EXHIBIT 1

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IN THE UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF WASHINGTON AT SEATTLE

RYAN KARNOSKI, et al., :
Plaintiffs :
v. CASE NO.: 2:17-CV-1297-MJP
DONALD J. TRUMP, et al., :
Defendants :

IN THE UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

AIDEN STOCKMAN; NICOLAS TALBOTT; TAMASYN REEVES; JAQUICE TATE; JOHN DOES 1-2; JANE DOE; and EQUALITY CALIFORNIA, :
RYAN KARNOSKI, et al., :
Plaintiffs :
v. CASE NO.: 5:17-CV-01799-JGB-KK
MARK ESPER, et al., :
Defendants :

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

JANE DOE 2, et al., :
Plaintiffs :
v. CASE NO.: 17-CV-1597 (CKK)
MARK ESPER, et al., :
Defendants :

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

BROCK STONE, et al., :
Plaintiffs :
v. CASE NO.: 1:17-CV-02459-GLR
DONALD J. TRUMP, et al., :
Defendants :

Videotaped Deposition of BRAD R. CARSON
Tuesday, January 28, 2020

Reported by: Lisa M. Blair, RMR, CRR

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Deposition of BRAD R. CARSON, held at the offices of:

THE JUDGE ADVOCATE GENERAL'S LEGAL CENTER
AND SCHOOL
600 Massie Road
Charlottesville, Virginia 22903

Pursuant to agreement, before Lisa M. Blair, RMR, CRR, Notary Public in and for the Commonwealth of Virginia.

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A P P E A R A N C E S

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A P P E A R A N C E S (Continued)

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A. I don't know. Again, these are the questions for RAND about things. And so, I see nothing in the report that suggests that's some kind of linchpin that their findings rest upon, but again, I don't know for sure.

Q. Did the Working Group consider that hormone treatments during the first year would account for zero non-deployability days?

A. As I remember it, we relied upon experts such as RAND who can best provide that information to us about what that would be.

Q. But do you remember what they -- how many days they calculated as non-deployability during the first year?

A. I believe people accepted the RAND Report and their numbers. Again, they were seen as dispassionate and dispositive on these matters.

Q. So it was zero?

A. As I recall, no one in the Working Group had grave concerns about the non-deployability -- no one -- of people getting hormone treatment, because after all, we send men to combat taking testosterone, women on birth control. So the hormone treatments are ubiquitous in some quarters. And so, this was not seen as

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something that was a major issue.

Q. I'm talking specifically about the first year where it requires the monitoring. The Transgender Working Group -- the Carter Transgender Working Group didn't think that that monitoring was an issue?

A. We heard from people like Wylie Hembree, the endocrinologist, that for a young, healthy population like this, the monitoring was not a significant barrier to any kind of work you wanted to do. And it would be very casual and relatively infrequent.

Q. Would you take the advice of one particular doctor on the Endocrine Society Guidelines over the collective doctors on the Endocrine Society Guidelines?

A. Well, he was the author of those particular guidelines, and so, could tell you what a young, healthy population like the military would be. So he is someone who I think has particular insight, so you would depend on it. And, of course, the AMA, the APA, both American Psychological and American Psychiatrist Association have opined on this issue too. So collectively, I do think it is safe to say that

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the medical professionals have no issues with this.

Q. But you have one person -- I mean, just -- so is it your opinion that the Department of Defense should be following the guidance of that one doctor and these AMA statements over the actual Endocrine Society Guidelines?

A. He was one input. We were surrounded by people who had spent their careers in uniform doing medical services for the Services -- the Surgeon Generals, their representatives, their experts. And so, he was one input into what was the medical opinion that hormone therapy would not be a serious barrier to anything we needed to do in the military. So it was the military experts, Surgeon Generals and others, who really authored this testimony. He was an input into that.

Q. And the Surgeon Generals, as you remember, they actually said that people would be deployable during that one year of hormone treatments?

A. As I remember, yes, they did.

Q. Are you aware that that hasn't happened in the actual -- under the Carter policy; the individuals were not deployed during that

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first year?

A. I have no knowledge of how it's been implemented under the Trump Administration. So, I don't know. I just do know that no Surgeon General had any concerns about that issue with medical professionals. And again, people have been taking hormone therapy in theater who are transgender. Men take testosterone, women on birth control. So people were taking hormones for many different reasons, many different population groups. And no one saw that as any serious or even insignificant barrier to military service.

Q. Do you have any knowledge of how -- how the hormone -- hormones were administered under the Obama Administration under the last part of it, because you had said none under the Trump Administration. Do you know whether or not these guidelines essentially were getting waived under the -- under the last few months of the Obama Administration?

A. I was no longer in the Administration at that time, so I don't know.

Q. Is it your opinion they should have been waived under that period?

A. I don't know.

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Q. But you seem to be offering the opinion that the -- and you can correct me if I'm wrong -- that the Department of Defense and the Department of Defense doctors should have been following -- rather than the Endocrine Society Guidelines they should have been following these statements from Mr. Hembree and the statements from the AMA; is that correct?

MR. PATTON: Objection, mischaracterizes the witness's testimony.

MR. CARMICHAEL: Oh, I asked him to correct me if I'm wrong.

MR. PATTON: I know, but you are mischaracterizing testimony he's already given, and I object.

You can answer.

THE WITNESS: And that is not what I said. The Department of Defense came to its own conclusions, of which Dr. Hembree was just one input into that. But we had people, again, who love the military, whose job was to take care of service members, and this was their opinion I'm just recounting to you.

BY MR. CARMICHAEL:

Q. Their opinion is that the Endocrine

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Society Guidelines should not be followed?

A. Their opinion was what's best for the military, right? We have a unique population of people who are very healthy, very young. Dr. Hembree had testified to this issue. That was one input. But in their medical judgment, no one thought hormone treatment was a barrier. Again, the same thing, women, men -- hormones are not simply of the transgender community.

Q. Do you know who specifically said that the Endocrine Society Guidelines should not be followed for the first year of treatment?

MR. PATTON: I object to the premise for that question, because it has not been established on this record. With that, you can answer.

THE WITNESS: I don't believe that is a characterization that we didn't follow them. The author of them said that for your population, here's what the rule should be. The very author who wrote them said that. So we're entirely consistent with, you know, what the rules are for a broader population of unhealthy, older people is different. And so, again, the experts weighed in who were medical

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professionals. They heard testimony. They researched it themselves, and this was their considered conclusion.

BY MR. CARMICHAEL:

Q. Is that your understanding of the Endocrine Society Guidelines, that it's one person writing it, and that one person sort of controls the guidelines?

A. I don't know how they reach their particular conclusions. I do know that the medical experts we spoke with, no one thought this was an issue. And these are people, again, who were military experts, endocrinologists, people who talked to endocrinologists. And no one felt they were a particular -- that they were an issue for a military-age population.

Q. No one thought that the monitoring was necessary?

A. Monitoring might be necessary to check in with your doctor, as it is if you're on birth control pills or something else, but that it wouldn't affect military performance.

Q. How can you check in with your doctor for -- and checking in with your doctor, do you mean actually blood samples?

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A. I don't know what that means for the doctors.

Q. Is it easy to get these samples in -- you know, where you were in Iraq in Basra? Can those get back?

A. Probably so, yes.

Q. How about --

A. It's important to remember the way the policy was drafted in Carter, that it was about military necessity. You didn't have any right to hormone therapy, right? If the commander felt you were being deployed, or schooling, or that it might somehow interfere with it, then the commander wouldn't approve that. It was a commander-led process.

Q. So in your -- do you think the commander, or your opinion is that the commander had the ability to override medical treatment from -- from a service member?

A. Yes. Not override medical treatment; but the ability to transition under the Carter plan, which involved getting medical treatment, was expressly dependent upon your commander's permission.

Q. And if somebody said, I want hormone

EXHIBIT 2

UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF WASHINGTON AT SEATTLE

RYAN KARNOSKI, et al., :
Plaintiffs, :
v. : CASE NO.:
DONALD J. TRUMP, et al., : 2:17-cv-1297-MJP
Defendants. :

DEPOSITION of MARGARET C. WILMOTH
Raleigh, North Carolina 27612
Wednesday, January 22, 2020
9:31 a.m. to 5:20 p.m.

Job No.: 280937
Pages 1 - 314
Reported by: Sophie Brock, RPR, RMR, RDR, CRR

Reporter's Note: Case captions in all cases pertinent to this deposition are reflected on the following pages.

UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF WASHINGTON AT SEATTLE

RYAN KARNOSKI, et al., :
Plaintiffs, :
v. : CASE NO.:
DONALD J. TRUMP, et al., : 2:17-cv-1297-MJP
Defendants. :

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

JANE DOE 2, et al., :
Plaintiffs, :
v. : CASE NO.:
MARK ESPER, in his official : 17-cv-1597 (CKK)
capacity as Secretary of the :
Department of Defense, et al., :
Defendants. :

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

BROCK STONE, et al., :
Plaintiffs, :
v. : CASE NO.:
DONALD J. TRUMP, in his : 1:17-cv-02459-GLR
official capacity as President :
of the United States, et al., :
Defendants. :

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MS. ENLOW: No. Go ahead.
MR. CARMICHAEL: The objections are noted for introducing this testimony later. So unless your counsel instructs you not to answer a question, you have to answer the question. So --
THE WITNESS: And I've answered the question to the best of my ability.
BY MS. ENLOW:
Q. So you are unable to tell me whether or not you know the answer to whether a person -- after they go through transition treatment, whether gender dysphoria can reoccur?
MR. LAMPROS: Objection. Asked and answered. Calls for speculation.
THE WITNESS: The view of the working group was that once someone transitioned, gender dysphoria would not reoccur.
BY MS. ENLOW:
Q. Okay. And what was that based on?
A. All of the readings and all of the conversations that we had as a working group.
Q. Okay. Was that based on any information provided by any behavioral health or mental health specialist?
A. It's a gestalt. I can't point out

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exactly who or where or how, but it was a gestalt of the understanding of the conversations that we had over a six-month period of time.
Q. Okay.
If we can look at the Transgender Service Review Work Group report.
A. Mm-hmm.
Q. That's Exhibit --
A. 14.
Q. 14. Thank you.
On page 8 --
A. Which is Bates whatever?
Q. Actually, I don't have the Bates number. It's Bates ending in 289847.
A. Okay.
Q. It says, about halfway down the page, (as read):
"There are some medical issues associated with the open service of transgender persons, which could affect medical readiness and deployability. As the work group discussed these issues, we concluded that existing policy and procedures exist to address each

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issue. For example:"
And then the first bullet says (as read):
"High rates of depression and suicide. Several studies suggest that those diagnosed with gender dysphoria have higher than normal associated rates of depression and suicide."
What studies did the working group review that said that?
MR. LAMPROS: Objection. Lack of foundation.
THE WITNESS: I don't see a footnote here to state which particular studies, so I don't want to speculate.
BY MS. ENLOW:
Q. Do you remember reviewing any studies that stated or suggested that individuals diagnosed with gender dysphoria have a higher than normal associated rate of depression and suicide?
A. We all did a lot of reading, both given to us and work -- reading we did independently, so I can't speculate or identify which particular studies. But I think the sentence here that says

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(as read):
"While some have opined that these higher rates are partly due to social stigma and lack of access to care and are improving..."
That was our big take-away, that suicide rates were higher in those who did not have access to care and those who were not allowed to transition, so that exacerbated their dysphoria. If someone had access to proper care and treatment to transition, then suicide rates would be reduced.
Q. If someone had proper access to care and transition treatment, would those suicide or suicidal ideation rates be reduced to the level of individuals that did not have gender dysphoria?
MR. LAMPROS: Objection. Vague. Incomplete hypothetical.
THE WITNESS: I don't know that I have enough memory of the research to give you an accurate answer.
BY MS. ENLOW:
Q. Okay. So you don't know?
A. I said I don't recall the details of the reading that I did.

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Q. Okay. So how much did the suicide and suicidal ideation rates decrease once an individual had access to transition care and treatment?

MR. LAMPROS: Objection. Vague. Incomplete hypothetical.

THE WITNESS: You're asking me to remember articles I may have read six years ago, and I honestly do not remember rates.

BY MS. ENLOW:

Q. Okay. Do you remember any specific articles you read that said that?

A. I don't recall all that I read.

Q. Do you remember any specific articles that talked about suicide rates?

A. I read multiple articles, yes, but I cannot tell you who the author was, what the journal was, when it was published.

Q. You read multiple articles about suicide rates in gender dysphoria?

A. I did my own homework to prepare me for the working group so that I was informed and could provide appropriate, educated information and participate fully in the work group.

Q. And did that homework that you're

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referring to -- did that include reviewing multiple articles about suicide rates and gender dysphoria?

A. Yes.

Q. Okay. How many?

A. I don't remember how many articles I read. That was in 2015.

Q. Okay. Was it more than one?

A. Most likely, but I can't give you a hard number.

Q. Okay. Was it more than five?

A. I don't recall.

Q. Okay.

How did the working group use those studies on suicide rates and gender dysphoria in developing its policy recommendations?

MR. LAMPROS: Objection. Vague. Lack of foundation.

THE WITNESS: You're asking me how. Again, it was based on conversations and discussions. And the way we -- we examined this, and the way we looked at normalizing any individual who was transgender, we tried not to separate them into a distinct category that could be discriminated against or pigeonholed.

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We looked at their rates of any kind of stress, anxiety, suicide, as we would anybody -- any other service member. We did not try to look at them as a unique group of individuals who came to the military with a medical dysfunction or an abnormality. We tried to normalize it as we would any other service member.

BY MS. ENLOW:

Q. Okay. But the working group recognized that gender dysphoria was a medical condition; right?

MR. LAMPROS: Objection --

THE WITNESS: As is pregnancy.

MR. LAMPROS: -- lack of foundation.

BY MS. ENLOW:

Q. Is that a "yes"?

A. Pregnancy is also considered a medical condition in the military. So it was viewed in the same way as any other medical condition was.

Q. Okay. Did the working group review any data from DoD or other services concerning utilization rates of medical care for treating gender dysphoria?

MR. LAMPROS: Objection. Vague.

THE WITNESS: Well, again, prior to

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the publication of the Carter policy, transgender individuals would have been forced to get medical care outside of the DoD, outside of the MHS, so there would not have been any MHS data to examine.

BY MS. ENLOW:

Q. Okay. So because there was no data to examine from MHS, it naturally concludes the working group didn't consider data from the Military Health System?

A. There wouldn't have been any data to examine.

Q. Okay. And did the working group review any data from DoD or other services concerning costs of medical care for treating gender dysphoria?

A. The only thing that I recall we went by was looking at costs of treating any service member with depression or anxiety. The cost of treating anybody who was -- had any other diagnosis will be the same as anybody else with depression or anxiety.

Treating PTSD; we know that was common. The costs would have been the same regardless of gender identity.

Q. So the working group considered the costs

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of treating depression?
MR. LAMPROS: Objection. Misstates the testimony. Lack of foundation.
THE WITNESS: I don't recall a health economist coming and talking to us specifically about costs.
I do believe the RAND study tried to do some estimates based on cost of care for transgendered individuals, but I don't recall where those numbers came from in the RAND study.
BY MS. ENLOW:
Q. Okay. But when you say that the working group considered costs for depression and anxiety, was that from the military health system or from RAND or from some other source?
A. If we considered cost -- and I can't remember specifically that we had a chart or any data that looked at mental health care costs inside of DoD; but if we had, it would have been regardless of being transgender or not, because, again, at that time, transgendered individuals were not openly allowed to obtain care inside of DoD.
Q. Okay. So it's fair to say, then, that the working group didn't consider cost data from

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DoD or other services for the cost of transition treatment for gender dysphoria?
MR. LAMPROS: Objection. Misstates testimony.
THE WITNESS: I think if you're trying to get to the point that we didn't do our proper homework and try to properly assess costs, then I think you're asking me to opine on data that were not available inside the MHS at the time.
BY MS. ENLOW:
Q. Okay.
A. So had there been data, and had there been cost data, we would have examined it; but again, we were forced to look elsewhere because, at the time, DoD did not allow transgendered individuals to obtain care inside the MHS. We did our due diligence with the data that we had at hand.
Q. If you had had that cost data, why did you say you would have -- the working group would have reviewed it? Why would that have been important?
MR. LAMPROS: Objection. Misstates the testimony. Incomplete hypothetical.

