

Jane Doe

vs.

Joseph Ladapo

June 23, 2023



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JANE DOE,
Plaintiff,
vs.
JOSEPH LADAPO,
Defendant.

CASE NO. 423CV114RHMAF

TRANSCRIPTION OF AUDIO RECORDING
FLORIDA BOARD OF MEDICINE AND OSTEOPATHIC MEDICINE
JOINT RULES/LEGISLATIVE COMMITTEE MEETING
JUNE 23, 2023

TRANSCRIBED AUDIO RECORDING BY:
Julie Thompson, CET

Job No.: 323393

1 Thereupon,

2 The following proceeding was transcribed from an
3 audio recording:

4 *****

5 CHAIRMAN ROMANELLO: This Florida Boards of
6 Medicine and Osteopathic Medicine Joint Rules and
7 Legislative Committee meeting to open.

8 MS. STRICKLAND, can we have a roll call.

9 MS. STRICKLAND: Yes. Mr. Romanello is
10 present.

11 Dr. Ackerman.

12 DR. ACKERMAN: Present.

13 MS. STRICKLAND: Dr. Benson.

14 DR. BENSON: Present.

15 MS. STRICKLAND: Dr. Derick.

16 DR. DERICK: Present.

17 MS. STRICKLAND: Dr. Di Pietro.

18 DR. DI PIETRO: Present.

19 MS. STRICKLAND: Dr. Kirsh.

20 DR. KIRSH: Present.

21 MS. STRICKLAND: Dr. Mortensen.

22 DR. MORTENSEN: Present.

23 MS. STRICKLAND: And Dr. Diamond,

24 Dr. Zachariah, Ms. Garcia, and Dr. Hunter have been
25 excused. Also present are Paul Vazquez, Executive

1 Director of Board of Medicine; Danielle Terrell,
2 Executive Director Board of Osteopathic Medicine;
3 Christopher Dierlam, board counsel; Donna McNulty,
4 board counsel, Cassandra Fullove, senior legal
5 assistant, Cherise Strickland, program operations
6 administrator, and Brad Dalton, public information
7 officer.

8 Chair, you have a quorum.

9 CHAIRMAN ROMANELLO: Thank you.

10 Mr. Vazquez, Ms. Terrell, do we have any
11 comments from either of the executive directors?

12 EXECUTIVE DIRECTOR VAZQUEZ: Yes. Good
13 afternoon. It's Friday, June 23, 2023. The time is
14 1:02 p.m. My name is Paul Vazquez; I'm the
15 executive director of the Florida Board of Medicine.
16 This is a duly noticed Joint Rules/Legislative
17 Committee meeting of the Boards of Medicine and
18 Osteopathic Medicine.

19 This is a public meeting and it's being
20 recorded. The audio will be available on the
21 boards' websites next week. I will now go over some
22 instructions, so this meeting will be successful,
23 and the committee members will be able to take care
24 of the matters that are before them today.

25 There is a court reporter in the meeting.

1 If you speak to the committee, it's important that
2 you state your name for the record. When
3 appropriate, the Chair will ask for public comments.
4 Therefore, please refrain from speaking during the
5 meeting until the appointed time. Please remember,
6 this is a public meeting and is being recorded. Any
7 side conversations may be recorded and become part
8 of the public record. At this time, please silence
9 all electronic devices.

10 The Boards of Medicine and Osteopathic
11 Medicine are apolitical bodies that have the primary
12 mission of protecting the people of the state of
13 Florida. As with any issue before the boards, the
14 board members will look to the available science and
15 appropriate standard of care while putting aside any
16 personal feelings they may have on the issues before
17 them today.

18 I want to take this opportunity to thank
19 the joint committee for its continued efforts to
20 address the requirements of Senate Bill 254 titled
21 Treatments for Sex Reassignment. The governor
22 signed SB 254 into law on May 17, 2023, and it
23 became effective upon signing. The law, as enacted,
24 requires the Boards of Medicine and Osteopathic
25 Medicine to do the following:

1 Adopt emergency rules within 60 days
2 pertaining to standards of practice under which a
3 patient younger than 18 years of age may continue to
4 be treated with a prescription if such treatment for
5 sex reassignment was commenced before and is still
6 active on the effective date of the law.

7 In developing rules under this paragraph,
8 the boards must consider requirements for physicians
9 to obtain informed consent from such patient's
10 parent or legal guardian. For such prescriptions
11 and treatments, the boards must consider the
12 provision of professional counseling services for
13 patients by a board-certified psychiatrist licensed
14 under chapter 458 or chapter 459, or a psychologist
15 licensed under chapter 490, in conjunction with any
16 prescription treatment.

17 The law also requires the boards to adopt
18 emergency rules regarding informed consent forms to
19 inform patients 18 years of age or older of the
20 nature and risks of sex reassignment prescriptions
21 or procedures in order for the patient to make a
22 prudent decision.

23 At a joint rules legislative committee
24 meeting held on June 1, 2023, the following
25 occurred:

1 An emergency rule was developed to attempt
2 to provide a way for patients receiving sex
3 reassignment prescriptions to continue to receive
4 such prescriptions while the boards worked to
5 implement the provisions of section 456.52(1), (2),
6 and (6), Florida statutes.

7 Pursuant to section 456.52 Florida
8 statutes, the committee began the process of and
9 made provision for the development of a standard of
10 practice and informed consents for minors continuing
11 to receive sex reassignment prescriptions, and
12 informed consents for adults who will receive sex
13 reassignment prescriptions and procedures.

14 An interim meeting was scheduled for June
15 23, 2023, at 1:00 p.m., with the intention of
16 completing the emergency rulemaking mandated by
17 section 456.52 Florida statutes.

18 The Boards of Medicine and Osteopathic
19 Medicine approved a modified version of the
20 committee's emergency rule on June 2nd and June 20th
21 respectively. The primary goals of today's joint
22 committee meeting are to final practice standards
23 for minors that were receiving treatment prior to
24 the effective date of the law to continue to receive
25 that treatment; finalize any necessary informed

1 consent forms for minors; and finalize informed
2 consent forms for adults.

3 A subsequent joint virtual meeting of the
4 Boards of Medicine and Osteopathic Medicine has been
5 scheduled for June 30, 2023, at 1:00 p.m. to
6 consider any actions the committee takes today.

7 In terms of how this meeting will be
8 conducted, it is the committee's expectation that we
9 will have a civil discourse while discussing the
10 issues on today's agenda. We require that everyone
11 refrain from making any disruptive comments or
12 taking any disruptive actions during the duration of
13 the meeting. The boards reserve the right to remove
14 any individual who chooses to disrupt the progress
15 of the meeting. Please conduct yourselves
16 accordingly.

17 Public comment will be allowed today as
18 time permits. Appearance cards are located at the
19 table outside of the meeting room. Please return
20 completed speaker cards to board staff at the table
21 in the back of the room. The following guidelines
22 will apply to public comments:

23 Interested parties will be limited to three
24 minutes to provide comment, which may only be
25 extended by the Chair if time permits based on the

1 number of proposed speakers. If an interested party
2 is part of a larger group of persons, you are
3 requested to identify one individual who will speak
4 on behalf of the group if possible. Interested
5 parties may use pseudonyms if they do not wish to
6 identify themselves on the record.

7 The public comment process will be
8 randomized and will be as equitable as possible.
9 However, it's possible that not everyone who wishes
10 to speak will be able to speak given the nature and
11 time constraints of the meeting.

12 If there are any publicly elected officials
13 with us today, please make yourself known to the
14 Chair during public comment to ensure that you have
15 an opportunity to speak. Thank you.

16 CHAIRMAN ROMANELLO: Ms. Terrell, anything?
17 No. Okay.

18 So before we start the discussion, I'd like
19 to provide an overview of the agenda for this
20 afternoon's meeting. The Boards of Medicine and
21 Osteopathic Medicine have been assigned the task of
22 developing an emergency rule pertaining to the
23 establishment of a standard of care for the
24 treatment of gender dysphoria in minors, which
25 includes language to be used in informed consent

1 forms. And two, an emergency rule outlining
2 informed consent procedures for the treatment of
3 gender dysphoria in adults.

4 I'll remind the committee and the members
5 of the public who are here today that these two
6 issues have been thoroughly discussed in a number of
7 public meetings beginning back in August of last
8 year in Dania Beach; in October of '22 in Tampa;
9 again in October in Orlando; in November of last
10 year in Orlando; earlier this year, February, up in
11 Tallahassee; and earlier this month in Tampa.

12 Moreover, the department and the board has
13 received an impressive number of letters and public
14 comments by folks wishing to express their opinion
15 on the rule and which the committees have taken into
16 consideration in forming the emergency rules today.

17 As advised by Mr. Vazquez, we're conducting
18 this emergency rulemaking process in accordance with
19 a statutory framework that requires the adoption of
20 the emergency rule. After today's hearing, we will
21 convene a virtual joint board meeting on June 30th
22 to consider whatever action the committee takes up
23 this afternoon.

24 On behalf of the joint committee and the
25 Department of Health staff that are here, I want to

1 extend a warm welcome to the members of the public
2 that are here today, including any elected office
3 holders who may be here. And I want to give you all
4 an indication of how we're going to proceed this
5 afternoon.

6 So the committee has under and for its
7 consideration six different informed consent forms,
8 and those consent forms are intended for different
9 patient demographics and presentations. And
10 although these forms are somewhat different, there's
11 a lot of overlap among those consent forms. The
12 committee is going to take up a discussion of those
13 consent forms first.

14 Following the discussion on the consent
15 forms, we'll take a short break and then we'll come
16 back, and we will take up a discussion on the two
17 emergency rules that are before us today. At the
18 conclusion of our discussion on the rules, we'll
19 open the meeting for public comment, and we'll take
20 public comment up through 4:30 this afternoon, at
21 which time we'll discontinue public comment, and the
22 committees will vote on whatever proposals are
23 before us. And we'll adjourn today's meeting at
24 5 o'clock.

25 Finally, grateful for the members of the

1 public who are here today, especially those who have
2 come to multiple meetings. Understand that this
3 issue holds significant importance for many people.
4 We appreciate the public comment and the interaction
5 with you, and we'll take your public comments into
6 consideration in the rulemaking process.

7 With that, do any other committee members
8 wish to make comments?

9 DR. ACKERMAN: Mr. Romanello, I would

10 CHAIRMAN ROMANELLO: Yeah. Dr. Ackerman.

11 DR. ACKERMAN: Thank you,

12 Mr. Romanello. And I also want to address the
13 committee and also the public.

14 For those of you who don't know who I am,
15 my name is Scott Ackerman; I'm the chairman of the
16 Florida Board of Medicine. And it's nice to see the
17 public here again today. I took a little walk
18 before the meeting. I went over to Starbucks, and I
19 wanted the lobby and I saw a lot of familiar faces,
20 and you know, welcomed the public who are here
21 today. I'm glad you guys are all here today. It's
22 good. We really do appreciate your input.

23 That being said, we have a lot of work to
24 do. We're mandated to put forth -- as you heard
25 from Mr. Romanello -- put forth consent forms and to

1 debate and to discuss amongst ourselves the nuances
2 of these consent forms. And we really will
3 appreciate your comments at the appropriate time.
4 What we're not going to appreciate is cheering and
5 jeering and that sort of stuff that's not very --
6 it's just disruptive to the meeting. And I'm going
7 to instruct law enforcement, as you can see who is
8 here today, to have anyone removed who participates
9 in those sort of activities.

10 We really want your constructive input, we
11 -- you know, having cheering and jeering and
12 snapping of fingers and those sort of things aren't
13 helpful to us. It just makes the meeting go longer
14 and it makes it so we can't do our job that we need
15 to get done. And we -- again, I want, and I think
16 the whole committee wants, is good, construction
17 comments as to what we can do.

18 Comments such as do away with everything
19 aren't very constructive because we're mandated to
20 do this process. We're mandated to put forth
21 consent forms. So comments saying that we should
22 not have a rule and we shouldn't have consent forms,
23 that's great, bring it up with the legislature, not
24 with us. We're mandated to do this and so please
25 don't take it out on us. We really want to be

1 helpful. We want to put forth a consent form that
2 is reasonable that is able to be enacted by
3 physicians throughout the state, and that's our job
4 today.

5 So again, thank you again for being here,
6 and please -- I want to thank you in advance for
7 participating with us in a meaningful, productive
8 way.

9 Thank you, Mr. Romanello.

10 CHAIRMAN ROMANELLO: Dr. Ackerman, thank
11 you.

12 Any other members of the committee?

13 Okay. So at the last meeting in Tampa
14 earlier this month, we delegated and asked Doctors
15 Mortensen and Benson to help develop one or more
16 informed consent forms. Dr. Mortensen did a lot of
17 the heavy lifting there and aided by Dr. Benson.
18 And I would look to them, as we want to discuss the
19 informed consents first, which one would logically
20 be the best place to start off with?

21 UNIDENTIFIED SPEAKER: Which one would be
22 the best place to start?

23 DR. ACKERMAN: I think we should start with
24 puberty -- we should start with the adolescents,
25 with the minors, and let's go in order. Let's do

1 puberty blockers, then do feminizing, then do
2 masculinizing.

3 CHAIRMAN ROMANELLO: Yep.

4 DR. BENSON: Yeah. I think that makes
5 sense to just follow the order.

6 DR. MORTENSEN: I agree.

7 DR. BENSON: Bates 264 is the first one.

8 CHAIRMAN ROMANELLO: But Doctors Benson or
9 Mortensen, do you want to introduce the concepts
10 here around the informed consents, or do we want to
11 open it up for questions from the fellow committee
12 members?

13 DR. MORTENSEN: So I took a good deal of
14 time, as we have over the last year of all the
15 information that's been provided to us and I've also
16 recently attended the Endocrine Society meeting in
17 Chicago to kind of take all that stuff and see if
18 anything else needed to be updated but I feel this
19 gives a very good representation of what the
20 concerns would be in regards to using puberty
21 suppression agents, or the continuation of them.

22 So more than happy to open it up for
23 discussion if anyone had any questions or concerns
24 about the verbiage or the side effects.

25 CHAIRMAN ROMANELLO: And so again, for

1 members of the committee, this is in the portal
2 under tab one. As Dr. Benson said, at Bates 264.
3 This is the consent for the use of puberty blockers.

4 DR. ACKERMAN: So I can make sure I
5 understand what this is. So Dr. Benson -- so the
6 public understands, as well -- Dr. Benson and
7 Dr. Mortensen each submitted a consent form that
8 they independently put together regarding puberty
9 blockers. In fact, for all of these different
10 things.

11 CHAIRMAN ROMANELLO: Right.

12 DR. ACKERMAN: Then staff took those
13 consent forms and kind of merged them into one. I
14 guess they both probably had a similar theme to them
15 and similar points in them, but then merged them
16 into one form that had -- so we can have one form
17 that we use rather by both the osteopathic
18 physicians as well as the allopathic physicians.

19 CHAIRMAN ROMANELLO: Yep.

20 DR. ACKERMAN: So that's what we have
21 before us. And I can tell you that I've thoroughly
22 looked through these forms over the last week and a
23 half --

24 EXECUTIVE DIRECTOR VAZQUEZ: I'd add one
25 other thing. So yes, DOH staff merged those two,

1 but also, the AG's office merged those two but also,
2 the AG's Office review them, as well.

3 DR. ACKERMAN: Attorney General's Office.

4 UNIDENTIFIED SPEAKER: Mr. Chairman?

5 DR. ACKERMAN: But that was all merged and
6 that's what we have in front of us today is this
7 merged entity that was done by Benson and Mortensen
8 independently and the staff put together.

9 CHAIRMAN ROMANELLO: Yes.

10 DR. ACKERMAN: And I can say that I've
11 looked through regarding the puberty blockers. I
12 think it's very -- you guys did a yeoman's work.
13 It's very, very thorough. It goes through -- you
14 know, for me, it reminds me of a lot of the consent
15 forms that I use in my practice when I have patients
16 that are involved in cancer treatment, especially
17 ones that are involved with getting multiple
18 different drugs and radiation. In that it's not
19 just a general consent form where you're signing
20 away -- you're signing not waiver. You're signing
21 saying, "I accept puberty blockers." But it's going
22 through each of the benefits, and risks of those
23 puberty blockers, and what one could accept over
24 time.

25 And I use the same sort of things in my

1 practice in those patients that are being put on --
2 we have a lot of patients in clinical trials. As
3 you guys know, I use proton radiation and it's very
4 complex stuff, I think. For me it's complex too.
5 And so with our patients, we go through all those
6 sort of things.

7 So I think that -- at first, I looked at it
8 and said, woah, this is a bit thorough, but after I
9 digested it a bit, I said, no, it's not. It's
10 really very similar to what I do in my cancer
11 practice. So I like this.

12 Turn on your mic.

13 DR. KIRSH: I echo that very much. I just
14 have a question. There's some holes in, or blanks
15 in it. Is that something for us to deal with or is
16 that what you're going to point out because there's
17 an inconsistency?

18 ATTORNEY MCNULTY: I think there's one on
19 page 1 of 8, regarding options. Is that the one
20 you're referring to, Dr. Kirsh?

21 DR. KIRSH: As an example, yes.

22 ATTORNEY MCNULTY: Yeah. I think that's
23 the only one in this form, and that's the same one
24 -- it flows through a number of forms. So to the
25 extent you -- and this would be true for any of the

1 changes that flow through all the forms. If you
2 change one thing, just make clear that you want it
3 changed on all the forms, so that way you don't
4 necessarily need to repeat it, and we'll flow
5 through those changes. And that's an option if the
6 minor does not want to continue treatment or the
7 adult doesn't want to continue treatment with said
8 medicine.

9 DR. ACKERMAN: So is that blank meant to be
10 filled in by the physician?

11 ATTORNEY MCNULTY: No, no. It's --

12 DR. ACKERMAN: Oh, okay. I read it as to
13 be filled in by the physician.

14 CHAIRMAN ROMANELLO: To answer your
15 question, you're right. That needs to be addressed
16 by the committee today and those blanks would need
17 to be filled in by the committee in the discussion
18 today.

19 DR. ACKERMAN: But that's the only blank
20 that's on each form. It's the same blank as on that
21 page --

22 ATTORNEY MCNULTY: Correct.

23 DR. ACKERMAN: -- of each form.

24 ATTORNEY MCNULTY: Correct.

25 CHAIRMAN ROMANELLO: Dr. Derick.

1 DR. DERICK: So in addition to this form,
2 it doesn't preclude a physician from providing
3 additional informed consent that they would --

4 ATTORNEY MCNULTY: Absolutely.

5 DR. DERICK: Because if there was something
6 that a physician would like to convey to a patient,
7 whether it be benefit or a risk, that could be a
8 supplemental consent form. So this is required as
9 the minimum.

10 ATTORNEY MCNULTY This is the mandatory,
11 that's correct. That's a good point. Nothing
12 prohibits a physician from having a supplemental --

13 DR. ACKERMAN: And that's consistent with
14 what physicians do. When I have patients in
15 clinical trials, we have a separate consent form for
16 the clinical trial, and we still use our regular
17 consent form.

18 DR. DERICK: The second thing I have a
19 question is related to the requirements to receive
20 the treatment. You know, the word prescribing
21 physician is used. "Undergoes an evaluation by the
22 prescribing physician at least every three months."
23 From a practical perspective, what happens if that
24 physician was on maternity leave or something else?
25 Is it not able to delegated to someone who is

1 covering for that physician or how is that going to
2 be contemplated?

3 ATTORNEY MCNULTY: But wouldn't that person
4 covering for them be a prescribing physician?

5 DR. DERICK: They wouldn't be -- that's a
6 good point, actually, Donna. If they prescribed the
7 medication, does that make them the prescribing
8 physician or it's the person who gave informed
9 consent discussion with that patient and originally
10 prescribed the medication?

11 ATTORNEY MCNULTY: I think in terms of who
12 is signing the form has to be the prescribing
13 physician, and the continuation of treatment is a
14 different issue, right. But if they're prescribing,
15 they have to be a physician, per statute.

16 DR. DERICK: So a patient comes in and sees
17 Dr. Jones in person, informed consent is signed.
18 And then three months later, Dr. Jones is on
19 maternity leave and needs to evaluate the patient,
20 but Dr. Smith then is the prescribing physician who
21 will write the prescription and then evaluates the
22 patient. Is that the understanding?

23 DR. ACKERMAN: Could you tell us where you
24 see this? What Bates page?

25 DR. DI PIETRO: It's on 265, and I think

1 she's referring to number --

2 DR. BENSON: Eight.

3 DR. DI PIETRO: Seven.

4 DR. BENSON: Or sorry, seven, yeah.

5 DR. DI PIETRO: I think Dr. Derick's point
6 is the way it's read, and I understand that can be
7 read two ways, but the way it reads now is the
8 original prescribing physician is the physician that
9 has to evaluate the patient at least every three
10 months. And to her point, if the original
11 prescribing physician is on maternity leave or on
12 vacation, how do you rectify that that prescribing
13 physician originally cannot see that patient? So do
14 we change "the" to "a" or --

15 DR. ACKERMAN: "Their."

16 DR. DI PIETRO: -- "their." "Their
17 prescribing physicians," maybe.

18 ATTORNEY MCNULTY: Does it have to be a
19 prescribing -- who do you want to -- could it be "a
20 physician"?

21 UNIDENTIFIED SPEAKER: I mean, it's true it
22 is sort of redundant. A physician is able to
23 prescribe as part of their job, so if it -- the way
24 that I read it, it sounded like the original person
25 for whom they did the consent form with.

1 DR. DI PIETRO: That's the way I read it,
2 too.

3 DR. BENSON: That's the way it's written.

4 UNIDENTIFIED SPEAKER: That is the way it's
5 written, so --

6 DR. ACKERMAN: You don't want to tie it to
7 just that physician because there's
8 multi-physician groups.

9 UNIDENTIFIED SPEAKER: Right.

10 UNIDENTIFIED SPEAKER: So Dr. Derick, would
11 you --

12 DR. DI PIETRO: I would say, I think, if
13 I'm reading it, if I read "a" or if I read -- I
14 think "a" could be kind of any physician. I would
15 write "their prescribing physicians," then you
16 incorporate anyone that could be in their practice.

17 CHAIRMAN ROMANELLO: I'm seeing nods from
18 "covering physicians."

19 DR. ACKERMAN: I don't like covering
20 physicians --

21 CHAIRMAN ROMANELLO: No, no. I'm not
22 saying the term, I'm asking the question. What
23 about covering physicians? So if they're not in the
24 same practice, and they cover your practice.

25 DR. DI PIETRO: But then that would still

1 be -- I mean, that patient is still under your care,
2 so it would still be part of "their physicians."
3 Right. If you write a prescription, legally,
4 they're under your care.

5 DR. ACKERMAN: Correct.

6 UNIDENTIFIED SPEAKER: If a patient decided
7 to switch doctors though, if we wrote it that way
8 then they couldn't continue with their new physician
9 because they're not part of that group.

10 DR. DI PIETRO: Okay. I mean, "a" --

11 DR. ACKERMAN: Couldn't you say something
12 like -- what type of physician is this? Is this a
13 physician who is treating gender dysphoria, right?
14 So could you say that in there? Because you don't
15 want them to just call some other random physician
16 and get some other random physician, an orthopedic
17 physician, you know. But you want a physician who
18 is actually treating their gender dysphoria, whether
19 it's their original one or their designate.

20 When I go on vacation, my partner does it.
21 Or maybe I'm a solo practice and I got some guy
22 across town that covers for me. But that guy
23 covering for me is still, I'm going to have someone
24 who, like me, treats gender -- if I was treating
25 gender dysphoria, I would have one of my buds who

1 treats gender dysphoria across town, you know, cover
2 for me.

3 DR. DI PIETRO: I think that's a very good
4 point, Dr. Ackerman. It really should be someone
5 who is experienced within gender dysphoria, not
6 someone's primary care physician.

7 DR. ACKERMAN: Right.

8 DR. DI PIETRO: I think that's the essence
9 of --

10 DR. ACKERMAN: So maybe saying, "Undergoes
11 evaluation by a gender dysphoria physician at least
12 every three months." A gender dysphoria physician.
13 A physician who specializes in gender dysphoria.

14 UNIDENTIFIED SPEAKER: That could be very
15 difficult because, you know --

16 DR. KIRSH: There's no --

17 DR. DI PIETRO: There's no board for that.

18 DR. KIRSH: -- there's no board for that.
19 How do you rectify that?

20 DR. ACKERMAN: I know.

21 DR. KIRSH: So I mean, it's what your
22 experience is and what you feel comfortable as, so
23 that's certainly limiting, you know, a population
24 from being taken care of. Maybe there's another
25 term that we can use.

1 DR. DI PIETRO: Could you just say, "a
2 physician who regularly treats gender dysphoria
3 patients"?

4 DR. ACKERMAN: Yeah.

5 UNIDENTIFIED SPEAKER: You know, that's --

6 DR. ACKERMAN: You wouldn't want someone
7 covering for you who doesn't do that because if the
8 drugs need to be tweaked, he's an orthopedic
9 surgeon, you know. As an absurd example.

10 DR. DI PIETRO: I just think the essence of
11 what it's trying to get at is the person -- and I
12 understand why we're having the discussion from the
13 beginning with -- you know, from what Dr. Derick is
14 saying. But the essence of what it's supposed to be
15 is the person who is prescribing it is supposed to
16 be following up with the patient, unless there's
17 something that happens, in which case, they can't.

18 I just hesitate to change it to where it's
19 like, "Well, they could go see this doctor this
20 month because they're a gender dysphoria doctor, or
21 this doctor this month because they're dysphoria
22 doctor." I want to keep the essence of it that
23 really, unless something happens, that it should be
24 the physician who is prescribing it on a regular
25 basis. Do you see what I'm saying?

1 DR. DERICK: Yeah. Continuity --

2 DR. DI PIETRO: It's just hard to make it
3 work.

4 DR. DERICK: Yeah. Continuity of care is
5 very important, I just get concerned with the
6 logistics of appointments and making sure that the
7 patients can fall within the window in order to get
8 the medication.

9 DR. DI PIETRO: Or, you know, maybe
10 someone's insurance changes and they can't see that
11 physician anymore, they have to see a different
12 physician. So we've just got to figure out a way to
13 make it work where it reads that it's the current
14 treating physician.

15 DR. ACKERMAN: Right. And you may be
16 current for just a week because someone is on
17 vacation, but you're still the treating physician.
18 And you're covering for someone, and you write a
19 prescription, you have full responsibility. That's
20 if you're the primary physician. You know, and
21 so --

22 DR. DI PIETRO: Well, how about
23 "prescribing physician or their designated
24 coverage"?

25 CHAIRMAN ROMANELLO: I like that.

1 DR. DI PIETRO: "Every three months."

2 DR. ACKERMAN: I'm good with that.

3 ATTORNEY MCNULTY: Or "their designated
4 coverage physician"?

5 DR. DI PIETRO: Yes. "Designated covering
6 physician." Covering. Because when you go away,
7 right, you designate someone to cover you, right? I
8 mean, I do.

9 DR. ACKERMAN: You have to.

10 DR. DI PIETRO: It's not some fly by night
11 thing, right. So --

12 DR. ACKERMAN: But generally when they --
13 if they're going to -- in my area, if they're going
14 to be prescribing radiation treatment when I'm not
15 there, they don't just do what I wrote down on the
16 piece of paper. They actually do an evaluation and
17 make sure that a lot of the work is already done,
18 but they see the patient.

19 CHAIRMAN ROMANELLO: Absolutely.

20 DR. ACKERMAN: Because otherwise, I could
21 have made a mistake and they could be treating the
22 wrong side, the wrong breast, the wrong --

23 DR. DI PIETRO: Then that would cover it
24 though, right? Because it's saying that they have
25 to undergo an evaluation. So "undergoes an

1 evaluation by the prescribing physician or their
2 designated coverage -- or the designated covering
3 physician every three months."

4 DR. ACKERMAN: Yeah. I like that.

5 UNIDENTIFIED SPEAKER: I go for that.

6 DR. ACKERMAN: So someone just doesn't call
7 it in, they have to actually see the patient.

8 UNIDENTIFIED SPEAKER: Right.

9 DR. DERICK: Well, that's the question I
10 had is define evaluation. Is that something that
11 could be done over -- the first one for sure in
12 statute has to be in person, but these follow up
13 visits, is it permissible or desirable to have all
14 of those be in person or is it permissible to have
15 the evaluation done via telemedicine?

16 DR. ACKERMAN: Well, that number seven
17 doesn't say in person, it just says evaluation.

18 CHAIRMAN ROMANELLO: Right.

19 UNIDENTIFIED SPEAKER: Every three months.
20 So just every three months.

21 CHAIRMAN ROMANELLO: And the statute does
22 address certain elements that have to be in person
23 prior to a new prescription being issued but as you
24 pointed out, the every three month, the statute
25 doesn't address, so it would not --

1 DR. DI PIETRO: So then my opinion on that
2 -- and thank you, Dr. Derick for bringing that up
3 too -- would be a sub under seven or after that
4 semicolon "with at least one in person visit
5 annually." So it can't just be telehealth in
6 perpetuity. I mean, we do that in primary care. I
7 require my primary care patients to come in and see
8 me once a year, so -- so "undergoes an evaluation by
9 the prescribing physician or a dedicated covering
10 physician."

11 UNIDENTIFIED SPEAKER: "Designated."

12 DR. DI PIETRO: Sorry. "Designated
13 covering physician at least every three months, with
14 one in person visit annually, in minimum." Or
15 something along those lines.

16 ATTORNEY MCNULTY: I thought you had, "with
17 at least one in person visit annually."

18 DR. DI PIETRO: Yes.

19 DR. BENSON: Well, I think though, part of
20 this is being -- if you read like the 2017 Endocrine
21 Society Guidelines, they specify certain things that
22 are supposed to happen at three months, such --
23 every three to six months, like anthropometry,
24 height, weight, sitting height, blood pressure,
25 tanner staging. So some of these things --

1 DR. ACKERMAN: Well, that would be in
2 person with the physician.

3 DR. BENSON: Yeah. But you can't
4 practically do that very easily virtually, you know,
5 most of these are done -- these kind of exams in
6 endocrinology are done in person.

7 DR. ACKERMAN: By the physician or by
8 the --

9 DR. BENSON: By the physician.

10 CHAIRMAN ROMANELLO: I don't think you're
11 taking away from it. I mean, I don't think you're
12 taking away from that, it's just giving the option.
13 You may practice differently than somebody else.
14 You know, I'm just wondering if that would, you
15 know, kind of limit --

16 DR. BENSON: Yeah.

17 CHAIRMAN ROMANELLO: You've got to worry
18 about access.

19 DR. BENSON: Well, I think maybe then a
20 simpler way to get around this would be say "every
21 three to six months." Give some flexibility there.
22 So if there's -- you know, if that's adhering with
23 the Endocrine Society Guidelines as far as what
24 evaluations are supposed to be done, and having a
25 range I think makes a lot more sense than just every

1 three months.

2 ATTORNEY MCNULTY: If you mean six months,
3 then say six months. Because remember, this is a
4 rule and it's -- if you have a range --

5 DR. BENSON: Well, the rule would be every
6 three to six months.

7 ATTORNEY MCNULTY: But then say, "at least
8 every six months."

9 EXECUTIVE DIRECTOR VAZQUEZ: Right.
10 Because from a prosecutorial standpoint, that's the
11 same as saying every six months, because saying
12 three to -- it could be every month, that still
13 would qualify as every six months. So we make get a
14 (indiscernible) letter if you include the "three to
15 six months." That's all.

16 UNIDENTIFIED SPEAKER: I just think it's a
17 little different for the adult population than the
18 pediatric population. I think for the adult
19 population doing the telemedicine visits are
20 appropriate, but for pediatrics, we do need height
21 measurements that tells you whether they're breaking
22 through therapy or what their final outcome is going
23 to be. And physical exams for pubital staging
24 cannot be done via telemedicine, and that's vital in
25 these assessments. So I think I'd rather stick to

1 what Dr. Benson is saying the "at least six months."

2 ATTORNEY MCNULTY: Right now you have three
3 months. So --

4 DR. DI PIETRO: Oh, I think they wanted to
5 change it to "in person at least every six months."

6 UNIDENTIFIED SPEAKER: Yeah. That makes
7 sense.

8 DR. ACKERMAN: Versus annually.

9 UNIDENTIFIED SPEAKER: Versus annually,
10 yes.

11 DR. ACKERMAN: The same language,
12 (indiscernible).

13 CHAIRMAN ROMANELLO: And that's for
14 pediatric patients, not for adults.

15 ATTORNEY MCNULTY: One in person visit
16 every six months?

17 DR. DERICK: At least every six months.
18 Because then if the doctor decided at three months
19 it was required to come in, then they could make
20 that decision.

21 DR. DI PIETRO: So it would be "undergoes
22 an in-person evaluation by the prescribing physician
23 or" -- what did we say -- "designated covering
24 physician at least every six months."

25 UNIDENTIFIED SPEAKER: Sorry to harp on

1 this just a little bit but if the patient switches
2 doctors, then to me, they would not be able to --
3 that's not the prescribing physician or the covering
4 physician.

5 DR. ACKERMAN: No, it's a new prescribing
6 physician.

7 DR. DI PIETRO: So then it would meet the
8 criteria.

9 ATTORNEY MCNULTY: So there's no need to
10 see the patient then for an evaluation in under six
11 months. Is that what I'm hearing? Because now you
12 want it --

13 DR. BENSON: Yes. Every six months.

14 ATTORNEY MCNULTY: So "undergo an
15 evaluation by the prescribing" --

16 DR. BENSON: "In person evaluation by the
17 prescribing physician or their designated covering
18 physician" -- is that the right --

19 UNIDENTIFIED SPEAKER: Yes.

20 DR. BENSON: -- "at least every six
21 months."

22 CHAIRMAN ROMANELLO: Getting nods.

23 DR. ACKERMAN: Endochronologists like that?

24 DR. DI PIETRO: Yes.

25 CHAIRMAN ROMANELLO: And just to clarify,

1 that's for minors, right?

2 UNIDENTIFIED SPEAKER: Yeah.

3 CHAIRMAN ROMANELLO: Okay. Thank you.

4 Dr. Derik, have we --

5 DR. DERIK: Yeah. I think it's -- we've

6 decided in person, the frequency seems reasonable.

7 If somebody wanted to do it more frequently, they

8 could. But it gives them flexibility to schedule

9 out.

10 DR. ACKERMAN: Someone else can cover.

11 DR. DERIK: Someone else can cover. It

12 seems more flexible and will allow --

13 CHAIRMAN ROMANELLO: Got it. Hey, let's

14 go --

15 ATTORNEY MCNULTY: And before you leave

16 this, do you want that to flow through all of the

17 forms for the minors?

18 UNIDENTIFIED SPEAKER: For the minors, yes.

19 DR. ACKERMAN: For the minors, yeah.

20 DR. BENSON: Not adults but minors.

21 DR. ACKERMAN: Do we need a motion for that

22 amendment? We don't have a motion for this. So why

23 don't we do this, why don't we move to accept this.

24 We're not going to vote until the very end.

25 UNIDENTIFIED SPEAKER: Right, right.

1 CHAIRMAN ROMANELLO: But we have to first
2 have a motion with a second, then we can make
3 amendment -- vote on the amendments, then eventually
4 have the last motion which would be the amended
5 original motion. Is that by Robert's Rules of
6 Order?

7 ATTORNEY MCNULTY: Well, we don't do
8 Robert's Rules, but yes. You can do that.

9 DR. ACKERMAN: Whatever rules of order, the
10 state rules of order.

11 DR. BENSON: Well, we can come back at the
12 end and talk about the consents as amended.

13 ATTORNEY MCNULTY: Yes.

14 DR. BENSON: You don't have to go through
15 every --

16 DR. ACKERMAN: Oh, that's fine. So I would
17 like to make the motion to amend it.

18 ATTORNEY MCNULTY: Or how about you just
19 vote on each of these changes that you flow through
20 as you go.

21 DR. ACKERMAN: Right.

22 ATTORNEY MCNULTY: And that way it's
23 clear --

24 DR. ACKERMAN: So I'm making a motion to
25 amend this with that change that we just said.

1 CHAIRMAN ROMANELLO: Is there a second?

2 UNIDENTIFIED SPEAKER: Second.

3 CHAIRMAN ROMANELLO: All in favor?

4 (Unanimous ayes)

5 Opposed?

6 It carries.

7 ATTORNEY MCNULTY: And just to clarify your
8 question, that covers all of this language in all of
9 the minor forms, correct?

10 CHAIRMAN ROMANELLO: Correct.

11 So if we can go back to Bates 264, there is
12 a blank that needs to be filled in in terms of
13 options.

14 DR. ACKERMAN: I like it when we have
15 multiple choice. Dr. Benson, can you give us some
16 multiple choices of words as to how you would fill
17 in that blank? I think I like true false better
18 than multiple choice.

19 DR. MORTENSEN: I didn't really see any
20 other options but left it open if anyone else had
21 any other insight.

22 DR. ACKERMAN: That's true false. False.

23 DR. BENSON: I mean, unfortunately, we
24 don't have studies to say -- there's no controlled
25 studies that say --

1 CHAIRMAN ROMANELLO: Dr. Mortensen, could
2 we just strike that? Another option is blank and
3 strike that language?

4 DR. MORTENSEN: Then you would probably
5 have to take out the word "one" at the beginning of
6 the paragraph.

7 DR. KIRSH: Yes.

8 DR. BENSON: I think it's implying that --

9 DR. ACKERMAN: I would change it -- there
10 may be other options you could discuss with your
11 physician.

12 DR. BENSON: -- no medical treatment is an
13 option for some people, and then some people do
14 choose that.

15 DR. ACKERMAN: Choose what?

16 DR. BENSON: Don't go through with hormonal
17 treatment always.

18 DR. ACKERMAN: Well, could you just say
19 there, instead of "another option is," say, you
20 know, "Other options can be discussed with your
21 physician"?

22 DR. BENSON: Yeah. I think that would be
23 fine.

24 DR. ACKERMAN: One option is "psychological
25 therapy" -- "other options can be discussed with

1 your physician." I don't know what other options
2 there are but maybe some practitioner has some other
3 options. Diet, I don't know.

4 CHAIRMAN ROMANELLO: So the proposed
5 modification is to strike "another option is," and
6 substitute in --

7 DR. ACKERMAN: "Other options may be
8 discussed with your physician."

9 CHAIRMAN ROMANELLO: Is there a motion for
10 that?

11 DR. ACKERMAN: So moved.

12 CHAIRMAN ROMANELLO: Dr. Ackerman.

13 DR. KIRSH: Second.

14 CHAIRMAN ROMANELLO: Second by Dr. Kirsh.

15 DR. ACKERMAN: And I move that that goes
16 through --

17 CHAIRMAN ROMANELLO: All through the --
18 yep.

19 ATTORNEY MCNULTY: And that would be all
20 the -- and the adults? This one?

21 DR. ACKERMAN: That one all -- both adults
22 and minors.

23 ATTORNEY MCNULTY: Correct.

24 CHAIRMAN ROMANELLO: All in favor?

25 (Unanimous ayes)

1 Opposed?

2 Motion carries.

3 DR. BENSON: So Bates 266 --

4 ATTORNEY MCNULTY: Before --

5 DR. BENSON: A question?

6 CHAIRMAN ROMANELLO: Dr. Benson?

7 DR. BENSON: So this phrase is kind of used
8 throughout the consent forms. I would say it's
9 similar in all the consent forms. It's not
10 identical in the youth and adult consent forms. But
11 it talks about that they're not FDA approved for
12 this treatment. And I think there should be some
13 language in there that, you know, we don't have a
14 lot of long-term perspective trials.

15 Most of the trials within interventions are
16 only going out 18 months, 2 years, and some have
17 reported very serious adverse events that have
18 happened in the population of kids, such as in the
19 Trans Youth Care study that just got published
20 earlier this year where they had 2 completed
21 suicides and 11 with, you know, suicidal ideation
22 and some other adverse outcomes.

23 But I think we need to maybe just include a
24 few paragraphs or a few sentences in this section
25 just to make it very clear that these therapies are

1 somewhat outcome indeterminate and there's a, you
2 know, high risk of potential side effects that we
3 just don't have a lot of research to support.

4 CHAIRMAN ROMANELLO: So two things.
5 Dr. Benson, if you can get closer to your mic,
6 please.

7 DR. BENSON: Oh, sorry.

8 CHAIRMAN ROMANELLO: That's good.

9 DR. BENSON: Yeah. Just something that
10 basically illustrates that these -- you know, it's
11 based on limited data. That we've seen some
12 improvement in psychological functioning in
13 short-term studies, but we have, you know, other
14 things that in longer term where people have reports
15 of, you know, adverse outcomes. And that I think
16 it's important that people understand the profound
17 uncertainty regarding the benefits and risks of
18 these medical therapies is -- there's somewhere we
19 just say that very clearly that we just don't -- you
20 know, this is speculative data that these therapies
21 are based on.

22 ATTORNEY MCNULTY: Maybe we can add that
23 further on the next one where it says, "Risks, the
24 adverse effects, and safety of puberty blockers used
25 for the treatment of gender dysphoria in minors is

1 not well known."

2 DR. BENSON: Yeah.

3 ATTORNEY MCNULTY: And then maybe add on,
4 "There's been limited data."

5 DR. BENSON: Yeah. That would be a good
6 place. I did provide some wording to the staff
7 earlier that maybe would be potential wording that
8 could be used.

9 ATTORNEY MCNULTY: I would suggest if it's
10 in this section where you are signing something off,
11 it would be like one sentence, something succinct.
12 Otherwise, I think a more appropriate place -- and
13 you would have to provide the exact wording -- would
14 be on page 1 of that form, second paragraph where
15 they talk about the off-label use from the FDA in
16 the beginning of the document.

17 DR. ACKERMAN: You mean 264?

18 ATTORNEY MCNULTY: Yes.

19 DR. BENSON: Are you talking about under
20 the second question?

21 ATTORNEY MCNULTY: Yes.

22 DR. BENSON: So yeah, so you know, I think
23 we just need to put in there --

24 ATTORNEY MCNULTY: Put in which section?

25 DR. BENSON: Put something in there that

1 just makes it very clear that these practices are --
2 we don't have extensive long-term data. We
3 definitely don't have controlled studies. So you
4 could use something like, you know, "Medical
5 treatment of children and adults with gender
6 incongruence is based on very limited data with only
7 subtle improvements seen in some patients'
8 psychological functioning, in some, but not all
9 research study. This practice is speculative, you
10 know." And then you could say --

11 CHAIRMAN ROMANELLO: Dr. Benson, where are
12 you reading from?

13 DR. BENSON: Sometime I wrote.

14 CHAIRMAN ROMANELLO: Okay. So we're going
15 to attempt to incorporate or consider what you're
16 reading but you've got to go a little slower.

17 DR. BENSON: Oh, I'm sorry.

18 CHAIRMAN ROMANELLO: Because you've got to
19 lawyers here and you've got the staff sprinkled all
20 over the place, right.

21 DR. ACKERMAN: I want to understand. We're
22 putting this into the preamble, if you will.

23 DR. BENSON: Yes.

24 ATTORNEY MCNULTY: But on page 264, that's
25 where you're talking about, Dr. Benson; is that

1 correct? On the middle of the page where the
2 paragraph that begins, "Pediatric endocrinologists"?

3 DR. BENSON: Yeah.

4 ATTORNEY MCNULTY: At the bottom of that
5 paragraph?

6 DR. BENSON: I mean, I think it could go
7 right at the top under "Patient information,
8 informed parental consent, and assent for minors."
9 You could put a paragraph there or you could put it
10 under the second one. I just think it needs to be
11 clear from the onset.

12 ATTORNEY MCNULTY: I think it -- you are
13 the doctors, but it seems like it would go where
14 you're talking about, the off-label use.

15 DR. DI PIETRO: I see it going as a second
16 box under that.

17 DR. ACKERMAN: No, no. We're in the
18 preamp, page 264.

19 ATTORNEY MCNULTY: No, not in the box. In
20 the explanation second.

21 DR. DI PIETRO: Well, I think it should go
22 in the boxes.

23 CHAIRMAN ROMANELLO: Let me ask, Matt. The
24 concept that you're introducing is that the
25 off-label use is not the product of --

1 DR. BENSON: I don't know that most people
2 understand what that really means --

3 CHAIRMAN ROMANELLO: Right.

4 DR. BENSON: -- who are not physicians,
5 scientists, et cetera. I just think we need to be
6 explicit about what we know and what we don't know.

7 CHAIRMAN ROMANELLO: So you want to
8 highlight the fact that the off-label use is not
9 predicated upon robust research and data. Is
10 that --

11 DR. BENSON: Yeah. It's not based on the
12 best kinds of quality data that typically would
13 underpin therapies that have significant risks
14 associated with them.

15 CHAIRMAN ROMANELLO: All right. So before
16 we decide where it goes, can we talk about the
17 language that you are proposing, and then maybe we
18 can figure out where it might best go into the form.
19 So again, for the lawyers who are going to scribble
20 this down, not me, can you walk us through that
21 proposed language?

22 DR. BENSON: I mean, you know, I wrote
23 about eight sentences here. I don't know if you
24 want me to read through it all?

25 CHAIRMAN ROMANELLO: So did you provide

1 that --

2 DR. BENSON: I did. They have a Word
3 document with it in there. Yes.

4 DR. ACKERMAN: Can you put it in one simple
5 sentence? Because the thing is, we're saying this
6 is off-label use. Now, I know that people pooh-pooh
7 off-label use because we prescribe medications all
8 the time for off-label use. So people do pooh-pooh
9 that. And I think that what you're saying is we
10 need something stronger in there that, although this
11 off-label use, this isn't just off-label use, you're
12 saying. This isn't just off-label use, but this is
13 off-label use that is not completely studied and
14 that, in fact, the studies that are out there are
15 mixed, and many of those studies have shown adverse
16 outcomes.

17 DR. BENSON: Okay. Let me give you this.
18 This would be a few sentences, okay.

19 DR. ACKERMAN: Okay.

20 DR. BENSON: "Medical treatment of children
21 and adults with gender incongruence is based on
22 very" --

23 CHAIRMAN ROMANELLO: Slow it down.

24 DR. BENSON: Oh, sorry. "Medical treatment
25 of children and adults with gender" -- I guess we

1 should stick with gender dysphoria because that's
2 what we've been consistent with -- "is based on very
3 limited, poor-quality research with only subtle
4 improvement seen in some patients' psychological
5 functioning, and some, but not all, research
6 studies. This practice is purely speculative, and
7 the possible psychological benefits may not outweigh
8 the substantial risks of medical treatments, and in
9 many cases, the need for lifelong medical
10 treatments." Something like that.

11 DR. DI PIETRO: How many sentences was
12 that?

13 DR. BENSON: It's three. I mean, you
14 know --

15 CHAIRMAN ROMANELLO: So first, I would look
16 to the committee to see if there's consensus that it
17 makes sense to include that language or add that
18 language to the consent.

19 DR. BENSON: And the way I intentionally am
20 writing this is it's something that could apply to
21 both. It would be the same form for all adult and
22 pediatric.

23 CHAIRMAN ROMANELLO: And to keep them on
24 their toes, I'm going to ask Donna or Paul to read
25 it back to us. No, I'm not. But do we have

1 consensus that type of disclaimer or addition to the
2 informed consent is appropriate?

3 DR. DI PIETRO: I don't have a problem with
4 it, I just feel like if we look at, on Bates 264,
5 what we should all be looking at, "What are
6 different medications that are used to suppress
7 puberty," second paragraph, halfway through. "None
8 of the medications have been approved by the FDA to
9 be used in minors with gender dysphoria, due to lack
10 of X, Y, Z." "Due to lack of randomized control" --
11 however you want to -- but you can -- I think you
12 can simply all of that into about 10 words.

