading to lifelong disabilities, I advocate for the complete cessation of prescribing them to gender dysphoric youth and for no other medical interventions to occur prior to age 25.

Thank you.

CHAIRMAN ZACHARIAH: Well, thank you so much, Ms. Cadison.

Next Helena Kershner (phonetic).

HELANA KERSHNER: Hello, my name is Helena Kershner and I'm 24 years old. I'm here today as a de-transitioner with grave concerns about the so-called gender-affirming model of responding to minors and young adults who believe they are transgender.

As a young girl, I had no discomfort with being female. What I did have was a history of family issues, difficulty fitting in with other girls, eating disorders, self-harm, and depression. When I was 14, I began spending a lot of time online in communities where countless other troubled adolescent girls were encouraging each other to interpret social, emotional, and body image difficulties as signs of gender dysphoria with the belief that body modification would be a transformative solution.

When I took steps in the direction of being trans, I received more positivity and encouragement than I had ever experienced. By age 17, I identified as a trans boy and was fully convinced

that my only chance at living a happy life would be to take hormones and undergo surgeries to change my body.

My school counselors and school therapist both affirmed my beliefs, and the psychologist even told my mother that she was risking my suicide if she would not agree to testosterone treatments. But thankfully, she was not intimidated.

I went to a Planned Parenthood a few weeks after my 18th birthday. None of the clinicians were interested in what was behind my desperation to change my body. They told me that because I seemed so sure they would prescribe the hormones that day, forgoing blood tests. I told the clinicians that I wanted a high dose, so I would see more changes in my body. They agreed and prescribed me 100 milligrams of testosterone per week.

The mental health effects of testosterone were profound. I began experiencing uncontrollable episodes of rage and paranoia where I was a danger to myself and others. I also became more suicidal and self-harming. Due to this, I was hospitalized twice. None of the clinicians in the hospital or outpatient center ever mentioned testosterone as a possible source for my mysterious new symptoms.

Instead, I was prescribed a litany of psychiatric drugs.

This time was so dark that it caused me to question the original promises of a joyful trans life, and after five years of identifying as trans gender, I stopped taking testosterone and began the journey of de-transitioning. My mysterious new mental illness went away soon after and has never returned.

I am forever grateful that clinicians were not able to affirm me any further. I am very fortunate to not have experienced any obvious physical detriments, but the negative impact of the so-called gender affirmative care on my life cannot be understated. Not only was I in serious danger under the influence of testosterone, but the mental process of returning to reality, accepting my body, coping with everything that happened, and facing the mental health issues that were compounded by these experiences has been very difficult.

I ask the board to see these dangers of gender affirmation and create a rule prioritizing exploratory psychotherapy and long-term health over dangerous cosmetic interventions for these vulnerable young people. Thank you.

Thank you, Ms. Helena.

Next is Ted Haley (phonetic). Yeah, please proceed.

TED HALEY: Yeah. I've got 31 minutes. I could do it but you all might not want to listen, I don't know. I want to be fair to everybody.

Okay. First of all, it is an honor and a privilege, and I am humbled to be here to testify to the Medical Board of Florida. I also want to say to all my trans friends, been there, done that, got the badge. Not many people are going to say this but being transgender is not easy. It takes a lot of courage, you have to be brave and determined. So no matter what you say, being transgender is difficult.

Well, with that, I want to say thank you to Dr. Laidlaw, I can confirm that what he says personally is true. All the things that he laid out, I got the badges. What makes me qualified? Well, at age eight, I too had gender dysphoria. But I was an old school because back then you couldn't do anything. So I had to wait until I was 50. But in that time, I had to wait until then, I had five adopted children and I was, you know, divorced and I had free range because my kids were adults, basically. But what did I do? I did it all.

Everything you could do. Two facial feminization surgeries, trach shave, in and out bottom surgery, hundreds of hours of electrolysis. If you've ever done that, it is painful.

So why am I telling you all this? I'm telling you because yeah, I was happy for a few years. It's kind of like buying a car, you know, an expensive one with the real expensive payments. Then a few months later, you get buyer's remorse. Well, that was me. I was very happy for about 8 to 10 years, then I started experiencing waves of depression so severe that, yes, I might not be here today had it been for my faith in God and the fact that I'm raising my granddaughter.

This is a serious issue. We don't take it lightly. I don't take it lightly. I have two friends that have died in these procedures, medical procedures. They're dangerous. This is something very, very serious. I have two trans friends that committed suicide. Yes, I know what it's about.

So what am I asking? Is that the medical board seriously consider delaying this until the age of consent. I was 50 years old when I transitioned, and it took me to 62 to figure it out. So if me at 62 can't figure out, how in God's green Earth is a

minor going to? They want to be a fireman one day, a policeman, a boy, or girl, whatever. But I know you all will make the right decision. They you for the privilege to being here and thank you trans friends for being here too.

CHAIRMAN ZACHARIAH: Thank you, Mr. Haley.

Next is Yako Shenfield (phonetic).

YAKO SHENFIELD: Ladies and gentlemen, good afternoon. What you're about to hear is tragic. My name is Yako Shenfield and last year on August 22nd, I buried my beloved daughter because of what gender transition treatment did to her. My daughter had been in counseling for depression since the age of 15 but had never said anything about gender dysphoria to her counselor.

At age 17, her mother told me that she was transgender. She did suffer from rejection in school and was seeking affirmation. Five of her friends announced they were transgender. When she said that she was trans, she finally had her peers' acceptance, so she thought. And she had not previously experienced in high school, I mean the acceptance.

When my daughter went to college, she began taking testosterone. When I saw her at the college,

she was very depressed. Actually, she was almost rejected for non-performance of her academic studies. A social worker presented a meeting with my daughter. Her name is Shannon Sonnet, MSW (phonetic). She told me that my daughter was going to get a double mastectomy. When I objected to her taking such a drastic step at such a young age at that point, 19 or 18 and a half, the social worker told me I was a typical chauvinist male. I am a typical chauvinist male who doesn't love his child enough. She said, "This is what we are going to do, and you need to just get on board." The social worker assured me that everything would be fine if I just loved my daughter.

My daughter had a double mastectomy at age 19. Exactly when, I don't know, because she didn't speak to me for about two years. It wasn't my decision, it was her decision. At some point, finally, it was very painful to me that separation from my child. Things were amended. I accepted her and to the best that I could because inside, I was in such dichotomy of feelings because I rejected this whole journey. I think it's against God. It's against biology as we heard from Dr. Laidlaw.

UNIDENTIFIED SPEAKER: Time.

I'm talking, okay.

UNIDENTIFIED SPEAKER: Time.

UNIDENTIFIED SPEAKER: These people also cheated. I was the second person here that handed in my speaker card and none of these people --

CHAIRMAN ZACHARIAH: Excuse me. You've got to stay quiet.

You know, Mr. Shenfield, thank you so much. Your three minutes has expired. I really appreciate you coming.

Now let's go on to -- you're next.

UNIDENTIFIED SPEAKER: Okay. I'd like to called --

CHAIRMAN ZACHARIAH: No, no. You had three minutes and that's it.

UNIDENTIFIED SPEAKER: Next, please, Bob Flynn (phonetic). Bob Flynn if you're here, we're calling you.

CHAIRMAN ZACHARIAH: Sir, we are not going to allow it. You have to sit down. You have to do an orderly manner and you're going to run this meeting. You sit down. I am just telling you, you sit down, or somebody will sit you down.

UNIDENTIFIED SPEAKER: We're calling Bob Flynn at this time.

Mr. Bob Flynn, please.

MARY FLYNN: Mary Flynn. We both have cards. Would you prefer just Bob and then I go later, or --

UNIDENTIFIED SPEAKER: No. I'm okay with both of you, please.

MARY FLYNN: Okay. I'll start in the essence of time. So my name is Dr. Mary Flynn; I'm a consulting psychologist and a proud mother of a transgender child who is now 12 years old. It's a joy to raise this beautiful child and everything we've heard before is nothing that I've ever heard before in any support group, by any physician, by anything.