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THE WITNESS: Again, our guidance from Secretary Carson was to examine this without a predetermined end in sight. So we took all data that we had, input from other individuals, to help us formulate our policy decisions. Had we had that data, it would have been a part of the policy decision-making -- MHS medical data. We didn't have that data from the MHS.
BY MS. ENLOW:
Q. Okay. And had you had data on the rates of utilization from MHS, would you have wanted the working group to consider that as well?
MR. LAMPROS: Objection. Incomplete hypothetical.
THE WITNESS: Those --
MR. LAMPROS: Assumes facts not in evidence.
THE WITNESS: Again, we don't have those data. I mean, any fact-based organization would want to use the data that they -- any and all data that they would have before them.
BY MS. ENLOW:
Q. Okay.
We were discussing before lunch the individuals that presented at the working group,

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and if you'd look again at the Transgender Service Review Work Group report, Exhibit 14.
A. Mm-hmm.
Q. I've had a chance to flip through it. There's some agendas in the middle. Starts on page 28 of the document.
A. Mm-hmm.
Q. And that's an agenda from August 19, 2015; right?
A. That's what it says, August 19th.
Q. Okay. And then the last sentence under "Overview" states (as read):
"Further, an overview of recently completed work by the Accession Medical Standards Working Group (AMSWG) will be covered to assist the group in understanding recommended changes."
I believe you mentioned AMSWG earlier, but can you just tell me what does that group do?
A. I only have a vague -- I've never -- this is the first time I've been on a committee with members of the AMSWG, so I only have a cursory understanding of their role. But this particular group reviews and evaluates medical standards for

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at all that the AMSWG presented to the working group?
MR. LAMPROS: Objection. Asked and answered. Lack of foundation.
THE WITNESS: That was four years ago. I do not have specific memory of each and every specific meeting I sat in.
BY MS. ENLOW:
Q. Okay. So the answer is no, you don't remember anything that the AMSWG presented to the working group?
MR. LAMPROS: Objection. Misstates the testimony. Asked and answered.
THE WITNESS: To the best of my recollection, at this particular point in time, I don't have any definitive information to provide you.
BY MS. ENLOW:
Q. Okay.
If the AMSWG had recommended that a certain stability period -- excuse me, if the AMSWG had recommended that there be a certain stability period before an individual with gender dysphoria could access into the military, would the working group have considered it?

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MR. LAMPROS: Objection. Incomplete hypothetical. Assumes facts not in evidence.
THE WITNESS: Can you point me to a specific accessions policy standard you're referring to?
BY MS. ENLOW:
Q. No, I'm asking, had the AMSWG presented a recommendation that an individual be stable for a certain period of time -- if they'd presented that recommendation to the working group, would the working group have considered that recommendation?
MR. LAMPROS: Objection. Incomplete hypothetical. Assumes facts not in evidence.
THE WITNESS: Is there a specific time period you're referring to, in terms of period of --
BY MS. ENLOW:
Q. Well, I mean, from the agenda, it looks like the AMSWG presented on August 19th, 2015 --
A. That was our very first meeting. That was four and a half years ago. I don't remember specifically what they presented at that particular meeting.
Q. Right. I'm saying, had the AMSWG presented a certain recommendation for a stability

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period before an individual with gender dysphoria could access into the military, would the working group have considered that information?
MR. LAMPROS: Objection. Incomplete hypothetical. Assumes facts not in evidence.
THE WITNESS: The working group considered a lot of information over a period of six months. I believe the recommendation we landed on at the end of that six-month period of time was an 18-month period of time an individual had to have successfully transitioned and been without gender dysphoria before they could access.
That would not have been a date that they dropped on us at the first meeting. That would have been the result of six months' worth of educating and discussion, policy formation that the group ended up at at the end of that six-month period of time.
BY MS. ENLOW:
Q. And would one of those discussions have been consideration of the AMSWG's recommendation?
A. I'm sure they had input into it, but I can't tell you where that -- who made that recommendation.
Q. Okay. Do you think it would have been

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important for the working group to consider that recommendation from AMSWG?
MR. LAMPROS: Objection. Assumes facts not in evidence. Incomplete hypothetical.
THE WITNESS: Which document was the final document that came from the -- that was the Carter recommendation?
BY MS. ENLOW:
Q. Are you talking about the Carter policy?
A. Carter policy.
Q. It's Exhibit 1.
A. They're all out of order.
Can you repeat your last question?
Q. I'm going to actually move from that.
A. Okay.
Q. I'm going to hand you what will be marked as Exhibit 16.
A. Y'all really are not into conserving trees, are you?
MS. ENLOW: Not really. Unfortunately.
(Exhibit No. 16 was marked for identification.)
THE WITNESS: Ah. Okay.
BY MS. ENLOW:
Q. And this is an email chain that's marked

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with the Bates stamp USDOE00238554.
I'm going to direct your attention to the bottom email.
A. From me. Yeah.
Q. Okay. And it's from you to Dr. Karen Guice, Major General Allen, Rear Admiral Iverson, and it's dated October 15, 2015; right?
A. Mm-hmm.
Q. Did you write this email?
A. Yes, I did.
Q. Who is Dr. Karen Guice?
A. Dr. Guice was the Principal Deputy to the Assistant Secretary of Defense, Health Affairs, Dr. Woodson.
Q. Okay. And who was Major General Roosevelt Allen?
A. He was the Deputy Surgeon General for the Air Force.
Q. And how about Rear Admiral Kenneth Iverson? Who was that?
A. Deputy Surgeon General of the Navy at the time.
Q. Okay. And you copied Colonel Mary Krueger on the email. Who is Colonel Krueger?

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A. She is an Army physician; and at the time, she was assigned to MRA inside the Army -- Manpower and Reserve Affairs.
Q. Okay. Did you work with Colonel Krueger at all?
A. Yes.
Q. In what capacity?
A. There was a lot of interactions between the Surgeon General's Office and Manpower and Reserve Affairs on a variety of military medical policies.
I worked with her on account management policy development, looking at the accessions for medical providers. So a variety of topics. A lot of interaction between the two offices.
Q. Okay. Over what period of time?
A. The two and a half years I was the Deputy Surgeon General for the Army Reserve.
Q. Okay. What's your opinion of Colonel Krueger?
A. Highly competent.
Q. Okay. As a doctor? Or as an Army colonel? Or --
A. As an officer.
Q. Okay. What is your opinion of her

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medical knowledge?
A. I had no -- have no reason to opine. She never took care of me, so I don't have an opinion of her medical knowledge.
Q. Did you discuss medicine when you were interacting in those two and a half years?
A. That wouldn't have been the nature of our conversation. We were interacting on policy matters, so not necessarily medical matters.
Q. Did the policy matters concern any medical issues?
A. Talent management has no medical issues. It was personnel policy for promotion.
The Transgender Service Working Group, it would have been development of personnel policies.
Q. Okay. Why did you send this email to Dr. Guise, Major General Allen, and Rear Admiral Iverson?
A. I was trying to offer an additional expert to the group to talk about transgender care from the behavioral health perspective.
Q. And why were you trying to offer an additional expert to talk about behavioral health?
A. Because I was doing due diligence and

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wanted to offer something to the committee.
Q. Did you not feel like the committee had already heard from sufficient perspectives on behavioral health?
A. We had. I just wanted to offer my input.
Again, we were all invited to and recommended that we offer names to be brought before the committee. Everybody had that blank invitation to recommend someone to come and speak to the committee.
Dr. Guice was the individual served with vetting individuals who came to the committee. So I was just doing my due diligence as a good, solid committee, doing my work.
Q. Okay. And why did you copy Colonel Krueger on this email?
A. I can't remember why I did.
Q. Okay. In the first line of your email, you state (as read):
"I understand that a BH expert will be coming to one of the TG work group meetings."
Is that a behavioral health expert?
A. Yes.
Q. Okay. Who was the behavioral health

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expert that you understood to be coming to your future working group meeting?
A. I didn't put the name here, and I can't remember.
Q. Okay. Was it a civilian or a military individual?
A. I think, as I said previously, most of the experts we invited to speak to us came from the civilian sector. So I'm assuming that what I was implying was a civilian behavioral health expert, but I cannot say for certain.
Q. Okay. Do you know if that civilian behavioral health expert came from an advocacy group?
A. The point of all of our experts came from individuals who had a well -- a broad and deep experience of working with transgendered individuals. So, again, whether or not they came from a professional organization or the surgeon from Ann Arbor, they would all have had the same depth and expertise in caring for transgendered individuals.
Q. Okay. But the behavioral health expert you're talking about in this email, was that going to be someone coming from an advocacy group?

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A. I have no idea. Again, there's no name here. I cannot link -- and I did not say where this expert would be coming from. I have no memory of what I was referring to.
Q. Is there any document, or anyone you could speak to, or anything at all that could refresh your recollection about who you're talking about as the behavioral health expert in this email?
A. I don't know of any documents that would have that -- who I was referring to on October the 15th, 2015. I don't have any documents to refresh my memory as to who that would be.
Q. Is there anyone you could speak to that would refresh your memory as to who that would be?
A. Now? At this precise point in time, no.
Q. Okay. So there's literally nothing you can think of that could refresh your memory of who that behavioral health expert might be?
MR. LAMPROS: Objection. Asked and answered.
THE WITNESS: I suppose I could go back through this list of agenda items and refer; but, again, I don't know that that would help me pinpoint specifically who this individual was.

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BY MS. ENLOW:
Q. Okay. Let's go to those agendas, actually. That's a good idea.
A. Glad I could help.
Q. They start on page 28 of Exhibit 14.
A. Okay.
Q. So on page 28, there's a list of speakers for the August 19, 2015, agenda?
A. Mm-hmm.
Q. Did any of those present on behavioral health?
MR. LAMPROS: Objection. Lack of foundation.
THE WITNESS: I think the subject and the speaker and the offices from which they came is listed on this agenda item.
BY MS. ENLOW:
Q. Okay. But I'm asking you, do you recall if Mr. Carson, Mr. Kurta, Dr. Guice, Ms. Miller, or Mr. Kurta was the expert that presented on behavioral health?
A. I do not believe any of them are behavioral health experts. The only physician in that group is Dr. Guice, and she's a surgeon.
Q. Do you remember Dr. Guice presenting any

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information regarding behavioral health?
A. I have no memory of what Dr. Guice presented at that particular meeting.
Q. Okay. Do you remember Dr. Guice ever presenting any information about behavioral health to the working group?
A. I don't recall that Dr. Guice presented anything to any of us.
Q. Okay.
If you look at the next agenda, September 3rd, 2015, there's four speakers listed there?
A. Mm-hmm.
Q. Do you recall, are any of these speakers behavioral health experts that presented to the working group?
A. We've already determined that Ms. Miller is from the accessions working group.
We already know who Admiral Kurta is.
And I do not know who Mr. Gruber is.
Q. Mr. Gruber is an attorney at DoD.
A. Okay. And Senior Airman Ireland, I believe, was an individual who's a transgendered service member.
Q. Okay. So none of those individuals on

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Did that email change your mind about -- that the prior speakers had come from the advocacy perspective?

A. I think she was correcting my thinking.

Q. Did it change your mind?

A. Yes, it did.

Q. Okay. And then she says (as read):

"Secretary Carter [sic] has asked me to vet each expert prior to inviting them to the working group."

A. Correct.

MR. CARMICHAEL: You said "Carter."

MS. ENLOW: Oh, it's Carson. Excuse me.

BY MS. ENLOW:

Q. Were you involved in that vetting process at all?

A. Was I involved in what vetting process?

Q. The vetting process Dr. Guice is referring to in her email.

A. Where she was asked to vet each expert?

Q. Mm-hmm.

A. No, I was not. Dr. Guice vetted the experts that presented to us.

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Q. Okay. Did anyone else work with Dr. Guice to vet the experts, that you know of?

A. I don't have any information -- I don't know the answer.

Q. Okay. Do you know what process Dr. Guice used to vet the experts?

A. No, I do not.

Q. Okay. Dr. Guice goes on to say in her email that she's identified some behavioral health experts "and will put your referred individual in the mix for my interview"?

A. Mm-hmm.

Q. Do you know which behavioral health experts Dr. Guice was referring to?

MR. LAMPROS: Objection. Lack of foundation.

THE WITNESS: No, I do not.

BY MS. ENLOW:

Q. Did Dr. Guice interview Dr. McHugh?

MR. LAMPROS: Objection. Lack of foundation.

THE WITNESS: All I know is what's in this email: that she put him in the mix for her interview. I do not know if she followed through and interviewed him or not. I have no way of knowing that.

BY MS. ENLOW:

Q. Okay. You didn't ask Dr. Guice if she had interviewed Dr. McHugh?

A. I did not follow up with her on it after I received this.

Q. Okay. Do you know what the result of your email exchange was with Dr. Guice?

MR. LAMPROS: Objection. Vague.

THE WITNESS: When you say "result," what do you mean?

BY MS. ENLOW:

Q. Did anyone contact Dr. McHugh?

A. I think I've already said that I don't have any knowledge of who all Dr. Guice vetted or if anyone contacted Dr. McHugh.

Q. Okay. And the working group didn't hear from Dr. McHugh; is that right?

A. If his name is not listed in any minutes, then no.

Q. You don't remember the working group hearing from Dr. McHugh; right?

A. I believe I said if his name is not listed in the minutes, then I don't recall if he presented or not. Probably not, but I cannot tell

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you specifically one way or another. If his name is not in here, he didn't present.

Q. Okay.

A. One more question and then a break?

Q. Sure.

Did you mention your concerns about hearing only from the advocacy perspective to anyone else?

MR. LAMPROS: Objection. Misstates the testimony and the document.

THE WITNESS: This email is the only conversation I had about that.

MS. ENLOW: Okay.

We can take a break.

THE WITNESS: Thanks.

MR. HEINZ: Actually, before we go off the record, Counselor, Exhibit 16, was that document initially withheld pursuant to the deliberative process privilege?

MS. ENLOW: I believe so, but it's been produced.

MR. HEINZ: Will defendants be producing all of the other withheld documents that relate to the Carter Working Group that are being withheld pursuant to the deliberative process

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privilege, since defendants selectively cherry-picked an email, produced it, and are now using it against plaintiffs and plaintiffs' expert witness?

MS. ENLOW: I think this conversation is better held not during a deposition; so we can talk about that later.

MR. HEINZ: Will you answer my question?

Will defendants be producing the other Carter Working Group documents that defendants are withholding?

MS. ENLOW: Again, I think that conversation is between the lawyers off the record. So we can go off the record.

MR. HEINZ: The record will reflect that counsel for defendants is refusing to answer my question and plaintiffs request that defendants produce the other documents that they've elected not to produce that relate to the subject matter.

(Recess taken from 3:39 p.m. to 4:12 p.m.)

BY MS. ENLOW:

Q. If we can look at the bibliography of documents in Exhibit B of your expert report. And we can look at the Stockman report again -- the

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most recent one -- Exhibit 5.