13 DR. BENSON: All I'm saying is I think it
14 should be a few lines that are very explicit in the
15 beginning. If you've ever gone over consent forms
16 with people, you need to give them enough time to go
17 through it. There's a lot in this to digest. And
18 people get tired after reading very long consent
19 forms, especially when they have long lists of side
20 effects that are nonspecific. I try to avoid that.
21 So I think just having something explicit in the
22 beginning would be helpful.

23 DR. ACKERMAN: Well, I agree. I really
24 agree with Dr. Di Pietro. I think that putting it
25 in that spot that she just identified, in 8 words or

1 less, or 10 words or less would be fine. Because
2 later on in the document, it goes through all those
3 specific things. And I don't want to get too crazy
4 now with all this stuff in the beginning saying that
5 there's poor studies and there's all sorts of crazy
6 outcomes and that sort of stuff. Because we have in
7 here a few pages later, "itchy eyes, ringing in the
8 ears, pain in the eyes, nausea," all that sort of
9 stuff is all there. All that stuff is there.

10 I think it's over -- a little bit
11 overreaching or a little bit overkill to put too
12 much of that in the beginning. But I agree with
13 Dr. Di Pietro in that second paragraph, the one that
14 begins with, "Pediatric endocrinologists." Putting
15 it in there would be very appropriate, just make it
16 shorter.

17 ATTORNEY MCNULTY: And while you are
18 thinking of what to fill in that space, in the
19 actual signature blocks where the parental consent,
20 under number two it says, "I know there may be other
21 unknown short-term and long-term effects or risks."

22 DR. ACKERMAN: I'm sorry, where are you?

23 ATTORNEY MCNULTY: I'm on the last -- on
24 page 6 of 8 where the parent --

25 DR. ACKERMAN: Give me the Bates number,

1 please.

2 UNIDENTIFIED SPEAKER: 269.

3 DR. ACKERMAN: Thank you. I'm sorry
4 because we have a different format. I know you have
5 it printed out.

6 ATTORNEY MCNULTY: I know, I just printed
7 it out.

8 DR. ACKERMAN: I know. 269. Go ahead.

9 ATTORNEY MCNULTY: On number two it says --
10 as part of the last sentence, it says, "The
11 information provided to me in the form and by the
12 prescribing includes the known effects and risks of
13 treatment with puberty blockers. I know that there
14 may be other unknown short-term and long-term
15 effects or risks." Just so you all know that that's
16 -- that they're signing to that, as well, while
17 you're thinking about how to fix that other
18 paragraph, if that's what you want to do.

19 DR. BENSON: I think it's important, too,
20 you understand a lot of these could be 8, 9, 10 year
21 old children who are undergoing this treatment, and
22 I just think for kids, I was on the IRB in my role,
23 I mean, you have to make things simple and clear.
24 Because these are for young kids, and especially the
25 ones --

1 DR. ACKERMAN: So do we want to put this
2 language in the beginning in the preamble? And I
3 think what Donna is saying is that we also have that
4 here. But I think Dr. Benson has a good point and I
5 think we should put some more stronger language in
6 the preamble. And again, I'll say what I said
7 before, I think Dr. Di Pietro's idea of putting it
8 in the middle of that paragraph is --

9 ATTORNEY MCNULTY: I need to know what to
10 -- what do you want -- I mean, what are the words?

11 DR. DI PIETRO: Well, I mean, I was just --
12 I just feel like it goes well there because it's
13 kind of like why it's not FDA approved, right. So
14 it's "None of these medications have been approved
15 the FDA to be used in minors and gender dysphoria
16 due to" -- and then you can say something about
17 "lack of long-term randomized controlled trials,
18 lack of, you know, long term outcomes -- data --
19 long-term outcome data."

20 DR. KIRSH: So Dr. Di Pietro, would you
21 mind considering one other thing? Is that don't
22 link it to that specific sentence. Go ahead and
23 start another sentence. Because the reason why
24 there's off-label use, and reason why the off-label
25 use is done is economics. It's the fact that the

1 drug companies don't go through those trials for the
2 purposes of that. And so 26 percent of our
3 medications are used off-label today. So the issue
4 is it's not because it's off-label is the reason.
5 You know, if we just leave that, I think that's
6 good. Just add another sentence.

7 CHAIRMAN ROMANELLO: So Dr. Benson, I'm
8 looking at the language that you proposed and I'm
9 looking at it on counsel's screen. What you read,
10 "Medical treatment of children and adults with
11 gender incongruence is based on very limited,
12 poor-quality research," that doesn't necessarily go
13 to FDA off-label use. That's a different issue,
14 right?

15 DR. BENSON: A different issue, yeah.

16 CHAIRMAN ROMANELLO: It's not -- the
17 conversation I'm concerning myself about is getting
18 into the rationale as to why FDA has approved or not
19 approved a certain medical therapy. So again,
20 Doctor, can you read what you propose to include
21 somewhere in the consent form, and then I might have
22 an idea of where we could place it.

23 DR. BENSON: Okay. "Medical treatment of
24 children and adults with gender dysphoria is based
25 on very limited, poor-quality research with only

1 subtle improvements seen in some patients'
2 psychological functioning, and some, but not all
3 research study. This practice is purely
4 speculative, and the possible psychological benefits
5 may not outweigh the substantial risks of medical
6 treatments, and in many cases, the need for life
7 long medical treatments."

8 CHAIRMAN ROMANELLO: Got it. So that
9 doesn't go to FDA off-label use, that goes to any
10 kind of therapy or intervention for gender
11 dysphoria. So I think, and I'll defer to the group,
12 that's either a preamble up at the top or on page --
13 the signature page for the parents or the guardian
14 at Bates 269. You could either add a number eight
15 to that list, or you put it at the top of the
16 consent form.

17 DR. ACKERMAN: I think you're right,
18 Mr. Romanello.

19 CHAIRMAN ROMANELLO: Because it's not --

20 DR. ACKERMAN: I think I like the first
21 page better than the last. Yeah. In the beginning,
22 first or second paragraph. But a separate paragraph
23 in and of itself.

24 DR. DI PIETRO: Right after the first
25 paragraph of the first page.

1 CHAIRMAN ROMANELLO: Okay.

2 DR. DERICK: What I liked about the consent
3 forms, in part, are that they're -- you know,
4 they're facts. Like "here is the side effect from
5 this medication," blah, blah, blah. This is more of
6 a -- like a summation point that's being proposed as
7 part of the consent form, like an overview, and so
8 it kind of changes the nature of the consent form a
9 little bit, I think. I just wanted to say that. I
10 mean, I think that the way it's written now, it's
11 more of, you know, "Here are the things that we
12 see," and adding that really gives it like an
13 element of -- I'd don't want to say judgement but
14 it's like a --

15 DR. ACKERMAN: That's why on the first
16 page, it's really not part of the consent form.

17 ATTORNEY MCNULTY: It is all part of the
18 consent form.

19 DR. ACKERMAN: Well, I know. But it's not
20 part of the --

21 CHAIRMAN ROMANELLO: The specific risks
22 and --

23 DR. ACKERMAN: The specific side effects.

24 CHAIRMAN ROMANELLO: Yeah.

25 DR. ACKERMAN: In there in the beginning,

1 the first -- the preamble page is --

2 CHAIRMAN ROMANELLO: 264 is questioned --

3 DR. ACKERMAN: You either not have it in
4 there at all, which I'm not sure if that's what
5 you're saying or not, Dr. Derick -- but you could
6 either not have this language, but if you do -- and
7 I can go either way. But if you do have the
8 language, I think the first page, you could say that
9 there's limited data and that's why we have this
10 consent form, is basically what you're saying.

11 DR. BENSON: Yeah. I think -- I mean, I
12 understand what you're saying but I think, you know,
13 I do a research study, I literally have to report
14 everything that happens to a kid when they're in a
15 research study getting drug XYZ. I have to report
16 things that probably aren't related to the
17 intervention. I report everything. But because we
18 don't have long-term controlled studies where you
19 typically would ascertain risks and benefits, a lot
20 of this is just cobbled together from case reports
21 and short-term studies that have been done.

22 So, you know, that's the nature of the
23 data. I don't think we're being disingenuous at all
24 as far as where we're at as far as what we know.
25 Hence, the reason the -- you know, the Dutch that

1 started this and now huge parts of Europe are
2 looking at this very acutely and making policy
3 changes. So I think it's just something that we
4 should make clear in there. That's all I'm saying.

5 DR. ACKERMAN: So in the interest of moving
6 on, could we just put --

7 CHAIRMAN ROMANELLO: Yeah. I was going to
8 say, is there a motion to add that language?

9 UNIDENTIFIED SPEAKER: Can I make a
10 suggestion before we do a motion, if you don't mind?
11 Just a couple of suggestions on the language. We
12 use the term "minor" throughout, and I would suggest
13 changing children to minor just to be consistent
14 with -- before we make a motion. And the other
15 thing I was going to ask, should we include adults
16 in that statement? Because this form is
17 specifically for minors. That was just my only
18 other thought.

19 DR. BENSON: The only reason I included it
20 is I was trying to somehow simplify it. I think
21 something similar should appear in the adult forms
22 but if you want to --

23 DR. ACKERMAN: Well, if we do language now
24 that says, "Neither adult nor minor," then we can
25 use it in all the forms, right. So if you repeat

1 the language back, I would make the motion we put it
2 as a paragraph two on page 264.

3 DR. BENSON: All right. I can read that.
4 Do you want me to read it?

5 DR. ACKERMAN: You understand where I want
6 to put it. On the preamble page as a new second
7 paragraph before the second -- before "What are
8 other options?"

9 DR. BENSON: So "Medical treatment of" --

10 UNIDENTIFIED SPEAKER: "Minors."

11 DR. BENSON: -- "people with gender
12 dysphoria is based on very limited, poor-quality
13 research with only subtle improvements seen in some
14 patients' psychological functioning, and some, but
15 not all, research studies. This practice is purely
16 speculative, and the possible psychological benefits
17 may not outweigh the substantial risks of medical
18 treatments, and in many cases, the need for
19 life-long medical treatment.

20 CHAIRMAN ROMANELLO: So there's a motion by
21 Dr. Ackerman to add that language as paragraph two
22 to Bates 264 at the top. Is there a second that
23 motion?

24 DR. DI PIETRO: I'll second.

25 CHAIRMAN ROMANELLO: Who second?

1 DR. DI PIETRO: I'll second. Yeah.

2 CHAIRMAN ROMANELLO: Di Pietro.

3 All in favor?

4 (Unanimous ayes)

5 Opposed?

6 Motion carries.

7 UNIDENTIFIED SPEAKER: Any everybody voted?

8 CHAIRMAN ROMANELLO: They did.

9 UNIDENTIFIED SPEAKER: And that was for all
10 forms?

11 CHAIRMAN ROMANELLO: That's for all forms.

12 ATTORNEY MCNULTY: And this is for all
13 forms, correct?

14 CHAIRMAN ROMANELLO: It is.

15 UNIDENTIFIED SPEAKER: Correct.

16 CHAIRMAN ROMANELLO: Any other observations
17 on this --

18 DR. ACKERMAN: Dr. Di Pietro shared with me
19 an observation a second ago and that was on page --
20 on Bates 269.

21 Dr. Di Pietro, do you want to say what you
22 just shared with me? I think it was --

23 DR. DI PIETRO: Yeah. I've got to remember
24 which paragraph it was in. Oh, paragraph number
25 two --

1 DR. ACKERMAN: Bullet two.

2 DR. DI PIETRO: -- bullet two. Somewhere I
3 feel like we should add the word "potentially
4 irreversible."

5 ATTORNEY MCNULTY: Do you mind repeating
6 what page again? I am working on the Word version
7 and I'm making changes as we strike through. Could
8 you tell me what section header you're on? That
9 would be helpful.

10 DR. DI PIETRO: Parental consent. It's the
11 signature page.

12 DR. ACKERMAN: Number two.

13 DR. DI PIETRO: So "The information
14 provided to me in this form and by the prescribing
15 physician includes the known effects and risks of
16 treatment with puberty blockers. I know that there
17 may be other known short term, and long term, and
18 potentially irreversible effects or risks." Is that
19 accurate?

20 DR. BENSON: You could just put "effects or
21 risks which may be irreversible."

22 DR. DI PIETRO: "Which may be
23 irreversible." That's fine.

24 UNIDENTIFIED SPEAKER: It says on Bates
25 266, "If a minor stops treatment with puberty

1 blockers, in a few months, their body may restart
2 the changes of puberty at the developmental stage
3 they were before starting medication. However, the
4 effects of these medications could be permanent."

5 So it's --

6 DR. DI PIETRO: Yeah. I just want a second
7 -- I want to double down on it on the signature
8 page.

9 DR. ACKERMAN: I think that's good because
10 that signature page is kind of like a --

11 DR. DI PIETRO: It's like the "Here's the
12 stuff you need to know one through seven."

13 DR. ACKERMAN: Right. It ties it all
14 together. I second Dr. Di Pietro's motions.

15 CHAIRMAN ROMANELLO: So let's read it back.

16 DR. ACKERMAN: Modified by Dr. Benson.

17 DR. BENSON: Yeah, I agree with that. I
18 mean, I think, too, in terms of puberty blockers,
19 it's clear from the British research that about 95
20 percent of people who do puberty blockers do go on
21 to cross-sex hormones. So it may be -- we don't
22 know but it may be that that even affects the
23 outcome in some sense. We don't know but that's an
24 important observation.

25 DR. ACKERMAN: There's been a motion and

1 second. Can we move on?

2 CHAIRMAN ROMANELLO: Yeah. So the motion
3 is to add "which may be irreversible" --

4 DR. DI PIETRO: "Which may be irreversible"
5 at the end of the sentence.

6 CHAIRMAN ROMANELLO: Yeah.

7 UNIDENTIFIED SPEAKER: Is that for the
8 adults and minors?

9 CHAIRMAN ROMANELLO: Yep.

10 All in favor of that motion?

11 (Unanimous ayes)

12 Opposed?

13 Motion carries. That will be for all
14 consents.

15 DR. DERICK: I have a --

16 CHAIRMAN ROMANELLO: Dr. Derick.

17 DR. DERICK: Yeah. On Bates 266 it says,
18 "(These medications will not change a minor's sex
19 chromosomes and it will not change a minor's
20 internal or external reproductive structures.)" Is
21 that accurate?

22 UNIDENTIFIED SPEAKER: Where are you
23 reading from, Dr. -- okay.

24 UNIDENTIFIED SPEAKER: Yes.

25 DR. ACKERMAN: I remember reading that.

1 It's on 266 where?

2 DR. DI PIETRO: 266.

3 DR. DERICK: I just was thinking like if
4 you failed to develop breasts, for example, that is
5 a change as related to this --

6 DR. ACKERMAN: Yeah. Doesn't it change
7 their structures?

8 UNIDENTIFIED SPEAKER: Right.

9 DR. DERICK: I think the intent is to say
10 that --

11 DR. ACKERMAN: Reproductive structures. It
12 doesn't change your ovaries to testes.

13 DR. DERICK: You wouldn't have external
14 genitalia that were --

15 DR. BENSON: Well, no. I mean, it doesn't
16 -- no. It just keeps them from enlarging.

17 DR. DERICK: If it keeps it from enlarging,
18 that seems to be a change.

19 UNIDENTIFIED SPEAKER: I think the key was
20 "reproductive."

21 DR. ACKERMAN: Yeah. Reproductive. What's
22 enlarging? You're not changing a testicle to an
23 ovary.

24 DR. BENSON: No, no.

25 DR. ACKERMAN: You're not changing an ovary

1 to a testicle.

2 DR. BENSON: No.

3 DR. DERICK: I guess it all depends on if
4 you consider your breasts reproductive organs.

5 DR. ACKERMAN: I don't.

6 DR. DERICK: Yeah, I know. But I
7 understand what she's trying to say, you know.
8 Ability to breast feed and --

9 DR. BENSON: Well, it is an organ,
10 definitely.

11 DR. ACKERMAN: It's not reproductive.

12 DR. BENSON: Well, it's a sex organ.

13 UNIDENTIFIED SPEAKER: It's reproductive.

14 DR. BENSON: Yeah, I know. But it's an
15 organ.

16 UNIDENTIFIED SPEAKER: But the language
17 here say reproductive organ.

18 DR. BENSON: Right, right.

19 DR. DERICK: I mean, I'm okay with it
20 written as is but I understand your point.

21 UNIDENTIFIED SPEAKER: I'm just trying to
22 clarify.

23 DR. BENSON: I mean, the only other last
24 thing that I think some people may want to add is
25 just something that says, "We do believe that 95

1 percent of those children who start puberty blockers
2 typically would go on to cross-sex hormones."
3 That's been showed now in multiple studies, and so
4 you might to state that but, you know. And that
5 could be a point eight at the very bottom of the
6 last page.

7 DR. ACKERMAN: Or the very first page.

8 DR. BENSON: Yeah.

9 DR. ACKERMAN: I wouldn't put a number in
10 there, I would use the word "many."

11 DR. BENSON: Yeah. Or "most."

12 DR. ACKERMAN: Okay. Wordsmithing.

13 ATTORNEY MCNULTY: Where --

14 DR. ACKERMAN: So he's saying -- what
15 Dr. Benson is saying is that he wants to give
16 notice, you know, put like an alert, a package alert
17 saying, "Package alert, you've used puberty blocking
18 drugs that most patients go on to using cross-sex
19 hormones."

20 ATTORNEY MCNULTY: Do you have a sentence?

21 DR. ACKERMAN: That's basically what he's
22 saying.

23 ATTORNEY MCNULTY: Which is fine. I mean,
24 where do you want to -- what is the sentence and
25 where would you like it for discussion?

1 DR. DI PIETRO: May I just make a comment?
2 Isn't that the point though? I mean, this is a
3 progression of people that are going from each stage
4 to the next. So I think that people would assume
5 that they would be down the road doing cross-sex
6 hormones if they're doing the puberty blocking in
7 general. I mean, to me it would seem --

8 DR. BENSON: Well, initially it was argued
9 that this was a way to pause an early puberty, so
10 that you could affect the differences in the
11 long-term and aesthetic outcomes. Because the early
12 data from the Netherlands in adults showed that
13 there was still a lot of bad outcomes long-term. So
14 they thought, well, if we can intervene earlier with
15 puberty blockers, then we could end up with an
16 aesthetically better result and maybe that would
17 help with psychological outcomes, et cetera.

18 So it was thought, well, it's a pause, too,
19 to give you time to evaluate and see what's going
20 on. But I think for a lot of people in the field,
21 it was quite surprising to see how many, well over
22 90 percent, do go on to cross-sex hormones. The
23 assumption was some people may decide not to do
24 that, but it seems that most people actually do.
25 The vast majority do.

1 DR. MORTENSEN: Right. But I would say
2 that these are people who are continuing therapy,
3 this isn't people who are starting therapy.

4 DR. BENSON: Right.

5 DR. MORTENSEN: So they may, or they may
6 not. So I don't know how relevant it's going to be.
7 Like how much are you encouraging that? Like,
8 "Well, because you're on it, this is where you're
9 going to go." You don't really know.

10 DR. BENSON: That's a good point.

11 DR. MORTENSEN: So I kind of feel that it's
12 kind of irrelevant and doesn't need to be mentioned.

13 CHAIRMAN ROMANELLO: Any more observations
14 on this form?

15 ATTORNEY MCNULTY: Thank you. On page 265,
16 and that's page 2 of 8, number 4 says, "Has adequate
17 psychological and social support during treatment."

18 DR. BENSON: Right.

19 ATTORNEY MCNULTY: Again, that's one of
20 those --

21 DR. BENSON: Vague terms.

22 ATTORNEY MCNULTY: Yeah. So my suggestion
23 is just to delete the word "adequate," so it reads,
24 "Has psychological and social support during
25 treatment," and to carry that through all forms and

1 the rule language.

2 DR. ACKERMAN: So moved.

3 CHAIRMAN ROMANELLO: So there's a motion by
4 Dr. Ackerman.

5 DR. KIRSH: Second.

6 CHAIRMAN ROMANELLO: A second by Dr. Kirsh.

7 All in favor?

8 (Unanimous ayes)

9 Opposed.

10 Motion carries.

11 ATTORNEY MCNULTY: Thank you. And then the
12 second item on that same page is in number 11 where
13 it requires the DEXA scan. But the other forms say
14 annual. Is there a length of time you want that
15 DEXA scan, like what period of time? Or just -- the
16 other forms say like annual bone scan but I'm not
17 sure --

18 DR. ACKERMAN: Other forms said a bone
19 scan. It's a DEXA scan, not a bone scan.

20 ATTORNEY MCNULTY: It says, "Bone DEXA
21 scan."

22 DR. ACKERMAN: No, no. It's a DEXA scan,
23 it's not a bone scan.

24 DR. BENSON: It's a bone density scan.

25 ATTORNEY MCNULTY: So what should the right

1 --

2 DR. ACKERMAN: A bone scan is a nuclear
3 study that looks at osteoblastic changes in the
4 bones. A DEXA scan is basically a low dose x-ray of
5 the bone to look at the bone density. So it should
6 be -- it's a DEXA scan, it's not a bone scan.

7 DR. BENSON: You could put a bone density
8 scan or something.

9 DR. ACKERMAN: Yeah. Bone density scan,
10 yeah. Bone density scan. Don't use -- so I move
11 that we change all of that terminology to say, "Bone
12 density scan (DEXA)."

13 ATTORNEY DIERLAM: Do you want it to say
14 annual across all --

15 DR. ACKERMAN: No, no. I didn't get there
16 yet.

17 ATTORNEY DIERLAM: Okay.

18 DR. ACKERMAN: We'll go with that in a
19 second. Let's clarify what it is. "Bone density
20 scan (DEXA scan)."

21 UNIDENTIFIED SPEAKER: Yeah, yeah.

22 DR. ACKERMAN: Because I get this -- it
23 happens to me all the time that a patient needs a
24 DEXA scan, and they get a bone scan. No, no.
25 Because -- all the time.

1 DR. BENSON: Or bone age. They even
2 sometimes confuse bone age with a bone scan.

3 DR. ACKERMAN: Right. But that's a
4 different one. Now, how often? It doesn't say how
5 often on this Bates 265.

6 ATTORNEY MCNULTY: But all the other forms
7 say annual, so I'm not sure -- and I think your rule
8 language says annual, as well.

9 DR. ACKERMAN: So I think -- so I don't
10 think -- I think for adolescents, or young adults,
11 pediatric and young adults, annually, but at some
12 point, I don't think you need it annually. I don't
13 do it annually on my patients that I put on some of
14 these hormones. I do it maybe every two or three
15 years.

16 DR. BENSON: You're talking about for
17 adults?

18 DR. ACKERMAN: Yeah. My 60-year-olds, my
19 70-year-olds that I have on these hormones for
20 treating cancer, it can cause the same problem with
21 bone density. I have women who I treat for breast
22 cancer with the same drugs, and we do extra bone
23 density studies on them but we don't do it annually.
24 You know, once it stabilizes, we do it every couple
25 three years. But at what point, I don't know.

1 That's you guys.

2 DR. MORTENSEN: I would say for pediatrics
3 annually is typically what we do. For the --

4 DR. ACKERMAN: Then you can annually for
5 the first five years, or -- you know, for adults you
6 can say annually for the first five years and
7 then --

8 DR. MORTENSEN: As needed.

9 DR. ACKERMAN: -- and then as needed.

10 DR. BENSON: Yeah. The adult guidelines
11 did specify. Let me just find that table.

12 DR. ACKERMAN: Yeah. I saw that in the
13 adult -- it said annually in the adults, and I
14 thought that that was --

15 ATTORNEY MCNULTY: All of them say annual
16 except for this one.

17 UNIDENTIFIED SPEAKER: So can I --

18 DR. ACKERMAN: I think for the kids, it
19 should be annually. I think for the adults, it
20 should be annually for the first five years and then
21 as needed after that.

22 DR. BENSON: That's reasonable.

23 ATTORNEY MCNULTY: Yeah. That's what I was
24 -- I was trying to clarify.

25 DR. ACKERMAN: Five years is very

1 arbitrary.

2 CHAIRMAN ROMANELLO: So Scotty, let's do
3 two motions. Let's do one for the minors --

4 DR. ACKERMAN: You called me Scotty.

5 CHAIRMAN ROMANELLO: Dr. Ackerman.

6 DR. ACKERMAN: It's okay.

7 CHAIRMAN ROMANELLO: Let's do two motions.

8 DR. ACKERMAN: My first motion is --

9 CHAIRMAN ROMANELLO: For the minors.

10 DR. ACKERMAN: Well, my first motion I
11 think we did, we changed the bone density --

12 CHAIRMAN ROMANELLO: Yes.

13 DR. ACKERMAN: Okay, good. So my first
14 motion is, in the pediatric forms, change the
15 language to say in that bullet number 11 that this
16 should be done annually. That the bone density --
17 whatever it is should be done annually.

18 CHAIRMAN ROMANELLO: Is there a second to
19 that motion?

20 DR. KIRSH: Second.

21 UNIDENTIFIED SPEAKER: Second.

22 CHAIRMAN ROMANELLO: All in favor?

23 (Unanimous ayes)

24 Opposed?

25 That motion carries. And that will be

1 limited to the pediatric forms.

2 And second motion for adults.

3 DR. ACKERMAN: Because now these adults
4 could be starting the drugs whenever. They could
5 start when they're 18, they could start when they're
6 30.

7 ATTORNEY MCNULTY: Wait, I can't hear what
8 you're saying, Doctor. For the adults?

9 DR. ACKERMAN: Adults, they could be --
10 might be starting these drugs when they're 18, they
11 could be starting these drugs when they 30 years
12 old. Who knows whenever. So I would say for the
13 adults, annually for the first 5 years --

14 DR. KIRSH: Do you think that's really
15 necessary and is it --

16 DR. ACKERMAN: Annually?

17 DR. KIRSH: Right. And do you think that
18 we should limit it to say like transgender female?

19 DR. ACKERMAN: I do it on my men that are
20 on Lupron.

21 DR. BENSON: I mean, what the adult -- the
22 2017, they say for transgender males, if they stop
23 testosterone treatment, they're more at risk for
24 bone density issues. But otherwise, they're a lower
25 risk group for that. The higher risk group is trans

1 females who they recommended baseline bone mineral
2 density testing in individuals at low risk.
3 Screening for osteoporosis is conducted around 60
4 years of age.

5 DR. ACKERMAN: Okay. So help me,
6 Dr. Benson. I get a little confused. So the men
7 that are transitioning to women are being put on
8 estrogen therapy, so the bone density will go down,
9 right. Do I have that right?

10 DR. BENSON: Yes.

11 DR. ACKERMAN: Okay. So those should have
12 the bone density study done annually for the first
13 five years and then --

14 DR. BENSON: That's reasonable. Yeah.

15 DR. ACKERMAN: And the women that are
16 becoming men are getting testosterone -- they're not
17 getting Lupron, they're getting testosterone, so
18 they don't need it.

19 DR. BENSON: Generally, no.

20 DR. ACKERMAN: Okay. Good. So --

21 ATTORNEY MCNULTY: So for the non-doctors,
22 do you mind repeating this? Thank you.

23 DR. DI PIETRO: That's in the adult forms.
24 Do you want to hold off until we can get to the
25 adult forms?

1 CHAIRMAN ROMANELLO: Yeah. Let's do that.

2 DR. ACKERMAN: Okay. But keep that on the
3 side though, Donna. Don't let us forget.

4 CHAIRMAN ROMANELLO: So are we done with
5 this first form?

6 DR. DI PIETRO: So for the -- just to
7 clarify -- so for the minors we're saying "bone
8 density scan (DEXA), which will allow monitoring of
9 the minor's bone density, bone strength during
10 treatment, as puberty blockers may decrease bone
11 density" -- and you're putting the word annually in
12 there?

13 CHAIRMAN ROMANELLO: Yes.

14 DR. DI PIETRO: Okay.

15 ATTORNEY MCNULTY: So annual --

16 DR. DI PIETRO: Write the word "annual" in
17 the beginning.

18 CHAIRMAN ROMANELLO: Yep.

19 ATTORNEY MCNULTY: Yep. "Annual bone
20 density scan," blah, blah, blah.

21 CHAIRMAN ROMANELLO: Anything else on this
22 initial form?

23 DR. ACKERMAN: Huh?

24 CHAIRMAN ROMANELLO: Anything else on this
25 initial form?

1 Okay. Let's go to the next form. At Bates
2 272, "Feminizing Medications for Patients with
3 Gender Dysphoria." Now, some of the modifications
4 that we made are going to carry through here. So
5 separate and apart from those, are there any
6 observations or proposed modifications to this form
7 that are specific to this form? We don't need the
8 bone density here.

9 DR. BENSON: I highlighted a couple things,
10 give me one second.

11 CHAIRMAN ROMANELLO: Dr. Benson.

12 ATTORNEY MCNULTY: Dr. Benson, if you're
13 going to talk, can you please speak into the mic, so
14 people can hear.

15 DR. BENSON: Yeah. No, I'm just looking.
16 I highlighted a couple things. I just want to make
17 sure I'm addressing them.

18 CHAIRMAN ROMANELLO: As Dr. Benson is
19 looking through his notes, do any other members of
20 the committee have observations about this?

21 Dr. Di Pietro.

22 DR. DI PIETRO: So this is just a personal
23 thing that drives me crazy when people write --

24 CHAIRMAN ROMANELLO: What's your Bates
25 number?

1 DR. DI PIETRO: I'm sorry, Bates 274 is
2 where I saw it, but it might in other places. And I
3 should have thought about this in the last one,
4 although I didn't see these words in the last one.
5 The words male and female drive me crazy because it
6 doesn't say a male or female what. There's male and
7 female dogs, male and female zebras, male and female
8 everything. It should be man, or (boy), or woman
9 (girl).

10 DR. ACKERMAN: On page 274 --

11 DR. DI PIETRO: That's an adjective, that's
12 not a noun.

13 DR. ACKERMAN: So in the very first block
14 there on Bates 274, the very first one, and it may
15 be elsewhere.

16 UNIDENTIFIED SPEAKER: "Makes less like a
17 male and more like a female."

18 DR. DI PIETRO: Female what?

19 DR. ACKERMAN: Yeah. I think she's right.

20 DR. DI PIETRO: It drives me crazy. I see
21 it in notes all the time. So I would put --
22 especially since a minor is signing off on this,
23 right, I would put, "Appear less like a man (boy),
24 and more like a woman (girl)." Across the board for
25 everything.

1 DR. ACKERMAN: Just to toss this around,
2 masculine or feminine?

3 UNIDENTIFIED SPEAKER: Yeah.

4 DR. ACKERMAN: That way you don't have to
5 say man, boy, and all that, you know.

6 UNIDENTIFIED SPEAKER: Yeah. Masculine,
7 feminine. But male and female are adjectives and
8 shouldn't be used.

9 DR. ACKERMAN: So "less masculine and more
10 feminine."

11 DR. DI PIETRO: That's fine.

12 CHAIRMAN ROMANELLO: That's a motion by
13 Dr. Di Pietro. Is there a second?

14 DR. KIRSH: Second.

15 CHAIRMAN ROMANELLO: Second by Dr. Kirsh.
16 All in favor?

17 (Unanimous ayes)

18 Opposed?

19 Motion carries, and that will cascade
20 through all of the forms that have the words male
21 and female in there.

22 UNIDENTIFIED SPEAKER: It will be masculine
23 and feminine.

24 CHAIRMAN ROMANELLO: Masculine and
25 feminine.

1 Dr. Benson.

2 DR. BENSON: Yeah. So this is something I
3 think that's important for the adult forms as far as
4 cross-sex hormones, and for the pediatric. I did --
5 you know, I did some reading with American Medical
6 Association. There was a discussion regarding what
7 is legally required in consent forms for physicians
8 in general, just based on federal law, state law, et
9 cetera.

10 There was a case in the federal courts in
11 Washington, D.C., it was Canterbury versus Spence.
12 But what -- a real quick summary, but what happened
13 was a guy was going to get a laminectomy, it wasn't
14 disclosed by the physician that there's a risk of
15 paralysis with this procedure. The guy has the
16 surgery, falls out of the bed, becomes paralyzed for
17 the rest of his life. It ends up in court and they
18 basically established sort of that we should be
19 disclosing information if it's reasonable to do so.
20 Previously, they used the community disclosure
21 standard was sort of the standard for these consent
22 documents.

23 But as part of that, there's really five
24 elements that the federal court said should be part
25 forms. And I think on these documents, we've hit

1 all of them partially. But on two, we've already
2 addressed the one, and the first ones being the
3 condition being treated; the nature and character of
4 the proposed treatment or surgical procedure;
5 anticipated results being the third; recognize
6 possible alternative forms of treatment; and then
7 five, recognize serious possible risks,
8 complications, and anticipated benefits involved in
9 the treatment or surgical procedure, as well as
10 recognize possible alternative forms of treatment
11 including nontreatment.

12 So those are the five elements. I think we
13 did great. I think that overall, the consent
14 documents are perfect. I think we addressed the
15 nature and character already with the modification
16 we just made. But in terms of anticipated results,
17 desistance, persistence, and regret are mentioned
18 nowhere in the consent documents at all. And I
19 think while historically we've through desistance
20 rates were very low, that was based on a lot of the
21 older data. And in the last three to five years
22 now, there's much more Pace publications, much more
23 being published, and now we're seeing rates of 10 to
24 30 percent.

25 These are outcomes that if the 1 percent

1 was the standard in this case where the guy had a
2 paralysis, I think we need to at least have a little
3 bit of verbiage in these consent documents that talk
4 about the possibility. "You could have desistance
5 that's transient, and these are the reasons why, and
6 we can see that from literature that's been
7 published. You might be persistent in your
8 desistance. You might decide to go back to your
9 birth gender, for example, and these are the reasons
10 why some people have done that."

11 And I think just stating that somewhere in
12 there, we're covering that important outcome. I
13 mean, the Dutch thought this was a very important
14 outcome to consider. That's why the Dutch in their
15 original protocol didn't do early social transition,
16 because they knew for natal males who were initially
17 the most common group to present with gender
18 dysphoria, 85 to 90 percent of them, by the time
19 adolescence, puberty came around, they didn't
20 persist. Some of them became gay men as adults,
21 some of them had other things going on. But it was
22 very important to them not to influence those
23 desistance rates and so they had very strict
24 criteria.

25 But now we're starting to see older kids

1 coming with cross gender identification, some of
2 them have other psychiatric comorbidities, and the
3 rates of regret, desistance, are definitely now
4 definitely now different than what they were
5 originally reported.

6 CHAIRMAN ROMANELLO: So Dr. Benson, do you
7 have proposed language to add?

8 DR. ACKERMAN: And where to add it. Should
9 this be something in the very beginning in the
10 preamble?

11 DR. BENSON: Yeah. But I mean, I don't
12 think this is something that's amenable to like two
13 words or three sentences. This is a little bit more
14 complex. But I did send it, I did include that, as
15 well, so you all should have a copy of that. I
16 think it's basically two paragraphs, similar to the
17 length of the previous. I fit all of this on one
18 page.

19 UNIDENTIFIED SPEAKER: You're killing me.

20 DR. BENSON: But there's -- it just lists,
21 you know -- but yeah, do you want me --

22 DR. KIRSH: Dr. Benson, can I make a
23 suggestion? I take your comments well-founded, and
24 I'm not sure though that today, in the context of an
25 emergency rule, given the time that -- the time

1 constraints that we're under, that we can give your
2 proposal adequate consideration. And I know that
3 they don't like the word adequate. Can we --

4 DR. ACKERMAN: Thorough.

5 DR. KIRSH: Can we ask you to work on some
6 proposed language which --

7 DR. BENSON: Well, I have the language
8 already.

9 DR. KIRSH: So is it the language that you
10 sent to the Attorney General's Office?

11 DR. BENSON: Yeah. Well, I sent it to I
12 think Donna and Chris.

13 ATTORNEY DIERLAM: And just kind of I guess
14 some clarification, is I do believe we did receive
15 this language. However, I think it was sent over to
16 us this morning. Is that correct?

17 UNIDENTIFIED SPEAKER: Very true.

18 ATTORNEY DIERLAM: So I don't think that we
19 had -- I don't think the boards said they had an
20 opportunity to get it in front of members.

21 CHAIRMAN ROMANELLO: Let me make a friendly
22 suggestion, Dr. Benson, that you continue to work
23 with the Attorney General's Office and Board staff
24 to refine that language to make it more rule worthy
25 and we will take it up under consideration in the

1 permanent rule.

2 DR. BENSON: Sounds good.

3 CHAIRMAN ROMANELLO: Yeah.

4 DR. BENSON: Makes sense.

5 DR. ACKERMAN: Yeah. I agree, I think it
6 needs to be in there, some statement.

7 DR. BENSON: Yeah. Right.

8 DR. ACKERMAN: Not a whole page or eight
9 paragraphs.

10 DR. BENSON: No, no. It's not. It's a
11 half a page. I mean --

12 CHAIRMAN ROMANELLO: Yeah. And that's why,
13 I mean, I'm looking at it --

14 DR. ACKERMAN: We should have adequate time
15 to take a look at it.

16 DR. DI PIETRO: Mr. Chair, one other thing
17 I forgot to mention earlier, if you don't mind, my
18 preference would be for there to be initials at the
19 bottom of every page. There's some non-signature
20 pages, like the first page is a non-signature page,
21 which is probably one of the most important pages in
22 the entire document. And I'd like to have initials
23 -- an initial line.

24 CHAIRMAN ROMANELLO: Makes sense. So the
25 motion is to add initial --

1 DR. DI PIETRO: Yeah. The parent --

2 DR. ACKERMAN: On every page.

3 DR. DI PIETRO: Yeah. The parent, the
4 minor, and then the optional second parent.

5 CHAIRMAN ROMANELLO: On every page of all
6 the consent forms.

7 DR. DI PIETRO: Every page, yes.

8 UNIDENTIFIED SPEAKER: Well, adults
9 wouldn't need the parent --

10 DR. ACKERMAN: Yes. Adults, as well.

11 CHAIRMAN ROMANELLO: That's a motion by
12 Dr. Di Pietro and a second by Dr. Ackerman. All in
13 favor?

14 (Unanimous ayes)

15 Opposed?

16 That motion carries and it will cascade
17 through all of the consent forms.

18 DR. BENSON: And one other question I have:
19 we're all comfortable with just one parent signing
20 this document? What if another parent was opposed
21 to it?

22 DR. ACKERMAN: That by the legislature.

23 ATTORNEY MCNULTY: That's by the statute.

24 ATTORNEY DIERLAM: Yeah. The statute
25 specifically says, "A parent or legal guardian,"

1 singular.

2 DR. BENSON: Then we don't have to deal
3 with that.

4 ATTORNEY MCNULTY: Correct.

5 DR. ACKERMAN: Makes it a lot easier.

6 CHAIRMAN ROMANELLO: Anything else on the
7 consent that begins at Bates 298 which was
8 "Feminizing Medications for Patients"?

9 DR. BENSON: You mean the minors, right?

10 DR. ACKERMAN: 272.

11 CHAIRMAN ROMANELLO: I'm sorry, 272.

12 DR. BENSON: I don't have anything else.

13 CHAIRMAN ROMANELLO: Then if not, we're
14 going to move to the consent that starts at Bates
15 284, "Masculinizing Medications for Patients with
16 Gender Dysphoria." Again, this is a minor form. We
17 talked about some changes that are cascading through
18 all of the forms. Those will impact this informed
19 consent, as well. Are there any observations in
20 addition to those which we have already made on the
21 forms?

22 Dr. Ackerman.

23 DR. ACKERMAN: I have an observation and I
24 just need some clarity from the endocrinologists in
25 the room. In the adult form, in the adult consent

1 for masculinization, there's a whole discussion
2 regarding the use of Finasteride that's not in the
3 pediatric form. So you don't use it in kids?

4 DR. MORTENSEN: Correct. It's not
5 approved. I haven't seen it --

6 DR. ACKERMAN: Nothing's approved.
7 Nothing's approved.

8 DR. MORTENSEN: That's true.

9 DR. BENSON: I mean, I don't even -- I'd be
10 interested to hear if many people are using
11 Finasteride. It's not been shown to be all that
12 beneficial in studies.

13 DR. ACKERMAN: Is it for adults or for
14 minors?

15 DR. BENSON: For -- in treatment in this
16 condition. It's --

17 DR. ACKERMAN: For adults or minors.

18 DR. BENSON: Yeah.

19 DR. ACKERMAN: Why is it -- is this being
20 used for hair growth?

21 DR. BENSON: Because once you lower the --
22 you know, once you lower the testosterone levels,
23 what benefit is there to blocking 5-alpha-reductase
24 which can --

25 DR. ACKERMAN: No, no. But are you using

1 it for masculinization to promote hair growth?

2 DR. BENSON: They actually use it for --
3 some of the patients become bald, so they give it to
4 them for that reason.

5 DR. ACKERMAN: Right. That's what I'm
6 saying. It's to promote -- I'm trying to understand
7 why it's being used. Again, as a
8 non-endocrinologist, I use it to shrink prostates.

9 DR. MORTENSEN: Right. You do.

10 DR. ACKERMAN: Okay. So why is it being
11 used here? I assume for hair growth?

12 DR. BENSON: Yes.

13 DR. ACKERMAN: Propecia, right? You spray
14 it on or something.

15 DR. BENSON: That's the main reason.

16 DR. ACKERMAN: And so it would be used for
17 women that want to become men --

18 UNIDENTIFIED SPEAKER: Correct.

19 DR. ACKERMAN: -- to give them more hair.

20 DR. BENSON: Yes.

21 UNIDENTIFIED SPEAKER: Correct.

22 DR. ACKERMAN: So would you not use it for
23 girls that want to become boys? Because they
24 already have hair. Is that why it's not in the
25 minor section?

1 DR. MORTENSEN: I just don't think it's
2 been used in the minor section. So the literature
3 that I looked at, I didn't see it used as that. I
4 don't see it in the World PATH recommendations
5 either. The adult data is limited. I treat women
6 with PCOS and adolescents with PCOS and elevated --

7 DR. ACKERMAN: PCOS?

8 DR. MORTENSEN: Polycystic Ovarian
9 Syndrome.

10 DR. ACKERMAN: Uh-huh (affirmative).

11 DR. MORTENSEN: And elevated androgens can
12 cause male pattern baldness, which is what this
13 population can be experiencing. Not all of them,
14 but a subset. So they were using it as an adjunct
15 therapy to try to prevent the side effect of using
16 high doses of testosterone. But they haven't really
17 looked at it in children, so I haven't seen any
18 literature that it was being used in anyone under
19 the age of 18.

20 DR. ACKERMAN: Okay.

21 DR. MORTENSEN: Which is why I didn't
22 include it.

23 DR. BENSON: Yeah. And I have a related
24 question about it, too. Are you done with this
25 point or are you still --

1 DR. ACKERMAN: Yeah. Well, I'd be
2 interested in hearing from the public in a second if
3 they have been using it --

4 DR. BENSON: I would, too.

5 DR. ACKERMAN: -- as a pediatric --

6 DR. BENSON: I have another question
7 related to that. Cyproterone acetate has been
8 mentioned. It is. It's in Bates -- what is it --
9 298. But that's not even available in the United
10 States. That drug is not --

11 CHAIRMAN ROMANELLO: Wait, that's the next
12 form.

13 DR. BENSON: Yeah, I know. I'm just
14 saying. But if we're going to ask the public for
15 comment, I'd be curious to know.

16 CHAIRMAN ROMANELLO: Got it.

17 DR. BENSON: Are people getting it from
18 Canada? Is this commonly being used?

19 DR. ACKERMAN: What drug is it?

20 DR. BENSON: Cyproterone acetate.

21 DR. ACKERMAN: Oh, it's the adult form of
22 the --

23 DR. BENSON: It's not available in the
24 United States. It's not available. At least it's
25 not available through the routine channels.

1 DR. ACKERMAN: Canadadrugs.com.

2 CHAIRMAN ROMANELLO: So let me try and
3 corral us back to the question at hand which is
4 comments or proposed --

5 DR. BENSON: I do. I have a comment.

6 CHAIRMAN ROMANELLO: Dr. Benson.

7 DR. BENSON: So I think this consent form
8 is based on a little bit older -- because oral
9 testosterone now is FDA approved. We've got three
10 different oral testosterone available. I don't
11 know how commonly that's already being used but at
12 the Endocrine Society just this last week, there was
13 a lot of discussion about it. Earlier forms of
14 testosterone had a lot of more liver toxicity.
15 These newer versions, much, much safer. But we're
16 talking about mostly transdermal, injectable, but we
17 don't mention oral. But I think it's going to
18 become increasingly more common --

19 CHAIRMAN ROMANELLO: So where would the
20 proposed change for that be?

21 DR. BENSON: Well, it's Bates 284, "How is
22 testosterone taken?"

23 I don't know. Monica, what do you think
24 about that, Monica?

25 DR. MORTENSEN: Well, we're looking at the

1 minor forms, and that might be relevant for the
2 adult forms but --

3 DR. BENSON: Or older adolescents.

4 DR. MORTENSEN: Right. But this is -- I
5 mean, I went to Endocrine Society, but I didn't know
6 everybody is using it for that. You could change
7 some of the verbiage in there because it says it's
8 typically not given in pill form, but you could just
9 change it that it may be available in pill form.

10 DR. BENSON: Yeah. Something like that.

11 DR. MORTENSEN: And just change the
12 verbiage that way.

13 DR. DI PIETRO: And just out of curiosity,
14 you never use like -- like in adults we'll use gel
15 and things like -- that's never used?

16 DR. BENSON: No. It's used sometimes in
17 kids but it's difficult sometimes because I've had
18 patients who were using AndroGel, get it on their
19 hands or whatever, hug their mother, hug their
20 sister, then you've got a sibling with a bone age of
21 12 and they're 6 years old.

22 DR. ACKERMAN: Well, I guess we should have
23 all that covered in there. It should not just be
24 the injection, it should be the gel and the pills.

25 DR. DI PIETRO: Or just various forms of

1 testosterone?

2 DR. MORTENSEN: You can add it. It's just
3 it's not typically used in like the induction of
4 male puberty for what pediatric endocrinologists
5 usually do. Because you can't --

6 DR. BENSON: And there aren't doses
7 appropriated for lower --

8 DR. MORTENSEN: -- dose is very
9 specifically with the pump.

10 DR. ACKERMAN: And it does say here
11 "Usually injected, typically" --

12 CHAIRMAN ROMANELLO: Yeah. I was going to
13 say it's not that you could not administer oral
14 testosterone, it just says it's typically not given
15 in pill form.

16 DR. ACKERMAN: Or the gel.

17 CHAIRMAN ROMANELLO: Or the gel.

18 DR. BENSON: Yeah.

19 DR. DI PIETRO: Okay. Then I'm fine with
20 it.

21 DR. BENSON: Just leave it then.

22 ATTORNEY MCNULTY: Just leave it?

23 DR. KIRSH: But maybe the bigger point we
24 could give some further consideration to this in the
25 permanent rule? Clean it up a little bit.

1 DR. BENSON: Yeah. I think that's
2 reasonable. I mean, it does say, "Typically, it's
3 not given," so it doesn't rule out the possibility
4 that it could --

5 ATTORNEY MCNULTY: So, Dr. Benson, are you
6 suggesting leave it as is for now?

7 DR. BENSON: Yeah. Just leave it as is.

8 DR. DERICK: I have another comment.

9 CHAIRMAN ROMANELLO: Dr. Derick.

10 DR. DERICK: Page Bates 286. This is a --
11 just to be consistent. "Summary of testosterone
12 benefits and risks." One of the benefits is,
13 "Appear more like a man." Just "appear more
14 masculine."