So to be clear, our child at age 4 was -- came out as transgender. She told us who she is. We worked with a panel of experts, just to your point. We have a full team of people. She meets with a psychologist every single week. She's met with three over the years.

For the past 8 years, we've been on this beautiful journey helping our child who had suicidal ideation at age 5 and now is a healthy, happy 12-year-old thriving in Florida. But we are scared we're going to have to move because she has started

gender-affirming care at age 12. She has a puberty blocker. And you all have the power to save her life and all of the lives of these people that need this medicine. You actually have the power here.

If we did not have this medicine, she would not be alive. We are so proud of her, and we are so proud to be in Florida where they have allowed her to get her care. What you're talking about is waiting until age 18. Well, they won't be here. This group commits suicide. They will not be here. So we need the medication, please.

BOB FLYNN: We want to put the hands -- we want to put the control in the hands of the parents, right. We want to be able to make these decisions for our kids. One lady said, "Wait until they're 25." We all have the ability to be able to make these decisions as adults. For every study, there is always a counter study, right. We've heard that today through in and throughout.

And I feel that, you know, we can answer these questions and we should let these children proceed and put the capability in the hands of the parents, so that the kids can do their thing, okay. When you take that medication away, we can't do that decision. And now the burden is on our daughter.

We'll probably have to move, and that is even deeper despair for her.

And what happens in the Netherlands is the same thing that happening here. It's all political. 100 and 30 something bills have already been positioned, and that, as a result, against transgender care. And that to me is just atrocious. We're here to support our kid. I need you to help us support our kid. At least keep us to have the tools to support our kid.

UNIDENTIFIED SPEAKER: Thank you very much.

CHAIRMAN ZACHARIAH: Thank you. Next is Blaze Treatis (phonetic).

BLAZE TREATIS: Good morning. I'd like to thank State Surgeon General Joseph Ladapo for seeking Florida medical guidelines which prohibit medical doctors from prescribing puberty blockers and cross-sex hormones for children, and from performing sex change surgeries on children. Dr. Ladapo correctly asserts that puberty blocker drugs and cross sex hormones cause irreversible lifelong injury to children such as loss of bone mass, blood clots, and lifelong sterility.

Until the Florida legislature criminalizes medical doctors performing genital mutilation

surgery on children, the Board of Medicine and Board of Osteopathic Medicine should adopt the recommendations of State Surgeon General Ladapo. It is an oxymoron to call sex change surgery for children "gender-affirming care." As there is no care being provided but instead only child abuse which has been outlawed and criminalized in some states in America.

What is happening is that social media, such as TikTok, promotes gender dysphoria which leads to peer pressure among teenagers and preteens to succumb to the pressure to believe that they should try to become the opposite sex. In the extremely rare cases of gender dysphoria, the child invariably is experiencing depression will pass with time and perhaps, treatment. The solution to the temporary depression in children is not irreversible side effects of puberty blocking drugs and cross-sex hormones and life altering, irreversible sex change surgery.

It is way past time for women and feminists to reject men's false assertion that men can become women by putting on a dress and makeup and take some hormones. When feminist succumb to the false demands of these transgender men who claim now to be

women, the feminist are victims of what they say they are fighting against, which is patriarchal men dominating and controlling them, women. Transgender men dominating girls and women in high school sports, in college sports, public discourse, public policy, and every other aspect of society. Women should stand up against this attempt by transgender men to dominate women.

University of Kentucky swimming champion Riley Gaines has been outspoken on television arguing against transgender men such as Leah Thomas being allowed to dominate women swimmers in the college swimming championships. Ms. Gaines spoke the truth when she said that "Womanhood is not a mental disorder suffered by men." That concludes my remarks.

I would just like to say that I agree with the board member in the front who says to leave the clinical studies out of this proposed rule. It seems to be complicating it greatly. And as the gentleman said, there's 49 other states where these studies can be done, and I think it would be better to leave that out. I appreciate you. It looks like you're going in the right direction. Please continue. Thank you.

ATTORNEY MCNULTY: Thank you. Calling Hope McClay, please.

HOPE MCLAY: Hi, I'm Hope McClay. This is my mother. I am not a medical professional. I am not a scientist. I am just here as a mother. In 2023, I was a mother to three little boys. Today, I am the mother of two little boys and one beautiful little girl.

Our journey started since my daughter could walk or talk. Ever since she could walk or talk, she presented as female. I thought I had a very creative little boy, possibly would grow up to be gay and never leave his mother. She would wear dresses, fashion long hair out of t-shirts.

And it wasn't until -- and we allowed this to continue inside the home, but outside the home, we forced her to conform and to be a boy. We physically, at times, had to force her to put her boy clothes on. We physically had to force her to cut her hair and keep a short haircut. And these escalated to such an extent that it was becoming distressing, really for all of us, to physically force a child.

My daughter is a very determined person. She's always known who she is. At one point, she

came up to me at about three and a half years old and begged me, crying, and said, "Please, don't make me be this way anymore. This is not who I am. I want to die." And while I know it sounds profound that a three-and-a-half-year-old would be able to say these words, we still did not support her. What we did was we educated ourselves and we went to professionals.

We went to some of the best professionals in the state of Florida who helped us understand what transgender is. I didn't really know what that was. And so we supported her social transition and her journey. Today she is almost 10 years old. She is a competitive synchronized swimmer. And no, she does not dominate the sport. She just had her level one test and failed magnificently, but she loves the sport.

She -- we're not looking to have surgery, we're not looking to do anything harmful to our daughter other than support her mental health. It would be psychologically damaging if she had to go through puberty as a male. It would be psychologically damaging for her siblings, for our family.

All we're asking is that the medical

professionals treat each patient individually. Our doctor is here in this room. We have sought out psychiatry, psychological, medical, pediatric, endocrinologist's help. So we do not make these decisions lightly, but these are the decisions that should be made by the families not by the state and not by a board. Thank you.

ATTORNEY MCNULTY: Thank you.

CHAIRMAN ZACHARIAH: Okay. Next is Dr. Edward Drass.

EDWARD DRASS: Good morning, Board. I'm Dr. Edward Drass. I practiced here in Florida for the last 40 years. I've done general internal medicine and family practice. I also chaired our hospital ethics committee for 12 years. Today I loudly speak out against all forms of chemical and surgical cross-sex therapy.

I've seen the full range of mental illness in children, adolescents, and young adults. We all agree mental illness is destructive for the individual, the family, and for society. Many of the individuals that I've seen that are LGBTQ or transgender have significant levels of mental illness, and often, this mental illness has not been satisfactorily addressed by counseling or

psychotherapy. Is it not the best practice to address psychopathology with approved psychotherapy before instituting lifechanging, unhealthy transition treatments?

Gender identity disorder only came to my attention five or six years ago, but it's now diagnosed in the code book for mental illness, the DSM-5 as Gender Dysphoria. It appears that we're dealing with an unprecedented epidemic of mental illness in adolescent females. This demographic comprises the bulk of the 4400 percent rise in new cases of gender dysphoria seen in the past few years.

So I ask you physicians, for what other disease do we allow an adolescent patient to make his own diagnosis and then demand a preferred treatment? As the Board of Medicine, what ethical standards must be met when providing sex reassignment? What standards of care have been established for this treatment? Does the board supervise quality control and satisfactory outcomes for doctors and clinics offering these services? What is a satisfactory outcome? These are all questions that need to be asked when you decide the rules for transgender treatment.

I think other countries and judicial systems are well ahead of the United States in making this determination. In the wake of the Bell versus Tavistock verdict, as you heard from Dr. Biggs, the NHS has reversed course in its transition treatment advice. Florida should take the lead from this decision.