A. I think I got them all out of numerical order here.

Q. It's okay, we've been shuffling a lot of pages.

A. And you were on Exhibit Bravo?

Q. Yes.

A. Okay.

Q. Does this Exhibit B to your expert report list all of the materials that you relied upon to forming your expert opinions in these cases?

A. The one caveat I would have is that my expert testimony -- initially, back in 2017, many of these documents were not yet public information, were not written, so I did not use them in my initial testimony back in 2017.

Q. Okay. But sitting here today with your most recent reports -- your expert opinions -- does this Exhibit B to your expert report list all of the materials you relied on in forming your opinions in these cases?

A. I think the caveat is "these cases," again, because not all of these documents were published when I formed my opinion or wrote my document for the first case.

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I think this most recent one, Stockman, the date would have been October of 2019. So for this most recent one, I think the majority of the documents had been published. So I reviewed them. I can't say read them in-depth.

Q. Okay. Is there anything missing from that list that you relied on to form your expert opinions in these cases?

A. The only thing I did not review prior to these were all these Tweets. I did not review those. But there's nothing additional.

Q. Okay. I'm not asking you what you reviewed for today's deposition --

A. Okay.

Q. -- I'm asking, in forming your expert opinions in this case, is this the complete list of documents that you relied on or considered?

A. I'm probably going to split hairs a little bit here, but if you're talking about documents that I referred to when I was part of the working group, it's probably more expansive than this, because I did a lot more independent reading. But in preparing this particular deposition, these were the documents.

Q. Okay. In preparing your opinions as set

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forth in your expert reports, Exhibit B is the complete list of documents that you relied on?

A. And again, a lot of my expert opinion came from the additional reading I did in 2015 and 2016 that may not be reflected in this Exhibit B.

Q. Okay. Do you remember any of what that reading would have been from 2015 or 2016?

A. Again, it was me doing my own due diligence and doing a scholarly review of articles so that I could have a broad range of understanding before I went into the working group.

Q. Okay. And sitting here today, can you recall any specific articles?

A. No. No, I can't recall specific articles I read.

Q. Okay. Did you consider -- in forming your opinions in this case, did you consider the administrative record that was before the Department of Defense's panel of experts?

A. Is that a specific document that is listed on here?

Q. No, it's not listed in your Exhibit B.

A. Can you refresh my memory of what administrative...

EXHIBIT 3

From: Krueger, Mary V COL USARMY HQDA ASA MRA (US)
To: Biggerstaff, William C (Casey) MAJ USARMY 3 ID (USA)
Subject: FW: JHU Psychiatrist (UNCLASSIFIED)
Date:

CLASSIFICATION: UNCLASSIFIED

Casey,

v/r
MVK

-----Original Message-----
From: Guice, Karen S SES (US)
Sent: Friday, October 16, 2015 10:23 AM
To: Wilmoth, Margaret C MG USARMY (US) <margaret.c.wilmoth.mil@mail.mil>; Allen, Roosevelt Jr Maj Gen USAF AF-SG (US) <roosevelt.allen4.mil@mail.mil>; Iverson, Kenneth J RDML USN BUMED FCH VA (US) <kenneth.j.iverson.mil@mail.mil>
Cc: Krueger, Mary V COL USARMY HQDA ASA MRA (US) <mary.v.krueger.mil@mail.mil>
Subject: RE: JHU Psychiatrist (UNCLASSIFIED)

Peggy:

Thank you for the reference. I do not believe the prior experts were advocates; rather they were experienced specialists who provide care to this population. Sec. Carson has asked me to vet each expert prior to inviting them to the WG. I have identified some behavioral health experts and will put your referred individual in the mix for my interview.

-----Original Message-----
From: Wilmoth, Margaret C MG USARMY (US)
Sent: Thursday, October 15, 2015 7:58 PM
To: Guice, Karen S SES (US); Allen, Roosevelt Jr Maj Gen USAF AF-SG (US); Iverson, Kenneth J RDML USN BUMED FCH VA (US)
Cc: Krueger, Mary V COL USARMY HQDA ASA MRA (US)
Subject: JHU Psychiatrist (UNCLASSIFIED)

Classification: UNCLASSIFIED
Caveats: FOUO

Dr. Guice and colleagues,

I understand that a BH expert will be coming to one of the TG Work group meetings. All of the speakers we have had speak come from an advocacy perspective.

I have learned of a Johns Hopkins psychiatrist, Dr. Paul R. McHugh, who might view the BH aspects of TG from the opposite perspective which I believe might help us in providing the Senior leader group with the opportunity to have hear from all sides of the issue. Using the "Abilene" analogy, I would rather we get to a decision knowing how we got there by hearing from all sides of this important decision rather than just hearing from advocates.

He is an Emeritus professor at Hopkins; his contact info can be found at:
www.hopkinsmedicine.org/profiles/results/directory/profile/0003340/paul-mchugh
I am happy to contact him on behalf of the group.
Thoughts?

v/r
Peggy

Margaret C. Wilmoth, PhD, MSS, RN, FAAN
Major General
Deputy Surgeon General for Mobilization, Readiness and
Army Reserve Affairs
Office of the Surgeon General

Cell [redacted]
Office: 703-681-8151/6298
Email: Margaret.C.Wilmoth.mil@mail.mil

Classification: UNCLASSIFIED
Caveats: FOUO

CLASSIFICATION: UNCLASSIFIED

EXHIBIT 4

FILED UNDER SEAL

EXHIBIT 5

FILED UNDER SEAL

EXHIBIT 6

FILED UNDER SEAL

EXHIBIT 7

FILED UNDER SEAL

EXHIBIT 8

Subject: DATA BRIEFING ATTACHED - Medical Personnel Executive Steering Committee (MEDPERS) Meeting - Transgender Policy Review

Location: Pentagon - Decision Support Center - Room 2E579

Start: 10/30/2017 2:00 PM

End: 10/30/2017 4:00 PM

Show Time As: Tentative

Recurrence: (none)

Meeting Status: Not yet responded

Organizer: Brown, Gary W LTC USARMY OSD OUSD P-R (US)

Required Attendees: Hebert, Lernes J SES OSD OUSD P-R (US); Adirim, Terry A SES OSD HA (US); Blanks, Julie A SES OSD OUSD P-R (US); West, Nadja Y LTG USARMY HQDA OTSG (US); Ediger, Mark A Lt Gen USAF AF-SG (US); Burke, Robert P VADM USN CNO (US); Grosso, Gina M Lt Gen USAF AF-A1 (US); Woods, Robert L SES USN ASSTSECNAV MRA DC (US); Sitterly, Daniel R SES USAF SAF-MR (US); Chinn, Colin G RADM USN JS OCJCS (US); Kremer, Kyle J Brig Gen USAF JS J1 (US); Seamands, Thomas C LTG USARMY HQDA DCS G-1 (US); Rauch, Terry M CIV OSD HA (US); Faison, C Forrest (Forrest) VADM USN BUMED FCH VA (US); Schwartz, Erica G RADM USPHS (US); Shaffer, Gayle D RDML USN BUMED FCH VA (US); Gillingham, Bruce L RADM USN BUMED FCH VA (US); Nelson, Michael A (Snap) Jr. Col USAF NGB A2/3/6 (US); Horoho, Raymond T SES USARMY HQDA ASA MRA (US); Mckinley, Andrew S RDML USCG HQS (US)

Optional Attendees: Atkins, Diana E CTR OSD HA (US); Hofmann, Matthew T MAJ USARMY OSD OUSD P-R (US); Askins, Kishla A LCDR USN OSD HA (US); Ortel, Jesse K COL USARMY OSD OUSD P-R (US); Smith, David J SES OSD OUSD P-R (US); Rychalski, Jon J SES OSD HA (US); MILLER, Stephanie P SES OSD OUSD P-R (US); Arendt, Christopher P CIV OSD OUSD P-R (US); Wellman, Aaron C LTC USARMY OSD OUSD P-R (US); Mulcahy, Patricia SES OSD OUSD P-R (US); Melillo, Michael R CIV OSD OUSD P-R (US); Bauer, Kent P CIV OSD OUSD P-R (US); Clardy, Herman S III LtGen USMC OSD OUSD P-R (US); Clark, Jeffrey B MG USARMY DHA HEALTH OPNS (US); Beyler, Juliet M SES (US); Soto, Karen M CTR DHA CMD GRP (US); Artis, Wanda L CIV USARMY HQDA ASA MRA (US); Cassell, Mitchell E Col USMC USN ASSTSECNAV MRA DC (US); Van Heest, Deborah L CIV USARMY HQDA PMG (US); Perez, John D MCPO USN VCNO (US); Vargas, Ana S CIV USAF AF-SG (US); Carino, S M (Sad) CDR USN JS J1 (US); Fedrigo, John A SES USAF SAF-MR (US); Soper, Martha P CIV USAF SAF-MR (US); 'edward.sullivan@usmc.mil'; Mitchell, Ashley M CTR DHA HA SUPPORT (US); McCaffery, Thomas P SES (US); Findley, Andrew L Jr CIV (US); Demartino, Robert E CAPT USPHS (US); Bono, Raquel C VADM USN DHA (US); Richardson, Shannon

T CTR (US); Young, Heather J CIV USMC MANDR AFFAIRS (US); Bird, Amy M LTC USARMY HQDA OTSG (US); Kirkland, Latoya C CPO USN COMNAVSEASYSCOM DC (US); Hower, Brian S A1C USAF (US); Mitton, Robert H CAPT USN BUMED FCH VA (US); Corbridge, Joshua D LT USN BUMED FCH VA (US); Klinger, Jeffrey J CDR USN BUMED FCH VA (US); Kehrle, Michele M MAJ USARMY DHA DIR SUPPORT (US); Mayes, Michael D LTC USARMY OSD OUSD P-R (US); Washington, Lovetta L CPT USARMY OSD OUSD P-R (US); Goldinger, Donna J CIV DHS (US); Allen, Roosevelt Jr Maj Gen USAF AF-SG (US)

Resources: Pentagon - Decision Support Center - Room 2E579

MEDPERS,

LTC Gary Brown
10/27/2017

**********Historical Email**********

MEDPERS,

Draft Agenda

1. Transgender Policy Review Process & Timeline. (No Presentation: Discussion Only) – Mr. Lernes Hebert, DASD MPP, MEDPERS Co-Chair

2. Multi-disciplinary Review and Study of Relevant Transgender Data. (Anticipate a late submittal read ahead) – Dr. Terry Adirim, DASD HSP&O, MEDPERS Co-Chair

LTC Gary Brown
10/24/2017

**********Historical Email**********

MEDPERS,

Save the date placeholder.

Transgender Policy Review

3. Multi-disciplinary Review and Study of Relevant Data.

4. Authorized Gender Dysphoria Medical Procedures Policy.

5. Dialogue with Military Physicians that have provided care to transgender Service Members.

Read ahead documents to follow.

Very Respectfully,

Gary W. Brown
Lieutenant Colonel, USA
Assistant Director, Reserve and Medical Manpower

Office of The Under Secretary of Defense for Personnel and Readiness
Military Personnel Policy-Accession Policy Office
1500 Defense Pentagon, Room 3D1066
Washington, DC 20301-1500
(703) 697-9273
gary.w.brown.mil@mail.mil

EXHIBIT 9

FILED UNDER SEAL

EXHIBIT 10

FILED UNDER SEAL

EXHIBIT 11

FILED UNDER SEAL

EXHIBIT 12

FILED UNDER SEAL

EXHIBIT 13

TRANSGENDER POLICY PANEL MEETING AGENDA

Date: December 22, 2017
Time: 0900-1100
Room: 3D1063

Overview:
Panel of Experts will discuss a proposed policy recommendation submitted by the USMC and discuss additional research questions to complement other submitted questions.

Subject	Speaker	Duration
Opening Remarks	HON Robert Wilkie	0900-0910
Proposed policy discussion	Mr. Lernes Hebert	0910-1030
Discussion of additional Research questions	Mr. Lernes Hebert	1030-1100

Meeting Homework/Deliverables:

Save the following dates for upcoming meetings: Thursday, 4 January 2018 (T), Thursday 11 January 2018 (T). Both meetings tentatively scheduled from 1500 – 1700.

Administrative:
Questions or issues please contact, LTC Aaron Wellman ([HYPERLINK "mailto:aaron.c.wellman.mil@mail.mil"] or 703-697-7594).

EXHIBIT 14

TRANSGENDER POLICY PANEL MEETING AGENDA

Date: January 4, 2018
Time: 1500-1700
Room: 3D1063

Overview:
Panel of Experts will discuss proposed policy recommendations and discuss additional research questions to complement other submitted questions.

Subject	Speaker	Duration
Opening Remarks	HON Robert Wilkie	1500-1510
Proposed policy discussion	Mr. Lernes Hebert	1510-1610
Discussion of additional Research questions	Mr. Lernes Hebert	1610-1700

Meeting Homework/Deliverables:

Save the following dates for upcoming meetings: Thursday 11 January 2018 from 1500 – 1700.

Administrative:
Questions or issues please contact, LTC Aaron Wellman ([HYPERLINK "mailto:aaron.c.wellman.mil@mail.mil"] or 703-697-7594).

EXHIBIT 15

TRANSGENDER POLICY PANEL MEETING AGENDA

Date: January 11, 2018
Time: 1500-1700
Room: 3D1063

Overview:
Panel of Experts will discuss proposed policy recommendations and review proposed SECDEF brief.

Subject	Speaker	Duration
Opening Remarks	HON Robert Wilkie	1500-1510
Proposed policy discussion	Mr. Lernes Hebert	1510-1700

Meeting Homework/Deliverables:

Save the following dates for upcoming meetings: TBD

Administrative:
Questions or issues please contact, LTC Aaron Wellman ([HYPERLINK "mailto:aaron.c.wellman.mil@mail.mil"] or 703-697-7594).

EXHIBIT 16

TRANSGENDER POLICY PANEL MEETING AGENDA

Date: December 13, 2017
Time: 1500-1730
Room: 3D1063

Overview:
The Panel will review minutes from previous meetings and will receive the brief created for the Deputy Secretary of Defense on 15 December. Any corrections to products going to the 15 December meeting will be updated during the meeting.

Subject	Speaker	Duration
Overview	HON Robert Wilkie	1500-1505
Presentation of Meeting Minutes	Mr. Lernes Hebert	1505-1520
Pre-brief of DSD presentation	Mr. Lernes Hebert	1520-1700

Meeting Homework/Deliverables:
Approve meeting 6, 8 and 9 minutes; approve DSD Brief

Save the following dates for upcoming meetings: DSD/VCJCS meeting is scheduled for 1530, 15 December.

Administrative:
Questions or issues please contact, LTC Aaron Wellman ([HYPERLINK "mailto:aaron.c.wellman.mil@mail.mil"] or 703-697-7594).

EXHIBIT 17

Malloy, Emily N.

From: Powers, James R. (CIV) <James.R.Powers@usdoj.gov>
Sent: Friday, January 31, 2020 3:19 PM
To: Heinz, Jordan M.
Cc: Barsanti, Vanessa; Ikard, Sam; *prenn@lambdalegal.org; *tborelli@lambdalegal.org; *Rachel@newmanlaw.com; Siegfried, Daniel I.; Stallings-Ala'ilima, Chalia (ATG); *colleen.melody@atg.wa.gov; *jason@newmanlaw.com; Rosenberg, Michael E.; Carmichael, Andrew E. (CIV); Enlow, Courtney D. (CIV); Skurnik, Matthew (CIV); Norway, Robert M. (CIV); Gerardi, Michael J. (CIV)
Subject: [EXT] RE: Karnoski, et al. v. Trump, et al.

Jordan,
I have provided responses to your requests in red below.