15 UNIDENTIFIED SPEAKER: Yes.

16 DR. DERICK: "A masculine appearance."

17 ATTORNEY MCNULTY: And those changes will
18 be made throughout the forms, Dr. Derick. I think
19 you all -- that's what you all decided, right?

20 DR. BENSON: I mean, I like the wordage as
21 it is. You know, I think for kids that are reading
22 this, it's important for them to have simple words
23 as much as possible.

24 DR. ACKERMAN: But it doesn't say male.

25 DR. DERICK: Yeah. I just don't like the

1 word male and female. Man, woman, masculine,
2 feminine, fine. Male, female, no. So I'm okay with
3 it saying, "appear more like a man." That's fine
4 with me, just not "like a male."

5 DR. BENSON: Okay.

6 DR. DERICK: It's just a pet peeve.

7 DR. ACKERMAN: Although you could say in
8 the risk the "male pattern baldness," that's
9 actually -- we have that there.

10 EXECUTIVE DIRECTOR VAZQUEZ: Question. Is
11 there a desire to be consistent throughout the
12 documents because we have it two different ways now.

13 DR. BENSON: Paul, could you clarify that?

14 EXECUTIVE DIRECTOR VAZQUEZ: Well, we went
15 to masculine and feminine in one place and now we're
16 going to have man and --

17 DR. ACKERMAN: No. It says --

18 UNIDENTIFIED SPEAKER: Male and female to
19 masculine and feminine.

20 EXECUTIVE DIRECTOR VAZQUEZ: We changed
21 male and female to masculine and feminine and we're
22 going to -- it's the same statement. That
23 "Testosterone may be prescribed to make a minor
24 look" -- we said, "less masculine and more
25 feminine," in the other one.

1 DR. ACKERMAN: I know. But this doesn't
2 say male.

3 CHAIRMAN ROMANELLO: This doesn't say male
4 or female.

5 DR. ACKERMAN: We took the male and female.

6 EXECUTIVE DIRECTOR VAZQUEZ: So we're going
7 to use masculine and feminine in one place and man
8 and woman in another?

9 DR. ACKERMAN: Yes.

10 EXECUTIVE DIRECTOR VAZQUEZ: Okay. That's
11 fine. Just clarifying.

12 DR. ACKERMAN: Just not use the word male
13 or female, because that's not necessarily human.

14 EXECUTIVE DIRECTOR VAZQUEZ: Correct.

15 UNIDENTIFIED SPEAKER: You don't need to
16 change it.

17 DR. ACKERMAN: Don't need to change it.

18 UNIDENTIFIED SPEAKER: Don't need a change.

19 DR. ACKERMAN: Nope.

20 CHAIRMAN ROMANELLO: Anything else?

21 DR. ACKERMAN: Now, I just want to point
22 out, we are using the word male in the next column
23 under "Risks," but that's a clinical diagnosis of
24 male pattern baldness.

25 UNIDENTIFIED SPEAKER: Right.

1 DR. ACKERMAN: So that's allowed to be used
2 there.

3 DR. DI PIETRO: It should be hyphenated.

4 DR. ACKERMAN: Not man pattern baldness.

5 CHAIRMAN ROMANELLO: Why did you look at me
6 when you said that?

7 DR. ACKERMAN: Well --

8 CHAIRMAN ROMANELLO: Anything else on this
9 form?

10 DR. ACKERMAN: I've got Kirsh -- Kirsh is
11 in my eyes, too.

12 CHAIRMAN ROMANELLO: Dr. Benson.

13 DR. BENSON: So I don't remember which
14 meeting it was at, but someone came forward and
15 spoke about their personal experience with extreme
16 vaginal dryness that led to painful like intercourse
17 and they had like ulcers and abscesses in the pelvic
18 related to that. Just saying vaginal dryness, if --
19 and I looked at actually some consents from some
20 other studies that have been done.

21 It's Bates 287 under "The following changes
22 could be permanent but may not improve if I stop
23 taking testosterone." The last three are, "More
24 muscle mass and strength, more sexual interests."
25 But if people have typical penetrative sex, there's

1 a risk for very thin vagina --

2 DR. ACKERMAN: Right. Dyspareunia.

3 DR. BENSON: Yeah. For dyspareunia and
4 tears and et cetera that can lead to infections and
5 the like. I think we should just be a little more
6 granular with that. I wasn't even aware of that, at
7 the time, happening. And after that was said, I
8 started reading about it and this has been reported
9 a few times.

10 CHAIRMAN ROMANELLO: So do we have proposed
11 language then? What would you add?

12 DR. ACKERMAN: He wants to add a few more
13 bullets.

14 DR. BENSON: "Painful penetrative
15 intercourse," or something like that.

16 CHAIRMAN ROMANELLO: Under the last dot
17 point?

18 DR. BENSON: "Abscess infection."

19 ATTORNEY MCNULTY: Wait, you're going --

20 CHAIRMAN ROMANELLO: So on Bates 287.

21 ATTORNEY MCNULTY: Right.

22 CHAIRMAN ROMANELLO: The last dot point
23 that is "vaginal dryness," we're going to add --

24 DR. BENSON: "Which could lead to painful
25 penetrative intercourse, infections, et cetera," you

1 know.

2 CHAIRMAN ROMANELLO: Not et cetera.

3 ATTORNEY MCNULTY: "Which could lead to" --

4 UNIDENTIFIED SPEAKER: What about just
5 saying "vaginal dryness which may lead to tearing --
6 which increases the risk of tearing"?

7 DR. BENSON: Well, what I think that they
8 need to be aware of is that the vagina itself
9 becomes thinner and they're more at risk for tears
10 and infections if they have, you know --

11 DR. ACKERMAN: Yeah. "Vaginal dryness,
12 vaginal tearing, vaginal pain, vaginal infections."

13 DR. BENSON: Painful intercourse.

14 DR. DI PIETRO: Painful intercourse. Yeah.

15 DR. ACKERMAN: Got all those?

16 ATTORNEY MCNULTY: Nope. You guys are
17 going to need to tell us the exact language wish.

18 DR. ACKERMAN: Okay. It has vaginal
19 dryness.

20 ATTORNEY MCNULTY: We've got that.

21 DR. ACKERMAN: So vaginal pain --

22 UNIDENTIFIED SPEAKER: "Vaginal dryness
23 which may lead to" --

24 DR. ACKERMAN: No. You don't need to say,
25 "may lead to," just additional bullets.

1 DR. BENSON: Yeah. Just bullets.

2 DR. ACKERMAN: "Vaginal pain, vaginal
3 tearing, vaginal bleeding, painful intercourse,
4 vaginal infection."

5 DR. BENSON: Yeah.

6 DR. ACKERMAN: I'll say it again, "Vaginal
7 pain, vaginal tearing, vaginal infection, vaginal
8 bleeding, painful intercourse."

9 CHAIRMAN ROMANELLO: That's a motion by
10 Dr. Ackerman. Second by Dr. Benson. All in
11 favor --

12 ATTORNEY MCNULTY: Wait, wait. We don't
13 have --

14 DR. ACKERMAN: Pain.

15 ATTORNEY MCNULTY: We have pain.

16 DR. ACKERMAN: Tearing, bleeding.

17 ATTORNEY MCNULTY: Bleeding.

18 DR. ACKERMAN: Infection. Those all are
19 vaginal whatever. And then finally, painful
20 intercourse. Pain, bleeding, tearing, infection,
21 and painful intercourse.

22 DR. BENSON: I think that's great. Yeah.

23 DR. ACKERMAN: Do our lawyers understand
24 that?

25 ATTORNEY DIERLAM: Yes, we do.

1 CHAIRMAN ROMANELLO: Again, that's a motion
2 by Dr. Ackerman, seconded by Benson. All in favor?

3 (Unanimous ayes)

4 Opposed?

5 Motion carries. Anything else on this
6 form?

7 ATTORNEY MCNULTY: And would this be
8 transferred to any similar -- wherever that is for
9 any form, correct?

10 CHAIRMAN ROMANELLO: Yes.

11 DR. BENSON: I did want to -- I really
12 actually like the wording at Bates 290. It's in the
13 second big box, the bottom where it just discusses
14 that "The prescribing physician is required to
15 monitor the minor for any side effects during
16 treatment." I think that's really, really good.
17 "The undersigned parents are encouraged also to
18 report." I think it's important that, you know,
19 this is stated.

20 CHAIRMAN ROMANELLO: Yep. Any other
21 proposed modifications or observations on this form?

22 Hearing none, we're going to move to the
23 next consent form which is at Bates 298.

24 UNIDENTIFIED SPEAKER: (Indiscernible)

25 CHAIRMAN ROMANELLO: No. We're doing the

1 consents.

2 The next is the consent form found at page
3 298, which is titled "Feminizing Medications for
4 Patients with Gender Dysphoria." This is the adult
5 form. Again, recognizing that all the changes that
6 we've previously made have cascaded through to these
7 forms, are there any observations or proposed
8 changes that are specific to this informed consent
9 form?

10 DR. DERICK: So Bates 300, this is for
11 adults. It says, "The specific requirements for you
12 to receive and continue therapy include the
13 following." You know, there are -- these are adults
14 who are currently undergoing therapy, or possibly
15 new people who would be starting it. But like
16 evaluation every three months, or if we change it to
17 six months, you know, in perpetuity, I think if
18 someone is stable on these medications, it might be
19 an overkill to be so prescriptive in the frequency
20 of the visits that they need to have.

21 I mean, if someone starts it, maybe it
22 could be for the first year or two and then the
23 physician could decide after that. But to me, if
24 someone has been stable on a medication for 10
25 years, to have to come every 3 months for an

1 evaluation seems --

2 CHAIRMAN ROMANELLO: This is on number
3 nine, Dr. Derick?

4 DR. DERICK: Yeah. That's just an example.
5 And you know, suicide risk assessment for someone
6 who has been stable on these treatments for years --

7 DR. ACKERMAN: And remember, these are
8 adults now. So the other ones were kids, and so --

9 DR. DERICK: Yeah. This is the adults.

10 DR. ACKERMAN: I think under the age of 18,
11 I think they should be seen every 3 months. But I
12 agree 100 percent with Dr. Derick. Every 3 months
13 is a bit --

14 CHAIRMAN ROMANELLO: So is there a proposal
15 to modify that language?

16 DR. DERICK: I feel like -- I feel like if
17 someone has been in therapy and are continuing
18 therapy at the time this consent form is signed, I
19 don't think we should be prescriptive at all with
20 the follow up. I think they should have the
21 follow-up as they normally would do. I think if
22 someone's newly placed as an adult on these
23 medications then perhaps, we should consider
24 modifying it to every six months for like a finite
25 period of time. Because otherwise, you know, if it

1 seems -- you know, you obviously want to have follow
2 up with these treatments but, you know, four times a
3 year for the rest of life seems --

4 DR. ACKERMAN: Suicidal risk assessment
5 every three months for the rest their life --

6 DR. DERICK: Yeah. I mean, it's --

7 DR. ACKERMAN: -- is ridiculous.

8 DR. BENSON: I mean, can I just read from
9 the Endocrine Society Guidelines on this?

10 CHAIRMAN ROMANELLO: Sure.

11 DR. BENSON: They say, "Every three months
12 the first year," this is for both male and female.
13 And then "one to two times per year to monitor for
14 appropriate signs of virilization or feminization,
15 et cetera, and to monitor for adverse outcomes." So
16 that's what they say is --

17 DR. ACKERMAN: For how long?

18 DR. BENSON: Every three months the first
19 year of an adult starting this treatment and then
20 one --

21 DR. ACKERMAN: Semiannually for how long?

22 DR. BENSON: -- to two times a year after
23 that.

24 DR. ACKERMAN: One to two times a year
25 after that.

1 DR. BENSON: Uh-huh (affirmative).

2 DR. ACKERMAN: Okay.

3 DR. DERICK: And this is for people who are
4 newly on the medication, this isn't for a patient
5 who has been on it for 10 years --

6 DR. ACKERMAN: I agree, 100 percent.

7 DR. DERICK: -- and then has to have a
8 bunch of visits that seem unnecessary if they're
9 stable.

10 DR. ACKERMAN: I'd make the motion that we
11 change it to use Dr. Benson's language --

12 DR. BENSON: To be consistent with the --

13 DR. ACKERMAN: -- so that they undergo an
14 evaluation by the prescribing physician or their --
15 whatever we said before -- at least every three
16 months for the first year and --

17 DR. MORTENSEN: Returning induction.
18 Because if you're switching providers --

19 CHAIRMAN ROMANELLO: Hold on. So we're
20 talking about now Bates 300.

21 DR. ACKERMAN: Correct.

22 CHAIRMAN ROMANELLO: Number nine,
23 "Undergoes an evaluation by a prescribing physician
24 at least every three months."

25 ATTORNEY MCNULTY: I thought you were

1 talking about number 10, the suicide risk. Are you
2 talking --

3 CHAIRMAN ROMANELLO: We're getting there,
4 Donna.

5 DR. ACKERMAN: We'll get there, Donna.

6 CHAIRMAN ROMANELLO: So let's talk about
7 number nine.

8 ATTORNEY MCNULTY: Okay. So number nine.

9 CHAIRMAN ROMANELLO: Thank you. Let's talk
10 about number nine.

11 ATTORNEY MCNULTY: All right.

12 CHAIRMAN ROMANELLO: And the proposal is to
13 modify number nine to Dr. Benson.

14 Want to read us the language?

15 DR. BENSON: "Evaluate patient every three
16 months in the first year, and then one to two times
17 per year to monitor for appropriate clinical
18 changes," or something.

19 DR. ACKERMAN: Well, just say, "then once
20 to twice a year thereafter."

21 CHAIRMAN ROMANELLO: Do our lawyers have
22 that?

23 DR. ACKERMAN: Dr. Mortensen was just
24 saying something. I caught her saying it, but I
25 don't know what she was saying about induction. You

1 want to --

2 DR. MORTENSEN: Yeah. Because initially
3 you had said -- the way you had worded it, but then
4 Dr. Benson said initially.

5 DR. ACKERMAN: Okay.

6 DR. MORTENSEN: So when you're being
7 induced through these medicines, you need in the
8 first year to be seen more frequently, because your
9 doses are going to have to be adjusted. But then if
10 you change providers and you're already on stable
11 treatment, you wouldn't need to be seen every three
12 months because you're already on that medication.
13 So it's just during induction that you would need
14 that.

15 DR. ACKERMAN: If we're putting a rule --

16 DR. MORTENSEN: But the way that he -- the
17 way that he --

18 DR. ACKERMAN: I think as a responsible
19 provider, if you have a new patient that wasn't
20 yours before, you would want to see that patient
21 more often once a year. If you're inheriting
22 somebody, even if they've been on the same
23 medications for 10 years, if I'm inheriting someone,
24 I see them more often for the first year because I
25 don't know them.

1 DR. MORTENSEN: I would do.

2 DR. BENSON: Absolutely. I agree with you.

3 In God I trust, everybody else, show me the data.

4 DR. ACKERMAN: Right. So as a rule, we
5 don't have to say that. So Dr. Benson, initially,
6 number nine, "Undergoes evaluation by a prescribing
7 physician or their designate every three months for
8 the initial year, and then at least annually
9 thereafter."

10 CHAIRMAN ROMANELLO: There's the motion.
11 Is there a second?

12 DR. KIRSH: Second.

13 CHAIRMAN ROMANELLO: Dr. Kirsh seconds.
14 All in favor?

15 (Unanimous ayes)

16 Opposed?

17 Motion passes.

18 DR. ACKERMAN: And then I would use the
19 same language for bullet 10.

20 CHAIRMAN ROMANELLO: Now for number 10,
21 Dr. Benson, you want to read us from the --

22 DR. BENSON: As far as suicide risk?

23 CHAIRMAN ROMANELLO: Yeah.

24 DR. BENSON: They don't specifically say
25 that. But I think, I mean, that's a major, major

1 risk. I think, you know, you want to definitely
2 make sure that people are being monitored for that.
3 And the long-term studies --

4 DR. ACKERMAN: Well, how often? We have
5 every three months.

6 DR. BENSON: I think what we have here is
7 -- maybe -- you know, like maybe you want to do a
8 range, but I think -- I don't see anything specific
9 in here in terms of that, but --

10 DR. ACKERMAN: Then why can't we just say
11 the same thing? "Every three months, initially, and
12 then at least annually thereafter."

13 CHAIRMAN ROMANELLO: Okay. Is that a
14 motion?

15 DR. ACKERMAN: Yes, sir.

16 CHAIRMAN ROMANELLO: Is there a second?

17 DR. KIRSH: Second.

18 DR. DI PIETRO: Second.

19 CHAIRMAN ROMANELLO: Dr. Kirsh,
20 Dr. Di Pietro.

21 All in favor?

22 (Unanimous ayes)

23 Opposed?

24 Motion carries. Anything else on this
25 form?

1 DR. BENSON: Well, this is the form that
2 has the Cyproterone acetate on Bates 298 and the
3 Finasteride discussion. I don't know if --

4 DR. ACKERMAN: Where did staff get that
5 from? Is it not available --

6 DR. BENSON: It's at the very bottom in the
7 last two paragraphs.

8 DR. ACKERMAN: -- in the United States or
9 is it illegal?

10 DR. DI PIETRO: It's not available.

11 DR. BENSON: It's not available. I don't
12 think the FDA -- I don't think it's even approved.
13 It's not an approved treatment. It's not available.

14 DR. ACKERMAN: So if it's not available, we
15 shouldn't even have it in there.

16 DR. BENSON: I think it's available in
17 Canada, but I don't know for sure.

18 DR. MORTENSEN: I left it on there only
19 because when I was searching, you can buy these
20 things from Canada, and you can buy certain things
21 without prescriptions. So I just wanted to make
22 sure that if they were looking at it, they were
23 aware of the risks.

24 DR. DERICK: You know, the public has been
25 so great with listening and allowing us to go

1 through these details and maybe they can speak to
2 that when we're done with it if they are receiving
3 those medications.

4 DR. ACKERMAN: But if it's something that
5 can't be prescribed by a physician, I don't think it
6 should be in this form.

7 CHAIRMAN ROMANELLO: Right.

8 DR. ACKERMAN: If it's something that a
9 Florida licensed physician cannot prescribe, it
10 shouldn't be in this form.

11 CHAIRMAN ROMANELLO: Agreed.

12 DR. MORTENSEN: Well, maybe you could just
13 add, "This is not prescribed in the United States."
14 Because maybe when they're doing their research
15 they're saying, "How come you're not prescribing me
16 this?" And you could say, "Well, because of the
17 side effects and it's not available in the United
18 States."

19 CHAIRMAN ROMANELLO: Dr. Mortensen, let's
20 hold and wait until we hear if there are any public
21 comments around this issue.

22 DR. ACKERMAN: Yeah. Keep track of the
23 issues that we want, because I think I'd like to
24 call on those people that maybe can speak to that
25 first when we do public comments. This and there

1 was something else about youth using Finasteride and
2 whatever else there was, I can't remember.

3 DR. MORTENSEN: We'll talk about the pill
4 version of that.

5 DR. ACKERMAN: The pill version of
6 testosterone. These are things that --

7 CHAIRMAN ROMANELLO: Anything else on this
8 form?

9 DR. ACKERMAN: I saw also here that
10 Casodex Bicalutamide is on here, wasn't on the kids
11 form. Matt, do you want to --

12 DR. BENSON: Say it -- I'm sorry, I was
13 reading something else.

14 DR. ACKERMAN: Bicalutamide --

15 DR. BENSON: Bicalutamide, yes.

16 DR. ACKERMAN: -- is on here. It was not
17 on the kid's form. Is that correct or was it there,
18 too?

19 DR. BENSON: Yeah. I mean, there's some --
20 there's some experience. I've prescribed
21 Bicalutamide to kids with testotoxicosis.

22 DR. ACKERMAN: Was it on the kid's form?

23 DR. BENSON: No. It wasn't on the kid's
24 form and it's one of those things that I don't think
25 it's being routinely used.

1 DR. ACKERMAN: Do we need to put it on the
2 kid's form? I don't want to make things more
3 complicated if -- this is just the preamble, anyway,
4 so it's not that --

5 DR. BENSON: I -- you know --

6 DR. MORTENSEN: Maybe we can see from
7 public comment who's using it.

8 DR. BENSON: Yeah. I'd probably wait.
9 Maybe we can hear from the public about Bicalutamide
10 in children, and then Finasteride and Cyproterone
11 acetate in the adults.

12 CHAIRMAN ROMANELLO: All right. So using
13 that as a placeholder for further discussion, we're
14 going to move on to the informed consent proposed
15 form found at Bates 308. "Testosterone Treatment
16 for Patients with Gender Dysphoria."

17 Again, recognizing that the changes that we
18 previously made on the forms will kind of flow
19 through to these forms, does anybody have any
20 additional comments or proposed modifications to
21 this form?

22 DR. DI PIETRO: My only question is -- and
23 I guess for Dr. Benson and Dr. Mortensen,
24 testosterone, since it's a controlled substance,
25 usually the provider has them come in more than

1 annually. So I don't know if we need to change the
2 verbiage based upon the sheer fact it's a controlled
3 substance, or do we just leave it as is and then
4 it's up to the physician to understand the rules of
5 opiate -- you know, not opiate but controlled
6 substance prescribing in the state?

7 EXECUTIVE DIRECTOR VAZQUEZ: Right. And I
8 think to that point, it's important to point that
9 out that all of the remaining standard of care
10 elements --

11 DR. DI PIETRO: Fair.

12 EXECUTIVE DIRECTOR VAZQUEZ: -- all the
13 other standards that relate to the practice of
14 medicine, even if it's involving gender dysphoria,
15 would still apply. This rule would not alleviate
16 any of those obligations or requirements at any
17 point.

18 DR. DI PIETRO: Then I'm okay with leaving
19 it as is. Just I wanted to be on the record with
20 saying it is a controlled substance, so normally
21 it's at least every six months for controlled
22 substances.

23 UNIDENTIFIED SPEAKER: Very good point.

24 CHAIRMAN ROMANELLO: Any other observations
25 or proposed edits to this form?

1 DR. BENSON: We're talking about 308 and
2 after, right?

3 CHAIRMAN ROMANELLO: Yes.

4 DR. BENSON: Let's look through. I
5 highlighted a couple of things, but I don't think --
6 we have the vaginal dryness issue here, again.
7 Might be good to use the same word verbiage that we
8 used with the pediatric one.

9 CHAIRMAN ROMANELLO: Okay. So that's a
10 motion by Dr. Benson.

11 DR. BENSON: It's on Bates 312.

12 CHAIRMAN ROMANELLO: Yep.

13 DR. DI PIETRO: I actually have one
14 addition. On -- sorry -- on Bates 310.

15 CHAIRMAN ROMANELLO: Well, let me take up
16 Dr. Benson's proposal on --

17 DR. DI PIETRO: Oh, I'm sorry.

18 CHAIRMAN ROMANELLO: -- Bates 312. Bates
19 312 at the top, we have vaginal dryness, and the
20 motion is to include the previous language. Tears
21 -- so that's a motion by Dr. Benson. A second by --

22 DR. MORTENSEN: Second.

23 CHAIRMAN ROMANELLO: -- Dr. Mortensen. All
24 in favor?

25 (Unanimous ayes)

1 Opposed?

2 Motion passes.

3 Dr. Di Pietro.

4 DR. DI PIETRO: I've got to find my page
5 again now, sorry. On Bates 310, "Who should not
6 take," and then "It should be used with caution and
7 only after full discussion of risks by anyone who"
8 -- we need to add on there family history of --
9 actually, no, blood clot works. Never mind. I was
10 going to say pulmonary embolism, but blood clot
11 covers that. Scratch that.

12 CHAIRMAN ROMANELLO: Okay. Yep.

13 ATTORNEY MCNULTY: Mr. Romanello, there's
14 one on page 312 when you have a chance.

15 CHAIRMAN ROMANELLO: Ms. McNulty, yes.

16 ATTORNEY MCNULTY: Thank you. I think this
17 clarification needs -- the very last box on page 312
18 says, "Taking more testosterone than prescribed
19 could/may/will increase/will not" -- I mean, that is
20 awkward. I don't know what it should be. That's
21 the way the form is reading.

22 CHAIRMAN ROMANELLO: "Taking testosterone
23 more than prescribed" --

24 ATTORNEY MCNULTY: "Could or may."

25 CHAIRMAN ROMANELLO: -- "could" -- oh,

1 "could or may."

2 ATTORNEY MCNULTY: Maybe just both could
3 and may?

4 UNIDENTIFIED SPEAKER: And get read of
5 wills?

6 ATTORNEY MCNULTY: That way it just goes
7 "will increase health" --

8 CHAIRMAN ROMANELLO: "May increase health
9 risks, may not make changes happen more quickly."

10 DR. MORTENSEN: So I would just eliminate
11 the words "could" and "may."

12 ATTORNEY MCNULTY: Yeah.

13 DR. MORTENSEN: So that way it's "taking
14 more testosterone prescribed will increase health
15 risks, will not make changes."

16 CHAIRMAN ROMANELLO: Motion by
17 Dr. Mortensen.

18 DR. DI PIETRO: Second.

19 CHAIRMAN ROMANELLO: Second by Di Pietro.
20 All in favor?

21 (Unanimous ayes)

22 Opposed?

23 Motion carries.

24 ATTORNEY MCNULTY: Thank you.

25 CHAIRMAN ROMANELLO: Thank you,

1 Ms. McNulty. Anything else on this form?

2 Hearing nothing more on this form, going to
3 go to the form found at Bates 317. "Surgical
4 Treatment for Adults with Gender Dysphoria." Again,
5 we've made all the changes that are going to flow
6 through tot his form. Any further proposed
7 modifications, or observations, or proposed changes
8 here?

9 DR. BENSON: I think --

10 CHAIRMAN ROMANELLO: Dr. Benson.

11 DR. BENSON: -- one of the things that we're
12 starting to learn about vaginoplasty in people who
13 are blocked in earlier puberty is that the penile
14 tissue with which they use to surgically create a
15 vagina can sometimes be too small. So they then go
16 to other tissue sources now, like the colon, to
17 create a vagina. And so this is just a, if you've
18 been blocked from early on, you know, it can be a
19 much more difficult procedure and more risks of
20 major complications. So it may be good to have some
21 verbiage in here regarding that. That if you were
22 blocked from early on in puberty, your penile tissue
23 may be --

24 DR. ACKERMAN: Inadequate.

25 DR. BENSON: -- inadequate for the surgical

1 procedure. And then I'm sure that, you know, that
2 would be discussed by the surgeon and everything,
3 but it's -- do you see where that is, Bates 317?
4 It's under "Vaginoplasty."

5 ATTORNEY MCNULTY: Maybe not sufficient
6 versus inadequate?

7 DR. BENSON: Insufficient.

8 ATTORNEY MCNULTY: Insufficient.

9 DR. BENSON: Yeah.

10 UNIDENTIFIED SPEAKER: "May not be
11 sufficient."

12 DR. DERICK: Can you tell me one more time
13 where you are on the document?

14 DR. BENSON: Bates 317 under
15 "Vaginoplasty." There's bullets under "Genital or
16 bottom surgery. Orchiectomy, vaginoplasty,
17 phalloplasty."

18 ATTORNEY DIERLAM: And can you just one
19 more time read in the proposed sentence? I guess
20 you're talking about adding a sentence under the
21 "Vaginoplasty"?

22 DR. BENSON: "For those of you who are
23 treated with puberty blockers in childhood, an
24 additional complication of this surgery could be
25 related to inadequate penile tissue which may

1 necessitate the use of" -- sorry. I know, I do this
2 on a daily -- well, not surgery, but -- "treatment
3 with puberty blockers can lead to insufficient
4 penile tissue that may necessitate the use of
5 other" --

6 DR. ACKERMAN: Tissue sources.

7 DR. BENSON: -- "tissue sources, such as
8 the colon to create a vagina." Or something like
9 that.

10 ATTORNEY MCNULTY: Well, we need the
11 precise language.

12 UNIDENTIFIED SPEAKER: They're not as good
13 and fast as like Dragon or anything, so you got to
14 get a little bit more deliberate.

15 ATTORNEY MCNULTY: So "can lead to
16 insufficient penile tissue" --

17 DR. BENSON: "That would necessitate the
18 use of other tissues such as the colon to create a
19 vagina."

20 Monica, any suggestions there?

21 DR. MORTENSEN: I think that seems
22 reasonable.

23 DR. BENSON: You know, I don't know if it
24 would be -- if this is kosher, or if it could ever
25 happen but is it possible that -- I'm not a

1 urologist, I'm not a surgeon. Is it possible that
2 we could ever have a -- two or three people that do
3 this for a living to actually, at some point, look
4 at it and make sure that it's as robust as possible
5 for the surgeons that --

6 CHAIRMAN ROMANELLO: We're going to come
7 back and do a permanent rule. This is an emergency
8 rule.

9 DR. BENSON: Okay.

10 CHAIRMAN ROMANELLO: And we will start this
11 process all over again and have public comment
12 again.

13 DR. DI PIETRO: When that happens, I have a
14 contact in Miami, and this is her sole job --

15 CHAIRMAN ROMANELLO: We can invite those
16 folks. Yeah.

17 DR. DI PIETRO: -- is gender dysphoria
18 surgery, so I'm happy to invite her.

19 DR. ACKERMAN: We've invited some of these
20 people in the past --

21 CHAIRMAN ROMANELLO: We have.

22 DR. ACKERMAN: -- and they've chosen not to
23 participate.

24 CHAIRMAN ROMANELLO: So I want to -- Bates
25 317, the dot point "Vaginoplasty." Dr. Benson's

1 motion is to add language at the end of that dot
2 point that reads --

3 Mr. Dierlam.

4 ATTORNEY DIERLAM: I believe that this may
5 be -- I think I have it. Please correct me if I'm
6 wrong, Mr. Benson. I believe it was, "Continued
7 treatment with puberty blockers may result in
8 insufficient penile tissue that could necessitate
9 the use of other tissues to create a vagina."

10 DR. BENSON: What I would say, "For those
11 of you who may have been treated with puberty
12 blockers, or, you know, as a child, this is when
13 it's an issue." It's not typically an issue if you
14 started transition at 16 or 17. It's not an issue
15 then. It's an issue if you started puberty blockers
16 as a young child like 8, 9, 10.

17 CHAIRMAN ROMANELLO: Okay. So with that
18 addition, we have a motion by Dr. Benson. Is there
19 a second?

20 DR. MORTENSEN: Second.

21 CHAIRMAN ROMANELLO: Dr. Mortensen. All in
22 favor?

23 (Unanimous ayes)

24 Opposed?

25 Motion carries.

1 Any other observations here?

2 DR. BENSON: What is -- I do have one more
3 question. Bates 318, there's a question that says,
4 "What are some potential complications of surgery?"

5 CHAIRMAN ROMANELLO: Yep.

6 DR. BENSON: There's a bullet list.
7 "Changes in sexual sensation," et cetera. "Decrease
8 in function." What are we referring to? Could
9 we --

10 CHAIRMAN ROMANELLO: Wait, where are you?

11 DR. BENSON: Decrease in -- under "What
12 are some potential complications of surgery?"

13 ATTORNEY MCNULTY: 319.

14 CHAIRMAN ROMANELLO: Decrease in function,
15 right.

16 DR. BENSON: Because we talk about changes
17 in sexual sensation --

18 CHAIRMAN ROMANELLO: Right.

19 DR. BENSON: -- infection, nerve damage.
20 Decrease in function, do we know what we're
21 specifically?

22 DR. ACKERMAN: I think we can strike that.

23 CHAIRMAN ROMANELLO: Dr. Mortensen?

24 DR. BENSON: It just seems redundant or
25 something.

1 Do you know, Monica?

2 DR. MORTENSEN: I think it was related,
3 also, to urinary complaints. But I'm okay with
4 striking it.

5 DR. BENSON: Well -- yeah.

6 DR. ACKERMAN: Urinary function.

7 CHAIRMAN ROMANELLO: So motion by
8 Dr. Mortensen to strike the dot point "decrease in
9 function."

10 DR. ACKERMAN: Yeah. Function is just too
11 ambiguous.

12 CHAIRMAN ROMANELLO: Second by Dr. Benson.
13 All in favor?

14 (Unanimous ayes)

15 Opposed?

16 Motion carries.

17 ATTORNEY DIERLAM: And if I may, just on
18 the next page --

19 DR. ACKERMAN: Although, I would -- you
20 know, instead of "Trouble with bladder emptying," I
21 would just say -- you know, maybe combine those, the
22 function and that together. You know, "Diminishment
23 of bladder function -- or urinary function."

24 DR. BENSON: Yeah.

25 DR. ACKERMAN: Because it's not just

1 bladder emptying, it's -- you know, it's flow rate,
2 it's initiation of urination.

3 DR. BENSON: We did have people testify
4 about blood clots in their urine with this
5 treatment, so --

6 DR. ACKERMAN: Right. So instead of
7 "Trouble with bladder emptying," just say
8 "Diminishment of bladder function."

9 CHAIRMAN ROMANELLO: So the motion is to
10 change the dot point on Bates 318 from "Trouble with
11 bladder emptying" to --

12 DR. ACKERMAN: "Diminishment in bladder
13 function."

14 CHAIRMAN ROMANELLO: That's a motion by
15 Dr. Ackerman, a second by Benson. All in favor?

16 (Unanimous ayes)

17 Opposed?

18 Carries.

19 DR. ACKERMAN: Well --

20 DR. DI PIETRO: I have one more two.

21 DR. ACKERMAN: -- I just want to back pedal
22 a little bit. Bladder function or urinary function?

23 DR. MORTENSEN: Well, they have some
24 urinary complaints, as well.

25 DR. ACKERMAN: Right. So maybe just

1 "Diminishment in urinary function."

2 DR. MORTENSEN: Or urinary disfunction. Or
3 problems urinating.

4 DR. ACKERMAN: Right. "Problems
5 urinating."

6 CHAIRMAN ROMANELLO: So you want to add a
7 second --

8 DR. ACKERMAN: Add another bullet "Problems
9 with urination."

10 CHAIRMAN ROMANELLO: So motion by
11 Dr. Ackerman --

12 DR. ACKERMAN: Ackerman to add another
13 bullet saying, "Problems with urination."

14 CHAIRMAN ROMANELLO: Second by Dr. Di
15 Pietro. All in favor?

16 (Unanimous ayes)

17 Opposed?

18 It's added.

19 DR. DI PIETRO: And --

20 CHAIRMAN ROMANELLO: Dr. Di Pietro.

21 DR. DI PIETRO: -- one more bullet point,
22 sorry. Last bullet point where it says, "Side
23 effects of anesthesia, including death," I think we
24 should add, "Side effects of anesthesia and
25 infection, including death" or -- infection is a big

1 part of this surgery. It's always a surgical --

2 UNIDENTIFIED SPEAKER: The same page.

3 DR. DI PIETRO: Where is it? Oh,
4 infection. I'm sorry. Read right over it. Thank
5 you.

6 DR. ACKERMAN: Never mind.

7 DR. DI PIETRO: Dr. Ackerman, never mind.

8 CHAIRMAN ROMANELLO: Okay. Anything else
9 on this form? We're going to get to the AG and
10 staff in a second, I promise you. No?

11 Donna? Chris?

12 ATTORNEY DIERLAM: Yeah. So my only
13 comment, and it's on -- I believe it's the fifth box
14 on Bates 319, it states, "I understand that if I my
15 breast augmentation surgery." I think it should be,
16 "I understand that if I have my breast augmentation
17 surgery."

18 ATTORNEY MCNULTY: Not my. Just substitute
19 have for my.

20 ATTORNEY DIERLAM: Right. "So if I have
21 breast augmentation surgery."

22 ATTORNEY MCNULTY: Yes.

23 DR. ACKERMAN: Scribner's -- Scribner's
24 error.

25 ATTORNEY DIERLAM: Yes.

1 CHAIRMAN ROMANELLO: Staff? Danielle?

2 EXECUTIVE DIRECTOR TERRELL: Yes, sir. If
3 we can go back to -- and I apologize, I don't have
4 the Bates numbers. This is the "Masculinizing for
5 Adults Testosterone" form. On the third page when
6 we talk about the specific criteria, it seems number
7 two was repeated, and I just want to strike that.

8 CHAIRMAN ROMANELLO: Read what you're -- so
9 I'm --

10 EXECUTIVE DIRECTOR TERRELL: Oh, I
11 apologize. Minors -- "Masculinizing for Minors." I
12 apologize.

13 CHAIRMAN ROMANELLO: "Masculinizing for
14 Minors."

15 ATTORNEY MCNULTY: The third page?

16 EXECUTIVE DIRECTOR TERRELL: Yes, on the
17 third page. If you'll read the second and third
18 criteria are the same. There was just a repeat in
19 there that I would like to --

20 DR. DI PIETRO: Under which --

21 EXECUTIVE DIRECTOR TERRELL: Under the
22 specific requirements for minors to receive and
23 continue hormone replacement therapy.

24 DR. DI PIETRO: Page 285.

25 EXECUTIVE DIRECTOR TERRELL: 285.

1 DR. DI PIETRO: Oh, okay. Yeah, that's
2 duplicative.

3 EXECUTIVE DIRECTOR TERRELL: Yes. I just
4 wanted to get a motion, so that we could correct
5 that.

6 DR. DI PIETRO: I'll motion to strike
7 number two, Bates 285.

8 CHAIRMAN ROMANELLO: Motion by Dr. Di
9 Pietro.

10 DR. DERICK: Second.

11 CHAIRMAN ROMANELLO: Second by Dr. Derick.
12 All in favor?

13 (Unanimous ayes)

14 Opposed?

15 Carries.

16 DR. ACKERMAN: I have one more.

17 CHAIRMAN ROMANELLO: You what?

18 DR. ACKERMAN: I have one more.

19 CHAIRMAN ROMANELLO: Yeah, please. Which
20 one, Dr. Ackerman?

21 DR. ACKERMAN: Page 319, box 1, 2, 3, 4, 5,
22 6.

23 CHAIRMAN ROMANELLO: This is surgery.

24 DR. ACKERMAN: Right. On the surgery one.

25 CHAIRMAN ROMANELLO: Bates 319, yes.

1 DR. ACKERMAN: Box six, "I understand my
2 surgery -- risk factors." Those are breast cancer,
3 right, the breast cancer risk factors one?

4 CHAIRMAN ROMANELLO: Yes.

5 DR. ACKERMAN: So it says, "I.e." bracket
6 one, bracket to. Technically, it should be "E.g."

7 CHAIRMAN ROMANELLO: Okay.

8 DR. ACKERMAN: For example, not that is.
9 I.e. is that is, meaning those are the only two.
10 E.g. is for example. There's more than just those
11 two.

12 CHAIRMAN ROMANELLO: I appreciate the --

13 DR. ACKERMAN: Bates 319. Did you ask me
14 where? Yeah, Bates 219.

15 ATTORNEY DIERLAM: We're on hard copies.

16 CHAIRMAN ROMANELLO: Hold on, hold on.

17 ATTORNEY MCNULTY: Page 3 of 6.

18 DR. ACKERMAN: Of the surgery. Page 3 of 6
19 of the surgery, that fifth box down where it talks
20 about bracket one or bracket two.

21 ATTORNEY DIERLAM: I.e., e.g.

22 DR. ACKERMAN: It should be e.g. not i.e.

23 CHAIRMAN ROMANELLO: Nice catch.

24 DR. ACKERMAN: We're physicians here, we
25 know Latin.

1 DR. DERICK: I know, between you and I, the
2 two chairs are the grammar police.

3 CHAIRMAN ROMANELLO: Any other
4 observations? Thank you for the catch.

5 DR. ACKERMAN: I would think the lawyers
6 would know the Latin.

7 CHAIRMAN ROMANELLO: Ms. Terrell?

8 EXECUTIVE DIRECTOR TERRELL: Yes, sorry.
9 One more. If you will go back to the form we were
10 just one with the --

11 CHAIRMAN ROMANELLO: Which one was that?

12 EXECUTIVE DIRECTOR TERRELL: --
13 testosterone for minors, "Masculinizing Minors" is
14 what it's called.

15 CHAIRMAN ROMANELLO: Yep.

16 EXECUTIVE DIRECTOR TERRELL: We need to add
17 one and it has -- what happened was one got added
18 and one got taken away, and it's the same as the
19 other forms. "Has pubital changes resulting in an
20 increase in gender dysphoria," which is what the
21 other forms have, this one didn't have it.

22 DR. MORTENSEN: Oh, I copied it over.

23 DR. DI PIETRO: So I'll make a motion to
24 accept that, to pull it over from the other form.

25 DR. ACKERMAN: Second.

1 CHAIRMAN ROMANELLO: That's a motion from
2 Dr. Di Pietro, second by Dr. Ackerman. All in
3 favor?

4 (Unanimous ayes)

5 Opposed?

6 Motion carries.

7 Any further comments or observations by the
8 committee members with respect to any of the
9 informed consent forms?

10 I want to thank you all for the thoughtful
11 deliberation and the catches in Latin and grammar
12 and syntax that we did. We landed the plane within
13 two hours. Congratulations. We're going to take a
14 10-minute break and we're going to come back and
15 we're going to do the rules.

16 DR. ACKERMAN: Can you review with us the
17 agenda?

18 CHAIRMAN ROMANELLO: I'm sorry?

19 DR. ACKERMAN: Can you review the -- before
20 we take the break, just for the benefit of the
21 audience --

22 CHAIRMAN ROMANELLO: Right. We're going to
23 come back and talk -- so we'll take a 10-minute
24 break. We're going to come back and do rules, the
25 two rules, and then we're going to take public

1 comment.

2 UNIDENTIFIED SPEAKER: Until 4:30?

3 CHAIRMAN ROMANELLO: Until 4:30, and then

4 we'll take --

5 DR. ACKERMAN: And the rules shouldn't take

6 too long.

7 CHAIRMAN ROMANELLO: No.

8 DR. ACKERMAN: Because the rules are very

9 short.

10 CHAIRMAN ROMANELLO: Correct.

11 Ten-minute break.

12 (Recess taken)

13 CHAIRMAN ROMANELLO: I'm going to call the

14 joint committee meeting back to order. Thank

15 everybody for keeping it to 10 minutes. Appreciate

16 that. Before we move on to the actual rules, staff

17 had -- I think Mr. Vazquez had some questions about

18 the titling or the naming of the informed consent

19 form. So I'll turn it over to Mr. Vazquez with the

20 questions.

21 EXECUTIVE DIRECTOR VAZQUEZ: Just one quick

22 point. The titles seem to be consistent with the

23 exception of the "Treatment with Testosterone for

24 Adults," I believe it is. Is that correct that it

25 should be "Testosterone Treatment for Patients with

1 Gender Dysphoria," or should it be "Masculinizing
2 Medications for Patients with Gender Dysphoria"?

3 DR. ACKERMAN: I think it should be
4 Masculinizing.

5 DR. DI PIETRO: Second.

6 CHAIRMAN ROMANELLO: All in favor?

7 (Unanimous ayes)

8 Opposed?

9 None. You've got a poll. Got it. Okay.

10 We're now going to turn to a consideration
11 of the actual rules, and we'll start with Bates 294,
12 which is the draft rule. "Sex Reassignment Standard
13 of Practices in Minors." And I'm going to start
14 with board counsel who had some technical
15 observations, proposed changes, and then one that is
16 going to flow through from the informed consent
17 discussion earlier.

18 So Ms. McNulty.

19 ATTORNEY MCNULTY: Thank you,

20 Mr. Romanello. On Bates page 295 --

21 DR. ACKERMAN: Donna, before you begin
22 that, just again for our benefit -- pretend I don't
23 know anything, but I do, but maybe for the
24 audience's benefit, this rule is a rule that we put
25 forth to allow minors to continue their medication

1 -- for those minors who are already in the program,
2 who are already undergoing gender affirming care, to
3 continue that care. That's what this emergency rule
4 is for. Right?

5 ATTORNEY MCNULTY: Yes. And it adopts --
6 it does two things for the minors. It sets forth
7 standards of practice and incorporates the informed
8 consent forms you all just decided about.

9 DR. ACKERMAN: Right. And this is for
10 those minors that were -- whose sex reassignment
11 healthcare was commenced before and was still active
12 as of May 17, 2023.

13 ATTORNEY MCNULTY: Correct.

14 DR. ACKERMAN: Okay. Just wanted to make
15 sure that I understand that, and that's also for the
16 benefit of the public that's here today.

17 ATTORNEY MCNULTY: And that is by statute.

18 DR. ACKERMAN: Right. Not our decision.
19 This is by statute. Thank you. Ms. McNulty, I'm
20 sorry.

21 ATTORNEY MCNULTY: No. Thank you for that
22 big picture. It's helpful.

23 On Bates page 295 under subsection 4,
24 "Standards of practice," the line before subsection
25 8, "Patient evaluations," there's a -- it just says,

1 "Clinical determinations," and I suggest that that
2 be deleted, because that really is repeated in
3 subsection B. So it says, "Clinical
4 determinations." I think it's unnecessary and
5 should be stricken.

6 DR. ACKERMAN: Move to strike.

7 CHAIRMAN ROMANELLO: Motion to strike by
8 Ackerman, second by Derick. All in favor?

9 (Unanimous ayes)

10 Opposed?

11 Passes. Next.

12 ATTORNEY MCNULTY: Then also in number 4 on
13 the following page, it says, "The patient will have
14 adequate psychological and social support during
15 treatment." Again, as you've done previously, to
16 strike the word adequate.

17 DR. ACKERMAN: Move to strike adequate.

18 CHAIRMAN DERICK: Second.

19 CHAIRMAN ROMANELLO: All in favor?

20 (Unanimous ayes)

21 Opposed?

22 Passes. Next?

23 ATTORNEY MCNULTY: The next, as was
24 discussed previously, subsection G says, "Bone DEXA
25 scan." To clarify as you did before to have it read

1 "Bone density scan (DEXA scan) -- or DEXA -- DEXA
2 scan."

3 DR. ACKERMAN: Just DEXA.

4 ATTORNEY MCNULTY: Just DEXA.

5 DR. ACKERMAN: Bone density scan or bone
6 density study? What did we say before?

7 ATTORNEY MCNULTY: Scan.

8 DR. DI PIETRO: Motion.

9 CHAIRMAN ROMANELLO: Motion by Dr. Di
10 Pietro, second by Dr. Kirsh. All in favor?

11 (Unanimous ayes)

12 Opposed?

13 Motion passes. Next?

14 ATTORNEY MCNULTY: And that's it.

15 UNIDENTIFIED SPEAKER: Do we have to adjust
16 C?

17 DR. ACKERMAN: Yeah.

18 CHAIRMAN ROMANELLO: Yeah. We modified on
19 Bates 296, sub (c). We had modified that language
20 in the consent forms.

21 ATTORNEY MCNULTY: Well, did you do that
22 for minors? This is just for minors, not adults.

23 UNIDENTIFIED SPEAKER: We did not.

24 ATTORNEY MCNULTY: You only did that for
25 adults, is my understanding. Oh, for the covering

1 physician?

2 UNIDENTIFIED SPEAKER: Yeah. The
3 physician, I think we decided on six months, not
4 three.

5 DR. ACKERMAN: Can we just say, "a
6 physician"?

7 UNIDENTIFIED SPEAKER: The covering
8 physician.

9 CHAIRMAN ROMANELLO: C is patient visits
10 and the quarterly evaluations.

11 DR. ACKERMAN: The physician or covering
12 physician.

13 UNIDENTIFIED SPEAKER: Right.

14 DR. DERICK: Can we just carry over the
15 language that we did --

16 CHAIRMAN ROMANELLO: So Dr. Derick is
17 making a motion to carry over that language from the
18 informed consent.

19 DR. ACKERMAN: Second.

20 CHAIRMAN ROMANELLO: Second by

21 Dr. Ackerman. All in favor?

22 (Unanimous ayes)

23 Opposed?

24 Carries. Any other questions or proposed
25 changes to the rule?

1 DR. BENSON: I do have a question on Bates
2 295. There's "A board approved informed consent
3 form is not executed until" -- and then there's A,
4 B, C, D. When we have like studies with children,
5 we often have a parent permission form which is a
6 consent form, and we actually are mandated a lot of
7 times by the IRB to make a different ascent form
8 that's usually one page or less that is in like very
9 basic -- you know, very simple, basic language.