A summary review of transgender medical research concludes there's no support for medical intervention for gender confused minors. Medical transition procedures do not reduce youth suicide. Childhood gender dysphoria usually dissipates by adulthood. And the dramatic increase in gender dysphoria in the recent past is likely driven by social factors.

My recommendation to the rules committee is that cross-sex medical and surgical treatment should not be supported by organized medicine, the Board of Medicine, the legislature, or insurance companies. Thank you for what you're doing.

CHAIRMAN ZACHARIAH: Dr. Drass, thank you so much.

ATTORNEY MCNULTY: I'm going to ask the crowd to please be controlled. What we're trying to do is to allow everybody to make comments, so please

contain your -- we've got to control this, so that we can allow everybody to have their time. So I'm going to call Jude Spiegel (phonetic), and again, if the crowd starts disrupting the speaker, you're going to be asked to leave.

Jude Spiegel.

UNIDENTIFIED SPEAKER: They went to the restroom real quick. Can we come back to them?

ATTORNEY MCNULTY: Okay. Then we'll call the next, Ada Lopez (phonetic). And a reminder, Ada, you have only three minutes.

ADA LOPEZ: Hello, my name is Ada Lopez and I thank the board for giving me a chance to speak. I'm a proud mom of a transgender son. Our child attended Catholic school from pre-K through eight. He was in the Girl Scouts, sang in the choir, was an alter server. He used his recess time to raise money for Operation Smiles. Those were the things he was involved in at that time. He insisted on being the first one to arrive at school every day. He worked as a safety patrol. He used to volunteer to stay after to help the teachers clean their rooms. He was passionate about books, astronomy.

All of that started to change at the age of 13. He became reclusive, did not want to leave his

room. He did not want to go to school. He lost interest in all the things that he loved. We didn't know what to do. He wanted to die. We took him to therapists, doctors. I signed him up for teen club. Even a youth group called Girl Talk. I gave him a kitten. Nothing worked.

Finally, he came out to us at the age of 14 as a transgender boy. This was something new for us. As a registered nurse, I knew how to look for established national guidelines, recommendations. I learned about WPATH and I took him, at that time, to medical experts right here in Florida, starting with his pediatrician who had known him since birth. We saw endocrinologists, psychiatrists, psychologists, social workers. I was presented with options and made difficult decisions.

Today, my son has a new name that matches his gender. He is a very happy 21-year-old college student currently majoring in physics and astronomy. Gender-affirming care made all the difference for him. I am so grateful every day to have him. Next month we're going camping. Now he spends his free time going to the rock-climbing gym with his friends.

I ask the board to keep all these

lifesaving WPATH options open for all Floridians. I can't even think of the harm that would have come to him if we hadn't been able to access these treatments. And when it's time to make difficult decisions for parents, other people's opinions don't matter. People want to have access to all the options that can save their child's life.

ATTORNEY MCNULTY: Thank you.

CHAIRMAN ZACHARIAH: Thank you. Next is Robert Roper (phonetic).

ATTORNEY MCNULTY: No, next.

CHAIRMAN ZACHARIAH: Next is Robert Roper.

JUDE SPEIGEL: You said my name when I was in the bathroom.

CHAIRMAN ZACHARIAH: I understand that. You're going to wait.

Robert Roper.

ROBERT ROPER: My name is Robert Roper. I've been authorized to tell a story of a patient named CG -- that's a pseudonym -- who has been irreversibly harmed by medical transition as a minor. Says this, "Had a rule placing restrictions on gender transition treatments been in place in my street, then I would not have been placed on the fast-track to medical and surgical interventions and

I would not at age 21 be facing a lifetime of sterility and a mutilated body.

Like many de-transitioning young people, I was a gender nonconforming child who was on the autism spectrum and suffered from depression and anxiety. At age eight, I did not like stereotypical boy stuff. Instead, I liked girl stuff and the ways girls behaved. Transgender websites told me I was a girl if I like girl things. I began talking with trans identifying people through phone apps.

At age 14, I told my parents that I was trans and believed that I was a girl trapped in a boy's body. My parents celebrated my trans identity and took me to see gender-affirming therapists. The therapist immediately affirmed my trans identity without any psychological testing or exploring why I believed I was trans. I then saw an endocrinologist and a gender clinic at Providence Hospital. The endocrinologist prescribed Estradiol and spironolactone.

At age 15, I began the hormone regiment. I experienced significant psychological complications from the treatments. I became depressed to the point that I was not getting out of bed. I became too anxious to go anywhere or talk to people and

ended up dropping out of school. I also developed an eating disorder and an addiction to the internet. I was not functioning healthfully, but my parents continued to move me along the gender-affirming path, scheduling surgery at age 17.

Soon after turning 18, I was flown to Washington, D.C. where my testicles and penis were removed. I was given a vaginoplasty to create an artificial vagina and receive plastic surgery on my face. At no point was I offered any alternatives to medication and surgery. No one attempted to explore my underlying reasons for my depression and discomfort with my sex.

I soon realized that treatments had not improved my life and I discontinued them at age 18. Now at 21, I have a body that is completely ruined. I have worried that my body is now going to be a freak no matter what I do. Even with parental consent, these treatments are putting kids on a path of harm. I was not able to grow up in a healthy way as a result of having been scared by these treatments. I do not want to see other young people harmed in this way. I believe these treatments should be disallowed or seriously restricted for children and young people like myself." Thank you.

ATTORNEY MCNULTY: Jude Spiegel.

JUDE SPIEGEL: Hi, I'm Judge Spiegel. I'm a transgender parent of two children and I've known I was transgender since I was very young. I suffered from suicidal ideation from the age of 10 to 26 and attempted suicide many times thinking it was wrong to be who I was. I wanted changes I didn't think I could ever have. I didn't feel safe opening up about who I was until later in life. But this isn't about me.

Let these decisions remain between parents, children, and their doctors. If rules must be adopted, then please adopt the World Professional Association for Transgender Health Standards of Care. I'm going to read the names of 17 transgender teens I researched who chose suicide over living in a world that refused to acknowledge or accept them. Andrew Elijah Martinez (phonetic), Ash Hafner (phonetic), Avril (phonetic), Blake Brockington (phonetic), Charles Knolls (phonetic), Daniel France (phonetic), Amelia Worth (phonetic), Emmot Castle (phonetic), Fluod (phonetic), Haley Gabrielle Feldman (phonetic), Jordan Howell (phonetic), Kyler Prescott (phonetic), Leila Alcorn (phonetic), Leo Etherington (phonetic), Melanie Rose (phonetic),

Taylor Alesena (phonetic), and Zander Nicholas MaHafeey (phonetic). Thank you.

ATTORNEY MCNULTY: Thank you.

CHAIRMAN ZACHARIAH: Next is Amie Aderberry (phonetic). Is Amy Aderberry here?

Next is January Littlejohn (phonetic).

JANUARY LITTLEJOHN: My name is January Littlejohn. I am a Florida mother of three children and a licensed mental health professional. I am here to offer my personal experience, not as a counselor, but as a mom. In the spring of 2020, our 13-year-old daughter told us she was experiencing distress over her sex, and she didn't feel like a girl. She had expressed no previous signs of gender confusion and her announcement came shortly after three of her friends at school also claimed transgender identities.

Soon afterwards, her mental health spiraled. We worked with a licensed mental health professional to help our daughter explore and resolve co-occurring issues including low self-esteem and anxiety. We also gave her more one on one time, in person activities away from trans influencers, limited her internet use, and declined to affirm her newly chosen name and pronouns. We

set appropriate boundaries and allowed her to choose her hair and clothing but denied harmful requests such as breast binders, puberty blockers, cross-sex hormones, and surgeries.

It was clear from conversations that our daughter was uncomfortable with her developing body and had an intense fear of being sexualized. She was filled with deep self-loathing and was in true emotional pain but had been encouraged by peers and influencers to believe that gender identity was the source of that pain. What she really needed was for us to help her make sense of her confusion and remind her that hormones and surgeries could never, ever change her sex or resolve her underlying mental health issues.