Thanks,
Jim

From: Heinz, Jordan M. <jheinz@kirkland.com>
Sent: Tuesday, January 28, 2020 2:38 PM
To: Powers, James R. (CIV) <jpowers@CIV.USDOJ.GOV>; Gerardi, Michael J. (CIV) <mgerardi@CIV.USDOJ.GOV>; Skurnik, Matthew (CIV) <maskurni@CIV.USDOJ.GOV>; Carmichael, Andrew E. (CIV) <ancarmic@CIV.USDOJ.GOV>; Enlow, Courtney D. (CIV) <cenlow@CIV.USDOJ.GOV>
Cc: Barsanti, Vanessa <vanessa.barsanti@kirkland.com>; Ikard, Sam <sam.ikard@kirkland.com>; *prenn@lambdalegal.org <prenn@lambdalegal.org>; *tborelli@lambdalegal.org <tborelli@lambdalegal.org>; *Rachel@newmanlaw.com <Rachel@newmanlaw.com>; Siegfried, Daniel I. <daniel.siegfried@kirkland.com>; Stallings-Ala'ilima, Chalia (ATG) <Chalia.SA@atg.wa.gov>; *colleen.melody@atg.wa.gov <colleen.melody@atg.wa.gov>; *jason@newmanlaw.com <jason@newmanlaw.com>; Rosenberg, Michael E. <michael.rosenberg@kirkland.com>
Subject: Karnoski, et al. v. Trump, et al.

> Drew,
>
> During the December 10, 2019 conference with the Court, Defendants represented that there were nine Panel of Experts meetings. *See* Hr. Tr. 6:15-18. Plaintiffs have received the meeting minutes for these first nine meetings through December 7, 2017. However, based on a review of the produced documents, it appears that there were four additional Panel meetings: December 13, 2017; December 22, 2017; January 4, 2018; and January 11, 2018. Plaintiffs have not received meeting minutes for these final four meetings. Please promptly produce the meeting minutes for these final four meetings or confirm that no such meeting minutes exist.

I have been advised there were not meeting minutes for these 4 meetings.

> Defendants also implied during the December 10, 2019 conference that the Panel "briefed Secretary Mattis" in January 2018, "[a]nd the briefings we've given over to plaintiffs." Hr. Tr. 26:25 & 26:1-9. Plaintiffs have been unable to identify these briefings. Please identify these briefings by bates number.

The documents presented to Secretary Mattis were the Action Memo from former Under Secretary Wilkie (AR_003059-AR_003067) and its accompanying materials included in the AR.

> Additionally, Defendants claim to have now fully produced all documents responsive to RFP No. 36, which seeks all "complaints arising from or attributed to open service by transgender service members, accessions by

transgender individuals, or the Carter Policy," because the Defendants have now produced the two Equal Opportunity complaints referenced in DoD's Report and Recommendation. Within the incident description for one of these complaints, USDOE00076582, it states "Anonymous complainant alleges that the BnCO and SgtMaj have been fostering, condoning, and failing to correct, a hostile working [sic] which discriminates and segregates the transgendered Marine. ***See attachment for the detailed complaint provided to the EOA by the anonymous complainant***." (emphasis added). Plaintiffs have been unable to identify the referenced attachment. Please identify the referenced attachment or else please promptly produce this attachment; until then, Plaintiffs do not consider Defendants to have fully complied with RFP 36.

Defendants have identified and collected the attachment you appear to be referring to. We will produce it shortly.

Regards,

Jordan

Jordan M. Heinz

KIRKLAND & ELLIS LLP
300 North LaSalle, Chicago, IL 60654
T +1 312 862 7027
F +1 312 862 2200

jordan.heinz@kirkland.com

EXHIBIT 18

UNDER SECRETARY OF DEFENSE
4000 DEFENSE PENTAGON
WASHINGTON, D.C. 20301-4000

PERSONNEL AND READINESS

ACTION MEMO

JAN 11 2018

TO: SECRETARY OF DEFENSE

THROUGH: DEPUTY SECRETARY OF DEFENSE
VICE CHAIRMAN OF THE JOINT CHIEFS OF STAFF

FROM: Robert Wilkie, Under Secretary of Defense for Personnel and Readiness

SUBJECT: Recommendations by the Transgender Review Panel of Experts

- On September 14, 2017, you directed the establishment of a Panel of Experts to review and recommend changes to Department of Defense policies regarding the service of transgender individuals (Tab A), in accordance with direction from the President on August 25, 2017 (Tab B).
- The Panel, which I chaired, comprised the officials performing the duties of the Under Secretaries of the Military Departments, the Uniformed Services' Vice Chiefs, and Senior Enlisted Advisors.
- You directed the Panel to conduct its review and render recommendations consistent with military readiness, lethality, deployability, budgetary constraints, and applicable law.
- The Panel was informed by testimony from commanders with transgender troops, currently-serving transgender Service members, military physicians, and other health experts.
- The Panel considered available DoD data and information on currently-serving transgender personnel and relevant external research and studies.
- Based on the individual and collective experience leading warfighters and their expertise in military operational and institutional effectiveness, the Panel makes the following recommendations:
    - Transgender individuals should be allowed to enter the military in their biological sex, subject to meeting all applicable accession standards. A diagnosis of gender dysphoria is disqualifying for accessions unless medical documentation establishes stability in his/her biological sex for no less than 36 consecutive months—as determined by a qualified Department of Defense medical provider—at the time of application. [*Gender Dysphoria*: a medical diagnosis involving significant distress or problems functioning resulting from a difference between the gender with which an individual identifies and the individual's biological sex]

- Transgender Service members should be permitted to serve openly, but only in their biological sex and without receiving cross-sex hormone therapy or surgical transition support.
- In order to keep faith with those transgender Service members who receive a diagnosis of gender dysphoria from a qualified military medical provider prior to the implementation of a revised DoD policy in 2018, they should be authorized all medically necessary and appropriate care and treatment, including cross-sex hormone therapy and medically necessary surgery. Such care and treatment should be authorized and provided at government expense even if it is determined to be necessary and appropriate only after the implementation of a revised policy in 2018.
- Transgender Service members should be subject to the same retention standards applicable to all other Service members.

- To ensure consistent application of the policies, procedures, and guidance currently in effect with regard to the accession[1] and in-service transition[2] of transgender individuals, I intend to issue a memorandum clarifying existing guidance regarding privacy concerns that may arise.

RECOMMENDATION: As discussed, based on your review of these recommendations, and other information and input you elect to consider, we will develop a writing by which you would advise the President of your conclusions and recommendations in this matter.

COORDINATION: TAB C

Attachments:
As stated

[1] As required by court order.
[2] As authorized by DoDI 1300.28, *In-Service, Transition for Transgender Service members*, dated July 1, 2016.

SECRETARY OF DEFENSE
1000 DEFENSE PENTAGON
WASHINGTON, DC 20301-1000

9/14/17

MEMORANDUM FOR SECRETARIES OF THE MILITARY DEPARTMENTS
CHAIRMAN OF THE JOINT CHIEFS OF STAFF
UNDER SECRETARIES OF DEFENSE
COMMANDANT, U.S. COAST GUARD
DEPUTY CHIEF MANAGEMENT OFFICER
CHIEF, NATIONAL GUARD BUREAU
GENERAL COUNSEL OF THE DEPARTMENT OF DEFENSE
DIRECTOR OF COST ASSESSMENT AND PROGRAM EVALUATION
INSPECTOR GENERAL OF THE DEPARTMENT OF DEFENSE
DIRECTOR OF OPERATIONAL TEST AND EVALUATION
CHIEF INFORMATION OFFICER OF THE DEPARTMENT OF DEFENSE
ASSISTANT SECRETARY OF DEFENSE FOR LEGISLATIVE AFFAIRS
ASSISTANT TO THE SECRETARY OF DEFENSE FOR PUBLIC AFFAIRS
DIRECTOR OF NET ASSESSMENT
DIRECTOR, STRATEGIC CAPABILITIES OFFICE
DIRECTORS OF DEFENSE AGENCIES
DIRECTORS OF DOD FIELD ACTIVITIES

SUBJECT: Military Service by Transgender Individuals - Interim Guidance

The Department of Defense ("DoD") has received the Presidential Memorandum, *Military Service by Transgender Individuals*, dated August 25, 2017 ("Presidential Memorandum"). DoD will carry out the President's policy and directives in consultation with the Department of Homeland Security ("DHS") with respect to the U.S. Coast Guard. Not later than February 21, 2018, I will present the President with a plan to implement the policy and directives in the Presidential Memorandum. Consistent with military effectiveness and lethality, budgetary constraints, and applicable law, the implementation plan will establish the policy, standards and procedures for transgender individuals serving in the military. The Deputy Secretary of Defense and the Vice Chairman of the Joint Chiefs of Staff, supported by a panel of experts ("Panel"), shall propose for my consideration recommendations supported by appropriate evidence and information.

To comply with the Presidential Memorandum, ensure the continued combat readiness of the force, and maximize flexibility in the development of the implementation plan, the attached Interim Guidance takes effect immediately and will remain in effect until I promulgate DoD's final policy in this matter. By agreement with the Acting Secretary of Homeland Security, this Interim Guidance also applies to the U.S. Coast Guard.

Attachment:
As stated

James Mattis

cc:
Secretary of Homeland Security

Interim Guidance

First and foremost, we will continue to treat every Service member with dignity and respect.

Accessions: The procedures set forth in Department of Defense Instruction (DoDI) 6130.03, *Medical Standards for Appointment, Enlistment, or Induction in the Military Services*, dated April 28, 2010 (Change 1), which generally prohibit the accession of transgender individuals into the Military Services, remain in effect because current or history of gender dysphoria or gender transition does not meet medical standards, subject to the normal waiver process.

Medical Care and Treatment: Service members who receive a gender dysphoria diagnosis from a military medical provider will be provided treatment for the diagnosed medical condition. As directed by the Memorandum, no new sex reassignment surgical procedures for military personnel will be permitted after March 22, 2018, except to the extent necessary to protect the health of an individual who has already begun a course of treatment to reassign his or her sex.

In-Service Transition for Transgender Service Members: The policies and procedures set forth in DoDI 1300.28, *In-Service Transition for Transgender Service Members*, dated July 1, 2016, remain in effect until I promulgate DoD's final guidance in this matter.

Separation and Retention of Transgender Service members:

Service members who have completed their gender transition process and whose gender marker has been changed in DEERS will continue to serve in their preferred gender while this Interim Guidance remains in effect.

An otherwise qualified transgender Service member whose term of service expires while this Interim Guidance remains in effect, *may*, at the Service member's request, be re-enlisted in service under existing procedures.

As directed by the Memorandum, no action may be taken to involuntarily separate or discharge an otherwise qualified Service member solely on the basis of a gender dysphoria diagnosis or transgender status. Transgender Service members are subject to the same standards as any other Service member of the same gender; they may be separated or discharged under existing bases and processes, but not on the basis of a gender dysphoria diagnosis or transgender status.

Reestablishment of the Office of the Under Secretary of Defense for Personnel and Readiness (OUSD(P&R)) Central Coordination Cell: The OUSD(P&R) will reestablish the Central Coordination Cell (CCC) to provide expert advice and assistance to the Military Departments and Services and to commanders with regard to this Interim Guidance. The CCC may be reached at https://ra.sp.pentagon.mil/DoDCCC/SitePages/HomePage.aspx.

SECRETARY OF DEFENSE
1000 DEFENSE PENTAGON
WASHINGTON, DC 20301-1000

9/14/17

MEMORANDUM FOR SECRETARIES OF THE MILITARY DEPARTMENTS
CHAIRMAN OF THE JOINT CHIEFS OF STAFF
UNDER SECRETARIES OF DEFENSE
COMMANDANT, U.S. COAST GUARD
DEPUTY CHIEF MANAGEMENT OFFICER
CHIEF, NATIONAL GUARD BUREAU
GENERAL COUNSEL OF THE DEPARTMENT OF DEFENSE
DIRECTOR OF COST ASSESSMENT AND PROGRAM EVALUATION
INSPECTOR GENERAL OF THE DEPARTMENT OF DEFENSE
DIRECTOR OF OPERATIONAL TEST AND EVALUATION
CHIEF INFORMATION OFFICER OF THE DEPARTMENT OF DEFENSE
ASSISTANT SECRETARY OF DEFENSE FOR LEGISLATIVE AFFAIRS
ASSISTANT TO THE SECRETARY OF DEFENSE FOR PUBLIC AFFAIRS
DIRECTOR OF NET ASSESSMENT
DIRECTOR, STRATEGIC CAPABILITIES OFFICE
DIRECTORS OF DEFENSE AGENCIES
DIRECTORS OF DOD FIELD ACTIVITIES

SUBJECT: Terms of Reference - Implementation of Presidential Memorandum on Military Service by Transgender Individuals

Reference: Military Service by Transgender Individuals – Interim Guidance

I direct the Deputy Secretary of Defense and the Vice Chairman of the Joint Chiefs of Staff to lead the Department of Defense (DoD) in developing an Implementation Plan on military service by transgender individuals, to effect the policy and directives in Presidential Memorandum, *Military Service by Transgender Individuals*, dated August 25, 2017 ("Presidential Memorandum"). The implementation plan will establish the policy, standards and procedures for service by transgender individuals in the military, consistent with military readiness, lethality, deployability, budgetary constraints, and applicable law.

The Deputy Secretary and the Vice Chairman, supported by a panel of experts drawn from DoD and the Department of Homeland Security (DHS) ("Panel"), shall propose for my consideration recommendations supported by appropriate evidence and information, not later than January 15, 2018. The Deputy Secretary and the Vice Chairman will be supported by the Panel, which will be comprised of the Military Department Under Secretaries, Service Vice Chiefs, and Service Senior Enlisted Advisors. The Deputy Secretary and Vice Chairman shall

designate personnel to support the Panel's work to ensure Panel recommendations reflect senior civilian experience, combat experience, and expertise in military operational effectiveness. The Panel and designated support personnel shall bring a comprehensive, holistic, and objective approach to study military service by transgender individuals, focusing on military readiness, lethality, and unit cohesion, with due regard for budgetary constraints and consistent with applicable law. The Panel will be chaired by the Under Secretary of Defense for Personnel and Readiness and will report to the Deputy Secretary and the Vice Chairman at least every 30 days and address, at a minimum, the following three areas:

Accessions: The Presidential Memorandum directs DoD to maintain the policy currently in effect, which generally prohibits accession of transgender individuals into military service. The Panel will recommend updated accession policy guidelines to reflect currently accepted medical terminology.

Medical Care: The Presidential Memorandum halts the use of DoD or DHS resources to fund sex-reassignment surgical procedures for military personnel, effective March 23, 2018, except to the extent necessary to protect the health of an individual who has already begun a course of treatment to reassign his or her sex. The implementation plan will enumerate the specific surgical procedures associated with sex reassignment treatment that shall be prohibited from DoD or DHS resourcing unless necessary to protect the health of the Service member.

Transgender Members Serving in the Armed Forces: The Presidential Memorandum directs that the Department return to the longstanding policy and practice on military service by transgender individuals that was in place prior to June 2016. The Presidential Memorandum also allows the Secretary to determine how to address transgender individuals currently serving in the Armed Forces. The Panel will set forth, in a single policy document, the standards and procedures applicable to military service by transgender persons, with specific attention to addressing transgender persons currently serving. The Panel will develop a universal retention standard that promotes military readiness, lethality, deployability, and unit cohesion.

To support its efforts, the Panel will conduct an independent multi-disciplinary review and study of relevant data and information pertaining to transgender Service members. The study will be planned and executed to inform the Implementation Plan. The independent multi-disciplinary review and study will address aspects of medical care and treatment, personnel management, general policies and practices, and other matters, including the effects of the service of transgender persons on military readiness, lethality, deployability, and unit cohesion.