10 I'm just curious why do they have us do --
11 what does it mean when you say, "Assent to the
12 informed consent form"? This isn't -- because we
13 have the parents' permission to do it. It's just
14 the kid signing their signature on the form, that's
15 what you mean by that?

16 ATTORNEY MCNULTY: Yes. And that's what
17 you just did in the forms.

18 DR. BENSON: Okay. Yeah. I understand
19 that, I'm just -- it's not typical. It's not
20 typically done that way.

21 DR. ACKERMAN: Well, what do you typically
22 do?

23 DR. BENSON: We have like a separate assent
24 form for a child under 12.

25 DR. ACKERMAN: Okay. They don't sign it.

1 But this is different. This is much more --

2 DR. BENSON: Yeah. This is different. And
3 then the witness, is that a pretty standard thing,
4 too?

5 ATTORNEY MCNULTY: Well, this is -- the
6 medical boards have two other informed consent forms
7 by rule, and each of those have a witness to it. It
8 could be anybody, of course, and I didn't -- we
9 thought we would just put it in there, just if you
10 wanted to be consistent with what you have done in
11 the past. Doesn't mean you have to do that. It's
12 easier to take it out if you don't want it, but
13 that's just been done for the other informed consent
14 for the cataract surgery and medical marijuana
15 forms.

16 DR. BENSON: I think it's good to be
17 consistent. I mean, I don't have a problem with it.

18 DR. DI PIETRO: Yeah. I mean, every
19 consent I've ever seen in the hospital has a
20 witness, so --

21 CHAIRMAN ROMANELLO: Anything else?
22 We're going to move on to the adult rule.

23 DR. ACKERMAN: 323.

24 CHAIRMAN ROMANELLO: Thank you,
25 Dr. Ackerman. At Bates 323. I'll ask board counsel

1 if they have any technical modifications that they
2 want to propose?

3 ATTORNEY DIERLAM: We do not.

4 CHAIRMAN ROMANELLO: Thank you.

5 Committee members?

6 DR. ACKERMAN: And 30,000-foot view of this
7 again, like I did before --

8 CHAIRMAN ROMANELLO: Yep.

9 DR. ACKERMAN: -- was for adults. They
10 don't already have to be in the program. They can
11 be an adult who wants to undergo sex reassignment
12 healthcare can, by statute, and this is just saying
13 that they -- in order to do that, you have to have
14 appropriate informed consent.

15 UNIDENTIFIED SPEAKER: Required by statute.

16 DR. ACKERMAN: Or what's that?

17 UNIDENTIFIED SPEAKER: I said which is
18 required by statute.

19 DR. ACKERMAN: Which is required by
20 statute.

21 CHAIRMAN ROMANELLO: Any other observations
22 or proposed modifications to rule --

23 DR. ACKERMAN: And what this effects is
24 those adults who are already in the program that
25 want to modify their drugs, need to make sure this

1 -- this form needs to be signed before the drugs or
2 surgery can happen. So there's adults in Florida
3 right now whose surgery has been canceled because
4 this form does not exist. And so it's imperative
5 that we get this form out, so those people can have
6 the surgery as they want to.

7 CHAIRMAN ROMANELLO: Okay. If there is
8 nothing else on the rule, we're going to start the
9 public comment portion of the meeting. I want to
10 start -- we're going to start by asking those
11 members of the public who have specific observations
12 or comments on those questions that the committee
13 had during its conversation about the consent forms
14 and the rules. So we talked about experiences with
15 respect to oral testosterone, and we talked about
16 other drugs who I'm going to botch the pronunciation
17 of, but Dr. Ackerman has the --

18 DR. ACKERMAN: And during the break, I went
19 out into the audience for a little bit --

20 CHAIRMAN ROMANELLO: Yep.

21 DR. ACKERMAN: -- and shared with them,
22 because -- to kind of clarify with them the four
23 issues that I remembered that had come up. There
24 was a fifth one. What was the fifth one that
25 someone said?

1 CHAIRMAN ROMANELLO: I had four.

2 DR. ACKERMAN: Right. And so I think some
3 of them -- help me. Who was speaking to me?
4 Someone wanted to -- you, come on up a second.

5 CHAIRMAN ROMANELLO: So as we start to do
6 that, we're going to ask folks to come up to the
7 microphone and state your name. You'll be granted
8 the opportunity to comment up to three minutes.

9 DR. ACKERMAN: The four things we wanted to
10 know about was --

11 CHAIRMAN ROMANELLO: Asking you to speak on
12 the rule or on those issues that we've solicited
13 comment on. Any comments that are outside the rule
14 or outside those items will be considered out of
15 order. And there may be a risk of forfeiting your
16 time if you make a public comment that is out of
17 order.

18 I've got to emphasize that folks who misuse
19 their allocated time to disrupt the proceedings will
20 be deemed out of order and risk being asked to
21 leave. I appreciate the group's cooperation in
22 helping us to maintain a respectful and constructive
23 environment during the public comment section of the
24 meeting.

25 So with that --

1 DR. ACKERMAN: Let me just say the four
2 things again for them.

3 CHAIRMAN ROMANELLO: Please.

4 DR. ACKERMAN: So the first one is, is
5 there widespread use or any use of testosterone in
6 oral form?

7 The second question that we had -- and
8 endocrinologists help me if I misstate any of this
9 -- is there use of Bicalutamide, Casodex, in the
10 pediatric population?

11 The fourth question is, is there use of
12 Finasteride, also more commonly known as Proscar --
13 that's for hair loss -- in the male pattern baldness
14 in the pediatric population.

15 CHAIRMAN ROMANELLO: Oh, that's right.
16 Yeah.

17 DR. ACKERMAN: And the fifth -- the fourth
18 thing was, there was a drug here -- and help me with
19 the -- it was a masculinizing drug, right?

20 UNIDENTIFIED SPEAKER: Cyproterone acetate.

21 DR. ACKERMAN: That's a masculinizing drug?

22 DR. BENSON: Yeah. It -- no. It's a drug
23 that it's very similar to 17-hydroxyprogesterone,
24 which is one of the adrenal steroids that basically
25 binds the androgen receptor in competition with

1 testosterone and dihydrotestosterone.

2 DR. ACKERMAN: Oh, it's used for
3 feminizing.

4 DR. BENSON: Yes.

5 DR. ACKERMAN: I'm sorry. So it's
6 Cyproterone acetate, and apparently, it's not
7 available in the United States, so we're questioning
8 is there use of this? Is it being prescribed by
9 physicians, or is it just being recommended by
10 physicians?

11 And was there another thing, Dr. Derick?

12 DR. BENSON: I think it was just four.

13 DR. ACKERMAN: Just those four. Okay.

14 CHAIRMAN ROMANELLO: All right. And so
15 with that, you're recognized.

16 KATIE DANEHY-SAMITZ: Thank you. Thank you
17 for your time. Katie Danehy-Samitz, vice
18 president/founder of Women's Voices of Southwest
19 Florida. I'm sorry, I'm a little confused. I'm not
20 a doctor, I'm an activist. I know that, you know,
21 we're the one that -- to, I guess, get you to come
22 out from behind and answer those questions. But I
23 have nothing to offer this part of the conversation
24 and in lieu and consideration of the people behind
25 me that have this experience may have answers. And

1 the fact that we turned out -- like we filled out
2 forms for this, I'm just a little confused by like
3 the proceedings. So for this question, should
4 people be getting in line to speak?

5 CHAIRMAN ROMANELLO: Do you have a comment
6 that you would like to make about the rule?

7 KATIE DANEHY-SAMITZ: No, no. I was
8 confused about why I was called up.

9 CHAIRMAN ROMANELLO: Thank you.
10 Is there anybody who would like to make a
11 comment on the rule? Come up to the microphone,
12 please.

13 ANDRE MONTANEZ: My name is Andre Montanez
14 (phonetic). I am part of -- coming from Orlando
15 Heart Community Center. I am also part of the
16 Women's Voices of South Florida, and Equality
17 Florida. I was just a little confused when we had
18 the cards. So I want to explain something about the
19 rule, but you just asked question about the
20 medicines. I can tell that by my own experience,
21 but I'm not a doctor. But I was thinking here we
22 have the right to speak like we do with common
23 cards.

24 But anyway, you want to know about the
25 Finasteride, you had mentioned that one. Yeah.

1 That medicine is given to us for -- it's prescribed.
2 I was prescribed from the nurse practitioner I have
3 that. I hope that they can keep doing the
4 prescription because they really know about what
5 they're doing. And I received Finasteride as a
6 testosterone blocker.

7 They had another one, it's (indiscernible).
8 I'm sorry. I don't know doctors, so I don't know
9 the names. But because I suffer a little bit of
10 blood pressure. They don't want to combine that
11 because I've got my own -- my medicine for blood
12 pressure. So they decide to give me Finasteride,
13 and really my -- sorry, my testosterone came and
14 really blocked that until I got my Estradiol. I
15 just started with pills in estradiol. And they
16 working really good for more than five years. Now I
17 have to do an injection. I don't have anymore the
18 Finasteride because I don't need it. My levels of
19 testosterone are low.

20 I also did a surgery. (Indiscernible).
21 How we surviving this because (indiscernible). And
22 I got something that's like -- like the real -- you
23 know, the medical name (indiscernible). And I did
24 that and so my testosterone is coming totally down,
25 so I need Estradiol to survive.

1 And yes, they check my blood test every
2 three months because it's part of the -- every year
3 they do every kind of exam. Like every single year
4 (indiscernible). So I don't know -- I don't want to
5 go why they -- this is complication with this
6 (indiscernible).

7 I don't know, you cannot change the life
8 right now, but we still need the nurse practitioner
9 to do this because they really know what they do. I
10 think you're doctors, and you -- my cardiologist
11 that was before my transition, I was there, and
12 normally the nurse practitioner doing everything to
13 me. And another doctor trusting the nurse
14 practitioner. So I don't you can get us opportunity
15 in this emergency rule that we can use our
16 prescription from nurse practitioner.

17 I was denied my prescription last week in
18 Walgreens, like Walgreen pharmacy, because I don't
19 follow your rules. Because you get the rules, it's
20 still valid, and I had to fight with them to prove
21 the Board of Medicine give the emergency whatever if
22 it's signed before May 16th -- maybe I confused the
23 date --

24 DR. ACKERMAN: May 17th.

25 ANDRE MONTANEZ: I can have my medicine.

1 So please do that because we need these not have
2 more confusions everywhere. I really want to be
3 alive and continuing my life as a human like
4 everybody.

5 DR. ACKERMAN: So hold on, don't leave.
6 The question --

7 CHAIRMAN ROMANELLO: Thank you for your
8 comment. I appreciate it.

9 Dr. Ackerman, we're not going to go back
10 and forth with questions.

11 DR. ACKERMAN: Can I ask him a question?

12 CHAIRMAN ROMANELLO: No, go ahead.

13 DR. ACKERMAN: Because this is about
14 Finasteride.

15 ANDRE MONTANEZ: Yes, please.

16 DR. ACKERMAN: So did you receive
17 Finasteride as a minor?

18 ANDRE MONTANEZ: No.

19 DR. ACKERMAN: Okay.

20 ANDRE MONTANEZ: Because you don't have me
21 -- no. Because I started my transition older one in
22 the 90s. In the 80s, when I was younger,
23 unfortunately, we didn't have the opportunity that
24 kids have to save the life. Unfortunately, they
25 don't have in my time.

1 DR. ACKERMAN: I'm sorry, you started your
2 transition as an adult or a minor?

3 ANDRE MONTANEZ: Yes, as an adult.

4 DR. ACKERMAN: Adult, okay. Thank you.

5 ANDRE MONTANEZ: Thank you.

6 DR. MORTENSEN: I have a question.

7 CHAIRMAN ROMANELLO: Yep.

8 DR. MORTENSEN: There was testimony last
9 time that I think someone had quoted 80 percent of
10 all the transgender care was being performed by
11 nurse practitioners. So I know by statute, the
12 initial visit has to be done by a physician. So I
13 think that was the point that's being made. It
14 would be interesting to know, in general, like how
15 many people that are on these treatments have never
16 seen a physician.

17 CHAIRMAN ROMANELLO: I agree. Yeah.

18 So I can I also call up to the microphone
19 -- and forgive me if I don't get the names
20 pronounced rightly -- is -- ma'am, you can stay --
21 Vanessa Galindo-Jackson, Dean Price, and Erica
22 Imaoka.

23 Ma'am.

24 EMA ROY: Hi. I'm Ema Roy (phonetic). You
25 asked people to come forward about Cyproterone

1 acetate, and I was prescribed Cyproterone acetate as
2 a child. I was prescribed it as gender affirming
3 therapy. I'm a cis female. I had polycystic
4 ovarian disease that was chronic. I need eight
5 abdominal surgeries to remove cysts even with the
6 medication. So yes, I took Cyproterone acetate.
7 It's an anti-androgen because I had so much male
8 testosterone in my body.

9 I'm coming forward to say that because
10 based on the consent today that 500 pages that my
11 child read last night, I wouldn't have been able to
12 get that therapy. And because of the side effects
13 of polycystic ovarian disease, I would probably be
14 dead from heart disease at the moment. I would not
15 have had my two children. So not having access to
16 that care would have been forced sterilization, and
17 I'm delighted to have had two children.

18 I should have the same rights as a cis
19 female, as transgender females. I don't know why my
20 situation isn't in question here. I guess
21 technically this would make me intersex. You know,
22 you asked the audience to come forward about their
23 experiences with these medications, and I did. But
24 I don't know why you think that this is an
25 appropriate forum and not at my doctor's office, or

1 with my gynecologist, or with my endocrinologist.

2 I still don't know why we're here. This is
3 not the business of the state's governor appointed
4 board. But yes, it helped me with polycystic
5 ovarian disease. And by the way, I still have my
6 other speaker card that me, like everybody else,
7 filled out for the other parts of the 500 pages
8 related to disability. How you want people with
9 autism, et cetera, to be excluded. So I still want
10 to be called for that part. Does anybody have any
11 questions?

12 CHAIRMAN ROMANELLO: Thank you. I
13 appreciate your comment and we'll call you back when
14 we get back to your card. We'll certainly take your
15 comments into consideration as we deliberate further
16 this afternoon. Thank you.

17 EMA ROY: Thanks.

18 VANESSA GALINDO-JACKSON: Hello, I'm just
19 confused. Am I allowed to speak on what I
20 originally had intended, or can I not? Unless it --

21 CHAIRMAN ROMANELLO: Are you Vanessa?

22 VANESSA GALINDO-JACKSON: I am. Yes.

23 CHAIRMAN ROMANELLO: Welcome to the
24 meeting. Appreciate it.

25 VANESSA GALINDO-JACKSON: I appreciate you

1 guys.

2 UNIDENTIFIED SPEAKER: The question -- just
3 clarify, I think we're transitioning into normal
4 comments now, right? We're not talking about the
5 four questions.

6 CHAIRMAN ROMANELLO: Ma'am, you can speak
7 about whatever you want.

8 VANESSA GALINDO-JACKSON: Okay. Well,
9 first, hello. My name is Vanessa Galindo-Jackson.
10 I'm an occupational therapy doctoral student and I
11 take a Hippocratic oath, must like you do. So I
12 hope as you consider your choices, that you reflect
13 on the ethical standards that are sound and
14 equitable decisions. Standards that I think of such
15 as beneficence, which requires taking action to
16 promote good, and then non-maleficence, which
17 requires the avoidance of actions that would cause
18 harm. Right. This is the crux of our standards,
19 the whole do no harm.

20 But based on the previous board meeting and
21 kind of some of the comments that were mentioned
22 today about studies where individuals experience
23 adverse effects, I feel it's important to remind you
24 that we must work within the context of due care
25 which states that the benefits of care outweighs and

1 justifies the risk in order to achieve the goal of
2 their care. For example, we do know that
3 chemotherapy is really hard on the body, and we know
4 it can cause harm, but yet, it's a recommendation we
5 make every day. And we allow our clients the
6 freedom to choose that method. It's the power of
7 autonomy, the freedom our clients have to choose.

8 Now, I understand that we are at the mercy
9 of these atrocious bills that are already in place,
10 but please remember that all clients we serve
11 deserve the upmost respect and care. We take a
12 Hippocratic oath for a reason, regardless of the
13 laws and policies in place.

14 Moving forward, I challenge you, please
15 stand up for your clients not just when it is
16 presented to you in the face, but at all the
17 conferences you attend, the board meetings you sit
18 at, and so on. Please do not remain silent, as you
19 are complicit to the pain and agony that these
20 individuals experience. Afterall, these people are
21 not -- you are not just making decisions for them as
22 their patients that you serve, but they may very
23 well be your family, your friends, and maybe, just
24 maybe, your respected colleagues.

25 That's really all I have as far as this,

1 but I did want to bring up another point, since I
2 have just a few more seconds. The previous speaker
3 just mentioned about comorbidities. I was looking
4 at your rules, and I don't know if they've been
5 revised but it doesn't make sense to state "Does not
6 suffer from psychological comorbidities that
7 interfere with the diagnostic work." Why not
8 instead maybe suggest something like, "Any
9 psychological comorbidities might be managed or
10 overseen by a qualified mental health practitioner,"
11 something of the sort.

12 CHAIRMAN ROMANELLO: Thank you. We
13 appreciate your comments and certainly will take
14 them into consideration as we deliberate.

15 So next up is Dean Price. We have Erica
16 Imaoka. Again, apologies for the pronunciations.
17 Calling up on deck, please, Paul Erins (phonetic),
18 and Aaron James Clark.

19 DEAN PRICE: Hello. My name is Dean Price,
20 and I was wondering if I can defer to my son? He
21 has an appointment at 4:00 and we're going to have
22 to leave, so in case we didn't both get called. Is
23 that --

24 CHAIRMAN ROMANELLO: Sure.

25 DEAN PRICE: Thank you very much.

1 OCEAN PRICE: Hi. My name is Ocean Price
2 (phonetic), and I am a transgender man. I am 21
3 years old, and I've been going -- I've been
4 undergoing gender affirming hormone replacement
5 therapy for two years at this point. And I have
6 never once regretted my decision to undergo gender
7 affirming care. I've never had any sort of major
8 complications or side effects or anything like that.
9 And being able to access that care was really life
10 changing for me.

11 And at the beginning of the summer, I had
12 spoken to a surgeon, and I was supposed to receive
13 top surgery at the end of this month but
14 unfortunately, due to the -- due to the new
15 legislation requiring the consent forms, it ended up
16 having to be canceled because we didn't have the
17 consent form.

18 And that ended up being really disruptive
19 to my life, and I'm sure that a lot of other people
20 are going through similar things, as well. And so I
21 just wanted to say that I really hope that the
22 consent form gets done as soon as possible and that
23 it's -- it doesn't require any -- a lot of
24 unnecessary steps that are not medically supported
25 before accessing treatment that we would have been

1 able to access anyway.

2 And I also did want to say -- I wanted to
3 add a couple of other things, as well, that -- based
4 on what you had mentioned. First of all that I'm on
5 AndroGel. I know that had been mentioned. A big
6 reason that's not prescribed as much is because it
7 typically costs more.

8 And then I also wanted to state that I
9 think something important to add to the consent form
10 for testosterone, especially, is that it's not birth
11 control. Even though it often stops menstruation
12 it --

13 CHAIRMAN ROMANELLO: Ocean, in order to get
14 everybody who wants to speak their time, we're going
15 to have to hold everybody to three minutes, and
16 you've exceeded that. I appreciate you coming
17 before the committee and offering your comments.
18 We'll certainly take them into consideration as we
19 continue to consider the rules and the consent forms
20 today. I appreciate your time. Thank you.

21 OCEAN PRICE: Okay. Thank you.

22 DR. ACKERMAN: Just to clarify, these
23 consent forms should be all good to go in a week,
24 right?

25 CHAIRMAN ROMANELLO: We're going to come

1 back next week, and we will consider --

2 DR. ACKERMAN: Assuming things go as
3 planned.

4 CHAIRMAN ROMANELLO: Exactly.

5 ATTORNEY MCNULTY: And then after that
6 meeting, we'll have to have time to actually file
7 them. But with emergency rules, once they are filed
8 with the Department of State, they are effective the
9 day they're filed.

10 DR. ACKERMAN: Right. So for those of you
11 that care, 10 days, 2 weeks from now, it should all
12 be filed and good to go.

13 CHAIRMAN ROMANELLO: So we should have
14 Erica, Paul, Aaron, and then calling up Seneca
15 Bristol Manatee, I think -- and again, forgive me
16 for the pronunciations.

17 Ma'am, you're recognized.

18 ERICA IMAOKA: Hi, I'm Erica Imaoka. Not
19 too shabby on the name pronunciation. I'm an
20 advance practice nurse here in Florida. I work for
21 Folx Health providing telehealth gender affirming
22 care. I don't prescribe oral testosterone. We
23 don't at Folx, it's not part of our protocol.

24 But my question, I guess -- well, I know,
25 actually, you can't go back and forth. But I guess

1 my comment would be then, A, I didn't get
2 clarification, I don't think, on like the DEXA scans
3 for adult, what time would require that. If it's
4 immediately after starting hormone therapy or if
5 that's going to be only post operatively, or what
6 that recommendation or requirement would be.

7 And also, if the consent form -- and I'm
8 sorry if it's in there, but I didn't get to read it
9 -- includes the opportunity for advance practice
10 nurses to continue care and only the prescribing
11 portion outside of the informed consent is done by
12 physicians. We didn't really have physicians doing
13 care at Folx. We do now to meet the requirements of
14 the statute.

15 But many of advance practice nurses want to
16 continue to see our patients, so just wanting to get
17 clarification if it will be in the informed consent
18 that they can still receive care by advance
19 practitioners and only particular parts are required
20 by the physicians.

21 CHAIRMAN ROMANELLO: Yeah. So our rule is
22 for physicians and physician's assistance. That's
23 who we have jurisdiction over. It's the Board of
24 Nursing that would have jurisdiction over nurses
25 and --

1 ERICA IMAOKA: And so the consent form is
2 specific only to getting the initial informed
3 consent in person, not any other part of their care;
4 is that correct?

5 DR. ACKERMAN: Right.

6 ATTORNEY MCNULTY: Or if they -- separate
7 consent is required for any new prescription for a
8 product that they haven't taken before.

9 CHAIRMAN ROMANELLO: Right.

10 ATTORNEY MCNULTY: So if they switch drugs.
11 But like Mr. Romanello said, this is for -- you
12 know, you've got the statutory requirement. If you
13 have questions regarding the statutory
14 interpretation you need to seek the advice of legal
15 counsel.

16 ERICA IMAOKA: Okay. Thank you.

17 DR. ACKERMAN: And surgery needs its own
18 form. So there's three consent forms, hormone
19 blocking, masculinization versus feminization, and
20 then surgery. They all have a consent form.

21 CHAIRMAN ROMANELLO: Thank you, Ms. Imaoka.
22 I appreciate it.

23 ERICA IMAOKA: So was the DEXA scan
24 requirement included in the adult form?

25 ATTORNEY MCNULTY: It's required -- it's in

1 all the forms.

2 ERICA IMAOKA: And that's for five years
3 annually after starting therapy?

4 DR. ACKERMAN: Yes. Yes. Five years,
5 annually, and then PRN -- as needed.

6 CHAIRMAN ROMANELLO: If Dr. Aaron is -- we
7 have Aaron James Clark, Seneca Bristol Manatee, and
8 then asking John Harris Maurer up to the microphone.

9 PAUL ERINS: Good afternoon, members of the
10 board. My name is Paul Erins; I live in
11 Tallahassee, and I'm a physician retired from the
12 Florida Department of Health where I was the medical
13 director for the HIV/AIDS program for 18 years. And
14 also, from 2001 to 2005 I was chair of the
15 Department of Health Institutional Review Board, the
16 IRB. So I've evaluated a lot of consent forms.
17 I've got five points I wish to make.

18 The form states, "I know enough to give
19 informed consent to take, refuse, or postpone taking
20 these medications." But there's no information if
21 stopped about whether the medications need to be
22 tapered, or what physical or mental changes are
23 likely to occur. There needs to be added
24 information about the pros and cons of
25 de-transitioning and what is necessary for stopping

1 safely.

2 Secondly, the form states that the
3 medication is off-label, not approved for this use
4 by the FDA. I think it's only fair to add, "But it
5 has been used effectively to treat gender dysphoria
6 for decades by licensed, reputable clinicians who
7 specialize in gender affirming care." Otherwise,
8 this is not fully informed consent.

9 Third, for a patient whose primary language
10 is not English, the interpreter certifies as the end
11 that they are "fluid in English." In this setting,
12 especially, fluid needs to be changed to fluent,
13 f-l-u-e-n-t.

14 CHAIRMAN ROMANELLO: Good catch.

15 PAUL ERINS: Next, I realize these are
16 emergency consents, but they are just not ready for
17 prime time. I ask you please to workshop them
18 further before publishing, with representative
19 gender diverse individuals, with specialist docs.
20 And I think your questions this afternoon have
21 reflected the need for that. And in consultation
22 with the Florida Bioethics Network whose MD/PhD
23 cochairs are at the University of Miami and the
24 University of Florida.

25 And finally, since the Florida statute and

1 Medical Board now officially recognize the validity
2 of full spectrum gender dysphoria care for adults
3 with informed consent and at least continuing
4 medication treatment for minors with parental
5 consent and assent, I urge you by formal resolution
6 to add your voice to that of the courts in
7 advocating for Medicaid reimbursement for such care
8 for an estimated 9000 Floridians who are otherwise
9 losing coverage. And I thank you for the
10 opportunity to testify.

11 CHAIRMAN ROMANELLO: Thank you for your
12 comments. We'll take them into consideration as we
13 deliberate these rules.

14 Aaron James Clark, Seneca Bristol, John
15 Maurer, and Jessica Wilson (phonetic).

16 You're recognized.

17 AARON JAMES CLARK: Good afternoon, members
18 of the board. My name is Aaron James Clark. I am
19 the former treasurer of Rainbow Democrats.
20 Recently, I resigned from my position because as a
21 transgender man, I would like to transition, and I
22 can no longer do that. I'm going to have to move in
23 order to get the care that I need.

24 Also, on the topic of comorbidities, I have
25 been chronically ill for my entire life. I was born

1 sick. And I really would urge you to consider to
2 please have separate psychological and medical
3 management for individual cases that are going under
4 the gender dysphoria comorbidity umbrella. I also
5 would like to -- if I am allowed to -- someone on
6 the board had mentioned the Dutch study. I have the
7 data in my hand. Am I allowed to present that in
8 brief to you?

9 CHAIRMAN ROMANELLO: If you have -- if you
10 want to make a public comment, this is the
11 opportunity to do it.

12 AARON JAMES CLARK: Okay. I wanted to make
13 sure that that was okay with all of you.

14 CHAIRMAN ROMANELLO: Sure.

15 AARON JAMES CLARK: So for the 2022 Dutch
16 study, 820,063 transmen and women were referred to
17 the Amsterdam VU University Medical Center during
18 the period time of 1972 to 2017. And this study
19 does not show increased suicide rates. And
20 specifically, by 20 times that of their peers of 10
21 to 15 years after reassignment, which is what I
22 typically hear from the study.

23 The data shows that over a period of 45
24 years, which is 1972 to 2017, the suicide deaths for
25 transwomen were about 64 of 100,000, and the suicide

1 deaths of transmen were 29 for 100,000. I'm sure
2 you all are very competent at math. But the suicide
3 rates did not increase over that period of time.

4 During 2013 to 2017, there was actually a
5 decline in suicide rates for the study participants.
6 It reached 43 over 100,000 transwomen, to 34 over
7 100,000 transmen. And suicide rates were found to
8 be 3 to 4 times higher than the average population.

9 CHAIRMAN ROMANELLO: Aaron, thank you for
10 your comments. We've got to -- in order to get to
11 as many people as we can --

12 AARON JAMES CLARK: No, you're fine. But
13 that's basically what the gist is, so --

14 CHAIRMAN ROMANELLO: Thank you. Appreciate
15 your comments.

16 SENECA BRISTOL: Hello. I'm Seneca
17 Bristol. Manatee is my county. I'm the vice
18 president of the U Chapter of Women's Voice of
19 Southwest Florida. Let's get something right.
20 Everything you're spreading is just misinformation.
21 This isn't to protect children, this isn't to
22 protect anybody. But you know what real information
23 has shown? According to HCP, suicide risks reduce
24 by 70 percent in transgender, nonbinary, et cetera,
25 youth and young adults when gender affirming care is

1 accessible.

2 According to --

3 CHAIRMAN ROMANELLO: Ms. Bristol, do you
4 have any comments related to the rules or the
5 informed consents that we've been discussing all
6 afternoon?

7 SENECA BRISTOL: Yes. I mean, I'm just
8 trying to give you all information. I'm trying to,
9 you know, help you all.

10 CHAIRMAN ROMANELLO: Do you have comments
11 related to the informed consents or the rules that
12 we've discussed this afternoon?

13 SENECA BRISTOL: Am I not doing that? Yes.

14 CHAIRMAN ROMANELLO: Could you make those
15 comments then, please.

16 SENECA BRISTOL: Okay. Yeah. According to
17 National Library of Medicine, it is shown that 82
18 percent of transgender folks have considered killing
19 themselves, and 41 percent have attempted suicide.
20 If you take this away, kids will kill themselves.
21 Okay. You need to look at your guys' selves in the
22 mirrors and realize the truth. And respectfully,
23 but not really, you need to put your white hoods on
24 and stop choking up lies and tell people the truth.
25 You want the trans community to be wiped out like

1 the Nazis. The only difference is --

2 CHAIRMAN ROMANELLO: You're out of order,
3 Ms. Bristol.

4 DR. ACKERMAN: I want to make sure I
5 understand --

6 CHAIRMAN ROMANELLO: Mr. Maurer.

7 DR. ACKERMAN: -- we're putting forth the
8 consent form --

9 CHAIRMAN ROMANELLO: No. Mr. Maurer is up.
10 We're going to have Jessica Wilson followed by Chels
11 Davis, I think is the name. Again, sorry for the
12 pronunciations. Followed by Monica DePaul
13 (phonetic).

14 JOHN HARRIS MAURER: Good afternoon, joint
15 committee. My name is John Harris Maurer and I
16 represent Equality Florida, the state's largest
17 civil right organization dedicated to securing full
18 LGBTQ equality. Respectfully, the proposed consent
19 forms are rife with incorrect and misleading
20 information and exceed the board's delegated
21 rulemaking authority. Equality Florida appreciates
22 that these forms must be finalized and adopted
23 urgently because the state legislature has created a
24 crisis of care for transgender Floridians, but this
25 product is insufficient.

1 The proposed rule and forms include
2 multiple substantive burdensome new requirements and
3 stipulations that the legislature never adopted or
4 approved. They impose undue and costly barriers to
5 care that are not about individualized assessment
6 and care.

7 With respect to adults' care in particular,
8 this is not an informed consent form. This is an
9 end run to create a new and unduly restrictive
10 standard of care. The legislature only required
11 these boards to adopt adult informed consent forms
12 that "inform the patient of the nature and risks in
13 order for a patient to make a prudent decision."
14 Yet, here are multiple examples of new "specific
15 requirements" for individuals to receive and
16 continue HRT treatment that are not informational or
17 on the nature and risks.

18 "The patient must be the criteria for
19 gender dysphoria. Gender dysphoria must be marked
20 and sustained. Patients may not suffer from certain
21 psychological comorbidities. Patients must have
22 adequate psychological and social support during
23 treatment. Mandatory evaluation by the treating
24 physician every three months. Mandatory suicide
25 assessment by a licensed medical care professional

1 every three months. Mandatory lab testing every six
2 months. Mandatory annual bone density scanning.
3 Mandatory mental health assessment by a board
4 certified, Florida licensed psychiatrist or
5 psychologist. And mandatory continued counseling
6 with a licensed mental health care professional."
7 This exceeds the board's authority and is likely to
8 lead to another lawsuit like the one recently
9 rejecting board rules.

10 The forms and process for minors similarly
11 suffer from misinformation and undue additional
12 burdens like a prohibition on delegating
13 responsibility for obtaining informed consent and
14 requiring additional witness signature. These are
15 about creating new burdens to care and not about
16 patient well-being.

17 The forms require more input from experts
18 with deep expertise in providing gender affirming
19 care. There are simply too many inaccuracies or
20 inconsistencies. Like meeting the requirement for
21 gender dysphoria to continuing care, when alleviating
22 that gender dysphoria is the purpose of being and
23 staying in care. Or referring to medication that's
24 not even available in the United States as we've
25 already talked about. Please revise these forms

1 with input from proper experts with the urgency
2 required by these state-imposed circumstances.

3 I'll also add, please do check the records.
4 I don't believe a motion was adopted on changing the
5 DEXA scan frequency for adult testing, if that will
6 be revisited. And also, the adult's regular
7 evaluation risk assessment requirement should be
8 based around induction and not just a change in
9 physicians.

10 We have adults who have been thriving in
11 care for years, potentially more than decades. The
12 fact that they may have to change physicians because
13 our providers are leaving the state because of the
14 state legislature isn't a reason that those adults
15 should have to subject to quarterly testing just
16 because they're changing provider. Please revise
17 the rules and take that into consideration.

18 CHAIRMAN ROMANELLO: Thank you for the
19 observations. We'll follow up on those as we
20 deliberate further this afternoon.

21 JESSICA WILSON: Hi, good afternoon. My
22 name is Jessica Wilson, and I am here as a mom of a
23 trans son. The legislators' only requirement -- I
24 understand you're mandated to create these forms.
25 The legislators' only requirement, however,

1 restricting trans adults from receiving care was
2 that they see a doctor instead of a nurse
3 practitioner, and that they sign informed consent
4 forms while in that doctor's presence saying that
5 they understand what the gender affirming care will
6 do. There is nothing in the statute that requires
7 blocking access to those with comorbidities or
8 psychiatric conditions.

9 I shared in previous Board of Medicine
10 meetings that my son has mental health diagnoses and
11 tried to end his life at least once. At least once
12 that I know of. And one of his many
13 hospitalizations resulted in a gender dysphoria
14 diagnosis at age 13. He has undergone years of
15 therapy and started testosterone last year. Since
16 beginning his medical transition, thoughts of
17 suicide have greatly diminished. He's thriving,
18 successfully employed, and a wonderful, attentive
19 dad to my granddaughter. His mental health
20 diagnoses have not gone away though.

21 If you proceed with blocking access to
22 those with psychological comorbidities, you will be
23 taking away life saving healthcare from adults who
24 need HRT to live. This was supposed to be about
25 protecting the kids but what you are proposing is

1 going to erase the trans population from Florida.
2 Many of those who can leave, are leaving. Many
3 already have. You at the board are overstepping the
4 already egregious law by establishing additional
5 barriers above and beyond what the statute requires.
6 These forms are not informed consent forms. They
7 are new requirements which are not outlined by the
8 law. It's a massive overreach by the boards. Stop
9 playing politics and do the job you're actually
10 mandated to do.

11 CHAIRMAN ROMANELLO: Thank you. Appreciate
12 the comment.

13 Calling up to the line Lucina Fenner
14 (phonetic), Stephen Esocough (phonetic), and Felix
15 Proia (phonetic). And thank you for spelling out,
16 Mr. Proia, the pronunciation of your name.

17 CHELS DAVIS: Good afternoon, my name is
18 Chels Davis. I'm a school counselor at the
19 secondary level. So I specialize in caring for
20 adolescents in the academic, career, and social
21 emotional aspects of their lives. My job is to get
22 my students graduated, help them explore career
23 options, and to help them reach adulthood alive.

24 This last point has become more difficult
25 this past year, and that's why I've come to speak

1 with you. I need your help to do my job well.
2 School counselors and medical professionals both
3 live, eat, and breath Maslow's Hierarch of Needs, so
4 please hear me when I say transgender kids don't
5 feel safe in Florida. There is a foundational need
6 going unmet at a state level. This past year has
7 left our most vulnerable Floridians shaken.

8 CHAIRMAN ROMANELLO: Ms. Davis, the purpose
9 of today's hearing is to talk about informed consent
10 forms that we've developed, and rules that we've
11 been tasked to do. I'm certainly happy to hear
12 those observations and comments with respect to the
13 rules.

14 CHELS DAVIS: Yes, sir. I was just
15 building up, sorry. Dr. Benson mentioned the risk
16 of suicide in transgender minors. I am compelled to
17 add clarification to that conversation specifically.
18 With transgender people, adults and children alike,
19 their level of suicidality is directly related to
20 their level of perceived support, their sense of
21 safety. This is from external forces, not internal.
22 When they feel supported by their family, when they
23 feel supported in their community, they don't want
24 to die. When they don't feel supported, they are
25 more likely to kill themselves. That's what we're

1 all trying to avoid here, and I think that's
2 something we have in common.

3 A family's support for their transgender
4 child is lifesaving and insulates the child from
5 suicidality. A transgender person having a
6 practical path to medical transition in their
7 community is similarly lifesaving. We're talking
8 about access. Please help me keep these kids safe,
9 help me keep them alive.

10 We need straight-forward caring rules.
11 Care in this state has had a major interruption, as
12 we've noted, and that is dangerous. It would be
13 wrong to implement rules which needlessly hinder
14 access to lifesaving medical care. Unethical
15 hinderances only endanger lives. WPATH, the World
16 Professional Association for Transgender Health,
17 standards have existed for decades. Those standards
18 are a robust and valid reference, but I only heard
19 them mentioned once in this conversation. Please
20 consider the proposed rules carefully and to give
21 our vulnerable populations the accessible care they
22 need. Thank you very much.

23 CHAIRMAN ROMANELLO: Thank you.

24 MONICA DEPAUL: Hi. I'm Monica DePaul.
25 I'm an English teacher; I also happen to be trans.

1 There's a lot of talk about studies over here. Let
2 me tell you, it took me five minutes to look on
3 Google and find a study showing that trans kids are
4 happier after they transition. It wasn't hard. It
5 was in the Journal of the American Medical
6 Association. So I noticed that none of the studies
7 that you all were talking about seemed to have any
8 citations with them. So I'm just going to assume it
9 came from some talking had on Fox News.

10 Now, I noticed that you included the
11 language of "subtle improvements" as sort of like
12 the only positive thing that would occur. That is,
13 to put it lightly, BS. Mainly because, I mean, I
14 have been on hormones for 10 years. When I meet new
15 people, they don't even know I'm trans. Usually, I
16 don't even have to mention it because why? The
17 amount of improvements that I have experienced are
18 far more than just subtle. Before I transitioned, I
19 had this brain fog that is gone now. I can actually
20 think. I can actually be myself. I don't have to
21 pretend to be someone else. That is not a subtle
22 improvement.

23 And now, here you are telling me that I
24 have to change my doctor, I have to go through all
25 of this, I have to sign an informed consent form

1 that has just lies on it. Lies. You all are lying.
2 That I have to agree to that despite me having been
3 doing this for 10 years. And only now is it
4 suddenly a problem. Only now is this suddenly that
5 I have to agree to all of this. We all know why.
6 It's because one man wants to be President and none
7 of you are willing to argue with him.

8 I knew I was a girl when I was nine, and
9 this is back in the '90s. I knew who I was. Now,
10 granted in the '90s, it would have been impossible
11 for a kid to get gender affirming care, and my
12 parents would never have taken me seriously.

13 On the matter of comorbidities, my ADHD has
14 nothing to do with my transition, at all. Those are
15 two very separate matters. And if you're going to
16 prevent people from accessing gender affirming care
17 because they have other like mental issues,
18 honestly, that's pretty fucked up.

19 CHAIRMAN ROMANELLO: You're out of order.
20 We're not going to accept that sort of language.

21 MONICA DEPAUL: You're all out of order.

22 CHAIRMAN ROMANELLO: Thank you. Next up is
23 Lucina Fenner. Esocough on deck, Proia. And
24 calling up Lola Smith.

25 ESOCOUGH: This is Esocough. I don't know

1 where Fenner is.

2 CHAIRMAN ROMANELLO: Okay.

3 ESOCOUGH: This is just my honest reaction
4 hearing the restrictions or hurdles that have been
5 inserted into this informed consent. It is
6 government overreach. It is being perpetrated
7 against one of the most targeted communities that we
8 are in need of protecting. You aren't protecting
9 anyone. What child whose parents and doctors are
10 not already informed enough to do the work to make
11 sure they're getting the care they need, what adult
12 whose doctor in tandem with that adult are not able
13 to decide what care they need? What additional
14 safeguards are you putting in here that is genuinely
15 protecting anyone who doesn't have a medical
16 professional by their side?

17 You are limiting access and
18 sensationalizing a lifesaving treatment that has
19 been around for decades. It's been around since the
20 '30s. There was a body of knowledge that was
21 destroyed by a particular group that we would be
22 referencing today if only that group had not been so
23 adamantly anti-trans. Because of that kind of
24 bigotry that has infected this state, and possibly
25 even this body, Americans will be harmed. Do the

1 right thing. Thank you.

2 CHAIRMAN ROMANELLO: Felix Proia, Lola
3 Smith, and Brandy Scappalis (phonetic).

4 FELIX PROIA: Good afternoon. Thank you
5 for coming to South Georgia, aka Northeast Florida,
6 and providing me the opportunity to provide comment.
7 My name is Felix Proia, and my pronouns are they and
8 them. I live and work in Duval County as a school
9 psychologist and I receive gender affirming care.

10 I cried tears of joy when I booked my first
11 appointment, feeling more empowered and cared for
12 than other. I am livid that the new prescriptions
13 and procedures are on hold until a consent form is
14 approved by this board. And taking this moment to
15 then put further rules is overreaching and harmful.

16 I am an adult living a life and this new
17 consent form that is what I'm hearing today is
18 overreaching from what the state had already put on
19 adults. I will consent to my care with a physician,
20 and I am an adult living a life that will be
21 impacted by these proposed restrictions to my care.
22 But what choice am I left with? I ask you to
23 consider my freedom from government oversight for
24 personal decisions.

25 This is my medication. It's medicine. The

1 discussion about my medical care should not be by a
2 governor-appointed board, it should be between my
3 doctor, and that's it. Being transgender is
4 beautiful. There is nothing inherently dangerous
5 about being transgender. I have gender euphoria, I
6 do not have gender dysphoria. And maybe that's
7 going to preclude me from getting care because of
8 the consent form that is being proposed. I will
9 consent to gender affirming care with a doctor. I
10 believe these forms are just wrong, wrong, wrong.
11 Thank you.

12 CHAIRMAN ROMANELLO: Thank you for your
13 comment. We appreciate it.

14 Lola Smith, Brandy Scappalis, and Madison
15 Natalya Hilt (phonetic).

16 LOLA SMITH: My name is Lola Smith. I'm 12
17 years old and I am nonbinary. And I am here today
18 with Women's Voices of Southwest Florida. You've
19 been speaking an awful lot lately about staying
20 within the scope. Our comments don't count nor
21 matter if they are not within the scope of what you
22 deem the subject is at hand. Yet, the rules and
23 steps you have laid out for the transgender adults
24 seeking treatment also do not consider the scope.

25 These hurdles you have created for folks

1 seeking care are beyond the financial and personal
2 scopes of many of the people required to fulfil
3 them. People have jobs, families, and commitments.
4 By demanding they commit so many hours and finances
5 to these continuous and unnecessary reviews, you are
6 ensuring many individuals will never receive the
7 care they need.

8 In creating an impossible road to care, you
9 are all participating in the active genocide of
10 transpeople here in Florida. Stop trying to paint
11 what you are doing as compassion or a compromise.
12 You cannot put a flower in an asshole and call it a
13 vase. Thank you.

14 CHAIRMAN ROMANELLO: Brandy Scappalis,
15 Madison Natalya Hilt, and Julie Mench (phonetic).

16 BRANDY SCAPPALIS: I am Brandy Scappalis.
17 I'm here today both as a social worker, PhD student
18 who has spent the last two years researching this,
19 reading all of the medical and mental health
20 literature, as well as someone who has been
21 receiving gender affirming care for over five years.

22 I wanted to comment on three main things.
23 Number one, several of the things on here are new
24 substantially burdensome requirements that are not
25 part of standard practice in providing or assessing

1 gender affirming care needs. And that includes the
2 x-rays, the bone density scan requirements, as well
3 as some of the -- like the annual mental health
4 assessments and suicide risk assessments. Those
5 will impose substantial financial burdens on
6 patients, and it will also impact insurance
7 companies when they cover this.

8 My employer provided health insurance. The
9 cost for a bone density scan, for just a copay would
10 be \$300. And that requirement for anyone is a
11 substantial burden on finances if it's an annual
12 requirement even for only five years. That's a
13 substantial amount of money.

14 Additionally, I wanted to comment on item
15 three on the informed consent form that gender
16 dysphoria be marked and sustained. The purpose of
17 gender affirming care is to alleve gender dysphoria.
18 So someone who is being properly treated for gender
19 dysphoria will no longer have marked and sustained
20 gender dysphoria because of that treatment.
21 Therefore, that is only valid for the initial
22 assessment. After that, the goal is to see the
23 reduction of gender dysphoria as a result of
24 treatment.

25 And finally, I noticed that the forms

1 considered today don't include consent for surgery.
2 These are hormone treatment forms. Many people have
3 already been denied access to surgeries that were
4 already planned prior to the passage of the bill,
5 and we definitely need surgical informed consent
6 forms as well. Thank you.

7 CHAIRMAN ROMANELLO: Thank you for your
8 comment.

9 MADISON HILT: Hello, Board. Madison Hilt;
10 I'm from Clay County, Florida. The real issues that
11 I have with the proposed informed consent forms,
12 really numbers 5 and 13 are my biggest issues.
13 Number 5 stating that we can't have any mental
14 health comorbidities. That's kind of like a cat
15 chasing its own tail, right. When somebody has
16 gender dysphoria, one of the biggest things that
17 affects them is depression and increased suicidal
18 ideation. We know this. It's been demonstrated in
19 multiple studies, multiple peer reviewed studies.
20 And as a matter of fact, it's listed in the
21 Endocrine Society positional statement and their
22 standards of care that was cited in this rulemaking
23 session.

24 Removing that care from people with any
25 kind of psychological comorbidity is going to just

1 increase their suicidality exponentially. I would
2 -- I mean, I know it's pretty obvious I'm not a
3 doctor, but I have been involved with medicine for
4 quite a while. My father was chronically sick, I'm
5 chronically sick, so on, Type I diabetes.

6 Anyway, that provision is going to just
7 make people hurt themselves even more. I would
8 highly suggest that you all follow the other
9 guidelines that are in the Endocrine Society's,
10 which are pretty conservative guidelines for the
11 treatment of transpeople. It says that you all need
12 to have a multi-module approach with a team of
13 physicians. It does not say that you need to
14 exclude people if they have a mental health issue.
15 Because studies have shown that suicidality upticks,
16 rather than goes down, if they lose that.

17 And number 13, a psychologist or a
18 psychiatrist having to assess once a year. That's a
19 bit burdensome when only 10 to 12 percent of the
20 mental health practitioners in the state of Florida
21 are psychologists or psychiatrists and your LMHCs
22 and LCSWs are way better trained in a lot of cases
23 at treating gender dysphoria because there's a lot
24 of them that specialize in it.