I shudder to think what could have happened if we had affirmed her false identity and consented to medical treatments as opposed to what we did through watchful waiting which was to lovingly affirm her as she is, beautifully unique, and irreplaceable, and undeniably female.

After several years, our daughter has desisted and is on a path to self-love. I have spoken to many parents in Florida, and they are not being informed of all treatment options when they

seek help for their child. Many times they are being convinced by medical professionals that affirmation and medicalization is their only option to avoid the impending suicide of their child. Suicide is told to these parents as if it is a guaranteed outcome versus a risk factor for these kids.

Unfortunately, gender dysphoric children are being encouraged through activism and peer pressure to disassociate from their bodies and to believe their body parts can simply be removed, modified, or replaced. The irreversible consequences of medical transitioning including loss of sexual and reproductive function cannot be fully understood by children or teens who lack the necessary cognitive maturity or experience.

These children deserve ethical, evidence-based treatment that helps them explore and resolve the true source of their distress. Please stop enabling doctors to chemically castrate and cut off the health organs of children and teens. Thank you.

ATTORNEY MCNULTY: Next, George Lopez. George Lopez (phonetic).

Cory Hill (phonetic).

Okay. I have a card. Mr. Lopez, would you

like to address the boards?

Okay. Cory Hill.

Jennifer Engles (phonetic).

JENNIFER ENGLES: I'm a licensed mental health counselor in the state of Florida. I speak for myself and my own experiences and education. I have been counseling transgender youth since 2013, and transgender people aged 13 and older, generally make up between 60 to 80 percent of my active client caseload at any time in my practice. I would not be encompassing the full scope of my career if I did not come here today to advocate for my clients' mental health and wellbeing.

Some of the ethics of my profession, according to the American Counseling Association's code of ethics, are to do no harm, to work for the good of the individual, and to respect the rights of one to control their own life. The American Medical Association's code of ethics echoes these themes. I have both of these here. Please allow those of us who specialize in working with certain issues to continue to do so unimpeded. Most professionals who work with the transgender community in any capacity have been trained in gender-affirming care per the WPATH standards of care, which I have here, version

eight. It is for you if you would like this copy.

So we do this because it is a worldwide standards of care that is best practice that has been used for 43 years and through 8 editions. So they do continue to evolve. This is not a static document from 43 years ago. The research is unbiased, apolitical, and well documented to be in the best interest of the client or patient. What is different about Florida's transgender citizens that our Department of Health feels the need to determine standards of care that are different from the entire rest of the world?

Please do not make your decision for political reasons. My clients, even the young ones, are well aware that they are being used as political pawns, and they are already being harmed by discussions like the one we are having today. Today the Department of Health and Board of Medicine are not upholding the ethic of do no harm. They hear you. They hear us. They are hurt.

Per WPATH, "Therapists and medical providers are already discussing potential risks and benefits of hormone therapy in order to write referral letters." We do this. I have a form that I fill out that I go through, check boxes of what I

discuss. How many transgender people have you had in depth conversations with regarding their lived experiences? If you had the insight I have gained from getting to know hundreds of transgender people as a therapist, friend, advocate to the community, and could understand how amazing transgender people are and how much they truly contribute to all facets of society, you would want to do everything you could to help them thrive.

What if transgender people are just real and just exist in greater numbers currently because they have more reason for hope for a fulfilling and authentically lived future? I want to be clear, I do not tell my clients what choices to make about their lives. I help them and their families to make their own decisions.

CHAIRMAN ZACHARIAH: Well, thank you so much. Next is Bob Framingham (phonetic).

BOB FRAMINGHAM: Members of the board, my name is Bob Framingham and I have been personally impacted by the harms of gender-affirming care through watching my son transition. My son was educated in Christian private schools from kindergarten to grade eight, was an average, well-behaved student. He played baseball little

league, was pretty good. He expressed no confusion over sex during childhood or adolescents. However, he was socially awkward and did have mental health issues.

Grades 9 through 12 he attended SAIL public school in Tallahassee. SAIL is a very progressive art school, and this is where he was exposed to the false idea that he could have been born into the wrong body. He earned a brown belt in Taekwondo and is an Eagle Scout. At age 18, he could do 20 pull-ups with one hand. Now he can't lift 40 pounds because of his therapy in order to help him grow breasts.

He was diagnosed with borderline personality and severe depression in 2023. His mental health issues began around age 14 shortly after he started at school. It was clear that he suffered from low esteem and self-hate. Tyler announced that he was transgender at age 22 and began transitioning for 6 years. This has not improved his quality of life or resolved his mental health issues. He dropped out of college, has no meaningful romantic relationships, and he's not anorexic. Clearly, there's a disconnect between Tyler's brain and his body.

He intends to alter his body, but I really think he needs to alter his mind. I am deeply concerned that his mental health will further deteriorate once he comes to the realization that making irreversible changes to his body will not fix his pain.

So I would urge you to create a rule that will protect children from making irreversible life-changing decisions when their brains are not fully developed. I would encourage you to put safeguards in place even for adults seeking transition, like counseling to address other mental issues that may be the root cause of the confusion prior to any surgery or hormonal intervention.

And I would suggest that having a true informed consent where patients are fully informed of the consequences of taking hormones, including the rate of regret and the high risk of suicide 7 or 10 years after transition. Thank you very much.

ATTORNEY MCNULTY: Next, I have George Lopez, Cory Hill, and Lindsay who would be next in line, but they've chosen not to speak. But they are opposed to the rule.

Next, I'll call Cassie.

Gus.

Kevin Astle.

KEVIN ASTLE: Good afternoon. My name is Dr. Kevin Astle. I'm an assistant professor with the University of South Florida Taneja College of Pharmacy. My statements today do not represent the views of my employer. I hold several credentials and board certifications including board certified pharmacotherapy specialist. So in this role, I'm a medication expert and I have the expertise to be able to determine when medications are appropriate and to evaluate the literature that's available for medications.

I could preach to you about the recommendations and rules that you are setting forth today and how they contradict the recommendations of all the major medical associations in the United States, but you all are already aware of that. One of the points discussed today is the informed consent process and how for the children that you want to continue on therapy that have already engaged in gender-affirming care need this enhanced informed consent process. That is already occurring. That, along with the recommendations made today, are evident that the guidelines have not been reviewed. That the board here does not know

what is actually being practiced in medical care today and that these standards being proposed by the board are outside of the standard practice in the world.

Another point brought up today was for research. You know, there's 49 states in the country, let's let them do the research. What does that say to our institutions here in the state of Florida? That we're second class to the rest of the United States? That the University of Florida, a top five public institution where I'm a proud alumni of, does not deserve to engage in research? Or myself at the University of South Florida we cannot engage in research for this topic just because we live in the state of Florida? That will make us second class to the rest of the United States and that is not what we want to do.

And then finally on that, you talk about not wanting to impair progress. This discussion today, the fact that we're having this is impairing progress, so that is all that's being done. This country was founded on the principle of individual rights and freedoms. Today you're making actions to violate those freedoms for Floridians. You have the right to choose whether or not you want to provide

gender-affirming care in your practice. You have that choice and that decision. You have the choice and decision whether you should pursue gender-affirming care yourself or for your children. Your actions today are going to take that right away for Floridians all across the state. And is that your decision to make?

As a Board of Medicine, you're here to guide medical practice. You're not here to determine what is medical practice and what is not. Your actions today would be in violation of your role. You know, you're here to allow for safe practice, not to dictate what is medical care and what is not. When you graduated from medical school, you took an oath to do no harm. These decisions today will completely violate that oath, and I think upon that your medical license should be reviewed and should be considered to be revoked if you pass this legislation. Thank you.

CHAIRMAN ZACHARIAH: Next is Patty Sullivan (phonetic). Before -- you can come to the podium. You will be the last speaker for the day. Let me finish. Don't shout, you're not going to win. What we're going to do, we'll give you an email for the state of Florida. You send your information and

whatever information you send will be a part of the record.