The Panel may obtain advice from outside experts on an individual basis. The recommendations of the Deputy Secretary and the Vice Chairman will be coordinated with senior civilian officials, the Military Departments, and the Joint Staff.

All DoD Components will cooperate fully in, and will support the Deputy Secretary and the Vice Chairman in their efforts, by making personnel and resources available upon request in support of their efforts.

cc:
Secretary of Homeland Security

THE WHITE HOUSE

WASHINGTON

August 25, 2017

MEMORANDUM FOR THE SECRETARY OF DEFENSE
THE SECRETARY OF HOMELAND SECURITY

SUBJECT: Military Service by Transgender Individuals

Section 1. Policy. (a) Until June 2016, the Department of Defense (DoD) and the Department of Homeland Security (DHS) (collectively, the Departments) generally prohibited openly transgender individuals from accession into the United States military and authorized the discharge of such individuals. Shortly before President Obama left office, however, his Administration dismantled the Departments' established framework by permitting transgender individuals to serve openly in the military, authorizing the use of the Departments' resources to fund sex-reassignment surgical procedures, and permitting accession of such individuals after July 1, 2017. The Secretary of Defense and the Secretary of Homeland Security have since extended the deadline to alter the currently effective accession policy to January 1, 2018, while the Departments continue to study the issue.

In my judgment, the previous Administration failed to identify a sufficient basis to conclude that terminating the Departments' longstanding policy and practice would not hinder military effectiveness and lethality, disrupt unit cohesion, or tax military resources, and there remain meaningful concerns that further study is needed to ensure that continued implementation of last year's policy change would not have those negative effects.

(b) Accordingly, by the authority vested in me as President and as Commander in Chief of the Armed Forces of the United States under the Constitution and the laws of the United States of America, including Article II of the Constitution, I am directing the Secretary of Defense, and the Secretary of Homeland Security with respect to the U.S. Coast Guard, to return to the longstanding policy and practice on military service by transgender individuals that was in place prior to June 2016 until such time as a sufficient basis exists

upon which to conclude that terminating that policy and practice would not have the negative effects discussed above. The Secretary of Defense, after consulting with the Secretary of Homeland Security, may advise me at any time, in writing, that a change to this policy is warranted.

Sec. 2. Directives. The Secretary of Defense, and the Secretary of Homeland Security with respect to the U.S. Coast Guard, shall:

(a) maintain the currently effective policy regarding accession of transgender individuals into military service beyond January 1, 2018, until such time as the Secretary of Defense, after consulting with the Secretary of Homeland Security, provides a recommendation to the contrary that I find convincing; and

(b) halt all use of DoD or DHS resources to fund sex-reassignment surgical procedures for military personnel, except to the extent necessary to protect the health of an individual who has already begun a course of treatment to reassign his or her sex.

Sec. 3. Effective Dates and Implementation. Section 2(a) of this memorandum shall take effect on January 1, 2018. Sections 1(b) and 2(b) of this memorandum shall take effect on March 23, 2018. By February 21, 2018, the Secretary of Defense, in consultation with the Secretary of Homeland Security, shall submit to me a plan for implementing both the general policy set forth in section 1(b) of this memorandum and the specific directives set forth in section 2 of this memorandum. The implementation plan shall adhere to the determinations of the Secretary of Defense, made in consultation with the Secretary of Homeland Security, as to what steps are appropriate and consistent with military effectiveness and lethality, budgetary constraints, and applicable law. As part of the implementation plan, the Secretary of Defense, in consultation with the Secretary of Homeland Security, shall determine how to address transgender individuals currently serving in the United States military. Until the Secretary has made that determination, no action may be taken against such individuals under the policy set forth in section 1(b) of this memorandum.

Sec. 4. Severability. If any provision of this memorandum, or the application of any provision of this memorandum, is held to be invalid, the remainder of this

memorandum and other dissimilar applications of the provision shall not be affected.

Sec. 5. General Provisions. (a) Nothing in this memorandum shall be construed to impair or otherwise affect:

(i) the authority granted by law to an executive department or agency, or the head thereof; or

(ii) the functions of the Director of the Office of Management and Budget relating to budgetary, administrative, or legislative proposals.

(b) This memorandum shall be implemented consistent with applicable law and subject to the availability of appropriations.

(c) This memorandum is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity by any party against the United States, its departments, agencies, or entities, its officers, employees, or agents, or any other person.

(d) The Secretary of Defense is authorized and directed to publish this memorandum in the *Federal Register*.

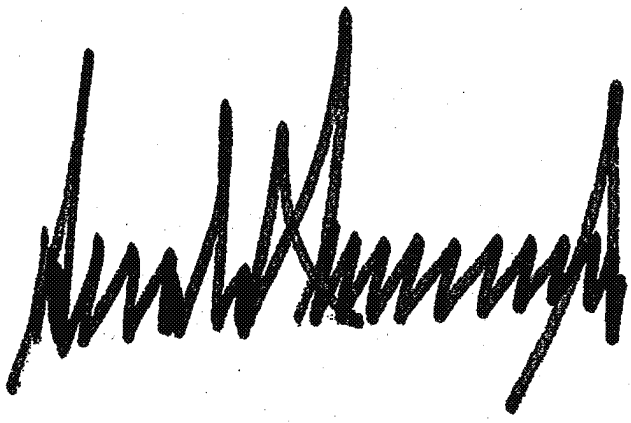

EXHIBIT 19

FILED UNDER SEAL

EXHIBIT 20

FILED UNDER SEAL

EXHIBIT 21

FILED UNDER SEAL

EXHIBIT 22

FILED UNDER SEAL

EXHIBIT 23

Subject: FW: [EXT] Fwd: FW: attachments
Attachments: witches mpd.pdf; Hayes Directory.pdf; 20170619_TNA52HruzMayerMcHugh.pdf; Long-Term Follow-Up of Transsexual Persons - Sweden.pdf

From: Paul McHugh
Sent: Monday, February 5, 2018 2:51 PM
To: 'william.bushman@sd.mil' <william.bushman@sd.mil>
Subject: attachments

Mr. Bushman, I mentioned these several articles in our conversation The Hayes Directory on evidence for sex reassignment surgery and other medical treatments , The long term follow-up from Sweden for transgender surgery, My article in Nature Medicine in 1995, and our recent article in the New Atlantis. I've attached them all here . Do tell me if they get through. Paul McHugh

EXHIBIT 24

COMMENTARY

Witches, multiple personalities, and other psychiatric artifacts

Contemporary psychiatric misdirections derived primarily from standard medical errors of oversimplification, misplaced emphasis, and invention are reviewed. These particular errors, however, were in part prompted and sustained by the sociocultural fads and fashions of the day. The results have been disastrous for everyone — patients, families, the public and psychiatry itself.

PAUL R. McHUGH

Psychiatry is a medical discipline long on disorders and short on explanations. Just a glance at the *Diagnostic and Statistical Manual* now in its fourth edition (DSM-IV) will confirm this verdict. DSM-IV presents hundreds of psychiatric disorders arranged according to their symptoms—depression, anxiety, schizophrenia and the like—but quite scrupulously avoids an etiological arrangement. Its authors are aware that psychiatrists tend to split up into camps, based on purported explanation — hence, biological, dynamic, behavioural, and even the eclectic — and go to war with one another.

However, this shortage of agreed-upon explanations brings good news and bad news. The good news is there is plenty of room for useful scientific research in psychiatry and a great deal of this is going on at the moment[1]. The bad news is, because practitioners in this discipline are hungry for explanations today, at least once each decade, psychiatry is swept by an enthusiasm for a fundamentally incoherent practice, and then must spend at least ten years subsequently digging out of the troubles that this practice produced. These misdirections of psychiatry rest squarely on standard medical mistakes such as oversimplification, misplaced emphasis or pure invention. The enthusiasms for these misdirections, however, usually derive from an uncritical acceptance of transient cultural attitudes and fashionable ideas. The repeated combination of these elements proves how all too often the discipline of psychiatry has been the captive of culture, to the detriment of everyone.

Anti-psychiatry

The most conspicuous misdirection of psychiatric practice — the precipitate dismissal of patients with severe, chronic mental disorders such as schizophrenia, from psychiatric hospitals — required a vastly oversimplified view of mental illness. Ironically, these actions were defended as efforts to bring 'freedom' to these people, sounding a typical 1960s cultural theme that marched right by the fact that it was the patients' illnesses that had deprived them of freedom in the first place. There were several collaborators in this sad enterprise. Prominent among them were state governments looking for release from the traditional but heavy fiscal burden of housing the mentally ill. Crucial to the process was the combination of fashionable opinions of the era about society's institutions as oppressive and oversimplified explanatory opinions about schizophrenia and other mental illnesses generated by the so-called anti-psychiatrists, Thomas Szasz, R.D. Laing, Erving Goffman, and Michel Foucault, notably among them.

A simple description of the mental problems of psychiatric patients was not the style of our 1960s commentators. They were more interested in painting a picture of their own devising. A picture that would provoke first suspicion and then disdain for contemporary psychiatric practices. And it did so, not by producing new standards or reforming specific practices, but by ridiculing and caricaturing efforts of the doctors and the institutions, just as fashion directed. The power of scorn was surprising and had amazing results, leading many in the public and not a few in the profession to believe that it was the institutions that provoked the patients' troubles rather than illness that called out for shelter and treatment. Here from Szasz's book, *Schizophrenia — The Sacred Symbol of Psychiatry*[2], is a typical comment: "The sense in which I mean that Psychiatry creates schizophrenia is readily illustrated by the analogy between institutional psychiatry and involuntary servitude. If there is no slavery there can be no slaves . . . . Similarly if there is no psychiatry there can be no schizophrenics. In other words, the identity of an individual as a schizophrenic depends on the existence of the social system of (institutional) psychiatry."

Effective replies to such commentary demanded knowledge first of the patients themselves, in schizophrenia, people impaired by delusions, hallucinations and disruptions of thinking capacities, but also understanding of how the concept of disease has, essentially since Sydenham, provided physicians with a coherent, logical, and stepwise approach to human afflictions, from symptom clusters to etiology, ultimately. The disparagement of this approach by the likes of Szasz demonstrated an ignorance of the explanatory potential of the concept of disease right from the start.

A saving grace for any medical theory or practice (the thing that spares it perpetual thralldom to the gusty winds of fashion) is the patients. They are real, they are around and a knowledge of their distressing symptoms guards against oversimplification. The claim that schizophrenic patients are in any sense living an alternative life style that our institutions were inhibiting was fatuous. Every urban citizen now recognizes, because of a familiarity with the many homeless people that the anti-psychiatric fad generated, that these patients have impaired capacities to comprehend the world and that they need protection and serious active treatment.

As well, and fortunately, the enterprises of brain research launched subsequent to these pronouncements have documented a cerebral source for many of the particular symptoms of schizophrenia[3,4]. This research tends to confirm that the conceptual model of epilepsy that helped sort out that condition (distinguishing symptomatic epilepsies, caused by some coarse brain pathology, from the idiopathic epilepsies, that rest upon genes) also makes sense of the group of conditions called schizophrenia[5]. The ultimate solutions for the homeless mentally ill are still to

be found but, as the saying goes, the anti-psychiatrists are history.

A question of gender

A similar combination of a cultural fad amidst a dearth of explanations led to the grim practice of sex reassignment surgery in the 1970s. I happen to know about this because Johns Hopkins was one of the places in the United States where this practice, with what at the time were called transsexuals, was given its start.

Typically a man comes to the clinic and says something like, "As long as I can remember, I've thought I was in the wrong body. True, I've married and had a couple of kids but always, in the back and now more often in the front of my mind, there's this idea that actually I'm more a woman than a man. I'm here because all this male equipment is disgusting to me. I want medical help to change my body: hormone treatments, silicone implants, surgical amputation of my genitalia and the construction of a vagina. Will you do it?"

. . . psychiatrists do not understand what is the problem here but hope surgery may do the poor wretch some good.

The patient claims it is a torture for him to live as a man, especially now that he has read in the newspapers about the possibility of switching surgically to womanhood. Upon examination it is not difficult to identify other mental and personality difficulties in him, but he is primarily disquieted because of his intrusive thoughts that his sex is not a settled issue in his life.

The skills of our plastic surgeons, particularly on the genitourinary system, are impressive. They were obtained, however, not to treat a presumptive gender identity problem but to repair congenital defects, injuries and the effects of destructive diseases such as cancer in this region of the body. That you can get something done doesn't always mean that you should do it. There are so many problems right at the start. In sex reassignment cases, the patient's claim that this has been a lifelong problem is seldom checked with others who have known him since childhood. It seems so intrusive and untrusting to discuss the problem with others even though they might provide a better gauge of the seriousness of the problem, how it emerged, its fluctuations of intensity over time and its connection with other experiences. When you discuss what the patient means by "feeling like a woman," you often get a sex stereotype in return and something that female physicians note immediately as a male caricature of women's attitudes and interests. One of our patients, for example, said that, as a woman, he would be more "invested with being than with doing."

Experts say that a sense of one's own maleness or femaleness rests upon a complicated biopsychological process and suggest that some derangement in this natural process may be the explanation for this problem. They venture that, although their research on those born with genital and hormonal abnormalities may not apply to a person with normal bodily structures, something must have gone wrong in this patient's early and formative life to cause him to feel as he does. Why not help him look more like what he says he feels? Our surgeons can do it.

On the other hand it is not obvious how this patient's sense that he is a woman trapped in a man's body differs from the feelings of a patient with anorexia nervosa that she is obese despite her emaciated, cachectic state. We don't do liposuction on anorexics. So why amputate the genitals of these patients? Surely, the fault is in the mind, not the member.

A plastic surgeon at Hopkins provided the voice of reality on this matter based on his practice and his natural awe at the mystery of the body. One day while we were talking about it, he said to me: "Imagine what it's like to get up at dawn and think about spending the day slashing with a knife at perfectly well formed organs, because you psychiatrists do not understand what is the problem here but hope surgery may do the poor wretch some good."

The zeal for this sex change surgery did not derive from critical reasoning or thoughtful assessments. The energy came from the fashions of the 1970s that invaded the clinic. If you can do it and he wants it, do it. This fashion was intregal to an aesthetic that saw diversity as everything, and could accept any idea, including that of surgical sex change, as interesting, and resistance to such ideas as uptight or even oppressive. Yet, moral matters should have some salience here. These include the confusions imposed on society where these men/women insist on acceptance even in athletic competition with women; the encouragement of the 'illusion of technique' which assumes that the body is like a suit of clothes to be hemmed and stitched to style; there is the ghastliness of the mutilated anatomy to consider; and finally, consider that this surgical practice has distracted effort from genuine investigations attempting to find out just what has gone wrong for these people. What has, by their testimony, given them years of torment and psychological distress and prompted them to accept these grim and disfiguring surgical procedures.

We now appreciate that this condition falls into the category of "overvalued ideas"[6] described very thoroughly by Carl Wernicke[7] at the beginning of the century. This is a category that includes morbid jealousies, anorexia nervosa and litigious personalities. Fortunately the diagnostic term transsexualism has been abandoned and replaced with the term Gender Identity Disorder making it clear that the problem is one of ideas rather than of bodily constitution and should be treated as such.

Psychiatrists collaborated in an exercise of folly with distressed people. and a misplaced emphasis proved hazardous when explanations were at a premium.

Artifactual behaviour

Medical errors of oversimplification and misplaced emphasis usually play themselves out with consequences all can see. Pure inventions can bring out a darker, hateful potential when psychiatric thought goes awry in search for an explanation. Most psychiatric histories choose to describe such invention by detailing its most vivid example — witches. The experience in Salem, Massachusetts, of 300 years ago is prototypical[8].