25 Effectively, what this is going to be is if

1 you all pass this as it's stated right now is it's
2 going to be a ban on care for trans adults. Because
3 this is almost the same exact language that they
4 used in Missouri. So you're going to see the courts
5 strike it down. We're going to be back here doing
6 this whole song and dance again. You all just
7 follow the Endocrine Society standards. Just for
8 one second think about the Hippocratic oath, care
9 about your patients, and show the trans Floridians
10 in this room that you want to help them, not make
11 rules that are going to cause them to leave or hurt
12 themselves. Thank you.

13 CHAIRMAN ROMANELLO: Hey, thank you for the
14 comments. They were helpful and I appreciate them,
15 really.

16 Julie Mench, Max Fenning (phonetic) -- who
17 has exceptional penmanship -- and Bryce Hackmeyer
18 (phonetic).

19 JULIE MENCH: Hello. Julie Mench. So one
20 thing that has struck me this entire time listening,
21 other than the willful misquoting of studies and
22 seemingly apparent lack of knowledge of the topic
23 that you were here to discuss, is your absolute, you
24 know, dismissal of any positive outcome of gender
25 affirming care.

1 Now, you can look behind me and I can show
2 you a room full of people that will tell you that
3 gender affirming care is lifechanging and a
4 wonderful thing. Our lives have only been made
5 better by gender affirming care, which has been, you
6 know, regulated and a practice for -- like they
7 said, since the '30s, with Christine Jorgensen being
8 one of the first Americans to undergo transgender
9 reassignment. And there was no reason for these
10 bills, these laws. Medically, there weren't.
11 Politically, well, we all know the answer to that.

12 So I really am just horrified to see that
13 everything has just been a negative comment about
14 gender affirming care from this board that is tasked
15 with making ruling on gender affirming care.

16 And speaking on the comorbidities of mental
17 health. Imagine going to a doctor, "Oh, hi. I'm
18 sorry, You have a glioblastoma. It might be
19 operable but it's fatal if we don't. But you seem
20 to be really depressed about this, so let's give you
21 six months of mental counseling to get rid of your
22 depression before we can get rid of your tumor that
23 is causing your depression."

24 You know, these things -- every tactic
25 you're trying is just saying you're deliberately

1 trying to block gender affirming care. You know,
2 it's not inapparent to us. We are very aware that,
3 you know, nobody on this board seems to be pro
4 gender affirming care despite the overwhelming
5 evidence, the thousands and thousands of papers
6 saying how effective it is. Millions of people
7 telling you how effective it is. But yet, deaf
8 ears.

9 So I mean, how is one really supposed to
10 read that? You know, as someone receiving gender
11 affirming care, how am I supposed to respect your
12 opinion that is so anti my existence? I would
13 really ask you to go and ask yourselves that.

14 And another thing I'm going to say is that
15 I've known many transpeople. I'm a trans activist.
16 And I have never heard them suicidal until State
17 Bill 254. So you are willfully causing harm with
18 your bills and your rulings, and I want you to look
19 into that and hold up your Hippocratic oath. Thank
20 you. I seed the rest of my time.

21 CHAIRMAN ROMANELLO: Thank you.

22 Max Fenning, Bryce Hackmeyer, and Kit M.
23 (phonetic), followed by Omar Martinez (phonetic).

24 MAX FENNING: Hello and thank you for
25 complimenting my impeccable handwriting. Hello, my

1 name is Max Fenning, and I am the president of
2 Prism, a youth-led nonprofit that works to expand
3 access to LGBT inclusive education and sexual health
4 resources for young people in South Florida.

5 As someone who works closely with trans
6 youth, I know the impact that gender affirming care
7 can have. Trans healthcare including puberty
8 blockers and hormone replacement therapy is safe,
9 well-tested, and most importantly, lifesaving.
10 Gender dysphoria can be debilitating. Transgender
11 youth are twice as likely to attempt suicide as
12 their cis gender peers, but suicidality drops
13 sharply when gender affirming care is paired with an
14 affirming and accepting environment. That's why
15 almost every major medical association has formed a
16 clear consensus that gender affirming care can lead
17 to positive outcomes for trans youth.

18 And not only that, the proposed informed
19 consent forms for both minors and adults is an
20 egregious obstacle course of hurdles and fiery hoops
21 to jump through. So while I appreciate the efforts
22 today to temper some of those restrictions in
23 discussion, this is still not reasonable informed
24 consent. It's a process that represents a
25 culmination of months of fear mongering and

1 dehumanization of transpeople of all ages and all
2 backgrounds, and our state diluting transpeople's
3 humanity to a political agenda of woke
4 indoctrination.

5 But transness is not a political agenda.
6 LGBTQ people do not want our lives, our bodies, and
7 who we love politicized. It should be the decision
8 between a child and their parents, or an adult
9 patient and their doctor. Trans healthcare saves
10 lives and it's why we've seen several injunctions
11 against both your rulemaking as a board and several
12 components of SB254, the legislation that
13 necessitated this process today.

14 I urge you to reconsider some of the most
15 cumbersome components of these informed consent
16 forms, especially those that exclude folks with
17 other mental health diagnoses, to ensure access to
18 this care for all transpeople who need it in our
19 state. Thank you for your time.

20 CHAIRMAN ROMANELLO: Thank you, Max.

21 BRYCE HACKMEYER: Sorry, I'm in heels. Hi,
22 my name is Bryce Hackmeyer and I'm the health and
23 technology director of Women's Voices of Southwest
24 Florida and cofounder of the Justice Advocacy
25 Network.

1 First of all, I'd like to remind the boards
2 that the Florida State Legislature in its drafting
3 of SB254 utilized arguments from both the Florida
4 Boards of Medicine and Osteopathic Medicine as well
5 as from the Florida Agency for Healthcare
6 Administration, AHCA.

7 The claims made by the surgeon general and
8 AHCA which triggered the board's rulemaking on
9 gender affirming care in the first place back in
10 August of 2021, had been debunked -- or 2022, excuse
11 me -- have been debunked extensively in court. See
12 Dekker v Weida, which I have already submitted to
13 the public record, as politically motivated and
14 discriminatory. I have many concerns regarding the
15 requirements for continuing HRT but will only delve
16 into a few for the interest of time.

17 First of all, what psychiatric
18 comorbidities impede diagnosis and treatment of
19 gender dysphoria? How expensive would it be to be
20 evaluated by both a psychiatrist and/or a
21 psychologist in order to continue HRT? Please
22 elaborate on specific comorbidities and also
23 research the expenses associated with such
24 evaluations.

25 Second of all, I don't believe decreased

1 bone density is a significant side effect of
2 testosterone HRT, but I could be wrong. There
3 exists less costly and invasive methods to gauge
4 bone mineral density than bone density scans, such
5 as peripheral blood cell counts. Specifically, red
6 blood cell, white blood cell, and platelet counts
7 when controlled for confounding factors are
8 positively associated with T scores, a measure of
9 bone density.

10 A complete blood count differential
11 including platelets, a routine blood test taken
12 during physical checkups can provide this data at no
13 extra cost to the patient. These relationships
14 elucidate the close connection between hematopoiesis
15 and bone formation. To those alarmed by the
16 decreased bone formation -- or decreased bone
17 density side effect of a particular form of HRT, I
18 would say that calcium supplements go a long way.

19 All informed consent forms I've seen
20 deliberated by these boards possess statements of
21 bias and opinion. E.g. -- not i.e., low quality
22 studies, purely speculative. Although you all are
23 welcome to your personal opinions on these studies,
24 I do not believe a consent form should contain
25 biased statements such as these.

1 The Boards of Medicine are currently
2 proposing additional restrictive and expensive
3 hurdles on all transpeople who seek lifesaving care.
4 These introduced requirements place undue burden,
5 both temporarily and physically, on providers and
6 their patients. I highly suggest that prior to the
7 development of official and if possible, emergency
8 consent forms members of the boards reevaluate all
9 previous claims made regarding gender affirming care
10 and conduct truthful scientific analysis of the vast
11 body of research currently available, free of cherry
12 picking, showing these patients the respect and
13 basic human dignity they deserve. Otherwise, you
14 will waste Floridian taxpayer money defending your
15 baseless claims in court.

16 I encourage each board member to remember
17 that these boards represent more than just board
18 members and their research but the entirety of the
19 practice of medicine in our beautiful state. Please
20 take all necessary courses of action to debias
21 yourselves to ensure Floridian gender affirming care
22 patients may pursue and continue their care in
23 peace. Thank you.

24 CHAIRMAN ROMANELLO: Thank you.

25 Kit M., followed by Omar Martinez, and

1 Katelyn Denehy-Samitz.

2 KIT M.: Hi, Kit. Yeah. So what's being
3 pretty clearly communicated is that what is and
4 isn't in the topic isn't entirely arbitrarily
5 decided by you all on whether you like the comment
6 or not. This is the most consistent way to
7 determine whether or not you are going to interrupt
8 randomly in the middle of a comment. For example,
9 you lied about suicide in the informed consent forms
10 but when corrected on suicide statistics, that is
11 suddenly off topic because they were mean to you.

12 There is no reason to believe in your
13 honesty. I mean, just look at your disgusted faces.
14 The public book for this meeting, first off, was
15 corrupted, which was very ironic (indiscernible)
16 this whole situation.

17 CHAIRMAN ROMANELLO: Kit, do you have
18 anything to offer on the rules or the informed
19 consents?

20 KIT M.: The context in which the rules are
21 made is necessarily relevant to the rules.

22 CHAIRMAN ROMANELLO: Do you have any
23 comments on the rules or the informed consents?

24 KIT M.: Yes.

25 CHAIRMAN ROMANELLO: Can you offer those

1 comments, please.

2 KIT M.: Over a dozen studies with a sample
3 size of -- with a sample size of 30,000 state the
4 efficacy of these in improving mental health and
5 decreasing suicidality, yet you lyingly state that
6 treatment with gender affirming care will not
7 prevent serious psychological events such as
8 suicide. If you're going to claim that this is not
9 on topic, this is directly from your consent form.

10 You are the most transparently corrupt
11 governmental body, but you appeal to an imagined
12 sense of decorum, again, with the relevancy of each
13 and every single comment, which again seems to be
14 entirely arbitrarily decided by whether or not
15 people are polite to you.

16 You cite organizations that have disowned
17 you repeatedly, such as the Endocrine Society, which
18 published an article in November of 2020 entirely
19 disowning the ruling as anti-science. Why require
20 both a DEXA scan and an x-ray every year, which
21 would cost approximately \$700 combined, even for
22 testosterone which increases bone density. The
23 point, very clearly, is to block poor people from
24 this which transpeople disproportionately are.

25 Why bar with -- and this is a direct quote

1 -- "any other active psychopathology"? This is not
2 from the informed consent forms, this is later on in
3 the public book, but it was relevant to be included
4 in the public and therefore, it would be relevant to
5 this meeting. This would include depression,
6 anxiety, ADHD, autism, et cetera.

7 Why recite the limonite lies of a social
8 contagion of rapid onset gender dysphoria? Why lie
9 about desistance rates by citing a 1968 study
10 calling the 12 patients "sissy boys and tomboyish
11 girls"? Why desperately hide your unanimous
12 DeSantis donations average \$20,000 per year, per
13 member, prior to being appointed by your whaler?
14 Grow a damn spine and own up to what you are doing.

15 CHAIRMAN ROMANELLO: Omar Martinez.

16 OMAR MARTINEZ: Yes. Good afternoon. My
17 name is Omar Martinez. I completed a dual degree in
18 law and public health. I also have a master's in
19 clinical research methods and completed a
20 post-doctoral fellowship. I have dedicated my
21 entire professional career to address health
22 disparities and inequities impacting sexuality in
23 minorities.

24 My work and the work of others have clearly
25 documented the impact of systemic factors including

1 the larger social context, policies like the one
2 passed in Florida, structural stigma,
3 discrimination, and racism that I suspect
4 disproportionately impact the transgender
5 population. We have also developed programs and
6 interventions that are resiliency based and really
7 highlight the beauty, the magic of the resilience
8 community.

9 Now, regarding the informed consent, in
10 developing these consent forms, I should actually
11 recommend considering the informed consent model,
12 also known as the affirmation element, to help
13 support the writing of this informed consent. The
14 model has been adopted by many healthcare
15 professionals. In particular, clinicians at the
16 Callen-Lorde Community Health Center in New York
17 City.

18 You have a duty to provide adequate and
19 accurate information to enable a person to make an
20 informed decision. The benefits have been clearly
21 established and this board -- this is where this
22 board has shown subjectivity, to my understanding,
23 and impartiality.

24 The truth is that data from more a dozen of
25 studies of more than 30,000 -- more than 30,000

1 transgender (indiscernible) and diverse youth
2 consistently show that access to gender affirming
3 care is associated with better mental health
4 outcomes and the lack of access to such care is
5 associated with higher suicidality, depression, and
6 self-harming.

7 A recent study, last year, 2022, published
8 by Tordoff and colleagues in JAMA with over 100
9 transgender youth found that mental health incomes
10 increase significantly with the medication aspects
11 of gender affirming care.

12 Another study published last year in
13 pediatric, but also (indiscernible) colleagues, with
14 over 300 -- 300 -- you want the data, you want the
15 sample size? You have it there -- transgender youth
16 found that the vast majority of those receiving
17 gender affirming cares do not regret transitioning
18 at all. Over 60, 60 high-quality, well-designed
19 studies published in reportable journals have
20 established the safety and efficacy of gender
21 affirming care.

22 The new requirements that you -- just
23 drafted are very problematic and not in line -- not
24 in line with the standards of gender affirming care
25 of data published in May of this year by JAMA, but

1 the World Professional Association of Transgender
2 Health.

3 I'm particularly concerned with requirement
4 number 10, requirement 13, requirement 5. I'm not
5 going to go into details. These requirement deviate
6 -- deviate from the standards of care. I'm actually
7 very concerned about the potential breach of the
8 standard of care and legal implications for this
9 board and medical professions. You're deviating
10 from well-established evidence and the standard of
11 care by providers.

12 CHAIRMAN ROMANELLO: Mr. Martinez, thank
13 you. Your time is expired. We appreciate your
14 comments, and we'll certainly take them into
15 consideration as we continue to discuss the rules.

16 Our final speaker of the afternoon is going
17 to be Katelyn Danehy-Samitz. Did I get that halfway
18 right?

19 KATELYN DENEHY-SAMITZ: Yeah. I feel like
20 other people -- yes, you did actually get it right.
21 But I think it's probably because of timing.

22 UNIDENTIFIED SPEAKER: Yeah.

23 KATELYN DENEHY-SAMITZ: Okay. Well, in the
24 interest of time, if I can keep it under three
25 minutes are we able to get another speaker since

1 it's 4:26 now.

2 CHAIRMAN ROMANELLO: You're going to be our
3 last speaker of the day. Thank you. So if you have
4 comments --

5 KATELYN DENEHY-SAMITZ: Regardless of the
6 4:30 cutoff?

7 CHAIRMAN ROMANELLO: You're going to be our
8 last speaker of the day. Thank you.

9 KATELYN DENEHY-SAMITZ: Awesome.

10 UNIDENTIFIED SPEAKER: It's not 4:30 yet.

11 KATELYN DENEHY-SAMITZ: It's not, but
12 that's fine.

13 Okay. Katelyn Denehy-Samitz, founder/vice
14 president of Women's Voices of Southwest Florida. I
15 would like to start off and apologize to you, sir,
16 because apparently, I'm not sure what
17 "masculinification" is but I don't think that hair
18 makes the man.

19 Actually, as well, too, something I usually
20 start off with and this is within the scope --
21 within the scope -- since I'm in a room full of
22 doctors, if anybody can help me and figure out how
23 to disjoint a human centipede, my email is on that
24 form. Please keep it. Send me an email,
25 admin@wvswfl.com.

1 So much to say and if I'm the last speaker,
2 that's great. Let me check on my notes here; I
3 might as well take my time.

4 Say that you're mandated to do this, and
5 it's been reviewed several times the fact that you
6 have been mandated to create the consent form. The
7 hate that you are warranting and making this care
8 that is lifesaving, which has been again shown over
9 and over again despite the cherrypicked references
10 -- oh, wow. I'm angry. I'm sorry. I'm not sorry.
11 I'm trying very hard to be cordial.

12 You admitted to cherry picking the research
13 that you choose to base these on. You are looking
14 at a room full of people who drove hours to be here.
15 I drove five hours here with my family, and we're
16 allotted -- nope, this is within the scope -- we are
17 allotted three minutes.

18 I would like to echo what Kit said and say
19 that everything -- every one of these person's
20 experiences is within the scope of what you are
21 doing, and by refusing to listen to them, by putting
22 your head in the sand for PR -- PR, putting your
23 head -- continuing to put your head in the sand, you
24 cannot allow Ron DeSantis to hide behind you and not
25 expect to have shit thrown at you. That's it. Have

1 a wonderful day. Oh, God is disappointed.

2 CHAIRMAN ROMANELLO: Thank you. Your
3 comments were incredibly helpful to the committee,
4 and we'll take them into consideration. Appreciate
5 it.

6 All right. We're now going to move towards
7 actual now consideration and a vote on the informed
8 consents and rules. And I'll ask Mr. Dierlam, just
9 a process. We did the informed consents first and
10 then the rules. Any --

11 DR. ACKERMAN: Do we have to act on the
12 rule first?

13 CHAIRMAN ROMANELLO: That's what I'm
14 asking. Right?

15 ATTORNEY DIERLAM: I don't think you have
16 to act on the rule separately. I would advise that
17 if the -- you know, first of all, the committee
18 needs to determine if it wants to reconsider any of
19 the prior discussions, make any changes to the
20 consent forms based on public comments.

21 If the committee is comfortable with the
22 consent forms as are, we would simply need a motion
23 to adopt. I believe it would be appropriate to do
24 the minor consent forms and rule language in one
25 vote, and then allow me to ask the sunset questions.

1 Then move forward with the exact same process for
2 the adults. You know, again --

3 DR. ACKERMAN: So Ms. McNulty, did you take
4 any notes? There were some issues that came up.
5 Should we --

6 ATTORNEY MCNULTY: Well, I mean, what in
7 particular are you looking for?

8 DR. ACKERMAN: I just remember --

9 DR. MORTENSEN: There was one about fluid
10 versus fluent.

11 DR. ACKERMAN: Yeah.

12 EXECUTIVE DIRECTOR VAZQUEZ: A technical
13 change, I think we can take care of.

14 DR. ACKERMAN: Okay. I just wanted to make
15 sure that we addressed that.

16 DR. DERICK: Okay. I have comments on the
17 adult consent form.

18 ATTORNEY DIERLAM: So are we going to start
19 with minor or --

20 CHAIRMAN ROMANELLO: Let's do minor first,
21 if we can. So we have the minor consent form and
22 then the minor rule. Any discussion that the
23 committee wants to make with respect to the consent
24 form or the rule that we discussed early, or any
25 responses or comments to the public comments that we

1 heard this afternoon?

2 All right. So if there's no comment, we
3 would entertain a motion to adopt the consent form
4 as amended and the rule.

5 DR. ACKERMAN: Move to adopt the consent
6 form as amended and the rule.

7 DR. DI PIETRO: Second.

8 CHAIRMAN ROMANELLO: Okay. There's a
9 motion by Dr. Ackerman, a second by Dr. Di Pietro.

10 Do we need to do the conforming questions
11 now or --

12 ATTORNEY DIERLAM: After we have a vote in
13 favor of the ruling.

14 CHAIRMAN ROMANELLO: Got it. All right.
15 All in favor of the motion?

16 (Unanimous ayes)

17 Opposed?

18 The motion passes.

19 ATTORNEY DIERLAM: So if you don't mind,
20 board members, I'll go ahead and ask the requisite
21 circ questions. The first question is: will the
22 proposed rule amendments have an adverse impact on
23 small business?

24 DR. DI PIETRO: I move that it will not.

25 DR. ACKERMAN: Second.

1 CHAIRMAN ROMANELLO: All in favor?

2 (Unanimous ayes)

3 Opposed?

4 Passes.

5 ATTORNEY DIERLAM: Is the proposed rule
6 amendment likely to directly or indirectly increase
7 regulatory costs to any entity, including the
8 government, in excess of \$200,000 within one year
9 after implementation?

10 DR. ACKERMAN: Move that it won't.

11 DR. DI PIETRO: Second.

12 CHAIRMAN ROMANELLO: All in favor?

13 (Unanimous ayes)

14 Passes.

15 ATTORNEY DIERLAM: Will this rule amendment
16 create an offense that would constitute a minor
17 violation under the rule?

18 DR. ACKERMAN: Move that it won't.

19 DR. DI PIETRO: Second.

20 CHAIRMAN ROMANELLO: All in favor?

21 (Unanimous ayes)

22 Opposed?

23 Passes.

24 ATTORNEY DIERLAM: And then the final issue
25 for consideration is a sunset provision and whether

1 or not the board wants to include one. I would
2 point out that A, this rule is required by statute,
3 and therefore, I don't know that a sunset provision
4 would be required. And B, it's also an emergency
5 rule, so --

6 DR. ACKERMAN: Move that there's no sunset
7 provision.

8 DR. DI PIETRO: Second.

9 CHAIRMAN ROMANELLO: All in favor?

10 (Unanimous ayes)

11 Opposed?

12 Passes.

13 Moving to the adult, any comments by
14 committee members? And I know that Dr. Derick had a
15 comment.

16 DR. DERICK: So starting on Bates 309, I
17 think that the audience actually had a lot of
18 compelling comments and I kind of just wanted to
19 walk through the issues related to the
20 qualifications for adults to receive and continue
21 HRT.

22 So I think if we go, number 1, meets the
23 criteria for gender dysphoria. That seems like
24 that's appropriate that they have gender dysphoria
25 if they're being treated for it.

1 DR. ACKERMAN: We're on 309?

2 CHAIRMAN ROMANELLO: Bates 309.

3 DR. DERICK: You know, there was a recent
4 knowledge that some people from a large transgender
5 group were sort of rubberstamping after a 20-minute
6 appointment with a provider. They were getting
7 letters to their insurance companies, you know,
8 saying that these people qualified, you know, for
9 these very serious, like (indiscernible), for
10 example, without really having a relationship with
11 those people. So I do think that -- and it wasn't
12 persistent, it had been like a month.

13 "Mental health and physical conditions that
14 could negatively impact the outcome of the treatment
15 have been assessed." So the comorbidity thing is
16 interesting. It sounds like from number 2, if
17 someone does have a mental health or physical
18 condition, and it's discussed, risks and benefits
19 are discussed, that that person could get the
20 treatment.

21 DR. DI PIETRO: Correct.

22 DR. DERICK: Right. I mean, it doesn't
23 preclude -- that one doesn't preclude it.

24 DR. DI PIETRO: Correct.

25 DR. DERICK: "3, gender dysphoria is marked

1 and sustained." I think the points that were made
2 from the audience, if you are already being treated
3 for gender dysphoria, you don't have sustained
4 gender dysphoria, so maybe that one is redundant to
5 the fact that you meet criteria for gender dysphoria
6 in general.

7 DR. MORTENSEN: That kind of speaks though
8 with hypertension, right. Like if you're taking
9 your medication, you don't have hypertension.

10 DR. DERICK: Yeah.

11 DR. MORTENSEN: So if they are taking their
12 medications, they still technically have gender
13 dysphoria.

14 DR. KIRSH: It's a diagnosis.

15 DR. MORTENSEN: It's a diagnosis.

16 DR. DERICK: I think maybe it's nuanced
17 with the way that it's written. But I mean, I think
18 that, you know, you wouldn't -- if someone was
19 stable and doing well, you wouldn't want to say that
20 they were -- someone said gender euphoric, which is
21 not gender dysphoria, so --

22 The next one, "Demonstrated capacity to
23 consent." That seems fine.

24 Number 5, "Does not" -- this one -- "does
25 not suffer from psychiatric comorbidity that

1 interferes with the diagnostic workup or treatment."
2 So this is saying that if you're a new patient who
3 is an adult and you have a psychiatric comorbidity
4 that would interfere with the diagnosis of gender
5 dysphoria then that would be taken into
6 consideration. I do think it's compelling. People
7 do have depression and other sorts of things that we
8 wouldn't want to state that they couldn't get their
9 treatments in adults, right. I mean, to me that
10 seems inappropriate.

11 DR. ACKERMAN: I think it's a
12 misunderstanding. I think that there could be a
13 psychiatric comorbidity but the fact that it has to
14 interfere --

15 CHAIRMAN ROMANELLO: Absolutely.

16 DR. ACKERMAN: -- with the diagnostic
17 workup or treatment. I mean, everybody has
18 multiple --

19 DR. DECKER: I mean, like if you have ADHD
20 and have gender dysphoria, it seems like those
21 things can be treated separately.

22 DR. ACKERMAN: Yeah. I agree.

23 DR. DECKER: If you have depression, gender
24 dysphoria, if you're treated maybe the depression
25 goes away or maybe it doesn't. Maybe it requires

1 additional treatment.

2 DR. ACKERMAN: I think it doesn't interfere
3 with the diagnostic workup or treatment.

4 CHAIRMAN ROMANELLO: Right.

5 DR. DECKER: "Number 7, demonstrates
6 knowledge and understandings of the risks." That
7 seems normal, or fine.

8 "Number 8, understands the effect of gender
9 affirming hormone treatment on reproduction."
10 That's just informed consent again.

11 "Number 9, undergoes evaluation by the
12 prescribing physician at least every three months."
13 And then also number 10, which is the suicide risk
14 assessment. You know, I sort of agree that, you
15 know, once the consent is --

16 CHAIRMAN ROMANELLO: But Dr. Derick, we
17 changed that, right.

18 DR. DERICK: No, I'm just reading the
19 former -- the timing was changed. But to me it
20 seems like in adults if they do informed consent in
21 person with a physician that maybe this is too
22 prescriptive in its language for adults.

23 Same with the bone scan and laboratory
24 testing and the annual mental health assessments.
25 You know, we were charged with creating a consent

1 form in adults to reeducate people on kind of the
2 newest stuff that's going on in this field because
3 it's -- you know, people here say we don't know the
4 studies, but we've read probably 20,000 pages of
5 studies. We've got 2 people up here who are
6 specialists in pediatric endocrinology, which is
7 like 4 years after college of medical school, and
8 then like 3 years of pediatrics, and then 2 years of
9 endocrine, or whatever it is. It's like a lot of
10 time. So these people, I mean, this is what they do
11 for a living. They see these patients and
12 everything else.

13 So I mean, I don't want people to think
14 we're not taking this seriously. We have very
15 serious concerns about some of these treatments.
16 But I do think that in adults in particular perhaps
17 some of the prescriptive appointments and all of
18 those things might be too much.

19 And I also think that would probably get
20 rid of the issue with the nurse practitioners
21 because then it would only be in the kids who were
22 in that window of time where they needed to have --
23 they got grandfathered in or whatever else, they
24 would need to be seen. But if we consider maybe
25 removing some of these other requirements that maybe

1 the access to their doctor, they should be seeing
2 their doctor regularly anyway.

3 So I don't know, I'm appreciative of the
4 public here. I think that, you know, the intent
5 always is to use all the knowledge that we have to
6 do the best job that we can with the data that's
7 presented and I think, unfortunately, there's just
8 such a chasm right now of, you know, you either
9 believe or don't believe and there's just so much
10 uncertainty related to all of this. So I appreciate
11 everyone's comments and I think that, you know,
12 perhaps we should consider removing some of these
13 requirements for adults.

14 CHAIRMAN ROMANELLO: Do you have any
15 specifics?

16 DR. DERICK: Yeah. I think -- yes, I do.
17 So if we go back through. I'm sorry to be so
18 tedious with this. But I think the mental health
19 comorbidity is -- if we're all on the same page
20 where we agree with the lawyers that if you do have
21 a mental health comorbidity it's just discussed as
22 part of the evaluation, it's not that you can't get
23 it if you have depression.

24 DR. ACKERMAN: Right. That's a
25 misunderstanding.

1 CHAIRMAN ROMANELLO: Right.

2 DR. DERICK: Okay. Because I think that
3 that's -- you know, that was a concern of a lot of
4 people that we heard.

5 You know, obviously --

6 DR. ACKERMAN: So we're leaving that as is.

7 DR. DERICK: Yeah. Able to give consent
8 and stuff like that, that should stay. I think
9 maybe number 9, number 10.

10 DR. ACKERMAN: Well, let's go through one
11 at a time. So number 9.

12 DR. DERICK: I'm saying that 1 seems
13 normal. 2 is okay. 3 is redundant. 4 is fine. 5
14 we've clarified. 6 is fine. 7 is fine. 8 is fine.
15 9 is -- I would -- we had changed it when we were
16 discussing it, before I heard public testimony on
17 it, to 6 months or something like that.

18 DR. ACKERMAN: We said three months for the
19 first year and annually thereafter.

20 DR. DERICK: Yeah. I feel like maybe that
21 one should be stricken. I think that the patient
22 probably as an adult will have a routine cadence of
23 visits anyway that doesn't necessarily need to be
24 mandated in this rule.

25 And the same thing with number 10, suicide

1 risk assessment. I did hear Dr. Benson, I'd like to
2 hear his opinion about if he thinks that this should
3 be a mandate, but I think that if it's good practice
4 for physicians who are prescribing this in adults
5 that it is an issue that hopefully they would do
6 that on their own.

7 The laboratory testing, same thing, and the
8 bone scan, same thing. I would consider not having
9 those. And then 13, annual mental health
10 assessment. And to be honest, I'm not saying these
11 things aren't important. They are very important.
12 I'm just not sure in the context of this task that
13 we were given that this should be included.

14 "Number 14, continuing counseling with a
15 licensed mental healthcare professional during
16 treatment," I think that one probably should be
17 taken out too. Not that that shouldn't happen, I
18 just am not sure it should be as part of this.

19 DR. MORTENSEN: It says, "with the
20 frequency recommended by the healthcare professional
21 though," so it's not like we're mandating that they
22 have to have it, we're just suggesting that if they
23 are seeing somebody and that person says, "You
24 really need to be seen more frequency," you do. And
25 if they say, "No, come back in a year, or two years,

1 or if you have problems."

2 DR. DERICK: I mean, I think that that one
3 is fine then if it's read that way. I mean, I think
4 it's appropriate if you have an annual mental health
5 assessment it can happen like maybe once, and if
6 it's needed to be done -- if people are happy and
7 they're not having problems with it and they're
8 adults and they're on stable medications for a long
9 period of time. I mean, I hear the access
10 arguments, I hear the cost arguments, I hear, you
11 know, a lot of those things and I feel that perhaps
12 in adults that we are -- our duty is to inform them
13 about the risks of the treatment, considering some
14 of these have become newly -- we're becoming more
15 aware.

16 You know, I know that the NHS in England
17 recently came out with even more stringent
18 guidelines related to not even promoting social
19 transitioning of children. So I mean, we're looking
20 at Europe, we're watching Europe. It's a constantly
21 evolving discussion. And so I think that the
22 refreshing of the informed consent -- and also, the
23 people's doctors are going to give them their own
24 informed consent, too. So they're going to get all
25 the consents. But yeah, so I think that that that

1 might --

2 DR. MORTENSEN: I think it would be fair to
3 strike some of it because as counsel had noted, the
4 physicians are required to handle the standards of
5 care and if you do look at the Endocrine Society
6 Guidelines and the World PATH guidelines, they do
7 recommend laboratory testing, bone mineral density,
8 all those other things. So you could strike it from
9 the consent because it falls on the physician to
10 follow those standards of care.

11 DR. DERICK: Maybe it would be --

12 DR. MORTENSEN: But it would be fair to
13 inform the patient to expect that these things are
14 the standard of care and that their provider might
15 be --

16 DR. DERICK: I like that idea. Instead of
17 saying it's a requirement that it would be included
18 in the informed consent that this is what you should
19 expect, or your -- this is what's considered
20 standard of care is to have these things done at
21 this sort of cadence. But not make it a requirement
22 where if someone doesn't have a bone scan they're
23 out of compliance if it's been, you know, 370 days.

24 DR. ACKERMAN: Well, the first line here
25 say above those numbers is "The specific

1 requirements for an individual," and then all these
2 things are in there. So we're requiring these. So
3 you want to loosen up on some of these requirements,
4 like number 9 and 10?

5 DR. DERICK: Yeah. I feel like -- sorry,
6 my computer shut like shut off. It's like --

7 DR. ACKERMAN: So number 9 says, "Undergo
8 an evaluation by a prescribing physician" -- and I
9 think we changed it -- "or their" --

10 DR. DERICK: Instead of making it a
11 requirement make it "It is suggested that you" --
12 blah, you know.

13 DR. MORTENSEN: So why not leave the things
14 that we need for specific requirements and then
15 create a second subsection that says, "The following
16 are recommendations" -- or the "The following may be
17 recommended by your physician" and then list the
18 other ones as recommendations?

19 DR. DERICK: I think that's a great
20 compromise. I think that that's something that I
21 think the audience would be supportive of.

22 DR. MORTENSEN: So we don't have to
23 reinvent the wheel on the consent.

24 DR. DERICK: You know, and I think that
25 it's --

1 DR. ACKERMAN: I think the economics of it
2 is important -- is a concern, yeah.

3 DR. DERICK: It's good medicine to do these
4 things, I just -- you know, if you require that they
5 can't get prescriptions filled if these things A, B,
6 and C haven't done, it's like a lot of burden to
7 make sure that you're not out of compliance and it
8 will make physicians nervous too to be prescribing
9 these medications to make sure that they're able to
10 comply.

11 DR. ACKERMAN: Right. But at the same
12 time, we need to protect the public and have some
13 requirements that -- I think there will be
14 physicians out there that will take advantage of
15 this and not see their patients and just -- you
16 know, they'll be doing telemedicine and not doing
17 these assessments in person. So I think we have to
18 have some requirement in there of a frequency that
19 they see a physician. So we said before every
20 three months, and I think we said during the
21 induction phase, or -- right? Help me with what we
22 had said.

23 CHAIRMAN ROMANELLO: First year.

24 DR. ACKERMAN: The first year, every three
25 months, and then annually thereafter. So you want

1 to strike that? You want to make it looser?

2 DR. KIRSH: Maybe the consideration might
3 be is some of the things that would have a major
4 impact financially, we put under recommendation by
5 the physician and the patient. And then those that
6 we believe are protective of the population we
7 continue the standard similar to meeting with the
8 physician on a regular basis at the beginning and
9 loosen that up as we already have in the end for the
10 adults. It's those things that may have the
11 financial impact that we may say is a
12 recommendation.

13 DR. DI PIETRO: But it shouldn't be about
14 financial impact. It should be about health,
15 safety, and welfare, right.

16 DR. KIRSH: Absolutely.

17 DR. DI PIETRO: And standards of care.

18 DR. KIRSH: Absolutely. But there is --

19 DR. DI PIETRO: So I mean, the standard of
20 care is a cardiac catheterization and it's way more
21 expensive than TPA. So I mean, it's -- although I
22 recommend -- excuse me. Although I understand the
23 financial aspects and even Dr. Ackerman and I were
24 looking up the cash pay prices on DEXA scan sitting
25 here. I mean, I get it. I deal with it every day.

1 I deal with uninsured patients in my hospital on a
2 daily basis. But when we're coming up with
3 standards and consents, it has to be standards of
4 care and health, safety, and welfare.

5 I am completely fine with leaving certain
6 requirements and then having a subtitle for things
7 as they stand and putting, you know, "These should
8 be expected as are recommended" if you want to put
9 by the board by the state -- however you want to
10 write it, I'm perfectly fine with that. But I don't
11 think they should be exclusively removed because I
12 think when things are in writing like this, it gives
13 the patient the opportunity to read things that
14 maybe their physician, if it's not a fantastic
15 physician, failed to mention to them.

16 DR. KIRSH: No. I happen to agree with you
17 but there are some things that, you know, is a
18 decision made by a group that may not look at the
19 full ramification, and so those things should be
20 recommended, as you said, and those things that we
21 believe is an absolute necessity, such as seeing the
22 patient on a particular period, is something that we
23 should keep that in the informed consent and fly it.

24 DR. ACKERMAN: Well, this is the standard
25 of care part, so let's -- I'd like to -- it would be

1 good to get through this and just do one at a time.

2 DR. DI PIETRO: But the other option could
3 be that the requirements apply to people who are new
4 adults to the treatments, and the people who are
5 currently under treatment, these are the
6 recommendations.

7 DR. KIRSH: How do you define that? That's
8 complicated. How would you define that from a --

9 CHAIRMAN ROMANELLO: Can I make a
10 suggestion? I'm not hearing a consensus on where
11 the committee wants to go on the issue. I'm hearing
12 a couple of different competing ideas, all of which
13 sound good. I think there is a general consensus to
14 somehow modify those requirements for folks who
15 receive hormone replacement therapy. I don't think
16 that we've coalesced as a group on where those
17 requirements or suggestions should reside.

18 As this is an emergency rule, this is not
19 going to be the last stop on this journey. We're
20 going to be back here for a permanent rule, and
21 we've already talked about some other items that
22 we've put kind of placeholders in this rule in that
23 we're going to reconsider and have much more time to
24 reconsider as we progress to the permanent
25 rulemaking. Is this an area where we could -- we've

1 got notes and a record of the conversation, is this
2 something that we can come back in the permanent
3 rulemaking process to take up?

4 DR. DERICK: I just think there's going to
5 be a gap between those two things and the physicians
6 aren't going to know what to do during A and B.

7 CHAIRMAN ROMANELLO: Okay. Fair enough.

8 DR. DERICK: I see both sides and I think
9 it's important to recognize that we can't lose our
10 transgendered patients to lack of follow up. And I
11 think that we're seeing a little bit of this
12 rubberstamping sort of large sprawl of transgendered
13 clinics where people have been on record saying that
14 they don't have any gatekeeping philosophy because
15 they believe everyone should be on these
16 medications. And I think that's something that we
17 really need to think hard about is that this is not
18 for everyone, especially in the kids. It's not --
19 it's good for some that need it and it also should
20 be considered that it might just take time to --

21 DR. BENSON: So I think the simple thing is
22 with the DEXA scan, I think if you really look at
23 the Endocrine Society Guidelines, they talk about a
24 lot of what we talked about. When to monitor
25 testosterone, when to get a hemoglobin and

1 hematocrit screening for osteoporosis. But for
2 trans males, the fracture risk is probably low if
3 they're staying on their testosterone. And for the
4 trans females, you know, again, similar monitoring,
5 checking testosterone, checking estrogen, shooting
6 for the physiologic range. But BMD testing at
7 baseline for that group, but the rest are low risk,
8 so you're requiring a DEXA scan that would be
9 something I think we could just eliminate for most
10 adults.

11 CHAIRMAN ROMANELLO: So then is there an
12 appetite? Because Dr. Derick has identified, and
13 we've circled in on numbers 9 through 14. Would
14 there be an appetite for the committee to consider a
15 new section, as Dr. Di Pietro pointed out, after the
16 specific requirements, another section that reads,
17 "The following requirements may also be recommended
18 by your physician," and we would take numbers 9 --

19 DR. ACKERMAN: Take out the word
20 requirements. "The following may be" --

21 CHAIRMAN ROMANELLO: Right. "The
22 following" --

23 DR. ACKERMAN: -- "may be also recommended
24 by your physician."

25 CHAIRMAN ROMANELLO: Okay. "The following

1 may also be recommended by your physician," and we
2 would take numbers 9 through 14 and put that in a
3 subsection?

4 DR. ACKERMAN: Yeah. I could live with
5 that. That would make it -- at least it's in there
6 and it makes it so they're not obligated to do it.
7 It's optional but, you know, if someone is not doing
8 any of those on a regular basis they could have --
9 it could be looked "frownly" upon. So I'd make the
10 motion to add an additional -- to after number 8,
11 put a space --

12 CHAIRMAN ROMANELLO: "The following may
13 also be recommended by your physician."

14 DR. ACKERMAN: "The following may also be
15 recommended by your physician for individuals who
16 receive and continue to receive HRT treatment."

17 DR. KIRSH: Second.

18 ATTORNEY DIERLAM: And that is for
19 masculinizing and feminizing forms? Obviously
20 wouldn't apply for the surgical forms but both for
21 the adults?

22 DR. ACKERMAN: Right. Masculinizing and
23 feminizing.

24 ATTORNEY DIERLAM: Thank you.

25 DR. ACKERMAN: "The following may be

1 required for individuals to receive or continue to
2 receive HRT treatment."

3 CHAIRMAN ROMANELLO: "The following may
4 also be recommended by your physician for an
5 individual to receive and continue HRT treatment."

6 DR. ACKERMAN: I wouldn't say "your." "The
7 following" -- you got to wordsmith it for me a
8 little bit. "The following may be recommended by
9 the physician." Because this isn't your, all this
10 is in third person or whatever. Yeah "by the
11 prescribing physician."

12 CHAIRMAN ROMANELLO: I have a motion by
13 Dr. Ackerman.

14 DR. DERICK: Second.

15 CHAIRMAN ROMANELLO: A second by
16 Dr. Derick. All in favor?

17 (Unanimous ayes)

18 Opposed?

19 It passes.

20 DR. ACKERMAN: Just fix the language there
21 to make it so that it's the proper tense.

22 CHAIRMAN ROMANELLO: So then are we going
23 to -- are there any other questions, or any other
24 observations, or motions that we want to make about
25 the informed consent --

1 DR. ACKERMAN: Yeah. Just regarding that,
2 I can tell you that in people that don't have gender
3 dysphoria that are treating with these drugs, I
4 think it should be required. I require it, so I
5 think it's a little -- you know, it's weird that
6 we're not requiring bone density studies with people
7 with estrogen blocking drugs, but that be as it may,
8 I just wanted to go on record saying that. I think
9 it's fine. They can do it ad-lib.

10 CHAIRMAN ROMANELLO: So with that, I would
11 entertain a motion to adopt the emergency rules as
12 amended, as well as the rule.

13 DR. ACKERMAN: Second. So moved.

14 DR. DI PIETRO: Second.

15 CHAIRMAN ROMANELLO: All in favor?

16 (Unanimous ayes)

17 Opposed.

18 If I said rule twice, I didn't mean to. I
19 meant to say the consent forms along with the rules.
20 So the consent forms as amended and the rule. A
21 motion and a second, all in favor.

22 (Unanimous ayes)

23 Opposed?

24 It passes. Mr. Dierlam's got -- yeah.

25 ATTORNEY DIERLAM: Will the proposed rule

1 amendments have an adverse impact on small business?

2 DR. ACKERMAN: No.

3 DR. DI PIETRO: Second.

4 CHAIRMAN ROMANELLO: All in favor?

5 (Unanimous ayes)

6 Opposed?

7 ATTORNEY DIERLAM: Is the proposed rule
8 amendment likely to directly or indirectly increase
9 regulatory costs to any entity including the
10 government in excess of \$200,000 within one year
11 after implementation?

12 DR. DI PIETRO: I move that it will not.

13 DR. MORTENSEN: Second.

14 CHAIRMAN ROMANELLO: All in favor?

15 (Unanimous ayes)

16 Opposed?

17 Carries.

18 ATTORNEY DIERLAM: Will this rule amendment
19 create an offense that would constitute a minor
20 violation under the rule?

21 DR. DI PIETRO: Move that it will not.

22 DR. ACKERMAN: Second.

23 CHAIRMAN ROMANELLO: All in favor?

24 (Unanimous ayes)

25 Opposed?

1 Carries.

2 ATTORNEY DIERLAM: And does the board
3 committee want to impose a sunset provision for this
4 rule or a rule amendment? All my prior comments for
5 the last rule apply again.

6 DR. DI PIETRO: I move that there should
7 not be a sunset.

8 DR. ACKERMAN: Second.

9 CHAIRMAN ROMANELLO: All in favor?

10 (Unanimous ayes)

11 Opposed?

12 Carries.

13 Again, I want to thank the committee for
14 its time and its dedication to the issue. I also
15 want to thank the members of the public who took the
16 time to be here today. Particularly those who have
17 come to multiple meetings and have commented on
18 multiple occasions. We certainly appreciate it.
19 And with that, we'll adjourn the meeting.