UNIDENTIFIED SPEAKER: (Indiscernible) out of the 100 or 1000 of people that are sitting in here that vote.

CHAIRMAN ZACHARIAH: You know what -- okay. Okay. Okay, that's fine.

Okay. Ms. Patty Sullivan, you may proceed.

UNIDENTIFIED SPEAKER: Their blood is on your hands. Their blood is on your hands.

CHAIRMAN ZACHARIAH: That's okay. Let's have some decency and quorum here.

Patty Sullivan, you may proceed.

PATTY SULLIVAN: Hi. My name is Patty Sullivan and I'm with Parental Rights Florida. And just a quick caveat since it was brought up, the American School Counselors Association, the American Medical Association, the American Pediatrics Association, this is why this board is needed to bring clear evidence-based rules and guidelines and standards. The past president of the American School Counselors Association in August in 2022 at a national conference basically said, "Here in Florida we have these laws made, and you need to learn the rules, so that you can break the rules." So this is

why you all are needed, and your expertise is needed to bring these clear evidence-based standards.

I spent thousands of hours researching to understand why specific Florida based and nationally advocacy groups consistently opposed commonsense family friendly legislation in Florida. I am a Florida citizen. I'm a Florida mom. The research that I did, hours and hours, confirmed these non-medical organizations push gender-affirming medical interventions even though real research shows the majority of these children will resolve distress after puberty.

UNIDENTIFIED SPEAKER: Bullshit.

PATTY SULLIVAN: Many of these parents with gender dysphoric children are not being presented with this critical information, nor are they being given all the treatment options available to them to treat their child's gender dysphoria such as watchful waiting and counseling. If what is being forced on these children and these families is so valiant, why are these groups, why were they hiding, and lying, and deceiving, and putting these support guides behind the scenes and keeping parents out of the loop. I have a school psychologist on video telling administrators how not to tell the parents,

through my research.

Why are these groups still pushing irreversible medical transition procedures on children when they know that the research shows that the rate of completed suicide increases to 19 times that of the normal population post transition? Children with gender dysphoric issues deal with profound and complex emotional issues. I had issues that resolved from a childhood, and I'm married 34 years.

The consequences to a child making permanent life altering decisions, taking drugs that alter their moods and bodies, and then having their genitals and breasts mutilated is beyond comprehension.

The Florida Medical Board can put clear, evidence-based rules, guidelines, and standards in place and bring clear consequences for those who would flagrantly break these rules and laws. And the time for courage is now. I commend you and I support you. Please do this and bring pause. Thank you.

ATTORNEY MCNULTY: Thank you.

CHAIRMAN ZACHARIAH: Well, thank you so much. The timing for the public comments have

ended.

UNIDENTIFIED SPEAKER: Excuse me, Board of Medicine, if --

CHAIRMAN ZACHARIAH: We'll take a five-minute recess.

UNIDENTIFIED SPEAKER: I'm a State House Representative here in Orlando. These are my constituents, they deserve to speak.

CHAIRMAN ZACHARIAH: I understand that. I understand that. You should know better. You are a Representative. You know how this -- you represent the House once in the state of Florida, so you should obey the same rules. And the meeting is adjourned for the next five minutes.

UNIDENTIFIED SPEAKER: You cut public comment by one hour in Fort Lauderdale and you're doing this shit again. We see you. We see everyone of you and as long as you continue --

UNIDENTIFIED SPEAKER: We respectfully ask for more time.

(Recess taken)

CHAIRMAN ZACHARIAH: Okay. Do you have a quorum now? Yeah. We have a quorum. Let's talk about the closing and the administrative matters. Let's start with drafting the rule.

Ed, do you want to start?

EXECUTIVE DIRECTOR TELLECHEA: We still need some guidance on this issue regarding the enhanced consent process. What do you want to see in the consent?

MR. ROMANELLO: So do you think, Ed, that you have enough specificity for the rule unrelated to the consent form?

EXECUTIVE DIRECTOR TELLECHEA: You are talking about the prohibition on the procedures for people under 18?

MR. ROMANELLO: Yes.

EXECUTIVE DIRECTOR TELLECHEA: And making it prospective?

MR. ROMANELLO: Yes.

EXECUTIVE DIRECTOR TELLECHEA: I have enough on that.

MR. ROMANELLO: Okay.

EXECUTIVE DIRECTOR TELLECHEA: The enhanced consent process though is what we're going to need some more specifics on. What specifically you want to see in that enhanced consent process.

MR. ROMANELLO: Got it. So I would propose, as Doctors Biggs and Kaltiala -- I'm sorry, as Doctors Dayton, Janssen, and McNamara propose,

that any consent be predicated on a multi-practitioner basis. Right. They all proposed a multidisciplinary approach.

DR. ACKERMAN: Multidisciplinary panel. We usually refer to it as a multidisciplinary panel.

MR. ROMANELLO: There you go.

DR. ACKERMAN: And we can say specifically who should be on that panel.

MR. ROMANELLO: Right. So consisting of pediatrics, psychiatry, endocrinology. And they both spoke -- or all three of them spoke about support systems and kind of mental health counseling. And I think it was Dr. McNamara who suggested a licensed clinical social worker when Dr. Diamond was asking if you recommend those surgical procedures to their patients and they said, "Well, it would depend upon what the social worker" -- you know, in part. So if we're going to have a multidisciplinary panel, then I would suggest it's pediatrics, psychiatry, endocrinology --

DR. DIAMOND: Pediatric endocrinology.

MR. ROMANELLO: Pediatric endocrinology and a licensed clinical social worker.

DR. ACKERMAN: So can I just make a small just recommendation? I don't think you need a

psychiatrist but having a psychologist or licensed clinical social worker, I think that's what I'm hearing from them that would fill that niche.

ATTORNEY MCNULTY: So I'm a little unclear about the role of a social worker.

DR. ACKERMAN: Well, a social worker is a counselor like a --

ATTORNEY MCNULTY: No, I know what they do. Just how that individual would integrate into this multispecialty team and at what phase?

DR. ACKERMAN: Well, I think we heard from them all that there was a psychological component to this, and so the multidisciplinary panel, having a psychological component to that. Because you have the medical component with the pediatrician, the endocrinologist component with the pediatric endocrinologist, and the psychological component with either a clinical psychologist or LCSW.

ATTORNEY MCNULTY: So where does the social worker --

DR. ACKERMAN: That's the LCSW.

ATTORNEY MCNULTY: Yeah. But again, the role of the social worker in that process.

DR. DERICK: To maybe evaluate the support network for the individual.

ATTORNEY MCNULTY: Okay.

DR. ACKERMAN: To assess, and to give counseling, and to share with the panel that the patient has been properly assessed.

ATTORNEY MCNULTY: Or, you know, Dr. Derick, I think you answered my question. To make sure that the individual has the appropriate family support. Because some of these children, you know, may not be in a two-parent family, you know, they may be wards, have guardians. So the social situation of the child I think answers my question.

CHAIRMAN ZACHARIAH: I have a question for Dr. Hunter. Dr. Hunter, you deal with these things. Do you think they should have a psychiatric evaluation, or some psychiatrist involved in this decision making?

DR. HUNTER: The level of mental healthcare, whether it's psychology, psychiatry, I think that's up for debate. One thing that I think any consent needs to recognize and needs to share with the patient and the family is the level of evidence and what the systematic reviews have shown. The NICE reviews out of England on puberty blockers and cross-sex hormones are the best English language reviews. The Swedish reviews are only summarized in

English. They have not been translated from the Swedish language to the English language with full reviews. But any informed consent needs to disclose the degree of evidence or lack thereof, whether who that's coming from.

I agree it needs to be a multidisciplinary process. That's what the Dutch said they would do. And that needs to be -- the informed consent is not a simple process in this setting. It has to include surgery. I think it needs to include surgery because once you're on the path of social transition, there is good evidence that social transition maintains that identity and changes the desistence rates.