Briefly, in 1692, several young women and girls who had for some weeks been secretly listening to tales of spells, voodoo, and illicit cultic practices from a Barbados slave suddenly displayed a set of mystifying mental and behavioural changes. They developed trance-like states, falling on the ground and flailing, and screaming at night and at prayer, seemingly in great distress and in need of help. The local physician, who witnessed this, was as bewildered as anyone else and eventually made a diagnosis of "bewitchment". "The

evil hand is on them", he said and turned them over to the local law officials for examination and ultimately for protection. The clergy and magistrates assumed, taking their lead from the doctor, that local agents of Satan were at work and, using as grounds the answers of these young women to leading questions, indicted several citizens for bewitching them. The accepted proof of guilt was bizarre. The young women spoke of ghostly visitations by the defendants to their homes to torment them, all occurring while the accused were known by the testimony of reliable witnesses to be elsewhere. The victims often screeched out in court that they felt the accused pinching them even as everyone could see the defendants sitting quietly on the other side of the court room. Strange as it seems this testimony had great weight because the judges and the juries believed that capacities of this kind — provoking injury from a distance or being in two places at the same time — were skills and powers of witches. On the basis of this "spectral" evidence they dismissed all protests of innocence by the defendants and promptly executed them. The whole exercise should have been discredited when, after the executions, there was no change in the distraught behaviour of the young women. Instead more and more citizens were indicted. Eventually, good sense began to prevail, in part because many citizens came to recognize that no one was safe against these accusations and in part because a prosecution depending on spectral evidence was recognized to be as irrefutable as it was undemonstrable. The trials ceased and ultimately several of the young women admitted that their beliefs had been "delusions" and their accusations false.

A psychiatric or psychological artifact . . . is a product of human crafting.

The proper psychiatric diagnosis for those young women is, of course, not bewitchment but any of a series of terms such as hysteria, factitious disorder or malingering, all attempting to communicate the view that the mental states and behaviours of these individuals should be recognized as artifacts. A psychiatric or psychological artifact, like a physical artifact, is a product of human crafting. It is not a product of nature, such as a disease, but something manufactured by some person or persons for some human purpose or action. Behavioural displays in which physical or mental disorders are imitated (artifactual clinical disorders) are common enough on any medical service. On inspection, the patient's manufactured imitations of illness derive from a variety of different sources of information and suggestion, and they serve a variety of personal goals. In this era artifactual clinical conditions usually represent an effort on the part of a troubled person to take on the sick role with the benefits of care, attention and support this status brings to an individual. The status of 'bewitched' in Salem of 1692 brought both attentive concern and the license to indict any enemy to young women previously scarcely noticed by the community.

Forms of artifactual behaviour whether they are physical activities, such as falling and shaking, or mental phenomena, such as pains, visions or memories are partially shaped by unintended suggestions from others and sustained by the attention of onlookers and especially onlookers such as doctors who are socially empowered to assign, by affixing a diagnosis, the status of patient to a person. Whenever a diagnostician mistakes an artifact for what it is attempting to imitate by misidentifying the artifact either as some natural process, such as epilepsy, or inventing some specious explanation for it, such as bewitchment, then the behavioural display will continue, expand, prove treatment resistant and, in certain settings, spread to others. The usual result is trouble. Over the last decade a remarkable example of manufactured artifactual behaviour has surfaced and has been misidentified and bolstered by an invented view of its cause that fits a cultural fashion. This condition is Multiple Personality Disorder (MPD).

Today's awful version of psychiatric invention is the notion that many people suffered sexual abuse — if only they remembered.

Multiple personality disorder

Patients who are eventually diagnosed as suffering from MPD come to therapists with standard psychiatric complaints such as depression or anxiety. Some therapists see much more in these symptoms and suggest to the patient, and to others, that the symptoms represent the subtle actions of several alternative personalities, alters, coexisting in the patient's mental life. These suggestions encourage many patients to see their problems in a new light. Suddenly they are transformed into odd people with repeated shifts of demeanor and deportment that they display on command and sometimes in response to hand signals from the therapist. An artifactual behaviour has been generated by the combination of the vulnerabilities of the patient to suggestion and the beliefs of the therapists.

Sexual politics in the 1980s and 1990s, particularly about sexual oppression and victimization, galvanizes these inventions. Forgotten (repressed) sexual mistreatment is the proffered explanation of MPD. Just as an epidemic of bewitchment served to prove the arrival of Satan in Salem, so in our day an epidemic of MPD is used to propose that a vast number of adults were sexually abused by guardians during their childhood, the MPD being one of the presumed expressions of the traumatic experience. Now, I do not for a moment deny that children are sometimes victims of sexual abuse or that such abuse would produce psychiatric symptoms. Such realities are not at issue. What I am concerned with here is what has been imagined from these realities and inventively applied.

Adults with MPD, so theory goes, were assaulted as young children by a trusted and beloved person, usually a father although grandfathers, uncles, brothers, or others, often abetted by women in their power, are also possibilities. This sexual assault, the theory holds, is blocked from memory (repressed and dissociated) because it was so shocking. This dissociating blockade itself is purported to destroy the integration of mind and evokes multiple personalities as separate, disconnected, sequestered, 'alternative' collections of thought, memory and feeling. These resultant distinct 'personalities' produce a variety of what might seem standard psychiatric symptoms, such as depression, weight problems, panic states or demoralization, that only careful review, by experts on psychic life, will reveal to be expressions of MPD and the outcome of sexual abuse.

These patients have not come to treatment reporting a sexual assault in childhood. Only as the therapy is developed is the possibility that they were sexually abused as children suggested to them. From recollections of the mists of childhood, a vague sense of vulnerability may

slowly emerge, facilitated and encouraged by the treating group. This sense of vulnerability is thought a harbinger of clearer memories of victimization that, although buried, have been active for decades producing the different 'personalities'. The long 'forgotten' abuse is finally 'remembered' after sessions of 'uncovering' therapy, during which long conversations take place, often enhanced by sodium amytal or by hypnotic inductions, between the therapist and alter personalities, personalities that usually will be of all age ranges, differing sexes and not uncommonly animals that must also be made to speak.

Any actual proof of the provocative sexual assault is thought unnecessary since the presence of the MPD is thought proof enough. Theory about how the mind works and how its manifestations are to be understood is considered quite adequate to accuse the patient's parents of vile and atrocious acts against the patient when she (some 85% are women) was a child, with nothing more than this new form of spectral evidence, evidence that is just as irrefutable as that at Salem.

The idea of MPD and its cause has caught on among large numbers of psychotherapists. Its partisans see the patients as victims, cosset them in groups, encourage more expressions of alters (up to as many as 100 or more), and are ferocious towards any defenders of the perpetrators of the abuse. Just as the divines of Massachusetts were convinced that they were fighting Satan by recognizing bewitchment, so the contemporary divines, these therapists, are confident that they are fighting sexual oppression and child abuse, by recognizing MPD. The incidence of MPD has of late taken on epidemic proportions particularly in certain treatment centers. Whereas its diagnosis was reported less than 200 times from a variety of supposed causes prior to 1970, it has been applied to more than 20,000 people in the last decade and largely attributed to sexual abuse.

I have been involved, either directly or indirectly, with more than thirty such cases in the last few years. In every one, the very same story has been played out in a stereotyped script-like way. In each, a young woman with a rather straightforward set of psychiatric symptoms (depression and demoralization) sought psychotherapeutic help and her case was stretched during a course of therapy into a diagnosis of repressed memories of sexual abuse, a delayed form of Post Traumatic Stress Disorder and usually MPD. In each case, an accusation of prior sexual abuse was levelled by her, usually against her father but in about thirty percent of cases against the mother. The accusation developed, always after the onset of therapy, first as vague feelings of dream-like childhood reminiscences of danger and darkness and eventually crystallizing, sometimes in a flash, into a recollection of father forcing sex upon the patient as a child. No other evidence of these events was presented. Refuting testimony, coming from former nursemaids or the other parent for example, was dismissed if presented.

On one occasion, the identity of the molester changed. This change was as telling about the nature of evidence as was the emergence of the original charge. A woman called her mother to

IMAGE
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Bettmann Archives

The Salem witch trial

claim that she had come to realize that when she was young she was severely and repeatedly sexually molested by a maternal uncle. The mother questioned the daughter about the dates and times of these incidents to determine if they were even possible. She soon discovered that her brother was on military service in Korea at the time of the alleged abuse and with this information, the mother went to her daughter with the hope of showing her that her therapist was misleading her in destructive ways. When she heard this new information, the daughter seemed momentarily taken aback, but then said, "I see, Mother. Yes. Well, let me think. If your dates are right, I suppose it must have been Dad." And with that, she began to claim that she had been a victim of her father's abusive attentions and nothing could dissuade her.

The accused parents whom I studied, denying the charges and amazed at their source, submitted to detailed reviews of their sexual lives and any other efforts up to and including polygraphic testing to try to prove their innocence. Professional requests by me to the daughters' therapists for better evidence of the abuse were dismissed as derived from the pleadings of the guilty and were deemed beneath contempt given that the diagnosis of MPD indicated, and the ultimate testimony of the patient's patently confirmed, the sex abuse.

Remembered trauma

In Salem, the convictions of the defendants depended on how judges thought witches behaved. In our day, similar convictions depend on how some therapists think memory of trauma customarily works. In fact, standard psychiatric teaching in the past held that severe traumas are usually remembered all too well. They are amplified in consciousness, remaining like grief to be reborn and re-emphasized on anniversaries and in settings that can simulate the environments where they occurred. Good evidence for this was found in the memories of children from concentration camps. More recently, the children of Chowchilla, California, who were kidnapped in their school bus and buried in sand for many hours, remembered every detail of their traumatic experience years later and needed psychiatric assistance, not to bring out forgotten material that was repressed but to help them move away from a constant ruminative preoccupation with the experience[9].

Many psychiatrists upon first hearing of these diagnostic formulations (MPD being a form of post traumatic stress and the result of repressed memories of sexual abuse in childhood) have fallen back upon what they think is an even-handed way of approaching it. The mind is very mysterious in its ways, they say, anything is possible in a family. In fact, this credulous stance towards evidence and the failure to consider the alternative of artifactual behaviours, memories and beliefs continue to support this crude psychiatric analysis, and if the kinds of practices that lie behind the diagnosis of MPD become standard in psychiatry, then no family with a member in psychotherapy is safe from a persecution galvanized by the same kind of energy and reasoning that launched the witches' court or the lynch mob.

The helpful clinical approach to the patient with putative MPD, as with any instance of an artifactual display, is to direct attention away from the manufactured behaviour — one simply never talks to an alter. Within a few days of a consistent therapeutic focus away from the MPD behaviour and on to the issues of depression and anxiety that were the presenting matters, preoccupations with alters and supposed repressed memories fade and generally useful psychotherapy begins.

This epidemic will end in the same way that the witch craze ended in Salem. The MPD phenomena will be seen as manufactured, the 'repressed memory' explanations will be recognized as misguided, and psychiatrists will become immunized against the practices that generated these artifacts[10]. Meanwhile, time is passing, many families are being hurt and confidence in the competence and impartiality of psychiatry is eroding.

A time to learn

Major psychiatric misdirections often share this intimidating mixture of a medical mistake and a trendy idea. Any challenge to such a misdirection must confront simultaneously the professional authority of the proponents and the political power of fashionable convictions. Such challenges are not for the faint-hearted or inexperienced. They seldom quickly succeed because they are often misrepresented as ignorant or, in the cant word of our day, uncaring.

In ten years much damage can be done, and much effort over a longer period of time is required to repair it. Thus with the mentally ill homeless, only a new crusade and social commitment will bring them adequate psychiatric services again. Age increases the sad caricature of the sexual reassigned and saps their bravado. Some, pathetically, even ask about re-reassignment. And groups of parents falsely accused of sexual mistreatment by their grown children are gathering together to fight back against psychotherapists in ways that are producing dramatic but distressing court room spectacles. How good it would have been if all these misguided programs had been avoided or at least their span abbreviated.

Psychiatry is a medical discipline. It is capable of medical triumphs and serious medical mistakes. We don't know the secret of human nature. We cannot build the New Jerusalem. We can describe how our explanations for mental disorders are devised and develop, and where they are strong and where they are limited. We can clarify the presumptions about what we know and how we know it. With more research, steadily, we can construct a clinical discipline that, while delivering less to fashion, will bring more to patients and their families.

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A prior version of this essay appeared entitled "Psychiatric Misadventures" in *The American Scholar*, 61, 497–510, (1992).

EXHIBIT 25

6/27/14
Tab 11
Produced Material
Cluster

Hayes directory

May 15, 2014

Sex Reassignment Surgery for the Treatment of Gender Dysphoria

PURPOSE OF TECHNOLOGY:

Sex reassignment surgery (SRS), which involves genital reconstruction surgery and chest surgery, is part of the treatment approach for persons with gender dysphoria (GD). Individuals with GD have persistent feelings of gender discomfort and inappropriateness of their anatomical sex, strong and ongoing cross-gender identification, and a desire to live and be accepted as a member of the opposite sex. SRS includes the surgical procedures by which the physical appearance and function of a person's existing sexual characteristics are changed to those of the other sex in an effort to resolve or minimize GD and improve quality of life.

EXECUTIVE SUMMARY:

Health Problem: People with gender dysphoria (GD) feel a severe incongruity between anatomical sex and gender identity. The prevalence of GD is 1 in 11,900 to 1 in 45,000 persons for male-to-female (MtF) and 1 in 30,400 to 1 in 200,000 persons for female-to-male (FtM) transgender persons.

The earlier term, *gender identity disorder* (GID), has given way to *gender dysphoria* (GD). This change was intended to reflect a consensus that gender nonconformity is not a psychiatric disorder, as it was previously categorized. However, since the condition may cause clinically significant distress and since a diagnosis is necessary for access to medical treatment, the new term was proposed. The diagnostic criteria for GD outlined in the *Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition* (DSM-5), as well as the criteria for GID in the Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition (DSM-IV), require that the individual believes there is a marked difference between the gender assigned to him or her by others and the gender he or she experiences or wishes to express. Additional criteria must also be met for a diagnosis of GD.

Determinants: The determinants of GD are poorly understood. Experts believe that gender identity develops as the result of a combination of biological factors, possibly including genetic and/or prenatal and perinatal hormonal influences, and environmental influences that have psychological effects.

Treatment: Individuals with GD seeking professional help begin with psychotherapy. An American Psychiatric Association Task Force recommends 2 goals for psychotherapy: (1) to explore issues related to the individual's commitment to living in the cross-gender role; and (2) to fully explore other options for the patient including whether to live as a homosexual person without medical and surgical treatments for gender transition.

The full therapeutic approach to GD consists of 3 elements or phases, typically in the following order: (1) hormones of the desired gender, (2) real-life experience for 12 months in the desired role; and (3) surgery to change the genitalia and other sex characteristics (e.g., breast reconstruction or mastectomy). However, not everyone with GD needs or wants all elements of this triadic approach.

Technology: Sex reassignment surgery SRS involves modification of the genitalia and/or breast/chest to resemble that of the opposite sex.

For the FtM patient, surgical procedures may include mastectomy, hysterectomy, salpingo-oophorectomy, vaginectomy, metoidioplasty, scrotoplasty, urethroplasty, placement of testicular prostheses, and phalloplasty.

For the MtF patient, surgical procedures may include breast augmentation, penectomy, orchiectomy, vaginoplasty, clitoroplasty, and labiaplasty.

Rationale: The goal of SRS is to feminize or masculinize the body to facilitate an individual's desire to live in the gender role opposite from the biological sex.