20 (END OF AUDIO RECORDING)

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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

\$	10-minute 130:14,23	71:5,10 87:19 101:10 159:13	2022 162:15 187:10 194:7
\$20,000 192:12	100 101:12 103:6 194:8	1968 192:9	2023 3:13 4:22 5:24 6:15 7:5 133:12
\$200,000 201:8 223:10	100,000 162:25 163:1, 6,7	1972 162:18,24	20th 6:20
\$300 179:10	11 39:21 66:12 70:15	1:00 6:15 7:5	21 154:2
\$700 191:21	12 90:21 137:24 177:16 181:19 192:10	1:02 3:14	219 128:14
(13 169:14 180:12 181:17 195:4 210:9	2	22 9:8
(2) 6:5	14 210:14 219:13 220:2	2 39:16,20 65:16 127:21 156:11 203:16 207:5,8 209:13	23 3:13 6:15
(6) 6:6	15 162:21	20 162:20	254 4:20,22 184:17
(c) 135:19	16 120:14	20,000 207:4	26 51:2
1	16th 146:22	20-minute 203:5	264 14:7 15:2 36:11 41:17 42:24 43:18 47:4 54:2 56:2,22
1 5:24 17:19 41:14 78:25 127:21 202:22 209:12	17 4:22 120:14 133:12	2001 159:14	265 20:25 65:15 68:5
10 47:12 48:1 49:20 78:23 100:24 103:5 104:1 105:23 106:19,20 120:16 131:15 156:11 162:20 173:14 174:3 181:19 195:4 206:13 209:9, 25 213:4	17- hydroxyprogeste rone 142:23	2005 159:14	266 39:3 58:25 60:17 61:1,2
	17th 146:24	2013 163:4	269 49:2,8 52:14 57:20
	18 5:3,19 39:16	2017 29:20 71:22 162:18,24 163:4	272 74:2 84:10,11
		2020 191:18	
		2021 187:10	

<p>274 75:1,10,14</p> <p>284 84:15 89:21</p> <p>285 126:24,25 127:7</p> <p>286 92:10</p> <p>287 95:21 96:20</p> <p>29 163:1</p> <p>290 99:12</p> <p>294 132:11</p> <p>295 132:20 133:23 137:2</p> <p>296 135:19</p> <p>298 84:7 88:9 99:23 100:3 108:2</p> <p>2nd 6:20</p> <hr/> <p style="text-align: center;">3</p> <hr/> <p>3 100:25 101:11,12 127:21 128:17,18 163:8 203:25 207:8 209:13</p> <p>30</p>	<p>7:5 71:6,11 78:24</p> <p>30,000 191:3 193:25</p> <p>30,000-foot 139:6</p> <p>300 100:10 103:20 194:14</p> <p>308 111:15 113:1</p> <p>309 202:16 203:1, 2</p> <p>30s 175:20 183:7</p> <p>30th 9:21</p> <p>310 113:14 114:5</p> <p>312 113:11,18,19 114:14,17</p> <p>317 116:3 117:3, 14 119:25</p> <p>318 121:3 123:10</p> <p>319 121:13 125:14 127:21,25 128:13</p> <p>323 138:23,25</p> <p>34 163:6</p> <p>370 212:23</p>	<hr/> <p style="text-align: center;">4</p> <hr/> <p>4 65:16 127:21 133:23 134:12 163:8 207:7 209:13</p> <p>41 164:19</p> <p>43 163:6</p> <p>45 162:23</p> <p>456.52 6:7,17</p> <p>456.52(1) 6:5</p> <p>458 5:14</p> <p>459 5:14</p> <p>490 5:15</p> <p>4:00 153:21</p> <p>4:26 196:1</p> <p>4:30 10:20 131:2,3 196:6,10</p> <hr/> <p style="text-align: center;">5</p> <hr/> <p>5 10:24 71:13 127:21 180:12,13 195:4 204:24 209:13</p>	<p>5-alpha-reductase 85:23</p> <p>500 149:10 150:7</p> <hr/> <p style="text-align: center;">6</p> <hr/> <p>6 48:24 90:21 127:22 128:17,18 209:14,17</p> <p>60 5:1 72:3 194:18</p> <p>60-year-olds 68:18</p> <p>64 162:25</p> <hr/> <p style="text-align: center;">7</p> <hr/> <p>7 206:5 209:14</p> <p>70 163:24</p> <p>70-year-olds 68:19</p> <hr/> <p style="text-align: center;">8</p> <hr/> <p>8 17:19 47:25 48:24 49:20 65:16 120:16 133:25 206:8 209:14 220:10</p> <p>80 148:9</p>
---	--	---	--

80s 147:22	Abscess 96:18	acetate 88:7,20 108:2	67:2,9,15,18, 22 68:3,9,18
82 164:17	abscesses 95:17	111:11 142:20	69:4,9,12,18, 25 70:4,5,6,
820,063 162:16	absolute 182:23 216:21	143:6 149:1,6	8,10,13 71:3, 9,16,19 72:5, 11,15,20
85 79:18	Absolutely 19:4 27:19	achieve 152:1	73:2,23 75:10,13,19
<hr/> 9 <hr/>	106:2 205:15	Ackerman 11:9,10,11,15	76:1,4,9 80:8
9 49:20 120:16	215:16,18	13:10,23	81:4 82:5,8, 14 83:2,10, 12,22 84:5, 10,22,23
206:11 209:9, 11,15 213:4,7	absurd 25:9	15:4,12,20	85:6,13,17, 19,25 86:5, 10,13,16,19, 22 87:7,10,20
219:13,18	academic 170:20	16:3,5,10	88:1,5,19,21
220:2	accept 16:21,23	18:9,12,19,23	89:1 90:22
90 64:22 79:18	34:23 129:24	19:13 20:23	91:10,16
9000 161:8	174:20	21:15 22:6,19	92:24 93:7,17
90s 147:22 174:9, 10	accepting 185:14	23:5,11 24:4, 7,10,20 25:4, 6 26:15 27:2, 9,12,20 28:4, 6,16 30:1,7	94:1,5,9,12, 17,19,21
95 59:19 62:25	access 30:18 149:15	32:8,11 33:5, 23 34:10,19, 21 35:9,16, 21,24 36:14, 22 37:9,15, 18,24 38:7, 11,12,15,21	95:1,4,7,10 96:2,12
<hr/> A <hr/>	172:8,14	41:17 42:21	97:11,15,18, 21,24 98:2,6, 10,14,16,18, 23 99:2
Aaron 153:18 156:14	175:17 180:3	43:17 45:4,19	101:7,10
159:6,7	185:3 186:17	47:23 48:22, 25 49:3,8	102:4,7,17, 21,24 103:2, 6,10,13,21
161:14,17,18	194:2,4 208:1	50:1 52:17,20	104:5,19,23
162:12,15	211:9	53:15,19,23, 25 54:3 55:5, 23 56:5,21	105:5,15,18
163:9,12	accessible 164:1 172:21	57:18 58:1,12	106:4,18
abdominal 149:5	accessing 154:25 174:16	59:9,13,16,25	107:4,10,15
Ability 62:8	accordance 9:18	60:25 61:6, 11,21,25	108:4,8,14
	accurate 58:19 60:21	62:5,11 63:7, 9,12,14,21	109:4,8,22
	193:19 225:3	66:2,4,18,22	110:5,9,14, 16,22 111:1

116:24 118:6 119:19,22 121:22 122:6, 10,19,25 123:6,12,15, 19,21,25 124:4,8,11,12 125:6,7,23 127:16,18,20, 21,24 128:1, 5,8,13,18,22, 24 129:5,25 130:2,16,19 131:5,8 132:3,21 133:9,14,18 134:6,8,17 135:3,5,17 136:5,11,19, 21 137:21,25 138:23,25 139:6,9,16, 19,23 140:17, 18,21 141:2,9 142:1,4,17,21 143:2,5,13 146:24 147:5, 9,11,13,16,19 148:1,4 155:22 156:2, 10 158:5,17 159:4 165:4,7 198:11 199:3, 8,11,14 200:5,9,25 201:10,18 202:6 203:1 205:11,16,22 206:2 208:24 209:6,10,18 212:24 213:7 214:1,11,24	215:23 216:24 219:19,23 220:4,14,22, 25 221:6,13, 20 222:1,13 223:2,22 224:8 act 198:11,16 action 9:22 151:15 189:20 225:7, 8 actions 7:6,12 151:17 active 5:6 133:11 178:9 192:1 activist 143:20 184:15 activities 12:9 actual 48:19 131:16 132:11 198:7 acutely 55:2 ad-lib 222:9 adamantly 175:23 add 15:24 40:22 41:3 46:17 51:6 52:14 55:8 56:21 58:3 60:3 62:24 80:7,8 82:25 91:2	96:11,12,23 109:13 114:8 120:1 124:6, 8,12,24 129:16 155:3, 9 160:4 161:6 168:3 171:17 220:10 added 124:18 129:17 159:23 adding 53:12 117:20 addition 19:1 47:1 84:20 113:14 120:18 additional 19:3 97:25 111:20 117:24 167:11,14 170:4 175:13 189:2 206:1 220:10 Additionally 179:14 address 4:20 11:12 28:22,25 192:21 addressed 18:15 78:2,14 199:15 addressing 74:17 adequate 65:16,23 81:2,3 82:14 134:14,16,17 166:22 193:18	ADHD 174:13 192:6 205:19 adhering 30:22 adjective 75:11 adjectives 76:7 adjourn 10:23 224:19 adjunct 87:14 adjust 135:15 adjusted 105:9 admin@wvswfl. com. 196:25 administer 91:13 Administration 187:6 administrator 3:6 admitted 197:12 adolescence 79:19 adolescents 13:24 68:10 87:6 90:3 170:20 adopt 5:1,17 166:11 198:23 200:3, 5 222:11
--	--	--	---

adopted 165:22 166:3 168:4 193:14	11,17 69:5, 13,19 71:2,3, 8,9,13 79:20 83:8,10 85:13,17 90:14 100:11, 13 101:8,9 111:11 116:4 126:5 131:24 135:22,25 139:9,24 140:2 161:2 163:25 168:10,14 169:1,23 171:18 176:19 177:23 182:2 185:19 199:2 202:20 205:9 206:20,22 207:1,16 208:13 210:4 211:8,12 215:10 217:4 219:10 220:21	advise 198:16	152:20
adoption 9:19		advised 9:17	afternoon 3:13 9:23 10:5,20 150:16 159:9 160:20 161:17 164:6,12 165:14 168:20,21 170:17 176:4 192:16 195:16 200:1
adopts 133:5		Advocacy 186:24	
adrenal 142:24		advocating 161:7	
adult 18:7 31:17,18 39:10 46:21 55:21,24 69:10,13 71:21 72:23, 25 77:3 84:25 87:5 88:21 90:2 100:4 101:22 102:19 138:22 139:11 148:2,3,4 157:3 158:24 166:11 168:5 175:11,12 176:16,20 186:8 199:17 202:13 205:3 209:22		aesthetic 64:11	
adult's 168:6		aesthetically 64:16	afternoon's 8:20
adulthood 170:23		affect 64:10	AG 125:9
adults 6:12 7:2 9:3 32:14 34:20 38:20,21 42:5 45:21,25 51:10,24 55:15 60:8 64:12 68:10,	adults' 166:7	affects 59:22 180:17	AG's 16:1,2
	advance 13:6 156:20 157:9,15,18	affirmation 193:12	age 5:3,19 68:1,2 72:4 87:19 90:20 101:10 169:14
	advantage 214:14	affirmative 87:10 103:1	Agency 187:5
	adverse 39:17,22 40:15,24 45:15 102:15 151:23 200:22 223:1	affirming 133:2 149:2 154:4,7 156:21 160:7 163:25 167:18 169:5 174:11, 16 176:9 177:9 178:21 179:1,17 182:25 183:3, 5,14,15 184:1,4,11 185:6,13,14, 16 187:9 189:9,21 191:6 194:2, 11,17,21,24 206:9	agenda 7:10 8:19 130:17 186:3, 5
	advice 158:14	Afterall	agents 14:21
			ages 186:1
			agony 152:19
			agree 14:6 47:23,24 48:12 59:17 82:5 101:12

103:6 106:2	allowed	Andre	anti-androgen
148:17 174:2,	7:17 95:1	144:13 146:25	149:7
5 205:22	150:19 162:5,	147:15,18,20	anti-science
206:14 208:20	7	148:3,5	191:19
216:16	allowing	Androgel	anti-trans
Agreed	108:25	90:18 155:5	175:23
109:11	alternative	androgen	anticipated
AHCA	78:6,10	142:25	78:5,8,16
187:6,8	ambiguous	androgens	anxiety
ahead	122:11	87:11	192:6
49:8 50:22	amenable	anesthesia	anymore
147:12 200:20	80:12	124:23,24	26:11 145:17
aided	amend	angry	apolitical
13:17	35:17,25	197:10	4:11
aka	amended	annual	apologies
176:5	35:4,12	66:14,16	153:16
alarmed	200:4,6	67:14 68:7,8	apologize
188:15	222:12,20	69:15 73:15,	126:3,11,12
alert	amendment	16,19 167:2	196:15
63:16,17	34:22 35:3	179:3,11	apparent
alike	201:6,15	206:24 210:9	182:22
171:18	223:8,18	211:4	apparently
alive	224:4	annually	143:6 196:16
147:3 170:23	amendments	29:5,14,17	appeal
172:9	35:3 200:22	32:8,9 68:11,	191:11
alleviate	223:1	12,13,23	appearance
179:17	American	69:3,4,6,13,	7:18 92:16
alleviate	77:5 173:5	19,20 70:16,	appetite
112:15	Americans	17 71:13,16	219:12,14
alleviating	175:25 183:8	72:12 73:11	apply
167:21	amount	106:8 107:12	7:22 46:20
allocated	173:17 179:13	112:1 159:3,5	112:15 217:3
141:19	Amsterdam	209:19 214:25	220:20 224:5
allopathic	162:17	answers	appointed
15:18	analysis	143:25	4:5 150:3
allotted	189:10	anthropometry	192:13
197:16,17	and/or	29:23	appointment
	187:20	anti	153:21 176:11
		184:12	

203:6	ascertain	Assuming	72:21 73:15,
appointments	54:19	156:2	19 74:12
26:6 207:17	aspects	assumption	81:10,13,18,
appreciates	170:21 194:10	64:23	23 83:23,24
165:21	215:23	atrocious	84:4 91:22
appreciative	assent	152:9	92:5,17
208:3	43:8 137:11,	attempt	96:19,21
approach	23 161:5	6:1 42:15	97:3,16,20
181:12	assess	185:11	98:12,15,17,
appropriated	181:18	attempted	25 99:7
91:7	assessed	164:19	103:25 104:8,
approved	203:15	attend	11 114:13,16,
6:19 39:11	assessing	152:17	24 115:2,6,
47:8 50:13,14	178:25	attended	12,24 117:5,
51:18,19	assessment	14:16	8,18 118:10,
85:5,6,7 89:9	101:5 102:4	attentive	15 120:4
108:12,13	166:5,25	169:18	121:13 122:17
137:2 160:3	167:3 168:7	attorney	125:12,18,20,
166:4 176:14	179:22 206:14	16:3 17:18,22	22,25 126:15
approximately	210:1,10	18:11,22,24	128:15,17,21
191:21	211:5	19:4,10 20:3,	132:19 133:5,
arbitrarily	assessments	11 21:18 27:3	13,17,21
190:4 191:14	31:25 179:4	29:16 31:2,7	134:12,23
arbitrary	206:24 214:17	32:2,15 33:9,	135:4,7,14,
70:1	asshole	14 34:15	21,24 137:16
area	178:12	35:7,13,18,22	138:5 139:3
27:13 217:25	assigned	36:7 38:19,23	156:5 158:6,
argue	8:21	39:4 40:22	10,25 198:15
174:7	assistance	41:3,9,18,21,	199:6,18
argued	157:22	24 42:24	200:12,19
64:8	assistant	43:4,12,19	201:5,15,24
arguments	3:5	48:17,23	220:18,24
187:3 211:10	association	49:6,9 50:9	222:25 223:7,
article	77:6 172:16	53:17 57:12	18 224:2
191:18	173:6 185:15	58:5 63:13,	225:6
ascent	195:1	20,23 65:15,	audience
137:7	assume	19,22 66:11,	130:21 140:19
	64:4 86:11	20,25 67:13,	149:22 202:17
	173:8	17 68:6	204:2 213:21
		69:15,23 71:7	audience's
			132:24

audio 3:20 224:20	134:9,20 135:11 136:22	191:25	92:10 95:21
augmentation 125:15,16,21	200:16 201:2, 13,21 202:10	barriers 166:4 170:5	96:20 99:12, 23 100:10
August 9:7 187:10	221:17 222:16,22 223:5,15,24 224:10	base 197:13	103:20 108:2 111:15 113:11,14,18 114:5 116:3 117:3,14 119:24 121:3 123:10 125:14 126:4 127:7, 25 128:13,14 132:11,20 133:23 135:19 137:1 138:25 202:16 203:2
authority 165:21 167:7		based 7:25 40:11,21 42:6 44:11 45:21 46:2 51:11,24 56:12 77:8 78:20 89:8 112:2 149:10 151:20 155:3 168:8 193:6 198:20	Beach 9:8
autism 150:9 192:6	<hr/> B <hr/>	baseless 189:15	beautiful 177:4 189:19
autonomy 152:7	back 7:21 9:7 10:16 35:11 36:11 46:25 56:1 59:15 79:8 89:3 119:7 123:21 126:3 129:9 130:14,23,24 131:14 147:9 150:13,14 156:1,25 174:9 182:5 187:9 208:17 210:25 217:20 218:2	baseline 72:1 219:7	beauty 193:7
average 163:8 192:12		basic 137:9 189:13	bed 77:16
avoid 47:20 172:1		basically 40:10 54:10 63:21 67:4 77:18 80:16 142:24 163:13	began 6:8
avoidance 151:17		basis 25:25 215:8 216:2 220:8	begin 132:21
aware 96:6 97:8 108:23 184:2 211:15		Bates 14:7 15:2 20:24 36:11 39:3 47:4 48:25 52:14 56:22 57:20 58:24 60:17 68:5 74:1,24 75:1,14 84:7, 14 88:8 89:21	beginning 9:7 25:13 37:5 41:16 47:15,22 48:4,12 50:2 52:21 53:25 73:17 80:9 154:11 169:16 215:8
Awesome 196:9	backgrounds 186:2		begins 43:2 48:14 84:7
awful 177:19	bad 64:13		
awkward 114:20	bald 86:3		
eyes 36:4 38:25 57:4 60:11 66:8 70:23 76:17 83:14 99:3 106:15 107:22 113:25 115:21 120:23 122:14 123:16 124:16 127:13 130:4 132:7	baldness 87:12 93:8 94:24 95:4 142:13		
	ban 182:2		
	bar		

behalf 8:4 9:24	23 54:11 55:19 56:3,9, 11 58:20	23 111:5,8,23 113:1,4,10, 11,21 116:9, 10,11,25	bills 152:9 183:10 184:18
beneficence 151:15	59:16,17 61:15,24	10,11,25 117:7,9,14,22	binds 142:25
beneficial 85:12	62:2,9,12,14, 18,23 63:8, 11,15 64:8	118:7,17,23 119:9 120:6, 10,18 121:2, 6,11,16,19,24	Bioethics 160:22
benefit 19:7 85:23 130:20 132:22,24 133:16	65:4,10,18,21 66:24 67:7 68:1,16 69:10,22	122:5,12,24 123:3,15 137:1,18,23 138:2,16	birth 79:9 155:10
benefits 16:22 40:17 46:7 52:4 54:19 56:16 78:8 92:12 151:25 193:20 203:18	71:21 72:6, 10,14,19 74:9,11,12, 15,18 77:1,2 80:6,11,20,22 81:7,11,22 82:2,4,7,10 83:18 84:2,9, 12 85:9,15, 18,21 86:2, 12,15,20	142:22 143:4, 12 171:15 210:1 218:21	bit 17:8,9 33:1 48:10,11 53:9 79:3 80:13 89:8 91:25 101:13 118:14 123:22 140:19 145:9 181:19 218:11 221:8
Benson 13:15,17 14:4,7,8 15:2,5,6 16:7 21:2,4 22:3 29:19 30:3,9, 16,19 31:5 32:1 33:13, 16,20 34:20 35:11,14 36:15,23 37:8,12,16,22 39:3,5,6,7 40:5,7,9 41:2,5,19,22, 25 42:11,13, 17,23,25 43:3,6 44:1, 4,11,22 45:2, 17,20,24 46:13,19 47:13 49:19 50:4 51:7,15,	87:23 88:4,6, 13,17,20,23 89:5,6,7,21 90:3,10,16 91:6,18,21 92:1,5,7,20 93:5,13 95:12,13 96:3,14,18,24 97:7,13 98:1, 5,10,22 99:2, 11 102:8,11, 18,22 103:1, 12 104:13,15 105:4 106:2, 5,21,22,24 107:6 108:1, 6,11,16 110:12,15,19,	Benson's 103:11 113:16 119:25	bladder 122:20,23 123:1,7,8,11, 12,22
		bias 188:21	blah 53:5 73:20 213:12
		biased 188:25	blank 18:9,19,20 36:12,17 37:2
		Bicalutamide 110:10,14,15, 21 111:9 142:9	blanks 17:14 18:16
		big 99:13 124:25 133:22 155:5	bleeding 98:3,8,16,17, 20
		bigger 91:23	block 75:13 184:1 191:23
		biggest 180:12,16	blocked 116:13,18,22 145:14
		bigotry 175:24	
		bill 4:20 180:4 184:17	

blocker 145:6	169:9 170:3 176:14 177:2	12 73:7,9,10, 19 74:8 90:20	brain 173:19
blockers 14:1 15:3,9 16:11,21,23 40:24 49:13 58:16 59:1, 18,20 63:1 64:15 73:10 117:23 118:3 120:7,12,15 185:8	180:9 183:14 184:3 186:11 189:16,17 193:21,22 195:9 200:20 202:1 216:9 224:2	134:24 135:1, 5 167:2 179:2,9 188:1,4,9,15, 16 191:22 206:23 210:8 212:7,22 222:6	Brandy 176:3 177:14 178:14,16
blocking 63:17 64:6 85:23 158:19 169:7,21 222:7	board's 165:20 167:7 187:8	bones 67:4	breach 195:7
blocks 48:19	board-certified 5:13	book 190:14 192:3	break 10:15 130:14, 20,24 131:11 140:18
blood 29:24 114:9, 10 123:4 145:10,11 146:1 188:5, 6,10,11	boards 3:17 4:10,13, 24 5:8,11,17 6:4,18 7:4,13 8:20 81:19 138:6 166:11 170:8 187:1,4 188:20 189:1, 8,17	booked 176:10	breaking 31:21
BMD 219:6	boards' 3:21	born 161:25	breast 27:22 62:8 68:21 125:15, 16,21 128:2,3
board 3:1,2,3,4,15 4:14 7:20 9:12,21 11:16 24:17,18 75:24 81:23 132:14 137:2 138:25 146:21 150:4 151:20 152:17 157:23 159:10,15 161:1,18 162:6 167:3,9	bodies 4:11 186:6	botch 140:16	breasts 61:4 62:4
	body 59:1 149:8 152:3 175:20, 25 189:11 191:11	bottom 43:4 63:5 82:19 99:13 108:6 117:16	breath 171:3
	bone 66:16,18,19, 20,23,24 67:2,5,6,7,9, 10,11,19,24 68:1,2,21,22 70:11,16 71:24 72:1,8,	box 43:16,19 99:13 114:17 125:13 127:21 128:1,19	bring 12:23 153:1
		boxes 43:22	bringing 29:2
		boy 75:8,23 76:5	Bristol 156:15 159:7 161:14 163:16,17 164:3,7,13,16 165:3
		boys 86:23 192:10	British 59:19
		bracket 128:5,6,20	Bryce 182:17 184:22 186:21,22
		Brad 3:6	BS 173:13

buds 23:25	178:12	8:23 23:1,4	170:20,22
building 171:15	called 70:4 129:14 144:8 150:10 153:22	24:6,24 26:4 29:6,7 39:19 112:9 133:2,3 148:10 149:16 151:24,25 152:2,11 154:7,9 156:11,22 157:10,13,18 158:3 160:7 161:2,7,23 163:25 165:24 166:5,6,7,10, 25 167:6,15, 19,21,23 168:11 169:1, 5 172:11,14, 21 174:11,16 175:11,13 176:9,19,21 177:1,7,9 178:1,7,8,21 179:1,17 180:22,24 182:2,8,25 183:3,5,14,15 184:1,4,11 185:6,13,16 186:18 187:9 189:3,9,21,22 191:6 194:3, 4,11,21,24 195:6,8,11 197:7 199:13 212:5,10,14, 20 215:17,20 216:4,25	192:21 carefully 172:20 cares 194:17 caring 170:19 172:10 carries 36:6 39:2 57:6 60:13 66:10 70:25 76:19 83:16 99:5 107:24 115:23 120:25 122:16 123:18 127:15 130:6 136:24 223:17 224:1,12 carry 65:25 74:4 136:14,17 cascade 76:19 83:16 cascaded 100:6 cascading 84:17 case 25:17 54:20 77:10 79:1 153:22 cases 46:9 52:6 56:18 162:3 181:22 cash 215:24
bullet 58:1,2 70:15 106:19 121:6 124:8,13,21, 22	Callen-lorde 193:16		
bullets 96:13 97:25 98:1 117:15	calling 153:17 156:14 170:13 174:24 192:10		
bunch 103:8	Canada 88:18 108:17, 20		
burden 179:11 189:4 214:6	Canadadrugs. com. 89:1		
burdens 167:12,15 179:5	canceled 140:3 154:16		
burdensome 166:2 178:24 181:19	cancer 16:16 17:10 68:20,22 128:2,3		
business 150:3 200:23 223:1	Canterbury 77:11		
buy 108:19,20	capacity 204:22		
<hr/> C <hr/>	card 150:6,14		
cadence 209:22 212:21	cardiac 215:20		
calcium 188:18	cardiologist 146:10		
call 23:15 28:6 109:24 131:13 148:18 150:13	cards 7:18,20 144:18,23		
	care 3:23 4:15	cared 176:11 career	

Casodex 110:10 142:9	cetera 44:5 64:17	21,24 74:11, 18,24 76:12,	131:3,7,10,13 132:6 134:7,
Cassandra 3:4	77:9 96:4,25 97:2 102:15	15,24 80:6 81:21 82:3,	18,19 135:9, 18 136:9,16,
cat 180:14	121:7 150:9 163:24 192:6	12,24 83:5,11 84:6,11,13	20 138:21,24 139:4,8,21
cataract 138:14	chair 3:8 4:3 7:25	88:11,16 89:2,6,19	140:7,20 141:1,5,11
catch 128:23 129:4 160:14	8:14 82:16 159:14	91:12,17 92:9 94:3,20 95:5,	142:3,15 143:14 144:5,
catches 130:11	chairman 3:9 8:16	8,12 96:10, 16,20,22 97:2	9 147:7,12 148:7,17
catheterization 215:20	11:10,15 13:10 14:3,8,	14 102:10 103:19,22	150:12,21,23 151:6 153:12,
caught 104:24	25 15:11,19 16:4,9 18:14,	104:3,6,9,12, 21 106:10,13,	24 155:13,25 156:4,13
causing 183:23 184:17	25 22:17,21 26:25 27:19	20,23 107:13, 16,19 109:7,	157:21 158:9, 21 159:6
caution 114:6	28:18,21 30:10,17	11,19 110:7 111:12 112:24	160:14 161:11 162:9,14
cell 188:5,6	32:13 33:22, 25 34:3,13	113:3,9,12, 15,18,23	163:9,14 164:3,10,14
Center 144:15 162:17 193:16	35:1 36:1,3, 10 37:1 38:4,	114:12,15,22, 25 115:8,16,	165:2,6,9 168:18 170:11
centipede 196:23	9,12,14,17,24 39:6 40:4,8	19,25 116:10 119:6,10,15,	171:8 172:23 174:19,22
CERTIFICATE 225:1	42:11,14,18 43:23 44:3,7,	21,24 120:17, 21 121:5,10,	175:2 176:2 177:12 178:14
certified 167:4	15,25 45:23 46:15,23	14,18,23 122:7,12	180:7 182:13 184:21 186:20
certifies 160:10	51:7,16 52:8, 19 53:1,21,24	123:9,14 124:6,10,14,	189:24 190:17,22,25
certify 225:2,5	54:2 55:7 56:20,25	20 125:8 126:1,8,13	192:15 195:12 196:2,7
CET-1036 225:13	57:2,8,11,14, 16 59:15	127:8,11,17, 19,23,25	198:2,13 199:20 200:8,
	60:2,6,9,16 65:13 66:3,6	128:4,7,12, 16,23 129:3,	14 201:1,12, 20 202:9
	70:2,5,7,9, 12,18,22	7,11,15 130:1,18,22	203:2 205:15 206:4,16
	73:1,4,13,18,		208:14 209:1 214:23 217:9

218:7 219:11, 21,25 220:12 221:3,12,15, 22 222:10,15 223:4,14,23 224:9 chairs 129:2 challenge 152:14 chance 114:14 change 18:2 21:14 25:18 32:5 35:25 37:9 60:18,19 61:5,6,12,18 67:11 70:14 89:20 90:6,9, 11 94:16,17, 18 100:16 103:11 105:10 112:1 123:10 146:7 168:8, 12 173:24 199:13 changed 18:3 70:11 93:20 160:12 206:17,19 209:15 213:9 changing 55:13 61:22, 25 154:10 168:4,16 channels 88:25 chapter 5:14,15	163:18 character 78:3,15 charged 206:25 chasing 180:15 chasm 208:8 check 146:1 168:3 197:2 checking 219:5 checkups 188:12 cheering 12:4,11 Chels 165:10 170:17,18 171:14 chemotherapy 152:3 Cherise 3:5 cherry 189:11 197:12 cherrypicked 197:9 Chicago 14:17 child 120:12,16 137:24 149:2, 11 172:4 175:9 186:8	childhood 117:23 children 42:5 45:20,25 49:21 51:10, 24 55:13 63:1 87:17 111:10 137:4 149:15, 17 163:21 171:18 211:19 choice 36:15,18 176:22 choices 36:16 151:12 choking 164:24 choose 37:14,15 152:6,7 197:13 chooses 7:14 chosen 119:22 Chris 81:12 125:11 Christine 183:7 Christopher 3:3 chromosomes 60:19 chronic 149:4 chronically 161:25 181:4, 5	circ 200:21 circled 219:13 circumstances 168:2 cis 149:3,18 185:12 citations 173:8 cite 191:16 cited 180:22 citing 192:9 City 193:17 civil 7:9 165:17 claim 191:8 claims 187:7 189:9, 15 clarification 81:14 114:17 157:2,17 171:17 clarified 209:14 clarify 33:25 36:7 62:22 67:19 69:24 73:7 93:13 134:25 140:22 151:3
--	---	--	--

155:22	114:9,10	141:8,13,16,	22,24 10:6,12
clarifying	clots	23 144:5,11	11:7,13 12:16
94:11	123:4	147:8 150:13	13:12 14:11
clarity	coalesced	157:1 162:10	15:1 18:16,17
84:24	217:16	170:12 176:6	46:16 74:20
Clark	cobbled	177:13 178:22	130:8 131:14
153:18 159:7	54:20	179:14 180:8	139:5 140:12
161:14,17,18	cochairs	183:13 190:5,	155:17 165:15
162:12,15	160:23	8 191:13	198:3,17,21
163:12	cofounder	200:2 202:15	199:23 202:14
Clay	186:24	commented	217:11 219:14
180:10	colleagues	224:17	224:3,13
Clean	152:24 194:8,	comments	committee's
91:25	13	3:11 4:3	6:20 7:8
clear	college	7:11,22 9:14	committees
18:2 35:23	207:7	11:5,8 12:3,	9:15 10:22
39:25 42:1	colon	17,18,21	common
43:11 49:23	116:16 118:8,	80:23 89:4	79:17 89:18
55:4 59:19	18	109:21,25	144:22 172:2
185:16	column	111:20 130:7	commonly
clients	94:22	140:12 141:13	88:18 89:11
152:5,7,10,15	combine	150:15 151:4,	142:12
clinical	122:21 145:10	21 153:13	communicated
17:2 19:15,16	combined	155:17 161:12	190:3
94:23 104:17	191:21	163:10,15	communities
134:1,3	comfortable	164:4,10,15	175:7
192:19	24:22 83:19	171:12 177:20	community
clinicians	198:21	182:14 190:23	77:20 144:15
160:6 193:15	commenced	191:1 195:14	164:25 171:23
clinics	5:5 133:11	196:4 198:3,	172:7 193:8,
218:13	comment	20 199:16,25	16
close	7:17,24 8:7,	202:13,18	comorbidities
188:14	14 10:19,20,	208:11 224:4	80:2 153:3,6,
closely	21 11:4 64:1	commit	9 161:24
185:5	88:15 89:5	178:4	166:21 169:7,
closer	92:8 111:7	commitments	22 174:13
40:5	119:11 125:13	178:3	180:14 183:16
clot	131:1 140:9	committee	187:18,22
		3:17,23 4:1,	comorbidity
		19 5:23 6:8,	162:4 180:25
		22 7:6 9:4,	

203:15 204:25	complications	conducting	43:8 46:18
205:3,13	78:8 116:20	9:17	47:2,15,18
208:19,21	121:4,12	conferences	48:19 51:21
companies	154:8	152:17	52:16 53:2,7,
51:1 179:7	complicit	conforming	8,16,18 54:10
203:7	152:19	200:10	58:10 77:7,21
compassion	complimenting	confounding	78:13,18 79:3
178:11	184:25	188:7	83:6,17 84:7,
compelled	comply	confuse	14,19,25 89:7
171:16	214:10	68:2	99:23 100:2,8
compelling	components	confused	101:18 111:14
202:18 205:6	186:12,15	72:6 143:19	130:9 131:18
competent	compromise	144:2,8,17	132:16 133:8
163:2	178:11 213:20	146:22 150:19	135:20 136:18
competing	computer	confusions	137:2,6,12
217:12	213:6	147:2	138:6,13,19
competition	concept	Congratulations	139:14 140:13
142:25	43:24	130:13	149:10
complaints	concepts	conjunction	154:15,17,22
122:3 123:24	14:9	5:15	155:9,19,23
complete	concern	connection	157:7,11,17
188:10	209:3 214:2	188:14	158:1,3,7,18,
completed	concerned	cons	20 159:16,19
7:20 39:20	26:5 195:3,7	159:24	160:8 161:3,5
192:17,19	concerns	consensus	165:8,18
completely	14:20,23	46:16 47:1	166:8,11
45:13 216:5	187:14 207:15	185:16	167:13 169:3
completing	conclusion	217:10,13	170:6 171:9
6:16	10:18	consent	173:25 175:5
complex	condition	5:9,18 7:1,2	176:13,17,19
17:4 80:14	78:3 85:16	8:25 9:2	177:8,9
compliance	203:18	10:7,8,11,13,	179:15 180:1,
212:23 214:7	conditions	14 11:25	5,11 185:19,
complicated	169:8 203:13	12:2,21,22	24 186:15
111:3 217:8	conduct	13:1,16 15:3,	188:19,24
complication	7:15 189:10	7,13 16:14,19	189:8 190:9
117:24 146:5	conducted	19:3,8,15,17	191:9 192:2
	7:8 72:3	20:9,17 21:25	193:9,10,11,
		39:8,9,10	13 197:6
			198:20,22,24
			199:17,21,23
			200:3,5

204:23	consistently	continued	copy
206:10,15,20,	194:2	4:19 120:6	80:15
25 209:7	constantly	167:5	cordial
211:22,24	211:20	continuing	197:11
212:9,18	constitute	6:10 65:2	corral
213:23 216:23	201:16 223:19	101:17 147:3	89:3
221:25	constraints	161:3 167:21	correct
222:19,20	8:11 81:1	187:15 197:23	18:22,24
consents	construction	210:14	19:11 23:5
6:10,12 13:19	12:16	Continuity	36:9,10 38:23
14:10 35:12	constructive	26:1,4	43:1 57:13,15
60:14 95:19	12:10,19	continuous	81:16 84:4
100:1 160:16	141:22	178:5	85:4 86:18,21
164:5,11	consultation	control	94:14 99:9
190:19,23	160:21	47:10 155:11	103:21 110:17
198:8,9	contact	controlled	120:5 127:4
211:25 216:3	119:14	36:24 42:3	131:10,24
conservative	contagion	50:17 54:18	133:13 158:4
181:10	192:8	111:24 112:2,	203:21,24
consideration	contemplated	5,20,21 188:7	corrected
9:16 10:7	20:2	convene	190:10
11:6 81:2,25	context	9:21	corrupt
91:24 132:10	80:24 151:24	conversation	191:10
143:24 150:15	190:20 193:1	51:17 140:13	corrupted
153:14 155:18	210:12	143:23 171:17	190:15
161:12 168:17	continuation	172:19 218:1	cost
195:15 198:4,	14:21 20:13	conversations	179:9 188:13
7 201:25	continue	4:7	191:21 211:10
205:6 215:2	5:3 6:3,24	convey	costly
considered	18:6,7 23:8	19:6	166:4 188:3
141:14 164:18	81:22 100:12	cooperation	costs
180:1 212:19	126:23 132:25	141:21	155:7 201:7
218:20	133:3 155:19	copay	223:9
consistent	157:10,16	179:9	could/may/will
19:13 46:2	166:16 187:21	copied	114:19
55:13 92:11	189:22 195:15	129:22	counsel
93:11 103:12	202:20 215:7	copies	3:3,4 132:14
131:22	220:16 221:1,	128:15	138:25 158:15
138:10,17	5		212:3
190:6			

counsel's 51:9	covering 20:1,4 22:18, 19,23 23:23 25:7 26:18 27:5,6 28:2 29:9,13 32:23 33:3,17 79:12 135:25 136:7, 11	59:21 63:2,18 64:5,22 77:4	dance 182:6
counseling 5:12 167:5 183:21 210:14	covers 23:22 36:8 114:11	crux 151:18	Danehy-samitz 143:16,17 144:7 195:17
counselor 170:18	crazy 48:3,5 74:23 75:5,20	culmination 185:25	dangerous 172:12 177:4
counselors 171:2	create 116:14,17 118:8,18 120:9 166:9 168:24 197:6 201:16 213:15 223:19	cumbersome 186:15	Dania 9:8
count 177:20 188:10	created 165:23 177:25	curiosity 90:13	Danielle 3:1 126:1
counts 188:5,6	creating 167:15 178:8 206:25	curious 88:15 137:10	data 40:11,20 41:4 42:2,6 44:9, 12 50:18,19 54:9,23 64:12 78:21 87:5 106:3 162:7, 23 188:12 193:24 194:14,25 208:6
county 163:17 176:8 180:10	cried 176:10	current 26:13,16	date 5:6 6:24 146:23
couple 55:11 68:24 74:9,16 113:5 155:3 217:12	crisis 165:24	cutoff 196:6	Davis 165:11 170:17,18 171:8,14
courses 189:20	criteria 33:8 79:24 126:6,18 166:18 202:23 204:5	Cyproterone 88:7,20 108:2 111:10 142:20 143:6 148:25 149:1,6	day 152:5 156:9 196:3,8 198:1 215:25
court 3:25 77:17,24 187:11 189:15	cross 80:1	cysts 149:5	days 5:1 156:11 212:23
courts 77:10 161:6 182:4	cross-sex	<hr/> D <hr/>	de-
cover 22:24 24:1 27:7,23 34:10,11 179:7		D.C. 77:11	transitioning 159:25
coverage 26:24 27:4 28:2 161:9		dad 169:19	
covered 90:23		daily 118:2 216:2	
		Dalton 3:6	
		damage 121:19	
		damn 192:14	

dead 149:14	193:20 216:18	degree 192:17	demonstrates 206:5
deaf 184:7	decisions 151:14 152:21 176:24	dehumanization 186:1	Denehy-samitz 190:1 195:19, 23 196:5,9, 11,13
deal 14:13 17:15 84:2 215:25 216:1	deck 153:17 174:23	Dekker 187:12	denied 146:17 180:3
Dean 148:21 153:15,19,25	DECKER 205:19,23 206:5	delegated 13:14 19:25 165:20	density 66:24 67:5,7, 9,10,12,19 68:21,23 70:11,16 71:24 72:2,8, 12 73:8,9,11, 20 74:8 135:1,5,6 167:2 179:2,9 188:1,4,9,17 191:22 212:7 222:6
death 124:23,25	decline 163:5	delegating 167:12	department 9:12,25 156:8 159:12,15
deaths 162:24 163:1	decorum 191:12	delete 65:23	Depaul 165:12 172:24 174:21
debate 12:1	decrease 73:10 121:7, 11,14,20 122:8	deleted 134:2	depends 62:3
debias 189:20	decreased 187:25 188:16	deliberate 118:14 150:15 153:14 161:13 168:20	depressed 183:20
debilitating 185:10	decreasing 191:5	deliberated 188:20	depression 180:17 183:22,23 192:5 194:5 205:7,23,24 208:23
debunked 187:10,11	dedicated 29:9 165:17 192:20	deliberately 183:25	Derick 18:25 19:1,5, 18 20:5,16
decades 160:6 168:11 172:17 175:19	dedication 224:14	deliberation 130:11	
decide 44:16 64:23 79:8 100:23 145:12 175:13	deem 177:22	delighted 149:17	
decided 23:6 32:18 34:6 92:19 133:8 136:3 190:5 191:14	deemed 141:20	delve 187:15	
decision 5:22 32:20 133:18 154:6 166:13 186:7	deep 167:18	demanding 178:4	
	defending 189:14	Democrats 161:19	
	defer 52:11 153:20	demographics 10:9	
	define 28:10 217:7,8	demonstrated 180:18 204:22	

22:10 25:13	designated	deviating	111:22
26:1,4 28:9	26:23 27:3,5	195:9	112:11,18
29:2 32:17	28:2 29:11,12	devices	113:13,17
53:2 54:5	32:23 33:17	4:9	114:3,4
60:15,16,17	desirable	DEXA	115:18,19
61:3,9,13,17	28:13	66:13,15,19,	119:13,17
62:3,6,19	desire	20,22 67:4,6,	123:20
92:8,9,10,16,	93:11	12,20,24 73:8	124:14,19,20,
18,25 93:6	desistance	134:24 135:1,	21 125:3,7
100:10 101:3,	78:17 79:4,8,	3,4 157:2	126:20,24
4,9,12,16	23 80:3 192:9	158:23 168:5	127:1,6,8
102:6 103:3,7	desistence	191:20 215:24	129:23 130:2
108:24 117:12	78:19	218:22 219:8	132:5 135:8,9
127:10,11	desperately	Di	138:18 200:7,
129:1 134:8,	192:11	20:25 21:3,5,	9,24 201:11,
18 136:14,16	destroyed	16 22:1,12,25	19 202:8
143:11 199:16	175:21	23:10 24:3,8,	203:21,24
202:14,16	details	17 25:1,10	215:13,17,19
203:3,22,25	109:1 195:5	26:2,9,22	217:2 219:15
204:10,16	determinations	27:1,5,10,23	222:14 223:3,
206:16,18	134:1,4	29:1,12,18	12,21 224:6
208:16 209:2,	determine	32:4,21 33:7,	diabetes
7,12,20 211:2	190:7 198:18	24 43:15,21	181:5
212:11,16	develop	46:11 47:3,24	diagnoses
213:5,10,19,	13:15 61:4	48:13 50:7,	169:10,20
24 214:3	developed	11,20 52:24	186:17
218:4,8	6:1 171:10	56:24 57:1,2,	diagnosis
219:12	193:5	18,21,23	94:23 169:14
221:14,16	developing	58:2,10,13,22	187:18
Derick's	5:7 8:22	59:6,11,14	204:14,15
21:5	193:10	60:4 61:2	205:4
Derik	development	64:1 72:23	diagnostic
34:4,5,11	6:9 189:7	73:6,14,16	153:7 205:1,
Desantis	developmental	74:21,22	16 206:3
192:12 197:24	59:2	75:1,11,18,20	die
deserve	deviate	76:11,13	171:24
152:11 189:13	195:5,6	82:16 83:1,3,	Dierlam
designate		7,12 90:13,25	3:3 67:13,17
23:19 27:7		91:19 95:3	81:13,18
106:7		97:14 107:18,	83:24 98:25
		20 108:10	

117:18 120:3, 4 122:17 125:12,20,25 128:15,21 139:3 198:8, 15 199:18 200:12,19 201:5,15,24 220:18,24 222:25 223:7, 18 224:2	diminished 169:17 Diminishment 122:22 123:8, 12 124:1 direct 191:25 directly 171:19 191:9 201:6 223:8 director 3:1,2,12,15 15:24 31:9 93:10,14,20 94:6,10,14 112:7,12 126:2,10,16, 21,25 127:3 129:8,12,16 131:21 159:13 186:23 199:12 directors 3:11 disability 150:8 disappointed 198:1 disclaimer 47:1 disclosed 77:14 disclosing 77:19 disclosure 77:20 discontinue 10:21 discourse 7:9	discrimination 193:3 discriminatory 187:14 discuss 12:1 13:18 37:10 182:23 195:15 discussed 9:6 37:20,25 38:8 117:2 134:24 164:12 199:24 203:18,19 208:21 discusses 99:13 discussing 7:9 164:5 209:16 discussion 8:18 10:12, 14,16,18 14:23 18:17 20:9 25:12 63:25 77:6 85:1 89:13 108:3 111:13 114:7 132:17 177:1 185:23 199:22 211:21 discussions 198:19 disease 149:4,13,14 150:5 disfunction 124:2 disgusted	190:13 disingenuous 54:23 disjoint 196:23 dismissal 182:24 disowned 191:16 disowning 191:19 disparities 192:22 disproportionat ely 191:24 193:4 disrupt 7:14 141:19 disruptive 7:11,12 12:6 154:18 diverse 160:19 194:1 docs 160:19 doctor 25:19,20,21, 22 32:18 51:20 71:8 143:20 144:21 146:13 169:2 173:24 175:12 177:3,9 181:3 183:17 186:9 208:1,2 doctor's 149:25 169:4 doctoral
Dierlam's 222:24 Diet 38:3 difference 165:1 differences 64:10 differential 188:10 differently 30:13 difficult 24:15 90:17 116:19 170:24 digest 47:17 digested 17:9 digital 225:3 dignity 189:13 dihydrotestoste rone 143:1 diluting 186:2			

151:10	double	due	202:23,24
doctors	59:7	47:9,10 50:16	203:25 204:3,
13:14 14:8	dozen	151:24 154:14	4,5,13,21
23:7 33:2	191:2 193:24	duly	205:5,20,24
43:13 145:8	draft	3:16	222:3
146:10 175:9	132:12	duplicative	
196:22 211:23	drafted	127:2	<hr/> E <hr/>
document	194:23	duration	e.g.
41:16 45:3	drafting	7:12	128:6,10,21,
48:2 82:22	187:2	Dutch	22 188:21
83:20 117:13	Dragon	54:25 79:13,	earlier
documented	118:13	14 162:6,15	9:10,11 13:14
192:25	drive	duty	39:20 41:7
documents	75:5	193:18 211:12	64:14 82:17
77:22,25	drives	Duval	89:13 116:13
78:14,18 79:3	74:23 75:20	176:8	132:17
93:12	drops	dyspareunia	early
dogs	185:12	96:2,3	64:9,11 79:15
75:7	drove	dysphoria	116:18,22
DOH	197:14,15	8:24 9:3	199:24
15:25	drug	23:13,18,25	ears
donations	51:1 54:15	24:1,5,11,12,	48:8 184:8
192:12	88:10,19	13 25:2,20,21	easier
Donna	142:18,19,21,	40:25 46:1	84:5 138:12
3:3 20:6	22	47:9 50:15	easily
46:24 50:3	drugs	51:24 52:11	30:4
73:3 81:12	16:18 25:8	56:12 74:3	eat
104:4,5	63:18 68:22	79:18 84:16	171:3
125:11 132:21	71:4,10,11	100:4 111:16	echo
dose	139:25 140:1,	112:14 116:4	17:13 197:18
67:4 91:8	16 158:10	119:17 129:20	economics
doses	222:3,7	132:1,2 160:5	50:25 214:1
87:16 91:6	dryness	161:2 162:4	edits
105:9	95:16,18	166:19	112:25
dot	96:23 97:5,	167:21,22	education
96:16,22	11,19,22	169:13 177:6	185:3
119:25 120:1	113:6,19	179:16,17,19,	effect
122:8 123:10	dual	20,23 180:16	53:4 87:15
	192:17	181:23 185:10	
		187:19 192:8	

188:1,17 206:8	elucidate 188:14	189:16	enforcement 12:7
effective 4:23 5:6 6:24 156:8 184:6,7	Ema 148:24 150:17	encouraged 99:17	England 211:16
effectively 160:5 181:25	email 196:23,24	encouraging 65:7	English 160:10,11 172:25
effects 14:24 40:2,24 47:20 48:21 49:12,15 53:23 58:15, 18,20 59:4 99:15 109:17 124:23,24 139:23 149:12 151:23 154:8	embolism 114:10	end 34:24 35:12 60:5 64:15 120:1 154:13 160:10 166:9 169:11 215:9 224:20	enlarging 61:16,17,22
efficacy 191:4 194:20	emergency 5:1,18 6:1, 16,20 8:22 9:1,16,18,20 10:17 80:25 119:7 133:3 146:15,21 156:7 160:16 189:7 202:4 217:18 222:11	endanger 172:15	ensure 8:14 186:17 189:21
efforts 4:19 185:21	emotional 170:21	ended 154:15,18	ensuring 178:6
egregious 170:4 185:20	emphasize 141:18	Endochronologis ts 33:23	entertain 200:3 222:11
elaborate 187:22	employed 169:18	endocrine 14:16 29:20 30:23 89:12 90:5 102:9 180:21 181:9 182:7 191:17 207:9 212:5 218:23	entire 82:22 161:25 182:20 192:21
elected 8:12 10:2	employee 225:6	endocrinologist 150:1	entirety 189:18
electronic 4:9	employer 179:8	endocrinologist s 43:2 48:14 84:24 91:4 142:8	entity 16:7 201:7 223:9
element 53:13 193:12	empowered 176:11	endocrinology 30:6 207:6	environment 141:23 185:14
elements 28:22 77:24 78:12 112:10	emptying 122:20 123:1, 7,11	ends 77:17	equality 144:16 165:16,18,21
elevated 87:6,11	enable 193:19		equitable 8:8 151:14
eliminate 115:10 219:9	enacted 4:23 13:2		erase 170:1
	encourage		Erica 148:21 153:15 156:14,18 158:1,16,23 159:2