Once that's started, then you're on puberty blockers. We've heard that puberty blockers lead 98 percent chance, 95 percent chance of cross sex hormones. Now we're in the irreversible territory. What percentage of those kids go on to surgery? So for a 12, 13, 14-year-old to understand that, they would then need to understand the surgical risks because they're starting on a pathway that may not go back, that may be irreversible.

So the consent process would have to involve a surgeon, I believe, too, for the family to

understand. The 12-year-old, 13, 14 year old might not understand that but the parents, I think, are due that knowledge of what the evidence review show and the full gamut of what may proceed over the next 4, 5, 6 years.

DR. DIAMOND: Mr. Chair?

CHAIRMAN ZACHARIAH: Yes.

DR. DIAMOND: So again, going through these different components, prospective rule I think is clear. Enhanced consent, pediatrician, pediatric endocrinologist, and I would say either a psychologist or a licensed clinical social worker. With respect to the point that Dr. Hunter is making, I don't think I would be in concurrence that a surgeon needs to be involved. I think that would be very, very difficult, you know, just logistically.

I can understand that, and I appreciate exactly where he's coming from but the logistics of that may be difficult, so I would eliminate that from the enhanced consent.

The third thing we were discussing is whether or not to proceed with a research exemption. And as know, Mr. Romanello made a motion, and it was seconded. Dr. Hunter essentially made an amendment, and I am supportive of that amendment. And in terms

of language to help you, I would be of the opinion that there's an exception that minors can be treated with GHRH agonist or cross-sex hormones but only under the auspices of a university sponsored/IRB approved longitudinal trial in which the parents give consent, the child gives assent, and there's a continuing condition of receiving that intervention that the child continue on that trial. And further, that that proposed study must be presented to the rules of the legislative committee for its approval as a first step. Is that enough specifics for you?

EXECUTIVE DIRECTOR TELLECHEA: Yes. I don't think you have the authority for that under a standard of care rule.

DR. DIAMOND: So how would we go and try and craft an exemption if that is the --

EXECUTIVE DIRECTOR TELLECHEA: I think you need to remove the approval by the board.

DR. DIAMOND: Remove the approval of --

EXECUTIVE DIRECTOR TELLECHEA: Having the -- coming before the board to have that type of process approved.

DR. DIAMOND: So your contention would be that my language would be sufficient except for that it requires approval by the Rules and Legislative

Committee; is that correct?

EXECUTIVE DIRECTOR TELLECHEA: I think that would be -- yeah.

DR. DIAMOND: Okay. I'll stand with that.

UNIDENTIFIED SPEAKER: I would.

DR. HUNTER: I would just add that that research is required to follow everyone well into adulthood. That's the NHS language.

ATTORNEY MCNULTY: Is there an age?

DR. HUNTER: They just say -- the NHS language -- they're still crafting their research, but they do specifically say --

DR. DIAMOND: So Dr. Hunter, the issue that we may have, while the child is receiving such intervention, that's easy. But how do you go when the person has now exceeded the age of majority and is no longer perhaps receiving hormonal therapy, how can it be required or mandated that the participation continue?

DR. HUNTER: Well, you said no longer receiving hormonal therapy. These transgender patients need hormonal therapy for the rest of their lives, so --

DR. DIAMOND: But also, we're not regulating the care of individuals once they have

reached majority.

DR. HUNTER: Correct. But this is where I need clarification. This board is here for all citizens of Florida, correct?

DR. DIAMOND: Of course.

DR. HUNTER: Not just those under the age of 18.

DR. DIAMOND: But the motion on the table is treatment of minors with gender dysphoria. My particular position is that for persons that have reached the age of maturity, that no intervention is necessary.

DR. HUNTER: If we were going to give an exception to research, I think we would want research that is going to be valid and reveal data that's legitimate and that would require long term, longitudinal follow up.

DR. DIAMOND: I'm 100 percent with you. How would we do that? How could we -- how could we -- how could you affect that?

DR. HUNTER: That's going to be how well the research is written. And that's beyond the authority of this board.

DR. DIAMOND: I guess what you'd have to do is maybe like any other study, if you sign up, we

are asking in good faith that you agree to participate in X period of time. But you know what, if you drop off, it's a free country, we can't do anything about that. I mean, perhaps that's the best way to approach it. There's no way to mandate that, of course.

DR. HUNTER: No.

CHAIRMAN ZACHARIAH: You know, Dr. Diamond, I just want clarification. You said they either get a psychologist on the case or a social worker. Is that true? Because --

DR. DIAMOND: Well, I think that was what -- I think that was what Dr. Hunter was saying is that would meet his requirements.

Is that sufficient for you, Dr. Hunter? A psychologist or a LCSW? Or was that not your intent?

DR. HUNTER: Well, a related but separate question. What does the current rule say just about informed consent in general?

DR. DIAMOND: I don't think it specified.

EXECUTIVE DIRECTOR TELLECHEA: We don't have rule that says -- about informed consent in general. With the exception of for medical marijuana and I think for --

ATTORNEY MCNULTY: And cataract. Cataracts.

EXECUTIVE DIRECTOR TELLECHEA: -- and for cataract surgery. That's it.

DR. HUNTER: Okay.

EXECUTIVE DIRECTOR TELLECHEA: See that's what I'm trying to get to. You know, when we did those informed consent forms, we sat there, and we drafted these forms in multiple meetings and we're not getting that right now. We're getting the broad outlines as what you want to see as part of your -- you know, the people, the entities that are going to participate in the informed consent.

But if you all want or are expecting an actual informed consent document to be used, you know, or you're expecting an informed consent procedure to be used, I'm going to need to know what all those elements of that informed consent, what those expectations are, so that they can be put in the rule, so that the people that you are regulating, the physicians who are involved in this will know what those expectations are.

UNIDENTIFIED SPEAKER: Mr. Tellechea, we don't have elements of the medical marijuana consent in the rule, we just publish the standard form to

use, right? I mean, the rule -- you don't go back into the rule, there's not elements in the rule. It's just here's the approved form.

ATTORNEY MCNULTY: But the rule adopted and incorporated by reference the form, but that's part of the rule.

UNIDENTIFIED SPEAKER: Why wouldn't we do the same thing here? Why would we try to now draft a form by committee? We've given -- I think we've given the broad brushstrokes. Can you come back with a proposed form that we can discuss? You've heard about pediatric endocrinology, licensed clinical social worker --

EXECUTIVE DIRECTOR TELLECHEA: We can work and try to bring something back.

ATTORNEY MCNULTY: But what we wouldn't have is the standards that you want, like all the studies, the this, that, and the other, the different prongs of it. For those other forms, there were many meetings and people would work on specific language that is inside the form. But for example, you indicated you wanted to have the certain risks associated with certain treatments.

MR. ROMANELLO: Yes.

ATTORNEY MCNULTY: But we don't know what

those are. We don't know, the lawyers don't know what those are.

MR. ROMANELLO: Yep. Agreed. I think that Dr. Hunter had started to expand upon what some of the risks associated with the therapies are, and I would defer to my other physician colleagues to modify or add to that list.

CHAIRMAN ZACHARIAH: Yeah, go ahead.

UNIDENTIFIED SPEAKER: I don't mean to divert from this discussion but, you know, one thing I heard was consistently from the experts the issue of behavioral health and psychiatric diagnoses. And I'm wondering if it would behoove us to have at least two psychological evaluations.

I agree with the multidisciplinary team, but hearing the testimony today, the fact that the behavioral health conditions are so prevalent, would it be appropriate to actually have the concurrence include two behavioral health evaluations, clinical psychologist, psychiatrist?

DR. PAGE: I agree with your statement. I would support that.

CHAIRMAN ZACHARIAH: Go ahead. Go ahead.

DR. PAGE: No. I would support what you're saying, like we have to make sure -- you know,

address the underlying mental health issue that could have triggered this gender dysphoria.