Controversy: The medical necessity of SRS for the treatment of GD is under debate. The condition does not readily fit traditional concepts of medical necessity since research to date has not established anatomical or physiological anomalies associated with GD. An evidence-based assessment of the effectiveness of SRS procedures for alleviation of symptoms associated with GD and improvement of recipients' well-being can make a helpful contribution to this controversy.

Relevant Questions:

- Has SRS been shown to be effective in improving patient-important outcomes such as relief of symptoms of GD, quality of life (QOL), satisfaction with sex characteristics, psychological well being, or sexual function?
- Does SRS confer additional benefits to hormone therapy alone?
- Do outcomes vary according to which components of SRS are performed?
- Is SRS safe?
- Have definitive patient selection criteria been established for SRS as treatment for GD?

Evidence Base: Nineteen peer-reviewed studies, primarily case series, cross-sectional studies or pretest-posttest studies assessing the effectiveness of SRS were analyzed in this report. In addition, 6 case series evaluating safety outcomes in ≥ 300 MtF patients or ≥ 200 FtM patients following SRS were analyzed.

Search Dates: November 2004 to April 2014.

Sample Sizes: 35 to 376 patients for main evidence review, 202-390 patients for safety evidence.

Patients: MtF patients (6 studies), FtM patients (6 studies), both MtF and FtM patients (7 studies).

Interventions: Chest surgery only (5 studies), genital surgery only (5 studies), both chest and genital surgery (4 studies), unspecified (5 studies).

Comparisons: Transgendered patients that had undergone SRS vs. those that had not undergone SRS (5 studies) and outcomes in SRS patients that were MtF vs. FtM (1 study).

Outcome Measures: GD, QOL, sexual experience, patient satisfaction, psychological outcomes, and safety outcomes.

Follow-Up: 1 month to 7 years.

Findings: Following SRS, patients reported decreased GD, depression and anxiety, and increased QOL. The majority of SRS patients were sexually active, but the ability to orgasm varied across studies. The majority of patients were satisfied with their aesthetic results following SRS.

Gender Dysphoria: GD was decreased following SRS relative to baseline (2 studies).

Quality of Life: Transgendered patients who underwent SRS had improved QOL relative to patients that had not undergone SRS (1 study), improved QOL relative to before SRS (2 of 3 studies), and had QOL scores similar to those of the general population (2 studies).

Sexual Function: The majority of patients were sexually active following SRS (4 studies), and the ability to orgasm varied across studies (5 studies).

Patient Satisfaction: The majority of patients were satisfied with aesthetic results following SRS (10 studies).

Psychological Outcomes: Depression (3 studies) and anxiety (2 studies) decreased following SRS.

Other Outcomes: Following SRS, almost all FtM patients were able to micturate while standing (1 study), and rates of employment were high (3 studies).

Comparative Effectiveness of Hormone Therapy Alone and SRS: The evidence was too sparse to allow any conclusion regarding the comparative benefits of SRS and hormone therapy alone.

Comparative Effectiveness of Different Types of SRS: The evidence was too sparse to allow any conclusion regarding the comparative benefits of different SRS procedures.

Safety: Following SRS, there were very low rates of regret of surgery (0% to 6%) (5 studies) and suicide (2 to 3%) (3 studies). Only 6 of the 19 studies reported on complications following SRS, and the most common complications were urinary tract complications (4% to 33%) (3 studies), necrosis of tissue (1% to 10%) (6 studies), vaginal stenosis or prolapse (2% to 14%) (3 studies), and need for revision surgery (4% to 29%) (3 studies). The most common complications reported in the 6 safety studies were need for revision surgery (22% to 40%) (5 studies), urinary tract complications (40% to 41%) (2 studies), and wound healing difficulties (11% to 33%) (2 studies). The majority of studies reported a length of follow-up of at least 1 year following surgery (12 studies).

Patient Selection Criteria: There is insufficient evidence to establish patient selection criteria for SRS to treat GD. Professional groups recommend that SRS be restricted to individuals who are referred for sex reassignment services by a qualified mental health professional, and that while 1 referral is sufficient for breast or chest surgery, 2 independent referrals should be required for genital SRS. Individuals who have medical contraindications to surgery should not undergo SRS.

Quality of Evidence: Very low.

Overall, the quality of the evidence was very low due to limitations of individual studies, including small sample sizes, few studies evaluating any 1 outcome, retrospective data, lack of randomization of patients to treatment groups, failure to blind outcome assessors to group assignment, lack of a control or comparator group or

minimal adjustment for confounders, lack of baseline assessments to assess change over time, a possible procedural learning curve, and a lack of objective and validated outcome measures.

Conclusions: The evidence suggests positive benefits but because of serious limitations permit only weak conclusions regarding sex reassignment surgery (SRS) for gender dysphoria (GD). No conclusions can be made about the comparative benefits of hormone therapy alone and SRS, or about different components of SRS.

- Patients who underwent chest/breast or genital surgery were generally pleased with the aesthetic results.
- Following SRS, patients reported decreased GD, depression and anxiety, and increased quality of life.
- The majority of SRS patients were sexually active, but the ability to orgasm varied across studies.
- Complications of surgery following SRS were common and could be serious.
- Rates of regret of surgery and suicide were very low following SRS.
- Data were too sparse to draw conclusions regarding whether SRS conferred additional benefits to hormone therapy alone.
- Data were too sparse to draw conclusions regarding whether outcomes vary according to which surgeries were performed.

Hayes Rating:

C - For sex reassignment surgery (SRS) to treat gender dysphoria (GD) in adults for whom a qualified mental health professional has made a formal diagnosis of GD, have undergone hormone therapy and psychotherapy, and have undergone a "real-life" test (i.e., in which they lived as the desired gender role). This Rating reflects the reporting of some positive evidence but serious limitations in the evidence of both effectiveness and safety.

D2 - For SRS to treat GD in adolescents. This rating reflects the paucity of data of SRS in adolescents.

INSIGHTS:

- Since part of the reason for the psychopathology experienced by transgender persons has to do with the reactions or expected reactions of family and society, evolving social norms theoretically could diminish the perceived need to undergo physical changes in order to live in the desired gender role.
- The majority of the studies selected for this report reflect the diagnostic criteria of *Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition*, rather than the somewhat expanded criteria published in 2013 in the *Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition*.

Hayes directory

May 19, 2014

Hormone Therapy for the Treatment of Gender Dysphoria

PURPOSE OF TECHNOLOGY:

Continuous feminizing or masculinizing hormone therapy is administered to some adolescents and adults who have a diagnosis of gender identity disorder (GID) or gender dysphoria (GD). The purpose of this therapy is to facilitate a transgender individual's desire to transition to a sexual identity other than his or her biological (natal) sex. Some individuals undergo hormone therapy as a prelude to sex reassignment surgery; other individuals seeking gender transition undergo hormone therapy without ever undergoing any type of surgery.

EXECUTIVE SUMMARY:

Health Problem: Individuals with gender dysphoria (GD) experience a severe incongruity between their biological sex and gender identity.

The prevalence of transsexualism is estimated to be 1 in 11,900 to 1 in 45,000 persons for male-to-female (MtF) prevalence and 1 in 30,400 to 1 in 200,000 for female-to-male (FtM) prevalence. The prevalence of gender dysphoria within the transsexual population is unknown. The earlier term, *gender identity disorder* (GID), has given way to *gender dysphoria* (GD). This change was intended to reflect a consensus that gender nonconformity is not a psychiatric disorder, as it was previously categorized. However, since the condition may cause clinically significant distress and since a diagnosis is necessary for access to medical treatment, the new term was proposed. The diagnostic criteria for GD outlined in the *Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition* (DSM-5), as well as the criteria for GID in the *Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition* (DSM-IV), require that the individual believes there is a marked difference between the gender assigned to him or her by others and the gender he or she experiences or wishes to express. Additional criteria must also be met for a diagnosis of GD.

Determinants: The determinants of gender dysphoria are poorly understood. Experts believe that gender identity develops as the result of a combination of biological factors, possibly including genetic and/or prenatal and perinatal hormonal influences, and environmental influences that have psychological effects.

Treatment: Individuals with GD seeking professional help begin with psychotherapy. An American Psychiatric Association Task Force recommends 2 goals for psychotherapy: (1) to explore issues related to the individual's commitment to living in the cross-gender role; and (2) to fully explore other options for the patient, including whether to live as a homosexual person without medical and surgical treatments for gender transition. The full therapeutic approach to GD consists of 3 elements or phases, typically in the following order: (1) hormones of the desired gender; (2) real-life experience for 12 months in the desired role; and (3) surgery to change the genitalia and other sex characteristics (e.g., breast reconstruction or mastectomy). However, not everyone with GD needs or wants all elements of this triadic approach.

Technology: The goal of cross-sex hormone therapy for GD is to alter secondary sex characteristics, including such features as fat distribution, hair growth, voice pitch, and muscle strength.

Cross-sex hormone therapy includes estrogens and testosterone-blocking agents administered to natal (biologic) males and androgens (usually testosterone) administered to natal females. Adolescents with a

diagnosis of GD may be eligible for puberty-delaying hormones as soon as pubertal changes begin; the effects of this treatment are fully reversible.

Rationale: Hormone therapy serves to feminize or masculinize the body to facilitate an individual's desire to live in the gender role opposite from biological sex.

Controversy: Numerous professional groups have advocated for third-party payers to cover all medically necessary treatments to alleviate GD. However, the condition does not readily fit traditional concepts of medical necessity since research to date has not established anatomical or physiological anomalies associated with GD.

An evidence-based assessment of the effectiveness of hormone therapy for alleviation of symptoms associated with GD and improvement of recipients' well being can make a helpful contribution to this controversy.

Relevant Questions:

- Has feminizing or masculinizing hormone therapy in adolescents and adults been shown to be effective in improving patient-important outcomes such as relief of symptoms of GD, psychological well-being, sex-specific function, quality of life (QOL), functional status, or employment status?
- How does hormone therapy alone as a treatment for GD compare with sex reassignment surgery (SRS)?
- Is feminizing or masculinizing hormone therapy safe?
- Have definitive patient selection criteria been established for feminizing or masculinizing hormone therapy as a treatment for GD?

Evidence Base: Ten peer-reviewed studies, primarily of a cross-sectional or pretest-posttest design, assessing the effectiveness of hormone therapy plus 11 other studies with safety data for ≥ 100 adult patients or any safety data for adolescent patients.

Search Dates: Inception of databases to April 2014.

Sample Sizes: 50 to 376 pts (effectiveness); 1 to 2307 (safety).

Patients: Adult or adolescent patients with a diagnosis of GD. Mean age in effectiveness studies of adults, 29 to 45 years. Mean age in safety studies of adults, 41 to 52 years. Typical patients had not undergone either chest or genital SRS.

Interventions: Cross-sex hormone therapy or pubertal suppression therapy.

Comparisons: No medical treatment, SRS (chest and/or genital).

Outcome Measures: QOL, functional status, or employment status; psychological well-being (e.g., depression, self-esteem, reduced incidence of suicide); sexual function and satisfaction; and complications of hormone therapy, regret, or any other adverse event attributable to treatment.

Follow-Up: 3 months to 1 year (effectiveness studies, usually not reported); 2 to 23 years (safety studies).

Findings: Studies that evaluated hormone therapy in adults suggested the possibility of a small effect on QOL and function, specific psychological symptoms, social support, and alcoholism. The findings were inconsistent with respect to a relationship between hormone therapy and general psychological health, substance abuse, suicide attempts, and sexual function and satisfaction (9 studies).

QOL/Functional Status (Adults): 5 studies (≥ 812 participants; ≥ 796 FtM) reported positive findings on ≥ 1 scale, but usually not on all scales used in the study. Differences between treated and untreated study participants were very small or of unknown magnitude in cross-sectional analyses that adjusted for potential confounders but were substantial in 1 pretest-posttest study.

Psychological Symptoms (Adults): In 6 studies, the results for a variety of specific psychological states (e.g., depression, anxiety) were positive, but overall measures of change in psychological symptomatology were mixed. In the studies that provided information on the magnitude of scales and/or cutoff points for normal ranges, the differences, if observed, were generally very small and scores for patients representing the control condition were typically already in the normal or mild range.

Other Outcomes (Adults): Improved social support and reduced alcoholism were suggested but the results regarding substance abuse were conflicting (2 studies). The prevalence of suicide attempts was not affected by hormone therapy (2 studies). Findings regarding the association of hormone therapy with sexual function and satisfaction were mixed (3 studies).

Comparative Effectiveness of Hormone Therapy Alone Versus Surgery (Adults): The evidence was too sparse to allow any conclusion regarding the comparative benefits of SRS and hormone therapy alone.

Adolescents (Pubertal Suppression): Evidence from a single small study was insufficient to suggest conclusions regarding the value of pubertal suppression therapy.

Safety (Adults): Hormone therapy has the potential to alter patients' risk of cardiovascular disease, cerebrovascular and thromboembolic events, osteoporosis, and cancer. The risk of no benefit must also be considered. There was an increased risk of cerebrovascular and thromboembolic events in MtF patients. There was *no* elevated risk of cancer in FtM patients. Hormone therapy and subsequent SRS failed to bring overall mortality, suicide rates, or death from illicit drug use in MtF patients close to rates observed in the general male population. It is possible that mortality is nevertheless reduced by these treatments, but that cannot be determined from the available evidence. Mortality data for FtM patients is less clear than for MtF patients. For safety issues other than the specific findings described here, the evidence was insufficient to suggest conclusions. There was no evidence concerning the prevalence of regret after hormone therapy.

Safety (Adolescents): The chief risks cited for pubertal suppression therapy are related to the possibility the GD could worsen because of the delay in definitive treatment. No serious side effects during pubertal suppression were reported. Older adolescents may begin cross-sex hormone therapy, but only a single case report provided long-term data for individuals who began therapy as adolescents. The body of evidence

concerning the safety of pubertal suppression and cross-sex hormone therapy in adolescents was too sparse and the studies too limited to suggest conclusions.

Patient Selection Criteria: The evidence is insufficient to support patient selection criteria for hormone therapy to treat GD. Professional associations recommend that hormone therapy be restricted to patients who have been referred for such treatment by a health professional who is qualified to assess GD. In adults, medical conditions that can be exacerbated by endocrine treatment must be evaluated and addressed prior to initiation of treatment. Practice guidelines advise that pubertal suppression therapy should not be initiated until adolescents have at least reached Tanner stage 2.

Quality of Evidence: Very low.

Most studies were considered to be of very poor quality due to the nature of the study designs, failure to control for confounders, possible recall bias and selection bias, lack of blinded outcomes assessment, and/or unknown or short follow-up intervals. Not all positive results were statistically significant. For other outcomes, the findings were conflicting. For QOL and function, almost all of the available data were collected from FtM individuals for whom a diagnosis of GD could not be verified. For outcomes other than QOL and function, the quantity of evidence was very small. In safety studies, the relatively young age of study participants at the time of outcomes assessment and the lack of adjustment for risk factors in comparisons of study participants with age-matched general populations seriously diminishes the reliability of the available adverse event rates. No studies analyzed safety outcomes according to whether patients had undergone SRS, which is significant since hormone doses are lowered after SRS. The safety evidence described for adults in the **EXECUTIVE SUMMARY** is considered to be of low quality, but all other adult safety evidence was considered to be of very low quality.

Conclusions: A substantial number of studies of cross-sex hormone therapy each show some positive findings suggesting improvement in well-being after cross-sex hormone therapy. However, there are several serious limitations to the evidence.