Erins 153:17 159:9, 10 160:15	159:16 187:20	exceeded 155:16	expand 185:2
error 125:24	evaluates 20:21	exceeds 167:7	expect 197:25 212:13,19
Esocough 170:14 174:23,25 175:3	evaluation 19:21 24:11 27:16,25 28:1,10,15,17 29:8 32:22 33:10,15,16 100:16 101:1 103:14,23 106:6 166:23 168:7 206:11 208:22 213:8	exception 131:23	expectation 7:8
essence 24:8 25:10, 14,22	evaluations 30:24 133:25 136:10 187:24	exceptional 182:17	expected 216:8
established 77:18 193:21 194:20	events 39:17 191:7	excess 201:8 223:10	expenses 187:23
establishing 170:4	eventually 35:3	exclude 181:14 186:16	expensive 187:19 189:2 215:21
establishment 8:23	everyone's 208:11	excluded 150:9	experience 24:22 95:15 110:20 143:25 144:20 151:22 152:20
estimated 161:8	evidence 184:5 195:10	excuse 187:10 215:22	experienced 24:5 173:17
estradiol 145:14,15,25	evolving 211:21	executed 137:3	experiences 140:14 149:23 197:20
estrogen 72:8 219:5 222:7	exact 41:13 97:17 182:3 199:1	executive 3:2,11,12,15 15:24 31:9 93:10,14,20 94:6,10,14 112:7,12 126:2,10,16, 21,25 127:3 129:8,12,16 131:21 199:12	experiencing 87:13
ethical 151:13	exam 146:3	exist 140:4	expertise 167:18
euphoria 177:5	examples 166:14	existed 172:17	experts 167:17 168:1
euphoric 204:20	exams 30:5 31:23	existence 184:12	expired 195:13
Europe 55:1 211:20	exceed 165:20	exists 188:3	explain 144:18
evaluate 20:19 21:9 64:19 104:15			explanation 43:20
evaluated			explicit 44:6 47:14,21

explore 170:22	197:5 204:5 205:13	57:3 60:10 66:7 70:22	213:5
exponentially 181:1	factors 128:2,3 188:7	76:16 83:13 98:11 99:2	feeling 176:11
express 9:14	192:25	106:14 107:21 113:24 115:20	feelings 4:16
extend 10:1	facts 53:4	120:22 122:13 123:15 124:15	Felix 170:14 176:2, 4,7
extended 7:25	failed 61:4 216:15	127:12 130:3 132:6 134:8,	fellow 14:11
extensive 42:2	fair 112:11 160:4	19 135:10 136:21	fellowship 192:20
extensively 187:11	212:2,12 218:7	200:13,15 201:1,12,20	female 71:18 75:5,6, 7,17,18 76:7, 21 93:1,2,18, 21 94:4,5,13 102:12 149:3, 19
extent 17:25	fall 26:7	202:9 221:16 222:15,21 223:4,14,23 224:9	females 72:1 149:19 219:4
external 60:20 61:13 171:21	falls 77:16 212:9	FDA 39:11 41:15 47:8 50:13,15 51:13,18 52:9 89:9 108:12 160:4	feminine 76:2,7,10,23, 25 93:2,15, 19,21,25 94:7
extra 68:22 188:13	false 36:17,22	fear 185:25	feminization 102:14 158:19
extreme 95:15	familiar 11:19	February 9:10	feminizing 14:1 74:2 84:8 100:3 143:3 220:19, 23
eyes 48:7,8 95:11	families 178:3	federal 77:8,10,24	Fenner 170:13 174:23 175:1
<hr/> F <hr/>	family 114:8 152:23 171:22 197:15	feed 62:8	Fenning 182:16 184:22,24
f-l-u-e-n-t 160:13	family's 172:3	feel 14:18 24:22 47:4 50:12 58:3 65:11 101:16 151:23 171:5,22,23, 24 195:19 209:20 211:11	
face 152:16	fantastic 216:14		
faces 11:19 190:13	fast 118:13		
fact 15:9 44:8 45:14 50:25 112:2 144:1 168:12 180:20	fatal 183:19		
	father 181:4		
	favor 36:3 38:24		

185:1	Finasteride	163:19	101:20 102:1
field	85:2,11 108:3	165:16,21	146:19 168:19
64:20 207:2	110:1 111:10	167:4 170:1	181:8 182:7
fiery	142:12 144:25	171:5 176:5	212:10 218:10
185:20	145:5,12,18	177:18 178:10	follow-up
fight	147:14,17	180:10 181:20	101:21
146:20	find	185:4 186:24	Folx
figure	69:11 114:4	187:2,3,5	156:21,23
26:12 44:18	173:3	193:2 196:14	157:13
196:22	fine	Floridian	forced
file	35:16 37:23	189:14,21	149:16
156:6	48:1 58:23	Floridians	forces
filed	63:23 76:11	161:8 165:24	171:21
156:7,9,12	91:19 93:2,3	171:7 182:9	foregoing
fill	94:11 163:12	flow	225:2
36:16 48:18	196:12 204:23	18:1,4 34:16	forfeiting
filled	206:7 209:13,	35:19 111:18	141:15
18:10,13,17	14 211:3	116:5 123:1	forget
36:12 144:1	216:5,10	132:16	73:3
150:7 214:5	222:9	flower	forgive
final	fingers	178:12	148:19 156:15
6:22 31:22	12:12	flows	forgot
195:16 201:24	finite	17:24	82:17
finalize	101:24	fluent	form
6:25 7:1	fit	160:12 199:10	13:1 15:7,16
finalized	80:17	fluid	16:19 17:23
165:22	fix	160:11,12	18:20,23
finally	49:17 221:20	199:9	19:1,8,15,17
10:25 98:19	flexibility	fly	20:12 21:25
160:25 179:25	30:21 34:8	27:10 216:23	41:14 44:18
finances	flexible	fog	46:21 49:11
178:4 179:11	34:12	173:19	51:21 52:16
financial	Florida	folks	53:7,8,16,18
178:1 179:5	3:15 4:13	9:14 119:16	54:10 55:16
215:11,14,23	6:6,7,17	141:6,18	58:14 65:14
financially	11:16 109:9	164:18 177:25	73:5,22,25
215:4 225:8	140:2 143:19	186:16 217:14	74:1,6,7
	144:16,17	follow	84:16,25 85:3
	156:20 159:12	14:5 28:12	88:12,21 89:7
	160:22,24,25		

90:8,9 91:15	forms	193:10	3:13
95:9 99:6,9,	5:18 7:1,2	198:20,22,24	friendly
21,23 100:2,	9:1 10:7,8,	220:19,20	81:21
5,9 101:18	10,11,13,15	222:19,20	friends
107:25 108:1	11:25 12:2,	forum	152:23
109:6,10	21,22 13:16	149:25	front
110:8,11,17,	15:13,22	forward	16:6 81:20
22,24 111:2,	16:15 17:24	95:14 148:25	frownly
15,21 112:25	18:1,3 34:17	149:9,22	220:9
114:21 116:1,	36:9 39:8,9,	152:14 199:1	fucked
2,3,6 125:9	10 47:15,19	found	174:18
126:5 129:9,	53:3 55:21,25	100:2 111:15	fulfil
24 131:19	57:10,11,13	116:3 163:7	178:2
137:3,5,6,7,	65:25 66:13,	194:9,16	full
12,14,24	16,18 68:6	foundational	26:19 114:7
140:1,4,5	70:14 71:1	171:5	161:2 165:17
142:6 154:17,	72:23,25	founder/vice	183:2 196:21
22 155:9	76:20 77:3,7,	196:13	197:14 216:19
157:7 158:1,	25 78:6,10	fourth	Fullove
18,20,24	83:6,17	142:11,17	3:4
159:18 160:2	84:18,21	Fox	fully
165:8 166:8	89:13 90:1,2,	173:9	160:8
173:25	25 92:18	fracture	function
176:13,17	100:7 111:18,	219:2	121:8,14,20
177:8 179:15	19 129:19,21	framework	122:6,9,10,
188:17,24	130:9 133:8	9:19	22,23 123:8,
191:9 196:24	135:20 137:17	free	13,22 124:1
197:6 199:17,	138:6,15	189:11	functioning
21,24 200:3,6	140:13 144:2	freedom	40:12 42:8
207:1	154:15	152:6,7	46:5 52:2
formal	155:19,23	176:23	56:14
161:5	158:18 159:1,	frequency	<hr/>
format	16 165:19,22	34:6 100:19	G
49:4	166:1,11	168:5 210:20,	<hr/>
formation	167:10,17,25	24 214:18	Galindo-jackson
188:15,16	168:24 169:4	frequently	148:21
formed	170:6 171:10	34:7 105:8	150:18,22,25
185:15	177:10 179:25	Friday	151:8,9
forming	180:2,6,11	gap	
9:16	185:19 186:16		
	188:19 189:8		
	190:9 192:2		

218:5	180:16 181:23	86:23 192:11	156:12 159:9
gatekeeping	182:24 183:3,	gist	160:14 161:17
218:14	5,14,15	163:13	165:14 168:21
gauge	184:1,4,10	give	170:17 176:4
188:3	185:6,10,12,	10:3 30:21	192:16 210:3
gave	13,16 187:9,	36:15 45:17	214:3 217:1,
20:8	19 189:9,21	47:16 48:25	13 218:19
gay	191:6 192:8	63:15 64:19	Google
79:20	194:2,11,17,	74:10 81:1	173:3
gel	20,24 202:23,	86:3,19 91:24	government
90:14,24	24 203:25	145:12 146:21	175:6 176:23
91:16,17	204:3,4,5,12,	159:18 164:8	201:8 223:10
gender	20,21 205:4,	172:20 183:20	governmental
8:24 9:3	20,23 206:8	209:7 211:23	191:11
23:13,18,24,	222:2	giving	governor
25 24:1,5,11,	general	30:12	4:21 150:3
12,13 25:2,20	16:19 64:7	glad	governor-
40:25 42:5	77:8 148:14	11:21	appointed
45:21,25 46:1	187:7 204:6	glioblastoma	177:2
47:9 50:15	217:13	183:18	graduated
51:11,24	General's	goal	170:22
52:10 56:11	16:3 81:10,23	152:1 179:22	grammar
74:3 79:9,17	generally	goals	129:2 130:11
80:1 84:16	27:12 72:19	6:21	granddaughter
100:4 111:16	Genital	God	169:19
112:14 116:4	117:15	106:3 198:1	grandfathered
119:17 129:20	genitalia	good	207:23
132:1,2 133:2	61:14	3:12 11:22	granted
149:2 154:4,6	genocide	12:16 14:13,	141:7 174:10
156:21 160:5,	178:9	19 19:11 20:6	granular
7,19 161:2	genuinely	24:3 27:2	96:6
162:4 163:25	175:14	40:8 41:5	grateful
166:19	Georgia	50:4 51:6	10:25
167:18,21,22	176:5	59:9 65:10	great
169:5,13	get all	70:13 72:20	12:23 78:13
174:11,16	211:24	82:2 99:16	98:22 108:25
176:9 177:5,	girl	112:23 113:7	197:2 213:19
6,9 178:21	75:9,24 174:8	116:20 118:12	greatly
179:1,15,17,	girls	138:16 145:16	
18,20,23		151:16 155:23	

169:17	guys'	happy	186:17,22
group	164:21	14:22 119:18	191:4 192:18,
8:2,4 23:9	gynecologist	171:11 211:6	21 193:16
52:11 71:25	150:1	hard	194:3,9 195:2
79:17 175:21,		26:2 128:15	203:13,17
22 203:5	<hr/> H <hr/>	152:3 173:4	206:24
216:18 217:16	Hackmeyer	197:11 218:17	208:18,21
219:7	182:17 184:22	harm	210:9 211:4
group's	186:21,22	151:18,19	215:14 216:4
141:21	hair	152:4 184:17	healthcare
groups	85:20 86:1,	harmed	133:11 139:12
22:8	11,19,24	175:25	169:23 185:7
Grow	142:13 196:17	harmful	186:9 187:5
192:14	half	176:15	193:14
growth	15:23 82:11	harp	210:15,20
85:20 86:1,11	halfway	32:25	hear
guardian	47:7 195:17	Harris	71:7 74:14
5:10 52:13	hand	159:8 165:14,	85:10 109:20
83:25	89:3 162:7	15	111:9 162:22
guess	177:22	hate	171:4,11
15:14 45:25	handle	197:7	210:1,2
62:3 81:13	212:4	HCP	211:9,10
90:22 111:23	hands	163:23	heard
117:19 143:21	90:19	head	11:24 172:18
149:20	handwriting	197:22,23	184:16 200:1
156:24,25	184:25	header	209:4,16
guidelines	happen	58:8	hearing
7:21 29:21	29:22 115:9	health	9:20 33:11
30:23 69:10	118:25 140:2	9:25 115:7,8,	88:2 99:22
102:9 181:9,	172:25 210:17	14 153:10	116:2 171:9
10 211:18	211:5 216:16	156:21	175:4 176:17
212:6 218:23	happened	159:12,15	217:10,11
guy	39:18 77:12	167:3,6	heart
23:21,22	129:17	169:10,19	144:15 149:14
77:13,15 79:1	happening	172:16 178:19	heavy
guys	96:7	179:3,8	13:17
11:21 16:12	happier	180:14	heels
17:3 69:1	173:4	181:14,20	186:21
97:16 151:1		183:17 185:3	height
			29:24 31:20

held 5:24	Hilt 177:15 178:15 180:9	hoops 185:20	189:13 196:23
helped 150:4	hinder 172:13	hope 145:3 151:12 154:21	humanity 186:3
helpful 12:13 13:1 47:22 58:9 133:22 182:14 198:3	hinderances 172:15	hormonal 37:16	hurdles 175:4 177:25 185:20 189:3
helping 141:22	Hippocratic 151:11 152:12 182:8 184:19	hormone 126:23 154:4 157:4 158:18 180:2 185:8 206:9 217:15	hurt 181:7 182:11
hematocrit 219:1	historically 78:19	hormones 59:21 63:2,19 64:6,22 68:14,19 77:4 173:14	hyphenated 95:3
hematopoiesis 188:14	history 114:8	horrified 183:12	<hr/> I <hr/>
hemoglobin 218:25	hit 77:25	hospital 138:19 216:1	i.e. 128:5,9,21,22 188:21
hesitate 25:18	HIV/AIDS 159:13	hospitalization s 169:13	idea 50:7 51:22 212:16
Hey 34:13 182:13	hold 72:24 103:19 109:20 128:16 147:5 155:15 176:13 184:19	hours 130:13 178:4 197:14,15	ideas 217:12
hide 192:11 197:24	holders 10:3	HRT 166:16 169:24 187:15,21 188:2,17 202:21 220:16 221:2,5	ideation 39:21 180:18
Hierarch 171:3	holds 11:3	hug 90:19	identical 39:10
high 40:2 87:16	holes 17:14	huge 55:1	identification 80:1
high-quality 194:18	honest 175:3 210:10	human 94:13 147:3	identified 47:25 219:12
higher 71:25 163:8 194:5	honestly 174:18		identify 8:3,6
highlight 44:8 193:7	honesty 190:13		ill 161:25
highlighted 74:9,16 113:5	hoods 164:23		illegal 108:9
highly 181:8 189:6			illustrates

40:10	importance	inapparent	incorporates
Imagine	11:3	184:2	133:7
183:17	important	inappropriate	incorrect
imagined	4:1 26:5	205:10	165:19
191:11	40:16 49:19	include	increase
Imaoka	59:24 77:3	31:14 39:23	115:7,8,14
148:22 153:16	79:12,13,22	46:17 51:20	129:20 163:3
156:18 158:1,	82:21 92:22	55:15 80:14	181:1 194:10
16,21,23	99:18 112:8	87:22 100:12	201:6 223:8
159:2	151:23 155:9	113:20 166:1	increase/will
immediately	210:11 214:2	180:1 192:5	114:19
157:4	218:9	202:1	increased
impact	importantly	included	162:19 180:17
84:18 179:6	185:9	55:19 158:24	increases
185:6 192:25	impose	173:10 192:3	97:6 191:22
193:4 200:22	166:4 179:5	210:13 212:17	increasingly
203:14 215:4,	224:3	includes	89:18
11,14 223:1	impossible	8:25 49:12	incredibly
impacted	174:10 178:8	58:15 157:9	198:3
176:21	impressive	179:1	independently
impacting	9:13	including	15:8 16:8
192:22	improve	10:2 78:11	indeterminate
impartiality	95:22	124:23,25	40:1
193:23	improvement	185:7 188:11	indication
impeccable	40:12 46:4	192:25 201:7	10:4
184:25	173:22	223:9	indirectly
impede	improvements	inclusive	201:6 223:8
187:18	42:7 52:1	185:3	indiscernible
imperative	56:13 173:11,	incomes	31:14 32:12
140:4	17	194:9	99:24 145:7,
implement	improving	incongruence	20,21,23
6:5 172:13	191:4	42:6 45:21	146:4,6
implementation	in-person	51:11	190:15 194:1,
201:9 223:11	32:22	inconsistencies	13 203:9
implications	inaccuracies	167:20	individual
195:8	167:19	inconsistency	7:14 8:3
implying	inadequate	17:17	162:3 213:1
37:8	116:24,25	incorporate	221:5
	117:6,25	22:16 42:15	

individualized 166:5	informational 166:16	initial 73:22,25 82:23,25 106:8 148:12 158:2 179:21	insulates 172:4
individuals 72:2 151:22 152:20 160:19 166:15 178:6 220:15 221:1	informed 5:9,18 6:10, 12,25 7:1 8:25 9:2 10:7 13:16,19 14:10 19:3 20:8,17 43:8 47:2 84:18 100:8 111:14 130:9 131:18 132:16 133:7 136:18 137:2, 12 138:6,13 139:14 157:11,17 158:2 159:19 160:8 161:3 164:5,11 166:8,11 167:13 169:3 170:6 171:9 173:25 175:5, 10 179:15 180:5,11 185:18,23 186:15 188:19 190:9,18,23 192:2 193:9, 11,13,20 198:7,9 206:10,20 211:22,24 212:18 216:23 221:25	initially 64:8 79:16 105:2,4 106:5 107:11	insurance 26:10 179:6,8 203:7
indoctrination 186:4		initials 82:18,22	intended 10:8 150:20
induced 105:7		initiation 123:2	intent 61:9 208:4
induction 91:3 103:17 104:25 105:13 168:8 214:21		injectable 89:16	intention 6:15
inequities 192:22		injected 91:11	intentionally 46:19
infected 175:24		injection 90:24 145:17	interaction 11:4
infection 96:18 98:4,7, 18,20 121:19 124:25 125:4		injunctions 186:10	intercourse 95:16 96:15, 25 97:13,14 98:3,8,20,21
infections 96:4,25 97:10,12		input 11:22 12:10 167:17 168:1	interest 55:5 187:16 195:24
influence 79:22		inserted 175:5	interested 7:23 8:1,4 85:10 88:2 225:8
inform 5:19 166:12 211:12 212:13		insight 36:21	interesting 148:14 203:16
information 3:6 14:15 43:7 49:11 58:13 77:19 159:20,24 163:22 164:8 165:20 193:19	inherently 177:4	Institutional 159:15	interests 95:24
	inheriting 105:21,23	instruct 12:7	interfere 153:7 205:4, 14 206:2
		instructions 3:22	interferes 205:1
		insufficient 117:7,8 118:3,16 120:8 165:25	interim 6:14
			internal

60:20 171:21	ironic	163:12	225:13
interpretation	190:15	jeering	jump
158:14	irrelevant	12:5,11	185:21
interpreter	65:12	Jessica	June
160:10	irreversible	161:15 165:10	3:13 5:24
interrupt	58:4,18,21,23	168:21,22	6:14,20 7:5
190:7	60:3,4	job	9:21
interruption	issue	12:14 13:3	jurisdiction
172:11	4:13 11:3	21:23 119:14	157:23,24
intersex	20:14 51:3,	170:9,21	Justice
149:21	13,15 109:21	171:1 208:6	186:24
intervene	113:6 120:13,	jobs	justifies
64:14	14,15 181:14	178:3	152:1
intervention	201:24 207:20	John	<hr/>
52:10 54:17	210:5 217:11	159:8 161:14	K
interventions	224:14	165:14,15	<hr/>
39:15 193:6	issued	joint	Katelyn
introduce	28:23	3:16 4:19	190:1 195:17,
14:9	issues	5:23 6:21 7:3	19,23 196:5,
introduced	4:16 7:10 9:6	9:21,24	9,11,13
189:4	71:24 109:23	131:14 165:14	Katie
introducing	140:23 141:12	Jones	143:16,17
43:24	174:17	20:17,18	144:7
invasive	180:10,12	Jorgensen	keeping
188:3	199:4 202:19	183:7	131:15
invite	itchy	Journal	key
119:15,18	48:7	173:5	61:19
invited	item	journals	kid
119:19	66:12 179:14	194:19	54:14 137:14
involved	items	journey	174:11
16:16,17 78:8	141:14 217:21	217:19	kid's
181:3	<hr/>	joy	110:17,22,23
involving	J	176:10	111:2
112:14	JAMA	judgement	kids
IRB	194:8,25	53:13	39:18 49:22,
49:22 137:7	James	Julie	24 69:18
159:16	153:18 159:7	178:15	79:25 85:3
	161:14,17,18	182:16,19	90:17 92:21
	162:12,15		101:8 110:10,

21 147:24	184:22 189:25	68:8 70:15	5,23,25
164:20 169:25	190:2,17,20,	80:7 81:6,7,	118:3,15
171:4 172:8	24 191:2	9,15,24 96:11	167:8 185:16
173:3 207:21	197:18	97:17 101:15	learn
218:18	knew	103:11 104:14	116:12
kill	79:16 174:8,9	106:19 113:20	leave
164:20 171:25	knowledge	118:11 120:1	19:24 20:19
killling	175:20 182:22	135:19	21:11 34:15
80:19 164:18	203:4 206:6	136:15,17	51:5 91:21,22
kind	208:5	137:9 160:9	92:6,7 112:3
14:17 15:13	kosher	173:11 174:20	141:21 147:5
22:14 30:5,15	118:24	182:3 198:24	153:22 170:2
39:7 50:13	<hr/>	206:22 221:20	182:11 213:13
52:10 53:8	L	large	leaving
59:10 65:11,	<hr/>	203:4 218:12	112:18 168:13
12 81:13	lab	larger	170:2 209:6
111:18 140:22	167:1	8:2 193:1	216:5
146:3 151:21	laboratory	largest	led
175:23	206:23 210:7	165:16	95:16
180:14,25	212:7	Latin	left
202:18 204:7	lack	128:25 129:6	36:20 108:18
207:1 217:22	47:9,10	130:11	171:7 176:22
kinds	50:17,18	law	legal
44:12	182:22 194:4	4:22,23 5:6,	3:4 5:10
Kirsh	218:10	17 6:24 12:7	83:25 158:14
17:13,20,21	laid	77:8 170:4,8	195:8
24:16,18,21	177:23	192:18	legally
37:7 38:13,14	laminectomy	laws	23:3 77:7
50:20 66:5,6	77:13	152:13 183:10	legislation
70:20 71:14,	landed	lawsuit	154:15 186:12
17 76:14,15	130:12	167:8	legislative
80:22 81:5,9	language	lawyers	5:23
91:23 95:10	8:25 32:11	42:19 44:19	legislators'
106:12,13	36:8 37:3	98:23 104:21	168:23,25
107:17,19	39:13 44:17,	129:5 208:20	legislature
135:10 204:14	21 46:17,18	LCSWS	12:23 83:22
215:2,16,18	50:2,5 51:8	181:22	165:23 166:3,
216:16 217:7	54:6,8 55:8,	lead	10 168:14
220:17	11,23 56:1,21	96:4,24 97:3,	187:2
Kit	62:16 66:1		

length 66:14 80:17	life-long 56:19	108:25 182:20	50:18 52:7
letter 31:14	lifechanging 183:3	lists 47:19 80:20	58:17 102:17, 21 131:6 188:18 211:8
letters 9:13 203:7	lifelong 46:9	literally 54:13	long-term 39:14 42:2 48:21 49:14 50:17,19 54:18 64:11, 13 107:3
level 170:19 171:6, 19,20	lifesaving 172:4,7,14 175:18 185:9 189:3 197:8	literature 79:6 87:2,18 178:20	longer 12:13 40:14 161:22 179:19
levels 85:22 145:18	lifting 13:17	live 159:10 169:24 171:3 176:8 220:4	looked 15:22 16:11 17:7 87:3,17 95:19 220:9
LGBT 185:3	lightly 173:13	liver 89:14	loosen 213:3 215:9
LGBTQ 165:18 186:6	limit 30:15 71:18	lives 170:21 172:15 183:4 186:6, 10	looser 215:1
Library 164:17	limited 7:23 40:11 41:4 42:6 46:3 51:11,25 54:9 56:12 71:1 87:5	livid 176:12	lose 181:16 218:9
licensed 5:13,15 109:9 160:6 166:25 167:4,6 210:15	limiting 24:23 175:17	living 119:3 176:16, 20 207:11	losing 161:9
lie 192:8	limonite 192:7	LMHCS 181:21	loss 142:13
lied 190:9	lines 29:15 47:14	lobby 11:19	lot 10:11 11:19, 23 13:16 16:14 17:2 27:17 30:25 39:14 40:3 47:17 49:20 54:19 64:13, 20 78:20 84:5 89:13,14 137:6 154:19, 23 159:16 173:1 177:19
lies 164:24 174:1 192:7	link 50:22	located 7:18	
lieu 143:24	list 52:15 121:6 213:17	logically 13:19	
life 52:6 77:17 102:3,5 146:7 147:3,24 154:9,19 161:25 169:11,23 176:16,20	listed 180:20	logistics 26:6	
	listen 197:21	Lola 174:24 176:2 177:14,16	
	listening	long 47:18,19	

181:22,23 202:17 207:9 209:3 211:11 214:6 218:24	main 86:15 178:22	220:5,9 221:21,24	mandate 210:3
love 186:7	maintain 141:22	makes 12:13,14 14:4 30:25 32:6 42:1 46:17 75:16 82:4,24 84:5 196:18 220:6	mandated 6:16 11:24 12:19,20,24 137:6 168:24 170:10 197:4, 6 209:24
low 67:4 72:2 78:20 145:19 188:21 219:2, 7	major 106:25 116:20 154:7 172:11 185:15 215:3	making 7:11 26:6 35:24 55:2 58:7 136:17 152:21 183:15 197:7 213:10	mandating 210:21
lower 71:24 85:21, 22 91:7	majority 64:25 194:16	male 75:5,6,7,17 76:7,20 87:12 91:4 92:24 93:1,2,4,8, 18,21 94:2,3, 5,12,22,24 102:12 142:13 149:7	mandatory 19:10 166:23, 24 167:1,2,3, 5
Lucina 170:13 174:23	make 5:21 8:13 11:8 15:4 18:2 20:7 26:2,13 27:17 31:13 32:19 35:2,17 39:25 48:15 49:23 55:4,9,14 56:1 64:1 74:16 80:22 81:21,24 93:23 103:10 107:2 108:21 111:2 115:9, 15 119:4 129:23 133:14 137:7 139:25 141:16 144:6, 10 149:21 152:5 153:5 159:17 162:10,12 164:14 165:4 166:13 175:10 181:7 182:10 193:19 198:19 199:14,23 212:21 213:11 214:7,8,9 215:1 217:9	males 71:22 79:16 219:2	marijuana 138:14
Lupron 71:20 72:17		man 75:8,23 76:5 92:13 93:1,3, 16 94:7 95:4 154:2 161:21 174:6 196:18	marked 166:19 179:16,19 203:25
lying 174:1		managed 153:9	Martinez 184:23 189:25 192:15,16,17 195:12
lyingly 191:5		management 162:3	masculine 76:2,6,9,22, 24 92:14,16 93:1,15,19, 21,24 94:7
<hr/> M <hr/>		Manatee 156:15 159:7 163:17	masculinificati on 196:17
made 6:9 27:21 74:4 78:16 84:20 92:18 100:6 111:18 116:5 148:13 183:4 187:7 189:9 190:21 204:1 216:18			masculinization 85:1 86:1 158:19
Madison 177:14 178:15 180:9			masculinizing 14:2 84:15 126:4,11,13 129:13 132:1,
magic 193:7			

4 142:19,21 220:19,22	39:4 40:22 41:3,9,18,21, 24 42:24 43:4,12,19 48:17,23 49:6,9 50:9 53:17 57:12 58:5 63:13, 20,23 65:15, 19,22 66:11, 20,25 68:6 69:15,23 71:7 72:21 73:15, 19 74:12 83:23 84:4 91:22 92:5,17 96:19,21 97:3,16,20 98:12,15,17 99:7 103:25 104:8,11 114:13,15,16, 24 115:2,6, 12,24 116:1 117:5,8 118:10,15 121:13 125:18,22 126:15 128:17 132:18,19 133:5,13,17, 19,21 134:12, 23 135:4,7, 14,21,24 137:16 138:5 156:5 158:6, 10,25 199:3,6	meaningful 13:7	medications 45:7 47:6,8 50:14 51:3 59:4 60:18 74:2 84:8,15 100:3,18 101:23 105:23 109:3 132:2 149:23 159:20,21 204:12 211:8 214:9 218:16
Maslow's 171:3		means 44:2	
mass 95:24		meant 18:9 222:19	
massive 170:8		measure 188:8	
master's 192:18		measurements 31:21	
maternity 19:24 20:19 21:11		Medicaid 161:7	
math 163:2		medical 37:12 40:18 42:4 45:20,24 46:8,9 51:10, 19,23 52:5,7 56:9,17,19 57:5 138:6,14 145:23 159:12 161:1 162:2, 17 166:25 169:16 171:2 172:6,14 173:5 175:15 177:1 178:19 185:15 195:9 207:7	medicine 3:1,2,15,17, 18 4:10,11, 24,25 6:18,19 7:4 8:20,21 11:16 18:8 112:14 145:1, 11 146:21,25 164:17 169:9 176:25 181:3 187:4 189:1, 19 214:3
Matt 43:23 110:11		medically 154:24 183:10	
matter 174:13 177:21 180:20 225:4		medication 20:7,10 26:8 53:5 59:3 100:24 103:4 105:12 132:25 149:6 160:3 161:4 167:23 176:25 194:10 204:9	medicines 105:7 144:20
matters 3:24 174:15			meet 33:7 157:13 173:14 204:5
Maurer 159:8 161:15 165:6,9,14,15			meeting 3:17,19,22,25 4:5,6 5:24 6:14,22 7:3, 7,13,15,19 8:11,20 9:21 10:19,23 11:18 12:6,13 13:13 14:16 95:14 131:14 140:9 141:24 150:24 151:20
Max 182:16 184:22,24 185:1 186:20			
McNulty 3:3 17:18,22 18:11,22,24 19:4,10 20:3, 11 21:18 27:3 29:16 31:2,7 32:2,15 33:9, 14 34:15 35:7,13,18,22 36:7 38:19,23	MD/PHD 160:22		
	meaning 128:9		

156:6 167:20	203:13,17	82:17 114:9	167:10 171:16
190:14 192:5	206:24	125:6,7	185:19
215:7 224:19	208:18,21	200:19	minutes
meetings	210:9,15	mineral	7:24 131:15
9:7 11:2	211:4	72:1 188:4	141:8 155:15
152:17 169:10	mention	212:7	173:2 195:25
224:17	82:17 89:17	minimum	197:17
meets	173:16 216:15	19:9 29:14	mirrors
202:22	mentioned	minor	164:22
member	65:12 78:17	18:6 36:9	misinformation
189:16 192:13	88:8 144:25	55:12,13,24	163:20 167:11
members	151:21 153:3	58:25 75:22	misleading
3:23 4:14 9:4	155:4,5 162:6	83:4 84:16	165:19
10:1,25 11:7	171:15 172:19	86:25 87:2	misquoting
13:12 14:12	mercy	90:1 93:23	182:21
15:1 74:19	152:8	99:15 147:17	mission
81:20 130:8	merged	148:2 198:24	4:12
139:5 140:11	15:13,15,25	199:19,20,21,	Missouri
159:9 161:17	16:1,5,7	22 201:16	182:4
189:8,18	method	223:19	misstate
200:20 202:14	152:6	minor's	142:8
224:15	methods	60:18,19 73:9	mistake
men	188:3 192:19	minorities	27:21
71:19 72:6,16	Miami	192:23	misunderstandin
79:20 86:17	119:14 160:23	minors	g
Mench	mic	6:10,23 7:1	205:12 208:25
178:15	17:12 40:5	8:24 13:25	misuse
182:16,19	74:13	34:1,17,18,	141:18
menstruation	microphone	19,20 38:22	mixed
155:11	141:7 144:11	40:25 43:8	45:15
mental	148:18 159:8	47:9 50:15	model
153:10 159:22	middle	55:17 56:10	193:11,14
167:3,6	43:1 50:8	60:8 70:3,9	modification
169:10,19	190:8	73:7 84:9	38:5 78:15
174:17 178:19	Millions	85:14,17	modifications
179:3 180:13	184:6	126:11,14,22	74:3,6 99:21
181:14,20	mind	129:13	111:20 116:7
183:16,21	50:21 55:10	132:13,25	139:1,22
186:17 191:4	58:5 72:22	133:1,6,10	
194:3,9		135:22 161:4	

modified 6:19 59:16 135:18,19	months 19:22 20:18 21:10 24:12 27:1 28:3,19, 20 29:13,22, 23 30:21 31:1,2,3,6,8, 11,13,15 32:1,3,5,16, 17,18,24 33:11,13,21 39:16 59:1 100:16,17,25 101:11,12,24 102:5,11,18 103:16,24 104:16 105:12 106:7 107:5, 11 112:21 136:3 146:2 166:24 167:1, 2 183:21 185:25 206:12 209:17,18 214:20,25	109:12,19 110:3 111:6, 23 113:22,23 115:10,13,17 118:21 120:20,21 121:23 122:2, 8 123:23 124:2 129:22 148:6,8 199:9 204:7,11,15 210:19 212:2, 12 213:13,22 223:13	136:17 168:4 198:22 200:3, 9,15,18 220:10 221:12 222:11,21
modify 101:15 104:13 139:25 217:14			motions 59:14 70:3,7 221:24
modifying 101:24			motivated 187:13
mom 168:22			move 34:23 38:15 60:1 67:10 84:14 99:22 111:14 131:16 134:6,17 138:22 161:22 198:6 199:1 200:5,24 201:10,18 202:6 223:12, 21 224:6
moment 149:14 176:14			moved 38:11 66:2 222:13
money 179:13 189:14		mother 90:19	moving 55:5 152:14 202:13
mongering 185:25		motion 34:21,22 35:2,4,5,17, 24 38:9 39:2 55:8,10,14 56:1,20,23 57:6 59:25 60:2,10,13 66:3,10 70:8, 10,14,19,25 71:2 76:12,19 82:25 83:11, 16 98:9 99:1, 5 103:10 106:10,17 107:14,24 113:10,20,21 114:2 115:16, 23 120:1,18, 25 122:7,16 123:9,14 124:10 127:4, 6,8 129:23 130:1,6 134:7 135:8,9,13	multi-module 181:12
Monica 89:23,24 118:20 122:1 165:12 172:24 174:21	morning 81:16		multi-physician 22:8
monitor 99:15 102:13, 15 104:17 218:24	Mortensen 13:15,16 14:6,9,13 15:7 16:7 36:19 37:1,4 65:1,5,11 69:2,8 85:4,8 86:9 87:1,8, 11,21 89:25 90:4,11 91:2, 8 103:17 104:23 105:2, 6,16 106:1 108:18		multiple 11:2 16:17 36:15,16,18 63:3 166:2,14 180:19 205:18 224:17,18
monitored 107:2			muscle 95:24
monitoring 73:8 219:4			
Montanez 144:13 146:25 147:15,18,20 148:3,5			
month 9:11 13:14 25:20,21 28:24 31:12 154:13 203:12			

<hr/> N <hr/>	negative 183:13	nonbinary 163:24 177:17	17:24 21:1 28:16 48:20, 25 49:9 52:14 57:24 58:12 63:9 65:16 66:12 70:15 74:25 101:2 103:22 104:1, 7,8,10,13 106:6,20 126:6 127:7 134:12 178:23 180:13 181:17 195:4 202:22 203:16 204:24 206:5,8,11,13 209:9,11,25 210:14 213:4, 7 220:10
names 145:9 148:19	negatively 203:14	nonprofit 185:2	numbers 126:4 180:12 212:25 219:13,18 220:2
naming 131:18	nerve 121:19	nonspecific 47:20	nurse 145:2 146:8, 12,13,16 148:11 156:20 169:2 207:20
natal 79:16	nervous 214:8	nontreatment 78:11	nurses 157:10,15,24
Natalya 177:15 178:15	Netherlands 64:12	normal 151:3 206:7 209:13	Nursing 157:24
National 164:17	Network 160:22 186:25	Northeast 176:5	<hr/> O <hr/>
nature 5:20 8:10 53:8 54:22 78:3,15 166:12,17	newer 89:15	noted 172:12 212:3	oath 151:11 152:12 182:8 184:19
nausea 48:8	newest 207:2	notes 74:19 75:21 197:2 199:4 218:1	obligated 220:6
Nazis 165:1	newly 101:22 103:4 211:14	Nothing's 85:6,7	
necessarily 18:4 51:12 94:13 190:21 209:23	News 173:9	notice 63:16	
necessitate 118:1,4,17 120:8	NHS 211:16	noticed 3:16 173:6,10 179:25	
necessitated 186:13	nice 11:16 128:23	noun 75:12	
necessity 216:21	night 27:10 149:11	November 9:9 191:18	
needed 14:18 69:8,9, 21 159:5 207:22 211:6	nods 22:17 33:22	nuanced 204:16	
needlessly 172:13	non-doctors 72:21	nuances 12:1	
	non-endocrinologist 86:8	nuclear 67:2	
	non-maleficence 151:16	number 8:1 9:6,13	
	non-signature 82:19,20		

obligations 112:16	7,8,11,12,13 50:24 51:3,4, 13 52:9 160:3	operatively 157:5	optional 83:4 220:7
observation 57:19 59:24 84:23	offense 201:16 223:19	opiate 112:5	options 17:19 36:13, 20 37:10,20, 25 38:1,3,7 56:8 170:23
observations 57:16 65:13 74:6,20 84:19 99:21 100:7 112:24 116:7 121:1 129:4 130:7 132:15 139:21 140:11 168:19 171:12 221:24	offer 143:23 190:18,25	opinion 9:14 29:1 184:12 188:21 210:2	oral 89:8,10,17 91:13 140:15 142:6 156:22
obstacle 185:20	offering 155:17	opinions 188:23	Orchiectomy 117:16
obtain 5:9	office 10:2 16:1,2,3 81:10,23 149:25	opportunity 4:18 8:15 81:20 141:8 146:14 147:23 157:9 161:10 162:11 176:6 216:13	order 5:21 13:25 14:5 26:7 35:6,9,10 131:14 139:13 141:15,17,20 152:1 155:13 161:23 163:10 165:2 166:13 174:19,21 187:21
obtaining 167:13	officer 3:7	opposed 36:5 39:1 57:5 60:12 66:9 70:24 76:18 83:15, 20 99:4 106:16 107:23 114:1 115:22 120:24 122:15 123:17 124:17 127:14 130:5 132:8 134:10, 21 135:12 136:23 200:17 201:3,22 202:11 221:18 222:17,23 223:6,16,25 224:11	organ 62:9,12,15,17
obvious 181:2	official 189:7		organization 165:17
occasions 224:18	officially 161:1		organizations 191:16
occupational 151:10	officials 8:12		organs 62:4
occur 159:23 173:12	older 5:19 78:21 79:25 89:8 90:3 147:21		original 21:8,10,24 23:19 35:5 79:15
occurred 5:25	Omar 184:23 189:25 192:15,16,17		originally 20:9 21:13 80:5 150:20
Ocean 154:1 155:13, 21	onset 43:11 192:8		
October 9:8,9	open 10:19 14:11, 22 36:20		
off-label 41:15 43:14, 25 44:8 45:6,	operable 183:19	option 18:5 30:12 37:2,13,19,24 38:5 217:2	

Orlando 9:9,10 144:14	ovary 61:23,25	painful 95:16 96:14, 24 97:13,14 98:3,8,19,21	parents' 137:13
orthopedic 23:16 25:8	overkill 48:11 100:19	paint 178:10	part 4:7 8:2 21:23 23:2,9 29:19 49:10 53:3,7, 16,17,20 77:23,24 125:1 143:23 144:14,15 146:2 150:10 156:23 158:3 178:25 208:22 210:18 216:25
osteoblastic 67:3	overlap 10:11	paired 185:13	partially 78:1
osteopathic 3:2,18 4:10, 24 6:18 7:4 8:21 15:17 187:4	overreach 170:8 175:6	paper 27:16	participants 163:5
osteoporosis 72:3 219:1	overreaching 48:11 176:15, 18	papers 184:5	participate 119:23
outcome 31:22 40:1 50:19 59:23 79:12,14 182:24 203:14	overseen 153:10	paragraph 5:7 37:6 41:14 43:2,5, 9 47:7 48:13 49:18 50:8 52:22,25 56:2,7,21 57:24	participates 12:8
outcomes 39:22 40:15 45:16 48:6 50:18 64:11, 13,17 78:25 102:15 185:17 194:4	oversight 176:23	paragraphs 39:24 80:16 82:9 108:7	participating 13:7 178:9
outlined 170:7	overstepping 170:3	paralysis 77:15 79:2	parties 7:23 8:5 225:7
outlining 9:1	overview 8:19 53:7	paralyzed 77:16	partner 23:20
outweigh 46:7 52:5 56:17	overwhelming 184:4	parent 5:10 48:24 83:1,3,4,9, 19,20,25 137:5	parts 55:1 150:7 157:19
outweighs 151:25	P	parental 43:8 48:19 58:10 161:4	party 8:1
ovarian 87:8 149:4,13 150:5	p.m. 3:14 6:15 7:5	parents 52:13 99:17 174:12 175:9 186:8	pass 182:1
ovaries 61:12	Pace 78:22		passage 180:4
	package 63:16,17		
	pages 48:7 82:20,21 149:10 150:7 207:4		
	pain 48:8 97:12,21 98:2,7,14,15, 20 152:19		

passed 193:2	32:14 63:18 68:13 74:2	77:4 85:3 88:5 91:4	123:3 140:5 143:24 144:4
passes 106:17 114:2 134:11,22 135:13 200:18 201:4,14,23 202:12 221:19 222:24	84:8,15 86:3 90:18 100:4 111:16 131:25 132:2 152:22 157:16 166:20,21 179:6 182:9 189:6,12,22 192:10 207:11 214:15 216:1 218:10	113:8 142:10, 14 194:13 207:6	148:15,25 150:8 152:20 154:19 163:11 164:24 171:18 173:15 174:16 178:2,3 180:2,24 181:7,14 183:2 184:6 185:4 186:6 191:15,23 195:20 197:14 203:4,8,11 205:6 207:1, 3,5,10,13 209:4 211:6 217:3,4 218:13 222:2, 6
past 119:20 138:11 170:25 171:6	patients' 42:7 46:4 52:1 56:14	pediatrics 31:20 69:2 207:8	peer 180:19
path 87:4 172:6 212:6	pattern 87:12 93:8 94:24 95:4 142:13	peer 180:19	peers 162:20 185:12
patient 5:3,21 10:9 19:6 20:9,16, 19,22 21:9,13 23:1,6 25:16 27:18 28:7 33:1,10 43:7 67:23 103:4 104:15 105:19,20 133:25 134:13 136:9 160:9 166:12,13,18 167:16 186:9 188:13 205:2 209:21 212:13 215:5 216:13, 22	Paul 3:14 46:24 93:13 153:17 156:14 159:9, 10 160:15	peeve 93:6	pediatric 31:18 32:14 43:2 46:22 48:14 68:11 70:14 71:1
patient's 5:9	pause 64:9,18	pelvic 95:17	penile 116:13,22 117:25 118:4, 16 120:8
patients 5:13,19 6:2 16:15 17:1,2, 5 19:14 25:3 26:7 29:7	pay 215:24	penmanship 182:17	people's 211:23
	PCOS 87:6,7	penetrative 95:25 96:14, 25	perceived 171:20
	peace 189:23	penis 4:12 11:3 37:13 40:14, 16 44:1 45:6, 8 47:16,18 56:11 59:20 62:24 64:3,4, 20,23,24 65:2,3 74:14, 23 79:10 85:10 88:17 95:25 100:15 103:3 107:2 109:24 116:12 119:2,20	percent 51:2 59:20 63:1 64:22 78:24,25 79:18 101:12 103:6 148:9 163:24 164:18,19 181:19
	pedal 123:21	people 4:12 11:3 37:13 40:14, 16 44:1 45:6, 8 47:16,18 56:11 59:20 62:24 64:3,4, 20,23,24 65:2,3 74:14, 23 79:10 85:10 88:17 95:25 100:15 103:3 107:2 109:24 116:12 119:2,20	perfect 78:14
	pediatric 31:18 32:14 43:2 46:22 48:14 68:11 70:14 71:1	performed 148:10	

period 66:15 101:25 162:18,23 163:3 211:9 216:22	221:10	188:12 203:13,17	physician's 157:22
peripheral 188:5	person's 197:19	physically 189:5	physicians 5:8 13:3 15:18 19:14 21:17 22:15, 18,20,23 23:2 44:4 77:7 128:24 143:9, 10 157:12,20, 22 168:9,12 181:13 210:4 212:4 214:8, 14 218:5
permanent 59:4 82:1 91:25 95:22 119:7 217:20, 24 218:2	personal 4:16 74:22 95:15 176:24 178:1 188:23	physician 18:10,13 19:2,6,12,21, 22,24 20:1,4, 8,13,15,20 21:8,11,13, 20,22 22:7,14 23:8,12,13, 15,16,17 24:6,11,12,13 25:2,24 26:11,12,14, 17,20,23 27:4,6 28:1,3 29:9,10,13 30:2,7,9 32:22,24 33:3,4,6,17, 18 37:11,21 38:1,8 58:15 77:14 99:14 100:23 103:14,23 106:7 109:5,9 112:4 136:1, 3,6,8,11,12 148:12,16 159:11 166:24 176:19 206:12,21 212:9 213:8, 17 214:19 215:5,8 216:14,15 219:18,24 220:1,13,15 221:4,9,11	physiologic 219:6
permissible 28:13,14	persons 8:2		picking 189:12 197:12
permission 137:5,13	perspective 19:23 39:14		picture 133:22
permits 7:18,25	pertaining 5:2 8:22		piece 27:16
perpetrated 175:6	pet 93:6		Pietro 20:25 21:3,5, 16 22:1,12,25 23:10 24:3,8, 17 25:1,10 26:2,9,22 27:1,5,10,23 29:1,12,18 32:4,21 33:7, 24 43:15,21 46:11 47:3,24 48:13 50:11, 20 52:24 56:24 57:1,2, 18,21,23 58:2,10,13,22 59:6,11 60:4 61:2 64:1
perpetuity 29:6 100:17	phalloplasty 117:17		
persist 79:20	pharmacy 146:18		
persistence 78:17	phase 214:21		
persistent 79:7 203:12	Phd 178:17		
person 20:3,8,17 21:24 25:11, 15 28:12,14, 17,22 29:4, 14,17 30:2,6 32:5,15 33:16 34:6 158:3 172:5 193:19 203:19 206:21 210:23 214:17	philosophy 218:14		
	phonetic 144:14 148:24 153:17 154:2 161:15 165:13 170:14,15 176:3 177:15 178:15 182:16,18 184:23		
	phrase 39:7		
	physical 31:23 159:22		