CHAIRMAN ZACHARIAH: Yeah. See but one of the reasons I ask the question, if you listen to the testimony of the experts and from the public, psychiatric issues was a major role in that. It really was, in almost all of them. And I strongly -- one thing I strongly believe is that these minors should have a psychiatrist or a psychology evaluation. Not to be all -- what does a social worker know about psychological issues? They're not trained in that. No, they're trained in, you know, homes and other issues.

EXECUTIVE DIRECTOR TELLECHEA: They're talking about licensed clinical social workers.

DR. ACKERMAN: Yeah. They're trained in psychological issues.

CHAIRMAN ZACHARIAH: Well, so far, their psychological training, I have no problem. But my concern is majority of them have significant psychological issues and they must get some kind of psychologic evaluation to make sure that that can be resolved in some other fashion.

DR. ACKERMAN: And LCSWs do that. Not just psychologists, LCSWs. They don't just arrange for

homecare, they also do counseling and evaluations.

CHAIRMAN ZACHARIAH: Okay. If they're trained to do so, I have no problem with that.

DR. DERICK: So if I'm understanding this correctly, if a parent and a child desire to undergo transitioning in the current proposed rule, they would be able to do so but only at an institution as part of a clinical trial with an IRB approval. And that if you are someone who is currently undergoing therapy, then this is where this informed consent comes in in a minor.

DR. DIAMOND: That's correct.

DR. DERICK: Where there would be -- not a cessation of treatment, but during the continuation of treatment that they would be then reinformed with consent with this multidisciplinary team that's chosen by the -- somebody, I don't know who that would be. The person who was currently providing care to them. And then the studies would be presented to those people for consideration and then they would be allowed to continue their therapy if they chose to do so. Is that correct?

ATTORNEY MCNULTY: So what I'm hearing is it's almost like we've got a staged evaluation. Should we look at consent at each phase of the

evaluation and therapy?

DR. DIAMOND: Well, I'm not sure I'm understanding correctly. My understanding is, is that the motion as intended was that as of a certain date, these interventions are prohibited unless it's under the strict auspices of a clinical trial, analogous to what our colleagues in the United Kingdom are doing.

Having said that, for individuals who are currently receiving intervention, we recognize that there may be actually some harm to stop, and therefore, we are going to say there is an opportunity to continue, but as a condition to continue, there must be a documentation of this more enhanced consent that occurs within a certain period of time. That was my understanding of how Mr. Romanello was trying to phrase it.

Nick, did I get that right?

MR. ROMANELLO: Yes.

ATTORNEY MCNULTY: And might as well, I guess what I didn't clarify is as each of these therapies evolve in advance, would an additional consent, or at least requirement that the risks associated with those therapies be -- you know, be given, understood, and consented to? So as the

individual progress, as the child progresses through each phase of the therapy, the consent is already there but do we want to add the additional consent for the risk of the medication --

DR. DIAMOND: I want to understand. So you're referencing a -- for example, a 12-year-old who may be currently on GHRH agonist therapy, and that the parent and the child express a wish to continue. They've gone through and done the enhance consent process. And then are you saying that it is your intent that if that child were to then, and the parents were then to have an interest in going on to cross sex hormones that there would be s second component of enhanced consent? Is that what you're saying?

ATTORNEY MCNULTY: Yeah. At least a comprehensive explanation of the consequences of those drugs. Now, whether it's has part of the first consent --

DR. DIAMOND: I don't know if that's going to add anything further to what we're doing.

ATTORNEY MCNULTY: Okay.

MS. JUSTICE: Do we need to address that in this rule? I mean, that has to occur already anyway because --

UNIDENTIFIED SPEAKER: It should.

MS. JUSTICE: Right. I mean, you're giving a new treatment and arguably, that patient is not in the same stage or condition that they were when they initiated the prior treatment. So informed consent is -- we don't need to address that in this rule, I don't think. I don't mean informed consent period, I mean at each phase.

ATTORNEY MCNULTY: Hearing the testimonies from some of these individuals was pretty compelling to the consequences --

MS. JUSTICE: I agree.

ATTORNEY MCNULTY: -- and you know, just trying to make sure that we capture --

MR. ROMANELLO: But what I think Ms. Justice is alluding to is if you're on puberty blockers today and a year from now you're recommended to start initiating cross sexual hormones, that would require a separate consent form because that's a new modality of treatment. And then if you go three years down the line and you're recommending surgical intervention, that would require yet another -- so you're always going to have those ongoing consent requirements, separate and apart from --

ATTORNEY MCNULTY: Maybe the simpler time, or at least to try to get around this is just list what that consent, or at least the consent that's provided, what that has to contain. Right. Which you've done. Instead of actually drafting the form.

DR. HUNTER: I think one of the problems with the -- and I think everybody has a problem worldwide in this consent area is there is so much that is unknown. So to give a valid informed consent requires the patient's understanding and their capacity. Okay. It's -- we all question, as a profession, the capacity of somebody under the age of 18 to consent, let alone you mix in mental health issues. So that's an issue. But the understanding is the hard part because there is so much unknown about this therapy.

So to provide an -- that's what makes it, in my opinion, experimental, because there is so much that is unknown and that's why it's moving back into the experimental realm in Sweden, Finland, England, as we've heard. So the ability to give informed consent is nearly impossible.

DR. DIAMOND: Mr. Chair, if there's no further discussion, perhaps we could call the question?

CHAIRMAN ZACHARIAH: Yeah. Because we only have 10 more minutes. So what -- we can call the question but what I really would suggest that let's ask Mr. Tellechea what else does he need to do his job?

DR. DIAMOND: Today.

EXECUTIVE DIRECTOR TELLECHEA: Well, I'm going to need someone to sit down with me and explain what you want to put in the informed consent, because you're not giving me enough at this point in time.

I mean, Donna? I mean --

ATTORNEY MCNULTY: I mean, I agree. Unless you -- I mean, I agree overall with Ed. The other option, which I think Dr. Schwemmer raised, was instead of having like this detailed board form for the informed consent, do you just want the elements in your rule?

DR. DIAMOND: Elements, elements.

EXECUTIVE DIRECTOR TELLECHEA: Right. But you need to tell me what the elements are.

ATTORNEY MCNULTY: But they need to be very specific for everything.

MR. ROMANELLO: So the first element is that it is a multidisciplinary panel that you are

going to get the consent from, and that multidisciplinary panel will include pediatric endocrinology, pediatrician --

DR. ACKERMAN: And either a clinical psychologist or licensed clinical social worker.

MR. ROMANELLO: -- and either a clinical psychologist or a licensed clinical social worker.

ATTORNEY MCNULTY: Behavioral health, two psych opinions?

MR. ROMANELLO: Yes. So --

ATTORNEY MCNULTY: Wait, wait. This is the informed consent we're talking about?

MR. ROMANELLO: Yes.

ATTORNEY MCNULTY: So you want two of them on there?

MR. ROMANELLO: Yes.

CHAIRMAN ZACHARIAH: Did he say two separate people?

ATTORNEY MCNULTY: Two psychological evaluations.

EXECUTIVE DIRECTOR TELLECHEA: Is this going to be a consent form that the patient and the family is going to read and sign off on?

DR. DERICK: I think the intention is that certain types of physicians would be involved in

provided the information that would be consented upon. I just think it does seem kind of complicated for people already undergoing therapy who have already consented to this treatment then be reconsented with a very specific group of people.

DR. DIAMOND: I agree with Dr. Derick. These folks are undergoing treatment. The intent, I believe, from Dr. Hunter and Mr. Romanello is to simply say, "Hey, the rule allows you to continue but please understand that you need to be aware of these complexities." And there needs to be sign off with the parent, the patient, of course, and I would say a pediatrician, endocrinologist, and either a psychologist or a LCSW and stop there. I wouldn't go beyond that. I mean, I just wouldn't.