72:23 73:6, 14,16 74:21, 22 75:1,11, 18,20 76:11, 13 82:16 83:1,3,7,12 90:13,25 91:19 95:3 97:14 107:18, 20 108:10 111:22 112:11,18 113:13,17 114:3,4 115:18,19 119:13,17 123:20 124:15,19,20, 21 125:3,7 126:20,24 127:1,6,9 129:23 130:2 132:5 135:8, 10 138:18 200:7,9,24 201:11,19 202:8 203:21, 24 215:13,17, 19 217:2 219:15 222:14 223:3,12,21 224:6 Pietro's 50:7 59:14 pill 90:8,9 91:15 110:3,5 pills 90:24 145:15 place 13:20,22	41:6,12 42:20 51:22 93:15 94:7 152:9,13 187:9 189:4 placeholder 111:13 placeholders 217:22 places 75:2 plane 130:12 planned 156:3 180:4 platelet 188:6 platelets 188:11 playing 170:9 point 17:16 19:11 20:6 21:5,10 24:4 50:4 53:6 62:20 63:5 64:2 65:10 68:12, 25 87:25 91:23 94:21 96:17,22 112:8,17,23 119:3,25 120:2 122:8 123:10 124:21,22 131:22 148:13 153:1 154:5 170:24 191:23 202:2	pointed 28:24 219:15 points 15:15 159:17 204:1 police 129:2 policies 152:13 193:1 policy 55:2 polite 191:15 political 186:3,5 politically 183:11 187:13 politicized 186:7 politics 170:9 poll 132:9 polycystic 87:8 149:3,13 150:4 pooh-pooh 45:6,8 poor 48:5 191:23 poor-quality 46:3 51:12,25 56:12 population 24:23 31:17, 18,19 39:18 87:13 142:10, 14 163:8	170:1 193:5 215:6 populations 172:21 portal 15:1 portion 140:9 157:11 position 161:20 positional 180:21 positive 173:12 182:24 185:17 positively 188:8 possess 188:20 possibility 79:4 92:3 possibly 100:14 175:24 post 157:5 post-doctoral 192:20 postpone 159:19 potential 40:2 41:7 121:4,12 195:7 potentially 58:3,18 168:11 power 152:6
---	---	---	---

PR 197:22	203:23	5:10,20 6:3, 4,11,13	111:18 134:15,24
practical 19:23 172:6	predicated 44:9	108:21 176:12 214:5	Price 148:21
practically 30:4	preference 82:18	prescriptive 100:19 101:19 206:22 207:17	153:15,19,25 154:1 155:21
practice 5:2 6:10,22 16:15 17:1,11 22:16,24 23:21 30:13 42:9 46:6 52:3 56:15 112:13 133:7, 24 156:20 157:9,15 178:25 183:6 189:19 210:3	prescribe 21:23 45:7 109:9 156:22	presence 169:4	prices 215:24
practices 42:1 132:13	prescribed 20:6,10 93:23 109:5,13 110:20 114:18,23 115:14 143:8 145:1,2 149:1,2 155:6	present 79:17 162:7	primary 4:11 6:21 24:6 26:20 29:6,7 160:9
practitioner 38:2 145:2 146:8,12,14, 16 153:10 169:3	prescribing 19:20,22 20:4,7,12,14, 20 21:8,11, 12,17,19 22:15 25:15, 24 26:23 27:14 28:1 29:9 32:22 33:3,5,15,17 49:12 58:14 99:14 103:14, 23 106:6 109:15 112:6 157:10 206:12 210:4 213:8 214:8 221:11	presentations 10:9	prime 160:17
practitioners 148:11 157:19 181:20 207:20	prescription 5:4,16 20:21 23:3 26:19 28:23 145:4 146:16,17 158:7	presented 152:16 208:7	printed 49:5,6
preamble 42:22 50:2,6 52:12 54:1 56:6 80:10 111:3	prescriptions	president 163:18 174:6 185:1 196:14	prior 6:23 28:23 180:4 189:6 192:13 198:19 224:4
preamp 43:18		president/ founder 143:18	Prism 185:2
precise 118:11		pressure 29:24 145:10, 12	PRN 159:5
preclude 19:2 177:7		pretend 132:22 173:21	pro 184:3
		pretty 138:3 174:18 181:2,10 190:3	problem 47:3 68:20 138:17 174:4
		prevent 87:15 174:16 191:7	problematic 194:23
		previous 80:17 113:20 151:20 153:2 169:9 189:9	problems 124:3,4,8,13 211:1,7
		previously 77:20 100:6	procedure 77:15 78:4,9 116:19 117:1

procedures 5:21 6:13 9:2 176:13	progression 64:3	propose 51:20 139:2	protocol 79:15 156:23
proceed 10:4 169:21	prohibition 167:12	proposed 8:1 38:4 44:21 51:8 53:6 74:6 78:4 80:7 81:6 89:4,20 96:10 99:21 100:7 111:14, 20 112:25 116:6,7 117:19 132:15 136:24 139:22 165:18 166:1 172:20 176:21 177:8 180:11 185:18 200:22 201:5 222:25 223:7	proton 17:3
proceedings 141:19 144:3	prohibits 19:12	pros 159:24	prove 146:20
process 6:8 8:7 9:18 11:6 12:20 119:11 167:10 185:24 186:13 198:9 199:1 218:3	Proia 170:15,16 174:23 176:2, 4,7	proscars 142:12	provide 6:2 7:24 8:19 41:6,13 44:25 176:6 188:12 193:18
product 43:25 158:8 165:25	promise 125:10	prosecutorial 31:10	provided 14:15 49:11 58:14 179:8 225:4
productive 13:7	promote 86:1,6 151:16	prostates 86:8	provider 105:19 111:25 168:16 203:6 212:14
professional 5:12 166:25 167:6 172:16 175:16 192:21 195:1 210:15, 20	promoting 211:18	protect 163:21,22 214:12	providers 103:18 105:10 168:13 189:5 195:11
professionals 171:2 193:15	pronounced 148:20	protecting 4:12 169:25 175:8,15	providing 19:2 156:21 167:18 176:6 178:25
professions 195:9	pronouns 176:7	protective 215:6	provision 5:12 6:9 181:6 201:25 202:3,7 224:3
profound 40:16	pronunciation 140:16 156:19 170:16		provisions 6:5
program 3:5 133:1 139:10,24 159:13	pronunciations 153:16 156:16 165:12		prudent 5:22 166:13
programs 193:5	Propecia 86:13		pseudonyms 8:5
progress 7:14 217:24	proper 168:1 221:21		psychiatric 80:2 169:8
	properly 179:18		
	proposal 81:2 101:14 104:12 113:16		
	proposals 10:22		

187:17 204:25 205:3,13	pubital 31:23 129:19	purely 46:6 52:3 56:15 188:22	<hr/> Q <hr/>
psychiatrist 5:13 167:4 181:18 187:20	public 3:6,19 4:3,6, 8 7:17,22 8:7,14 9:5,7, 13 10:1,19, 20,21 11:1,4, 5,13,17,20 15:6 88:2,14 108:24 109:20,25 111:7,9 119:11 130:25 133:16 140:9, 11 141:16,23 162:10 187:13 190:14 192:3, 4,18 198:20 199:25 208:4 209:16 214:12 224:15	purpose 167:22 171:8 179:16	qualifications 202:20
psychiatrists 181:21		purposes 51:2	qualified 153:10 203:8
psychological 37:24 40:12 42:8 46:4,7 52:2,4 56:14, 16 64:17 65:17,24 134:14 153:6, 9 162:2 166:21,22 169:22 180:25 191:7		Pursuant 6:7	qualify 31:13
psychologist 5:14 167:5 176:9 181:17 187:21	publications 78:22	pursue 189:22	quality 44:12 188:21
psychologists 181:21	publicly 8:12	put 11:24,25 12:20 13:1 15:8 16:8 17:1 41:23, 24,25 43:9 45:4 48:11 50:1,5 52:15 55:6 56:1,6 58:20 63:9,16 67:7 68:13 72:7 75:21,23 111:1 132:24 138:9 164:23 173:13 176:15,18 178:12 197:23 215:4 216:8 217:22 220:2, 11	quarterly 136:10 168:15
psychopathology 192:1	published 39:19 78:23 79:7 191:18 194:7,12,19, 25	putting 4:15 42:22 47:24 48:14 50:7 73:11 105:15 165:7 175:14 197:21,22 216:7	question 17:14 18:15 19:19 22:22 28:9 36:8 39:5 41:20 83:18 87:24 88:6 89:3 93:10 111:22 121:3 137:1 142:7,11 144:3,19 147:6,11 148:6 149:20 151:2 156:24 200:21
puberty 13:24 14:1,20 15:3,8 16:11, 21,23 40:24 47:7 49:13 58:16,25 59:2,18,20 63:1,17 64:6, 9,15 73:10 79:19 91:4 116:13,22 117:23 118:3 120:7,11,15 185:7	publishing 160:18		questioned 54:2
	pull 129:24		questioning 143:7
	pulmonary 114:10		questions 14:11,23 131:17,20 136:24 140:12 143:22 147:10 150:11 151:5 158:13 160:20 198:25
	pump 91:9		

200:10,21 221:23 quick 77:12 131:21 quickly 115:9 quorum 3:8 quote 191:25 quoted 148:9	rates 78:20,23 79:23 80:3 162:19 163:3, 5,7 192:9 rationale 51:18 reach 170:23 reached 163:6 reaction 175:3 read 18:12 21:6,7, 24 22:1,13 29:20 44:24 46:24 51:9,20 56:3,4 59:15 102:8 104:14 106:21 115:4 117:19 125:4 126:8,17 134:25 149:11 157:8 184:10 207:4 211:3 216:13 reading 22:13 42:12, 16 47:18 60:23,25 77:5 92:21 96:8 110:13 114:21 178:19 206:18 reads 21:7 26:13 65:23 120:2 219:16 ready 160:16	real 77:12 145:22 163:22 180:10 realize 160:15 164:22 reason 50:23,24 51:4 54:25 55:19 86:4,15 152:12 155:6 168:14 183:9 190:12 reasonable 13:2 34:6 69:22 72:14 77:19 92:2 118:22 185:23 reasons 79:5,9 reassignment 4:21 5:5,20 6:3,11,13 132:12 133:10 139:11 162:21 183:9 receive 6:3,11,12,24 19:19 81:14 100:12 126:22 147:16 154:12 157:18 166:15 176:9 178:6 202:20 217:15 220:16 221:1, 2,5 received 9:13 145:5 receiving 6:2,23 109:2 169:1 178:21	184:10 194:16 recent 194:7 203:3 recently 14:16 161:20 167:8 211:17 receptor 142:25 recess 131:12 recite 192:7 recognize 78:5,7,10 161:1 218:9 recognized 143:15 156:17 161:16 recognizing 100:5 111:17 recommend 193:11 212:7 215:22 recommendation 152:4 157:6 215:4,12 recommendations 87:4 213:16, 18 217:6 recommended 72:1 143:9 210:20 213:17 216:8,20 219:17,23 220:1,13,15 221:4,8 reconsider 186:14 198:18 217:23,24
<hr/> R <hr/>			
racism 193:3 radiation 16:18 17:3 27:14 Rainbow 161:19 ramification 216:19 random 23:15,16 randomized 8:8 47:10 50:17 randomly 190:8 range 30:25 31:4 107:8 219:6 rapid 192:8 rate 123:1			

record 4:2,8 8:6 112:19 187:13 218:1,13 222:8	refine 81:24	related 19:19 54:16 61:5 87:23 88:7 95:18 117:25 122:2 150:8 164:4, 11 171:19 202:19 208:10 211:18	remove 7:13 149:5
recorded 3:20 4:6,7	reflect 151:12	relationships 203:10	removed 12:8 216:11
recording 224:20 225:3	reflected 160:21	relationships 188:13	removing 180:24 207:25 208:12
records 168:3	refrain 4:4 7:11	relative 225:6	repeat 18:4 55:25 126:18
rectify 21:12 24:19	refreshing 211:22	relevancy 191:12	repeated 126:7 134:2
red 188:5	refuse 159:19	relevant 65:6 90:1 190:21 192:3, 4	repeatedly 191:17
reduce 163:23	refusing 197:21	remain 152:18	repeating 58:5 72:22
reduction 179:23	regret 78:17 80:3 194:17	remaining 112:9	replacement 126:23 154:4 185:8 217:15
redundant 21:22 121:24 204:4 209:13	regretted 154:6	remember 4:5 31:3 57:23 60:25 95:13 101:7 110:2 152:10 189:16 199:8	report 54:13,15,17 99:18
reeducate 207:1	regular 19:16 25:24 168:6 215:8 220:8	remembered 140:23	reportable 194:19
reevaluate 189:8	regularly 25:2 208:2	remind 9:4 151:23 187:1	reported 39:17 80:5 96:8
reference 172:18	regulated 183:6	reminds 16:14	reporter 3:25
references 197:9	regulatory 201:7 223:9		reports 40:14 54:20
referencing 175:22	reimbursement 161:7		represent 165:16 189:17
referred 162:16	reinvent 213:23		representation 14:19
referring 17:20 21:1 121:8 167:23	rejecting 167:9		representative 160:18
	relate 112:13		

represents 185:24	178:24 179:2 187:15 189:4	resiliency 193:6	resulted 169:13
reproduction 206:9	194:22 207:25 208:13 213:1, 3,14 214:13	resolution 161:5	resulting 129:19
reproductive 60:20 61:11, 20,21 62:4, 11,13,17	216:6 217:3, 14,17 219:16, 17,20	resources 185:4	results 78:5,16
reputable 160:6	requires 4:24 5:17 9:19 66:13	respect 130:8 140:15 152:11 166:7 171:12 184:11 189:12 199:23	retired 159:11
requested 8:3	151:15,17 169:6 170:5	respected 152:24	return 7:19
require 7:10 29:7 154:23 157:3 167:17 191:19 214:4 222:4	205:25	respectful 141:22	Returning 103:17
required 19:8 32:19 77:7 99:14 139:15,18,19 157:19 158:7, 25 166:10 168:2 178:2 202:2,4 212:4 221:1 222:4	requiring 154:15 167:14 213:2 219:8 222:6	respectfully 164:22 165:18	review 16:2 130:16, 19 159:15
requirement 157:6 158:12, 24 167:20 168:7,23,25 179:10,12 195:3,4,5 212:17,21 213:11 214:18	requisite 200:20	responses 199:25	reviewed 180:19 197:5
requirements 4:20 5:8 19:19 100:11 112:16 126:22 157:13 166:2, 15 170:7	research 40:3 42:9 44:9 46:3,5 51:12,25 52:3 54:13,15 56:13,15 59:19 109:14 187:23 189:11,18 192:19 197:12	responsibility 26:19 167:13	reviews 178:5
	researching 178:18	responsible 105:18	revise 167:25 168:16
	reserve 7:13	rest 77:17 102:3,5 184:20 219:7	revised 153:5
	reside 217:17	restart 59:1	revisited 168:6
	resigned 161:20	restricting 169:1	rid 183:21,22 207:20
	resilience 193:7	restrictions 175:4 176:21 185:22	ridiculous 102:7
		restrictive 166:9 189:2	rife 165:19
		result 64:16 120:7 179:23	rightly 148:20
			rights 149:18
			ringing 48:7

risk	11:9,10,12,25	20,25 101:2,	150:12,21,23
19:7 40:2	13:9,10 14:3,	14 102:10	151:6 153:12,
71:23,25 72:2	8,25 15:11,19	103:19,22	24 155:13,25
77:14 93:8	16:9 18:14,25	104:3,6,9,12,	156:4,13
96:1 97:6,9	22:17,21	21 106:10,13,	157:21 158:9,
101:5 102:4	26:25 27:19	20,23 107:13,	11,21 159:6
104:1 106:22	28:18,21	16,19 109:7,	160:14 161:11
107:1 128:2,3	30:10,17	11,19 110:7	162:9,14
141:15,20	32:13 33:22,	111:12 112:24	163:9,14
152:1 168:7	25 34:3,13	113:3,9,12,	164:3,10,14
171:15 179:4	35:1 36:1,3,	15,18,23	165:2,6,9
206:13 210:1	10 37:1 38:4,	114:12,13,15,	168:18 170:11
219:2,7	9,12,14,17,24	22,25 115:8,	171:8 172:23
	39:6 40:4,8	16,19,25	174:19,22
risks	42:11,14,18	116:10 119:6,	175:2 176:2
5:20 16:22	43:23 44:3,7,	10,15,21,24	177:12 178:14
40:17,23	15,25 45:23	120:17,21	180:7 182:13
44:13 46:8	46:15,23	121:5,10,14,	184:21 186:20
48:21 49:12,	51:7,16 52:8,	18,23 122:7,	189:24
15 52:5 53:21	18,19 53:1,	12 123:9,14	190:17,22,25
54:19 56:17	21,24 54:2	124:6,10,14,	192:15 195:12
58:15,18,21	55:7 56:20,25	20 125:8	196:2,7
78:7 92:12	57:2,8,11,14,	126:1,8,13	198:2,13
94:23 108:23	16 59:15	127:8,11,17,	199:20 200:8,
114:7 115:9,	60:2,6,9,16	19,23,25	14 201:1,12,
15 116:19	65:13 66:3,6	128:4,7,12,	20 202:9
163:23	70:2,5,7,9,	16,23 129:3,	203:2 205:15
166:12,17	12,18,22	7,11,15	206:4,16
203:18 206:6	73:1,4,13,18,	130:1,18,22	208:14 209:1
211:13	21,24 74:11,	131:3,7,10,13	214:23 217:9
road	18,24 76:12,	132:6,20	218:7 219:11,
64:5 178:8	15,24 80:6	134:7,19	21,25 220:12
Robert's	81:21 82:3,	135:9,18	221:3,12,15,
35:5,8	12,24 83:5,11	136:9,16,20	22 222:10,15
robust	84:6,11,13	138:21,24	223:4,14,23
44:9 119:4	88:11,16	139:4,8,21	224:9
172:18	89:2,6,19	140:7,20	Ron
role	91:12,17 92:9	141:1,5,11	197:24
49:22	94:3,20 95:5,	142:3,15	room
Romanello	8,12 96:10,	143:14 144:5,	7:19,21 84:25
3:9 8:16	16,20,22 97:2	9 147:7,12	182:10 183:2
	98:9 99:1,10,	148:7,17	

196:21 197:14	180:22 186:11	175:14	scanning
routine	187:8 217:25	safely	167:2
88:25 188:11	218:3	160:1	scans
209:22	rules	safer	157:2 188:4
routinely	5:1,7,18,23	89:15	Scappalis
110:25	9:16 10:17,18	safety	176:3 177:14
Roy	35:5,8,9,10	40:24 171:21	178:14,16
148:24 150:17	112:4 130:15,	194:20 215:15	schedule
rubberstamping	24,25 131:5,	216:4	34:8
203:5 218:12	8,16 132:11	sample	scheduled
rule	140:14 146:19	191:2,3	6:14 7:5
6:1,20 8:22	153:4 155:19	194:15	school
9:1,15,20	156:7 161:13	sand	170:18 171:2
12:22 31:4,5	164:4,11	197:22,23	176:8 207:7
66:1 68:7	167:9 168:17	save	science
80:25 81:24	171:10,13	147:24	4:14
82:1 91:25	172:10,13,20	saves	scientific
92:3 105:15	176:15 177:22	186:9	189:10
106:4 112:15	182:11	saving	scientists
119:7,8	190:18,20,21,	169:23	44:5
132:12,24	23 195:15	SB	scope
133:3 136:25	198:8,10	4:22	177:20,21,24
138:7,22	222:11,19	SB254	196:20,21
139:22 140:8	Rules/	186:12 187:3	197:16,20
141:12,13	legislative	scan	scopes
144:6,11,19	3:16	66:13,15,16,	178:2
146:15 157:21	ruling	19,21,22,23,	scores
166:1 198:12,	183:15 191:19	24 67:2,4,6,	188:8
16,24 199:22,	200:13	8,9,10,12,20,	Scott
24 200:4,6,22	rulings	24 68:2 73:8,	11:15
201:5,15,17	184:18	20 134:25	Scotty
202:2,5	run	135:1,2,5,7	70:2,4
209:24	166:9	158:23 168:5	Scratch
217:18,20,22	<hr/>	179:2,9	114:11
222:12,18,20,	s	191:20 206:23	screen
25 223:7,18,	<hr/>	210:8 212:22	51:9
20 224:4,5	safe	215:24 218:22	screening
rulemaking	171:5 172:8	219:8	72:3 219:1
6:16 9:18	185:8	safeguards	
11:6 165:21			

scribble 44:19	send 80:14 196:24	5:12	49:14 54:21
Scribner's 125:23	Seneca 156:14 159:7	session 180:23	shorter 48:16
searching 108:19	161:14 163:16	sets 133:6	show 106:3 162:19
secondary 170:19	164:7,13,16	setting 160:11	182:9 183:1
seconded 99:2	senior 3:4	sex 4:21 5:5,20	194:2
seconds 106:13 153:2	sensation 121:7,17	6:2,11,12	showed 63:3 64:12
section 6:5,7,17	sensationalizin 175:18	60:18 62:12	showing 173:3 189:12
39:24 41:10,	sense 14:5 30:25	95:25 132:12	shown 45:15 85:11
24 58:8 86:25	32:7 46:17	133:10 139:11	163:23 164:17
87:2 141:23	59:23 82:4,24	sexual 95:24 121:7,	181:15 193:22
219:15,16	153:5 171:20	17 185:3	197:8
securing 165:17	191:12	sexuality 192:22	shows 162:23
seed 184:20	sentence 41:11 45:5	shabby 156:19	shrink 86:8
seek 158:14 189:3	49:10 50:22,	shaken 171:7	shut 213:6
seeking 177:24 178:1	23 51:6 60:5	shared 57:18,22	sibling 90:20
seemingly 182:22	63:20,24	140:21 169:9	sick 162:1 181:4,5
sees 20:16	117:19,20	sharply 185:13	side 4:7 14:24
self-harming 194:6	sentences 39:24 44:23	sheer 112:2	27:22 40:2
Semiannually 102:21	45:18 46:11	shit 197:25	47:19 53:4,23
semicolon 29:4	80:13	shooting 219:5	73:3 87:15
Senate 4:20	separate 19:15 52:22	short 10:15 58:17	99:15 109:17
	74:5 137:23	131:9	124:22,24
	158:6 162:2	short-term 40:13 48:21	149:12 154:8
	174:15		175:16 188:1,
	separately 198:16 205:21		17
	serve 152:10,22		sides 218:8
	services		

sign 137:25 169:3 173:25	218:21	snapping 12:12	212:21 218:12
signature 48:19 52:13 58:11 59:7,10 137:14 167:14	simpler 30:20	social 65:17,24 79:15 134:14 166:22 170:20 178:17 192:7 193:1 211:18	sorts 48:5 205:7
signed 4:22 20:17 101:18 140:1 146:22	simplify 55:20	Society 14:16 29:21 30:23 89:12 90:5 102:9 180:21 182:7 191:17 212:5 218:23	sound 151:13 217:13
significant 11:3 44:13 188:1	simply 47:12 167:19 198:22	Society's 181:9	sounded 21:24
significantly 194:10	single 146:3 191:13	sole 119:14	sounds 82:2 203:16
signing 4:23 16:19,20 20:12 41:10 49:16 75:22 83:19 137:14	singular 84:1	solicited 141:12	sources 116:16 118:6, 7
signs 102:14	sir 107:15 126:2 171:14 196:15	South 144:16 176:5 185:4	Southwest 143:18 163:19 177:18 186:23 196:14
silence 4:8	sissy 192:10	space 48:18 220:11	speak 4:1 8:3,10,15 74:13 109:1, 24 141:11 144:4,22 150:19 151:6 155:14 170:25
silent 152:18	sister 90:20	speaker 7:20 13:21 16:4 21:21 22:4,9,10 23:6 24:14 25:5 28:5,8, 19 29:11 31:16 32:6,9, 25 33:19 34:2,18,25 36:2 49:2	
similar 15:14,15 17:10 39:9 55:21 80:16 99:8 142:23 154:20 215:7 219:4	sit 152:17	son 153:20 168:23 169:10	
similarly 167:10 172:7	sitting 29:24 215:24	song 182:6	
simple 45:4 49:23 92:22 137:9	situation 149:20 190:16	sort 12:5,9,12 16:25 17:6 21:22 48:6,8 77:18,21 153:11 154:7 173:11 174:20 203:5 206:14	
	size 191:3 194:15		
	Slow 45:23		
	slower 42:16		
	small 116:15 200:23 223:1		
	Smith 20:20 174:24 176:3 177:14, 16		

55:9 56:10	specific	spray	18 172:17
57:7,9,15	48:3 50:22	86:13	180:22 182:7
58:24 60:7,	53:21,23 74:7	spreading	194:24 195:6
22,24 61:8,19	100:8,11	163:20	212:4,10
62:13,16,21	107:8 126:6,	sprinkled	215:17 216:3
67:21 69:17	22 140:11	42:19	standpoint
70:21 75:16	158:2 166:14	stabilizes	31:10
76:3,6,22	187:22 212:25	68:24	Starbucks
80:19 81:17	213:14 219:16	stable	11:18
83:8 86:18,21	specifically	100:18,24	start
92:15 93:18	55:17 83:25	101:6 103:9	8:18 13:20,
94:15,18,25	91:9 106:24	105:10 204:19	22,23,24
97:4,22 99:24	121:21 162:20	211:8	50:23 63:1
112:23 115:4	171:17 188:5	staff	71:5 119:10
117:10 118:12	specifics	7:20 9:25	132:11,13
125:2 131:2	208:15	15:12,25 16:8	140:8,10
135:15,23	spectrum	41:6 42:19	141:5 196:15,
136:2,7,13	161:2	81:23 108:4	20 199:18
139:15,17	speculative	125:10 126:1	started
142:20 150:6	40:20 42:9	131:16	55:1 96:8
151:2 153:2	46:6 52:4	stage	120:14,15
195:16,22,25	56:16 188:22	59:2 64:3	145:15 147:21
196:3,8,10	spelling	staging	148:1 169:15
197:1	170:15	29:25 31:23	starting
speakers	Spence	stand	59:3 65:3
8:1	77:11	152:15 216:7	71:4,10,11
speaking	spent	standard	79:25 100:15
4:4 141:3	178:18	4:15 6:9 8:23	102:19 116:12
177:19 183:16	spine	77:21 79:1	157:4 159:3
speaks	192:14	112:9 132:12	202:16
204:7	spoke	138:3 166:10	starts
specialist	95:15	178:25 195:8,	84:14 100:21
160:19	spoken	10 212:14,20	state
specialists	154:12	215:7,19	4:2,12 13:3
207:6	spot	216:24	35:10 63:4
specialize	47:25	standards	77:8 112:6
160:7 170:19	sprawl	5:2 6:22	141:7 153:5
181:24	218:12	112:13 133:7,	155:8 156:8
specializes		24 151:13,14,	165:23
24:13			168:13,14

171:6 172:11	6:6,8,17	stricken	137:4 151:22
175:24 176:18	statutory	134:5 209:21	173:1,6
181:20 184:16	9:19 158:12,	Strickland	180:19 181:15
186:2,19	13	3:5	182:21
187:2 189:19	stay	strict	188:22,23
191:3,5 205:8	148:20 209:8	79:23	191:2 193:25
216:9	staying	strike	194:19 207:4,
state's	167:23 177:19	37:2,3 38:5	5 222:6
150:3 165:16	219:3	58:7 121:22	study
state-imposed	Stephen	122:8 126:7	39:19 42:9
168:2	170:14	127:6 134:6,	52:3 54:13,15
stated	steps	7,16,17 182:5	67:3 72:12
99:19 182:1	154:24 177:23	212:3,8 215:1	135:6 162:6,
statement	sterilization	striking	16,18,22
55:16 82:6	149:16	122:4	163:5 173:3
93:22 180:21	steroids	stringent	192:9 194:7,
statements	142:24	211:17	12
188:20,25	stick	stronger	stuff
states	31:25 46:1	45:10 50:5	12:5 14:17
88:10,24	stigma	struck	17:4 48:4,6,9
108:8 109:13,	193:2	182:20	59:12 207:2
18 125:14	stipulations	structural	209:8
143:7 151:25	166:3	193:2	subject
159:18 160:2	stop	structures	168:15 177:22
167:24	71:22 95:22	60:20 61:7,11	subjectivity
stating	164:24 170:8	student	193:22
79:11 180:13	178:10 217:19	151:10 178:17	submitted
statistics	stopped	students	15:7 187:12
190:10	159:21	170:22	subsection
statute	stopping	studied	133:23,24
20:15 28:12,	159:25	45:13	134:3,24
21,24 83:23,	stops	studies	213:15 220:3
24 133:17,19	58:25 155:11	36:24,25	subsequent
139:12,15,18,	straight-	40:13 42:3	7:3
20 148:11	forward	45:14,15 46:6	subset
157:14 160:25	172:10	48:5 54:18,21	87:14
169:6 170:5	strength	56:15 63:3	substance
202:2	73:9 95:24	68:23 85:12	111:24 112:3,
statutes		95:20 107:3	6,20

substances 112:22	suggesting 92:6 210:22	224:3,7	19 138:14
substantial 46:8 52:5 56:17 179:5, 11,13	suggestion 55:10 65:22 80:23 81:22 217:10	supplemental 19:8,12	140:2,3,6 145:20 154:13 158:17,20 180:1
substantially 178:24	suggestions 55:11 118:20 217:17	support 40:3 65:17,24 134:14 166:22 171:20 172:3 193:13	surgical 78:4,9 116:3, 25 125:1 180:5 220:20
substantive 166:2	suicidal 39:21 102:4 180:17 184:16	supported 154:24 171:22,23,24	surgically 116:14
substitute 38:6 125:18	suicidality 171:19 172:5 181:1,15 185:12 191:5 194:5	supportive 213:21	surprising 64:21
subtitle 216:6	suicide 101:5 104:1 106:22 162:19,24,25 163:2,5,7,23 164:19 166:24 169:17 171:16 179:4 185:11 190:9,10 191:8 206:13 209:25	supposed 25:14,15 29:22 30:24 154:12 169:24 184:9,11	survive 145:25
subtle 42:7 46:3 52:1 56:13 173:11,18,21	suicides 39:21	suppress 47:6	surviving 145:21
successful 3:22	summary 77:12 92:11	suppression 14:21	suspect 193:3
successfully 169:18	summation 53:6	surgeon 25:9 117:2 119:1 154:12 187:7	sustained 166:20 179:16,19 204:1,3
succinct 41:11	summer 154:11	surgeries 149:5 180:3	switch 23:7 158:10
suddenly 174:4 190:11	sunset 198:25 201:25 202:3,6	surgeons 119:5	switches 33:1
suffer 145:9 153:6 166:20 167:11 204:25		surgery 77:16 117:16, 24 118:2 119:18 121:4, 12 125:1,15, 17,21 127:23, 24 128:2,18,	switching 103:18
sufficient 117:5,11			Syndrome 87:9
suggest 41:9 55:12 134:1 153:8 181:8 189:6			syntax 130:12
suggested 213:11			systemic 192:25
			T
			tab

15:2	9:11 159:11	telehealth	61:22 62:1
table	Tampa	29:5 156:21	testify
7:19,20 69:11	9:8,11 13:13	telemedicine	123:3 161:10
tactic	tandem	28:15 31:19,	testimony
183:24	175:12	24 214:16	148:8 209:16
tail	tanner	telling	testing
180:15	29:25	173:23 184:7	72:2 167:1
takes	tapered	tells	168:5,15
7:6 9:22	159:22	31:21	206:24 210:7
taking	targeted	temper	212:7 219:6
7:12 30:11,12	175:7	185:22	testosterone
95:23 114:18,	task	temporarily	71:23 72:16,
22 115:13	8:21 210:12	189:5	17 85:22
151:15 159:19	tasked	Ten-minute	87:16 89:9,
169:23 176:14	171:11 183:14	131:11	14,22 91:1,14
204:8,11	taxpayer	tense	92:11 93:23
207:14	189:14	221:21	95:23 110:6
talk	teacher	term	111:15,24
35:12 41:15	172:25	22:22 24:25	114:18,22
44:16 74:13	team	40:14 50:18	115:14 126:5
79:3 104:6,9	181:12	55:12 58:17	129:13
110:3 121:16	tearing	terminology	131:23,25
126:6 130:23	97:5,6,12	67:11	140:15 142:5
171:9 173:1	98:3,7,16,20	terms	143:1 145:6,
218:23	tears	7:7 20:11	13,19,24
talked	96:4 97:9	36:12 59:18	149:8 155:10
84:17 140:14,	113:20 176:10	65:21 78:16	156:22 169:15
15 167:25	technical	107:9	188:2 191:22
217:21 218:24	132:14 139:1	Terrell	218:25 219:3,
talking	199:12	3:1,10 8:16	5
41:19 42:25	technically	126:2,10,16,	testosterones
43:14 68:16	128:6 149:21	21,25 127:3	89:10
89:16 103:20	204:12	129:7,8,12,16	testotoxicosis
104:1,2 113:1	technology	test	110:21
117:20 151:4	186:23	146:1 188:11	theme
172:7 173:7,9	tedious	testes	15:14
talks	208:18	61:12	therapies
39:11 128:19	Tallahassee	testicle	39:25 40:18,
			20 44:13

therapy 31:22 37:25 51:19 52:10 65:2,3 72:8 87:15 100:12, 14 101:17,18 126:23 149:3, 12 151:10 154:5 157:4 159:3 169:15 185:8 217:15	180:16 183:24 205:7,21 207:18 210:11 211:11 212:8, 13,20 213:2, 13 214:4,5 215:3,10 216:6,12,13, 17,19,20 218:5	time 3:13 4:5,8 7:18,25 8:11 10:21 12:3 14:14 16:24 45:8 47:16 64:19 66:14, 15 67:23,25 75:21 79:18 80:25 82:14 96:7 101:18, 25 117:12,19 141:16,19 143:17 147:25 148:9 155:14, 20 156:6 157:3 160:17 162:18 163:3 182:20 184:20 186:19 187:16 195:13,24 197:3 207:10, 22 209:11 211:9 214:12 217:1,23 218:20 224:14,16	tissues 118:18 120:9
thin 96:1	thinking 48:18 49:17 61:3 144:21	25 117:12,19 141:16,19 143:17 147:25 148:9 155:14, 20 156:6 157:3 160:17 162:18 163:3 182:20 184:20 186:19 187:16 195:13,24 197:3 207:10, 22 209:11 211:9 214:12 217:1,23 218:20 224:14,16	titled 4:20 100:3
thing 15:25 18:2 19:18 27:11 45:5 50:21 55:15 62:24 74:23 82:16 107:11 138:3 142:18 143:11 173:12 176:1 182:20 183:4 184:14 203:15 209:25 210:7, 8 218:21	thinks 210:2	141:16,19 143:17 147:25 148:9 155:14, 20 156:6 157:3 160:17 162:18 163:3 182:20 184:20 186:19 187:16 195:13,24 197:3 207:10, 22 209:11 211:9 214:12 217:1,23 218:20 224:14,16	titles 131:22
things 12:12 15:10 16:25 17:6 29:21,25 40:4,14 48:3 49:23 53:11 54:16 74:9,16 79:21 90:15 108:20 110:6, 24 111:2 113:5 116:11 133:6 141:9 142:2 154:20 155:3 156:2 178:22,23	thinner 97:9	141:16,19 143:17 147:25 148:9 155:14, 20 156:6 157:3 160:17 162:18 163:3 182:20 184:20 186:19 187:16 195:13,24 197:3 207:10, 22 209:11 211:9 214:12 217:1,23 218:20 224:14,16	titling 131:18
	Thompson 225:13	141:16,19 143:17 147:25 148:9 155:14, 20 156:6 157:3 160:17 162:18 163:3 182:20 184:20 186:19 187:16 195:13,24 197:3 207:10, 22 209:11 211:9 214:12 217:1,23 218:20 224:14,16	today 3:24 4:17 7:6,17 8:13 9:5,16 10:2, 17 11:1,17,21 12:8 13:4 16:6 18:16,18 51:3 80:24 133:16 149:10 151:22 155:20 175:22 176:17 177:17 178:17 180:1 185:22 186:13 224:16
	thoughtful 130:10	141:16,19 143:17 147:25 148:9 155:14, 20 156:6 157:3 160:17 162:18 163:3 182:20 184:20 186:19 187:16 195:13,24 197:3 207:10, 22 209:11 211:9 214:12 217:1,23 218:20 224:14,16	today's 6:21 7:10 9:20 10:23 171:9
	thoughts 169:16	141:16,19 143:17 147:25 148:9 155:14, 20 156:6 157:3 160:17 162:18 163:3 182:20 184:20 186:19 187:16 195:13,24 197:3 207:10, 22 209:11 211:9 214:12 217:1,23 218:20 224:14,16	toes 46:24
	thousands 184:5	141:16,19 143:17 147:25 148:9 155:14, 20 156:6 157:3 160:17 162:18 163:3 182:20 184:20 186:19 187:16 195:13,24 197:3 207:10, 22 209:11 211:9 214:12 217:1,23 218:20 224:14,16	tomboyish 192:10
	thriving 168:10 169:17	141:16,19 143:17 147:25 148:9 155:14, 20 156:6 157:3 160:17 162:18 163:3 182:20 184:20 186:19 187:16 195:13,24 197:3 207:10, 22 209:11 211:9 214:12 217:1,23 218:20 224:14,16	top 43:7 52:12,15 56:22 113:19 154:13
	thrown 197:25	141:16,19 143:17 147:25 148:9 155:14, 20 156:6 157:3 160:17 162:18 163:3 182:20 184:20 186:19 187:16 195:13,24 197:3 207:10, 22 209:11 211:9 214:12 217:1,23 218:20 224:14,16	topic 161:24 182:22 190:4,11 191:9
	tie 22:6	141:16,19 143:17 147:25 148:9 155:14, 20 156:6 157:3 160:17 162:18 163:3 182:20 184:20 186:19 187:16 195:13,24 197:3 207:10, 22 209:11 211:9 214:12 217:1,23 218:20 224:14,16	Tordoff
	ties 59:13	141:16,19 143:17 147:25 148:9 155:14, 20 156:6 157:3 160:17 162:18 163:3 182:20 184:20 186:19 187:16 195:13,24 197:3 207:10, 22 209:11 211:9 214:12 217:1,23 218:20 224:14,16	
		141:16,19 143:17 147:25 148:9 155:14, 20 156:6 157:3 160:17 162:18 163:3 182:20 184:20 186:19 187:16 195:13,24 197:3 207:10, 22 209:11 211:9 214:12 217:1,23 218:20 224:14,16	

194:8	154:2 161:21	162:25 163:6	161:4 166:16,
toss	163:24 164:18	treasurer	23 175:18
76:1	165:24 171:4,	161:19	177:24
tot	16,18 172:3,	treat	179:20,24
116:6	5,16 177:3,5,	68:21 87:5	180:2 181:11
totally	23 183:8	160:5	187:18 191:6
145:24	185:10 193:4	treated	203:14,20
town	194:1,9,15	5:4 78:3	205:1,17
23:22 24:1	195:1 203:4	117:23 120:11	206:1,3,9
toxicity	transgendered	179:18 202:25	210:16 211:13
89:14	218:10,12	204:2 205:21,	217:5 220:16
TPA	transient	24	221:2,5
215:21	79:5	treating	treatments
track	transition	23:13,18,24	4:21 5:11
109:22	79:15 120:14	26:14,17	46:8,10 52:6,
trained	146:11 147:21	27:21 68:20	7 56:18 101:6
181:22	148:2 161:21	166:23 181:23	102:2 148:15
trans	169:16 172:6	222:3	205:9 207:15
39:19 71:25	173:4 174:14	treatment	217:4
164:25 168:23	transitioned	5:4,16 6:23,	treats
169:1 170:1	173:18	25 8:24 9:2	23:24 24:1
172:25 173:3,	transitioning	16:16 18:6,7	25:2
15 182:2,9	72:7 151:3	19:20 20:13	trial
184:15 185:5,	194:17 211:19	27:14 37:12,	19:16
7,17 186:9	transmen	17 39:12	trials
219:2,4	162:16 163:1,	40:25 42:5	17:2 19:15
transcript	7	45:20,24	39:14,15
225:3	transness	49:13,21	50:17 51:1
TRANSCRIPTIONIS	186:5	51:10,23	triggered
T	transparently	56:9,19	187:8
225:1	191:10	58:16,25	Trouble
transdermal	transpeople	65:17,25	122:20 123:7,
89:16	178:10 181:11	71:23 73:10	10
transferred	184:15 186:1,	78:4,6,9,10	true
99:8	18 189:3	85:15 99:16	17:25 21:21
transgender	191:24	102:19 105:11	36:17,22
71:18,22	transpeople's	108:13 111:15	81:17 85:8
148:10 149:19	186:2	116:4 118:2	225:2
	transwomen	120:7 123:5	trust
		131:23,25	106:3
		134:15 154:25	

trusting 146:13	36:4 38:25 57:4 60:11	understand 11:2 15:5 21:6 25:12 40:16 42:21 44:2 49:20 54:12 56:5 62:7,20 86:6 98:23 112:4 125:14,16 128:1 133:15 137:18 152:8 165:5 168:24 169:5 215:22	22,24 61:8,19 62:13,16,21 67:21 69:17 70:21 75:16 76:3,6,22 80:19 81:17 83:8 86:18,21 92:15 93:18 94:15,18,25 97:4,22 99:24 112:23 115:4 117:10 118:12 125:2 131:2 135:15,23 136:2,7,13 139:15,17 142:20 151:2 195:22 196:10
truth 164:22,24 193:24	66:8 70:23 76:17 83:14 99:3 106:15 107:22 113:25 115:21 120:23 122:14 123:16	understanding 20:22 135:25 193:22	
truthful 189:10	124:16 127:13 130:4 132:7 134:9,20 135:11 136:22 192:11 200:16 201:2,13,21 202:10 221:17 222:16,22 223:5,15,24 224:10	understandings 206:6	
tumor 183:22		understands 15:6 206:8	uninsured 216:1
turn 17:12 131:19 132:10		undue 166:4 167:11 189:4	United 88:9,24 108:8 109:13,17 143:7 167:24
turned 144:1		unduly 166:9	University 160:23,24 162:17
tweaked 25:8		Unethical 172:14	unknown 48:21 49:14
type 23:12 47:1 181:5	uncertainty 40:17 208:10	UNIDENTIFIED 13:21 16:4 21:21 22:4,9, 10 23:6 24:14 25:5 28:5,8, 19 29:11 31:16 32:6,9, 25 33:19 34:2,18,25 36:2 49:2 55:9 56:10 57:7,9,15 58:24 60:7,	unmet 171:6
typical 95:25 137:19	undergo 27:25 33:14 103:13 139:11 154:6 183:8 213:7		unnecessary 103:8 134:4 154:24 178:5
typically 44:12 54:19 63:2 69:3 90:8 91:3,11, 14 92:2 120:13 137:20,21 155:7 162:22	undergoes 19:21 24:10 27:25 29:8 32:21 103:23 106:6 206:11		updated 14:18
	undergoing 49:21 100:14 133:2 154:4		upmost 152:11
<hr/> U <hr/>	undergone 169:14		upticks 181:15
Uh-huh 87:10 103:1	underpin 44:13		
ulcers 95:17	undersigned 99:17		
umbrella 162:4			
unanimous			

urge 161:5 162:1 186:14	vaginoplasty 116:12 117:4, 15,16,21 119:25	117:6 158:19 199:10	vulnerable 171:7 172:21
urgency 168:1	Vague 65:21	vice 143:17 163:17	<hr/> W <hr/>
urgently 165:23	valid 146:20 172:18 179:21	view 139:6	wait 71:7 88:11 96:19 98:12 109:20 111:8 121:10
urinary 122:3,6,23 123:22,24 124:1,2	validity 161:1	violation 201:17 223:20	waiver 16:20
urinating 124:3,5	Vanessa 148:21 150:18,21,22, 25 151:8,9	virilization 102:14	Walgreen 146:18
urination 123:2 124:9, 13	vase 178:13	virtual 7:3 9:21	Walgreens 146:18
urine 123:4	vast 64:25 189:10 194:16	virtually 30:4	walk 11:17 44:20 202:19
urologist 119:1	Vazquez 3:10,12,14 9:17 15:24 31:9 93:10, 14,20 94:6, 10,14 112:7, 12 131:17,19, 21 199:12	visit 29:4,14,17 32:15 148:12	wanted 11:19 32:4 34:7 53:9 108:21 112:19 127:4 133:14 138:10 141:4, 9 154:21 155:2,8 162:12 178:22 179:14 199:14 202:18 222:8
utilized 187:3	verbiage 14:24 79:3 90:7,12 112:2 113:7 116:21	visits 28:13 31:19 100:20 103:8 136:9 209:23	wanting 157:16
<hr/> v <hr/>	version 6:19 58:6 110:4,5	vital 31:24	warm 10:1
vacation 21:12 23:20 26:17	versions 89:15	voice 161:6 163:18	warranting 197:7
vagina 96:1 97:8 116:15,17 118:8,19 120:9	versus 32:8,9 77:11	Voices 143:18 144:16 177:18 186:23 196:14	Washington 77:11
vaginal 95:16,18 96:23 97:5, 11,12,18,21, 22 98:2,3,4, 6,7,19 113:6, 19		vote 10:22 34:24 35:3,19 198:7,25 200:12	waste 189:14
		voted 57:7	
		VU 162:17	

watching 211:20	white 164:23 188:6	198:1	working 58:6 145:16
ways 21:7 93:12	widespread 142:5	wondering 30:14 153:20	works 114:9 185:2,5
websites 3:21	willful 182:21	word 19:20 37:5 45:2 58:3,6 63:10 65:23 73:11,16 81:3 93:1 94:12,22 113:7 134:16 219:19	workshop 160:17
week 3:21 15:22 26:16 89:12 146:17 155:23 156:1	willfully 184:17	wordage 92:20	workup 205:1,17 206:3
weeks 156:11	wills 115:5	worded 105:3	World 87:4 172:15 195:1 212:6
Weida 187:12	Wilson 161:15 165:10 168:21,22	wording 41:6,7,13 99:12	worry 30:17
weight 29:24	window 26:7 207:22	words 36:16 47:12, 25 48:1 50:10 75:4,5 76:20 80:13 92:22 115:11	worthy 81:24
weird 222:5	wiped 164:25	wordsmith 221:7	wow 197:10
welcomed 11:20	wishes 8:9	Wordsmithing 63:12	WPATH 172:15
welfare 215:15 216:4	wishing 9:14	work 11:23 16:12 26:3,13 27:17 81:5,22 151:24 153:7 156:20 175:10 176:8 192:24	write 20:21 22:15 23:3 26:18 73:16 74:23 216:10
well-being 167:16	woah 17:8	worked 6:4	writing 46:20 193:13 216:12
well-designed 194:18	woke 186:3	worker 178:17	written 22:3,5 53:10 62:20 204:17
well-established 195:10	woman 75:8,24 93:1 94:8		wrong 27:22 120:6 172:13 177:10 188:2
well-founded 80:23	women 68:21 72:7,15 86:17 87:5 162:16		wrote 23:7 27:15 42:13 44:22
well-tested 185:9	Women's 143:18 144:16 163:18 177:18 186:23 196:14		
whaler 192:13	wonderful 169:18 183:4		
wheel 213:23			

<hr/> x <hr/>	168:11 169:14 173:14 174:3 177:17 178:18,21 179:12 207:7, 8 210:25	
x-ray 67:4 191:20		
x-rays 179:2	yeoman's 16:12	
XYZ 54:15	York 193:16	
<hr/> y <hr/>	young 49:24 68:10, 11 120:16 163:25 185:4	
year 9:8,10 14:14 29:8 39:20 49:20 100:22 102:3,12,13, 19,22,24 103:16 104:16,17,20 105:8,21,24 106:8 146:2,3 169:15 170:25 171:6 181:18 191:20 192:12 194:7,12,25 201:8 209:19 210:25 214:23,24 223:10	younger 5:3 147:22	
	youth 39:10,19 110:1 163:25 185:6,11,17 194:1,9,15	
	youth-led 185:2	
	<hr/> z <hr/>	
years 5:3,19 39:16 68:15,25 69:5,6,20,25 71:11,13 72:4,13 78:21 90:21 100:25 101:6 103:5 105:23 145:16 154:3,5 159:2,4,13 162:21,24	zebras 75:7	