DR. DERICK: So you're saying you wouldn't dictate what those people would be consenting about but that they would just need to be consented with those specialists.

DR. DIAMOND: They need to go and verify that to the best of their professional abilities, that the patient and the family are aware of the risks, benefits, and alternatives of treatment as we do whether it be cancer treatment or anything else.

DR. DERICK: For the record, I'm not aware

of how that's different from what's currently happening. Because these are the specialists who are treating this patient population and they're consenting the patients.

DR. HUNTER: I think the trouble we're having is what the Dutch described in their studies and in their papers is that informed consent in this area is not a form, it's a long process. And they talked about it being at least six months. I think some of the reference is longer than that. It's a process where they meet with all these people, and they understand.

MS. JUSTICE: That's right.

DR. HUNTER: Understand the limitations. Let me float this idea, because we're -- I see three points that we're sort of coalescing around. One, that psychological care be the standard. Number two is that there be a moratorium on puberty blockers, cross sex hormones, and surgery under 18. And three, that a clinical trial be the only way to go forward under 18.

The problem we're having is the problem that everybody else is having is the kids that are already being transitioned. And maybe we remain silent on that expect to say when the clinical

trials do exist, those kids need to be enrolled in those trials. Because that's where an informed consent process that is IRB approved, they'll spend hours, and hours, and hours, and hours on that. Okay. And maybe we remain silent on the kids already in this system, but when we rehash that issue at later meetings.

MR. DIAMOND: My bias would be to not do it that way. These are people that have already commenced under a certain understanding or set of understandings. And I think that to require them to go and then participate in a clinical trial, I think that may be a bit too much. I fully get what you're saying, it solves certain problems, but it may create additional issues.

CHAIRMAN ZACHARIAH: Dr. Di Pietro.

DR. DI PIETRO: Trying to step back and take a big picture view on this, I'm starting to think about the problems that might happen. And the biggest problem I can see beyond a lot is who is ultimately responsible for the patient's care in this informed consent. So is it the pediatrician? Is it the pediatric endocrinologist? Like who is responsible for making sure that the boxes have been checked?

DR. DIAMOND: Well, typically it would be the individual who is actually prescribing the medication.

DR. DI PIETRO: So it would -- okay. So that's -- you know --

MR. ROMANELLO: So Mr. Chair, in the -- as we're starting to get time compressed --

CHAIRMAN ZACHARIAH: Yes.

MR. ROMANELLO: -- can I suggest that we consider the motions separate and apart from the consent which we have not fully coalesced and come to a consensus on? But we did have a motion and a second and Dr. Diamond offered an amendment which I would gladly accept.

DR. DIAMOND: Well, that was Dr. Hunter, but I seconded it.

MR. ROMANELLO: Okay.

DR. PAGE: I have a question before you move on. So in your motion you're talking about conducting clinical trials. So do we need to elaborate more on that? Like which institutions are going to be allowed to do clinical trials? Can anybody just do their own clinical trials in their office or how do we go about that?

DR. DIAMOND: Well, like I said, in my

comment I thought it would need to be an IRB approved clinical trial at a university affiliated center. Those are the two main components.

DR. ACKERMAN: Approved by the rules committee?

DR. DIAMOND: No. Mr. Tellechea said that would be problematic and we dropped that.

EXECUTIVE DIRECTOR TELLECHEA: You've got to keep in mind, these are standard of practice rules, all right. We can't create research studies through standard of practice rules. We have to set -- these are the regulations that the doctors who are performing these procedures must adhere to. So going off and trying to approve studies and all that that's going to go way beyond your rulemaking authority in this particular area.

MR. ROMANELLO: And what Doctors Hunter and Diamond had come up with, an IRB approved study at an academic institution without approval of laws and rules I thought you said would have met --

EXECUTIVE DIRECTOR TELLECHEA: Yeah. That's fine.

MR. ROMANELLO: That's what we're going to --

EXECUTIVE DIRECTOR TELLECHEA: I know. But

Dr. Ackerman was coming back around to that issue, and I was trying to --

DR. ACKERMAN: Sorry, I was just trying to clarify.

CHAIRMAN ZACHARIAH: So is the board ready to vote on this motion?

DR. DIAMOND: Yes.

ATTORNEY MCNULTY: We need to maybe read it back.

EXECUTIVE DIRECTOR TELLECHEA: Just to clarify, we're not going to be dealing with informed consent now. That's somewhere down the line we'll deal with that.

MR. ROMANELLO: Yes.

EXECUTIVE DIRECTOR TELLECHEA: Okay. So my understanding is that you're going to put the prohibition on the puberty blockers, the cross-hormone therapy, and the surgery under the age of 18, for anyone under the age of 18, unless it's being done within the auspices of the language that you used, a university affiliated --

UNIDENTIFIED SPEAKER: IRB approved --

DR. DIAMOND: IRB approved.

EXECUTIVE DIRECTOR TELLECHEA: -- IRB approved --

DR. DIAMOND: University affiliated clinical trial.

EXECUTIVE DIRECTOR TELLECHEA: Which you're going to give me that specific language later on. That's what I'm hearing at this point in time.

DR. DIAMOND: And that the rule is a prospective rule.

EXECUTIVE DIRECTOR TELLECHEA: And it's prospective. Yes.

ATTORNEY MCNULTY: Early, Dr. Diamond, I think one board member mentioned that you also wanted it in the rule that the drugs remain available for treatment of other medical disorders and that once the person reaches 18, no restrictions on this. Did you want that in the rule?

DR. DIAMOND: Well, I think the easier way to do is say that this rule applies exclusively to minors with gender dysphoria. Make it easy. And I think by doing that, there's no need to address persons who reach the age of majority or other medical conditions.

MR. ROMANELLO: Right.

CHAIRMAN ZACHARIAH: So we have a motion. So restated the motion, seconded. Any further discussion?

DR. DI PIETRO: Sorry, so I just need to reclarify. So we're off on informed consent and we're back to IRB approved research for under 18?

MR. ROMANELLO: Yes.

DR. DERICK: I think there are three elements.

DR. DI PIETRO: Yeah. Because for me, they're not -- they're not separate issues because I can't -- it would be very difficult for me to vote on just that because the informed consent issue and the absence of research is a whole different element. So I'm just trying to clarify because I feel like they're two completely separate issues.

CHAIRMAN ZACHARIAH: You know what, we have a motion, the board second. Somebody had to vote on it because it's past 1 o'clock, the meeting has to end.

MS. PAGE: No. But I'm sorry, before we vote, I agree with her comment. I think the informed consent is very important.

EXECUTIVE DIRECTOR TELLECHEA: Then vote against it. We need to vote now. We have a hard stop on this meeting. It was noticed until 1 o'clock, so we have to --

CHAIRMAN ZACHARIAH: We have to stop the

meeting at 1 o'clock. So we have a motion, seconded. All in favor, say aye.

(Multiple ayes)

Any opposed?

(Multiple nays)

MR. ACKERMAN: They can't make motions.

CHAIRMAN ZACHARIAH: Let's see a motion in favor?

(Multiple ayes)

Any opposed?

(Multiple nays)

So two opposed?

MR. ACKERMAN: Three opposed.

CHAIRMAN ZACHARIAH: Can we have the hands up, the ones who opposed?

Okay. All in favor? Hold on, hold on. Ma'am, would you please quiet. I'm conducting the meeting. You are not conducting the meeting.

Okay. All in favor of the motion, raise your hand. You don't have to hear it.

Okay. All opposed?

Okay. And the motion carries, thank you so much and the meeting is adjourned.

(END OF AUDIO RECORDING)

CERTIFICATE OF TRANSCRIPTIONIST

I certify that the foregoing is a true and accurate transcript of the digital recording provided to me in this matter.

I do further certify that I am neither a relative, nor employee, nor attorney of any of the parties to this action, and that I am not financially interested in the action.

Julie Thompson

Julie Thompson, CET-1036

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