Statistically significant improvements have not been consistently demonstrated by multiple studies for most outcomes. Five studies representing primarily female-to-male (FtM) adults reported modestly positive findings on ≥ 1 of the multiple quality of life (QOL) or functional scales for individuals who had undergone cross-sex hormone therapy, but for most of these individuals, a diagnosis of gender dysphoria (GD) was not confirmed. Evidence regarding QOL and function in male-to-female (MtF) adults was very sparse. Evidence for less comprehensive measures of well-being in adult recipients of cross-sex hormone therapy was directly applicable to GD patients but was sparse and/or conflicting. The study designs do not permit conclusions of causality and studies generally had weaknesses associated with study execution as well. There are potentially long-term safety risks associated with hormone therapy but none have been proven or conclusively ruled out. The evidence for adolescent populations was too sparse to suggest any conclusions.

Hayes Rating:

Hormone-GD

C - For hormone therapy to treat GD in adults for whom a qualified mental health professional has made a formal diagnosis of GD and a recommendation for hormone therapy and who do not have any medical contraindications to endocrine therapy.
This Rating reflects the reporting of some positive evidence but serious limitations in the evidence of both effectiveness and safety. Also of concern is the fact that the magnitude of suggested benefit was typically small, which diminishes confidence in a true treatment effect.

D2 - For pubertal suppression therapy or cross-sex hormone therapy in adolescents.
This Rating is based on a paucity of data.

INSIGHTS:

- Since part of the reason for the psychopathology experienced by transgender persons has to do with the reactions or expected reactions of family and society, evolving social norms theoretically could diminish the perceived need to undergo physical changes in order to live in the desired gender role.
- The benefits of hormone therapy appear to be of very small magnitude in the studies published to date. The literature does not provide guidance for assessing the clinical relevance of improvements in this population. One factor that may prevent the observation of large improvements is that individuals with a better social support and a better baseline psychological profile are probably seen to be better candidates by the mental health professionals who make recommendations for treatment.
- As the population of recipients of hormone therapy ages, better data concerning long-term safety risks should become available.
- Most studies have been performed in Europe. The results may not be generalizable to the United States.
- The studies selected for this report reflect the diagnostic criteria of DSM-IV, rather than the somewhat expanded criteria published in 2013 in the DSM-5.

May 9, 2014

Ancillary Procedures and Services for the Treatment of Gender Dysphoria

PURPOSE OF TECHNOLOGY:

Some persons with gender dysphoria (GD) may seek hormone therapy and /or sex reassignment surgery (SRS) to resolve their incongruity between biological sex and gender identity. Additional ancillary surgeries or services, such as facial modifications, vocal cord surgery, or voice training, may be desired by transgender persons to further feminize or masculinize the body and/or perception of gender. In some cases, ancillary procedures are performed without SRS.

EXECUTIVE SUMMARY:

Health Problem: Individuals with gender dysphoria (GD) feel a severe incongruity between their biological sex and their gender identity. The prevalence of GD is 1 in 11,900 to 1 in 45,000 persons for male-to-female (MtF) and 1 in 30,400 to 1 in 200,000 persons for female-to-male (FtM) transgender persons.

The earlier term, *gender identity disorder* (GID), has given way to *gender dysphoria* (GD). This change was intended to reflect a consensus that gender nonconformity is not a psychiatric disorder, as it had been previously categorized. However, since the condition may cause clinically significant distress and since a diagnosis is necessary for access to medical treatment, the new term was proposed. The diagnostic criteria for GD outlined in the *Diagnostic and Statistical Manual of Mental Disorders* (DSM), Fifth Edition (DSM-V), as well as the criteria for GID in the DSM, Fourth Edition (DSM-IV), require that the individual believes there is a marked difference between the gender assigned to him or her by others and the gender he or she experiences or wishes to express. Additional criteria must also be met for a diagnosis of GD.

Determinants: The determinants of GD are poorly understood. Experts believe that gender identity develops as the result of a combination of biological factors, possibly including genetic and/or prenatal and perinatal hormonal influences, and environmental influences that have psychological effects.

Treatment: The treatment of GD is multifaceted. Psychotherapy helps the individual explore roles and expression and adopt various coping mechanisms to deal with societal and internal conflicts. Some transgender persons may seek hormone therapy to change their secondary sex characteristics and/or apply for sex reassignment surgery (SRS), which may include mastectomy/chest reconstruction or genital reconstruction. Additional ancillary surgeries or services, such as facial modifications, vocal cord surgery, or voice training, may be desired by transgender persons to further feminize or masculinize the body and/or perception of gender.

Technology: Ancillary procedures and services other than cross-sex hormone therapy or SRS for GD.

Some transgender persons desire procedures to feminize or masculinize their body and/or face. Also, some MtF transgender persons may desire voice therapy or vocal cord surgery to feminize their voice. Ancillary procedures include facial modifications, voice modification, reduction of the Adam's apple, enhancement of the buttocks, and permanent hair removal.

Rationale: Additional procedures may enhance the benefits of hormone therapy or SRS for GD, and for some individuals with GD, less comprehensive treatments may be sufficient for assuming the desired gender identity.

A transgender person who is readily accepted as their chosen gender may have a better quality of life and a reduction in the symptoms of GD.

Controversy: The medical necessity of treatments for GD is under debate. However, the condition does not readily fit traditional concepts of medical necessity since research to date has not established anatomical or physiological anomalies associated with GD. An evidence-based assessment of the effectiveness of ancillary procedures for alleviation of symptoms associated with GD and improvement of recipients' well-being can be a helpful contribution to this issue.

Relevant Questions:

- Have ancillary procedures and services been shown to be effective in improving patient-important outcomes such as relief of symptoms of GD or quality of life?
- Are ancillary procedures and services safe?
- Have definitive patient selection criteria been established for ancillary procedures and services as treatments for GD?

Evidence Base: Thirteen case series studies and chart reviews.

Search Dates: Inception of database to April 2014.

Sample Sizes: 10 to 76 patients; 1 study had 247 patients.

Patients: MtF (n=533) or FtM (n=3) adult transgender patients. It was not specified whether or not patients had a formal diagnosis of GD. The status of cross-sex hormone therapy or SRS among the study population was not reported by 4 of the studies. The remaining studies had variability regarding other GD treatments; however, none had inclusion criteria that specified these characteristics.

Interventions: Vocal cord surgery (5 studies), voice training (3 studies), rhinoplasty (2 studies), facial feminization surgery (2 studies), hair removal (1 study).

Comparisons: Twelve of the studies had no comparison group. One study of facial feminization surgery compared surgery recipients with patients who had not had facial surgery.

Outcome Measures: Patient satisfaction; voice characteristics; Voice Handicap Index; SF-36 Health Survey (QualityMetric Inc.) (1 study); grade, roughness, breathiness, asthenia, strain (GRBAS) Hirano scale.

Follow-Up: Mean of 6 to 30 months (5 studies did not report follow-up).

Findings: Patients were satisfied with the results of facial feminization and rhinoplasty; however, the results of vocal cord procedures and voice training were mixed.

Vocal Cord Procedures: Of the 5 reviewed studies of vocal cord surgery, 2 evaluated cricothyroid approximation, 2 evaluated laser vaporization, and 1 evaluated laryngoplasty. Cricothyroid approximation significantly raised the fundamental frequency of MtF transgender patients by a mean of 74 hertz (Hz). Laser vaporization significantly raised the fundamental frequency of MtF transgender patients by a mean of 48 Hz.

Feminization laryngoplasty significantly increased the fundamental frequency by 57 Hz. Patient satisfaction with the vocal cord surgery was variable, but the results suggest that patients were more satisfied following cricothyroid approximation than laser vaporization.

Voice Training: Three studies evaluated voice training as a method to increase the fundamental frequency of MtF transgender patients. The fundamental frequency increased by 14 to 28 Hz after voice training sessions and approximately half of the patients were satisfied with the outcome. One study evaluated voice training to decrease the fundamental frequency of 3 FtM patients; however, results of only 1 patient were available and his fundamental frequency decreased by 35 Hz after vocal training.

Rhinoplasty: Two studies evaluated feminization rhinoplasty on MtF transgender patients. All but 1 of the patients felt that their face had become more feminine in appearance and were satisfied with the results.

Facial Feminization Surgery: Two studies of facial feminization surgery were reviewed. In a retrospective case series study, MtF transgender patients who had various facial modification procedures felt that their faces had become more feminine in appearance. In a large retrospective cross-sectional study, quality of life was measured in MtF transgender patients who did or did not have facial feminization surgery. Patients who had facial feminization surgery were significantly more satisfied with their appearance than those who did not have facial surgery.

Permanent Hair Removal: One study of intense pulsed light epilation for permanent hair removal on MtF transgender patients was reviewed. After a mean of 9 epilation sessions, 90% of the patients achieved treatment success.

Safety: Most of the studies did not report complications; however, complications that were reported included bone nonunion following facial surgery (2% of patients); and dysphagia (34% of patients) or throat pain (29% of patients) following cricothyroid approximation.

Patient Selection Criteria: There is insufficient evidence to establish definitive patient selection criteria for ancillary procedures and services for the treatment of GD.

Quality of Evidence: Very low.

The individual study quality was generally very poor. The quality of the evidence was low because of study limitations, including small sample size and few studies evaluating each procedure category, lack of a control or comparator group, variable follow-up duration, inconsistent availability of results for all outcome measures, lack of baseline data for self-rated outcome measures, and lack of statistical analysis of results. Outcome measures were focused on technical success and patient satisfaction; only 1 study evaluated an overall measure of well-being using a validated instrument.

Conclusions: There is some evidence that transgender patients are satisfied with the results of rhinoplasty and facial feminization surgery, but patient satisfaction with vocal cord surgery and voice training was mixed. The evidence has serious limitations, and the effect of these procedures on overall individual well-being is unknown.

- Patients who had rhinoplasty or facial feminization surgery were generally pleased with the results.

- Vocal cord procedures and voice training had variable outcomes. Although the fundamental frequency was reduced by all treatment methods, patient satisfaction with the outcome was mixed.
- Most of the studies did not report complications; however, there was a low rate of bone nonunion following facial surgery, and moderate rates of dysphagia or throat pain following cricothyroid approximation.

Hayes Rating:

D2 - For vocal cord surgery for voice feminization in patients with GD.
This Rating reflects the positive but limited evidence of this technology for transgender patients.

D2 - For voice training for voice feminization in patients with GD.
This Rating reflects the limited evidence of this technology for transgender patients, and conflicting results.

D2 - For feminization rhinoplasty for patients with GD.
This Rating reflects the limited evidence of this technology for transgender patients, and conflicting results.

D2 - For facial feminization surgery in patients with GD.
This Rating reflects the positive but limited evidence of this technology for transgender patients.

D2 - For permanent hair removal technologies for patients with GD.
This Rating reflects the positive but limited evidence of this technology for transgender patients.

INSIGHTS:

- Since part of the reason for the psychopathology experienced by transgender persons has to do with the reactions or expected reactions of family and society, evolving social norms theoretically could diminish the perceived need to undergo physical changes in order to live in the desired gender role.
- As the population of recipients of ancillary procedures ages, better understanding concerning long-term safety risks should become available.

EXHIBIT 26

THE NEW ATLANTIS
A JOURNAL OF TECHNOLOGY & SOCIETY

Growing Pains

Problems with Puberty Suppression in Treating Gender Dysphoria

Paul W. Hruz, Lawrence S. Mayer, and Paul R. McHugh

Public controversies about how institutions should treat individuals who identify as a gender that does not correspond to their biological sex have recently been debated in the halls of government, in courtrooms, and on TV talk shows. Should males who identify as women have access to women's restrooms? Which school locker room should girls who identify as boys be permitted, or required, to use? Should teachers be compelled to use a student's preferred pronoun, or even a gender-neutral pronoun such as "ze" instead of "he" or "she"?

Alongside these questions of public concern, however, there are quieter matters of medicine and wellbeing. How should medical and mental health professionals care for patients who identify as the opposite sex, and how should families support loved ones who do so? The stakes are high: as detailed in a recent report in these pages, people who identify as transgender are disproportionately likely to suffer from a variety of mental health problems, including depression, anxiety, suicide attempts, and suicide.[1]

Psychiatrists who follow the American Psychiatric Association's *Diagnostic and Statistical Manual* use the term "gender dysphoria" for a condition in which "incongruence between one's experienced/expressed gender and assigned gender" is accompanied by "clinically significant distress or impairment in social, occupational, or other important areas of functioning."[2] In this context, "experienced/expressed gender" refers to

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the gender that the person subjectively identifies as or wishes to be publicly recognized as—what is often referred to as "gender identity"—while "assigned gender" refers in almost all cases to his or her unambiguous biological sex. (In rare cases, a person's biological sex is difficult to determine; such "intersex" individuals are born with biological features of both sexes. Most transgender individuals are not biologically intersex.[3])

There is strikingly little scientific understanding of important questions underlying the debates over gender identity—for instance, there is very little scientific evidence explaining why some people identify as the opposite sex, or why childhood expressions of cross-gender identification persist for some individuals and not for others.[4] Yet notwithstanding the limited data, physicians and mental health care providers have arrived at a number of methods for treating children, adolescents, and adults with gender dysphoria.

Of particular concern is the management of gender dysphoria in children. Young people with gender dysphoria constitute a singularly vulnerable population, one that experiences high rates of depression, self-harm, and even suicide.[5] Moreover, children are not fully capable of understanding *what it means* to be a man or a woman. Most children with gender identity problems eventually come to accept the gender associated with their sex and stop identifying as the opposite sex.[6] There is some evidence, however, that gender dysphoria and cross-gender identification become more persistent if they last into adolescence.[7]

In one prominent treatment approach, called "gender-affirming," the therapist accepts, rather than challenges, the patient's self-understanding as being the opposite sex. Gender-affirming models of treatment are sometimes applied even to very young children.[8] Often, the gender-affirming approach is followed in later youth and adulthood by hormonal and surgical interventions intended to make patients' appearances align more closely with their gender identity than their biological sex. In order to improve the success of the physical changes, interventions at younger ages are increasingly being recommended.[9]

Gender identity clinics offering gender-affirmative psychotherapy for children and adolescents have opened for business in the United States and several other countries.[10] Though there is little systematically collected data on the number of young people (or even the number of adults) who identify as transgender or who have undergone sex-reassignment surgery,* there is some evidence that the number of people receiving medical and psychotherapeutic care for gender identity issues is on the rise:

- The Gender Identity Development Service in the United Kingdom, which treats only children under the age of 18, reports that it received 94 referrals of children in 2009/2010 and 1,986 referrals of children in 2016/2017—a relative increase of 2,000%.[11] The service also reports that it received six referrals for children under the age of 6 in 2009/2010, compared to thirty-two referrals for children under the age of 6 in 2016/2017—a relative increase of 430%.[12]

- In a brief paper by psychologists from a gender clinic in Toronto, the authors reported a large increase in the number of referrals for children (ages 3 to 12) per year between 1988 and 1991, when the number of children referred went from around 40 per year to around 80, a rate that remained steady through 2011.[13] The authors also reported that between 2004 and 2007, the rate of adolescents (ages 13 to 20) referred to their clinic rose from roughly 20 per year to 60, and then to nearly 100 per year by 2011.[14]

- In a paper by clinicians at Children's Hospital Boston, the authors reported on the number of individuals who presented at the hospital with gender identity issues. Between 1998 and 2006, such patients presented to the hospital's Endocrine Division at an average rate of 4.5 patients per year, but in the period from 2007 to 2009, after the hospital opened a gender identity clinic, the annual average of patients presenting with gender identity issues rose to 19 patients per year.[15]

- In a paper published in 2016, physicians from an Indianapolis pediatric endocrinology clinic reported a "dramatic increase" in referrals for gender dysphoria since 2002, finding that of 38 patients referred between 2002 and 2015, "74% were referred during the last 3 years."[16] The authors emphasized that their clinic does not specialize in gender dysphoria, and that "the remarkable increase in the number of new patients seen in our clinic over the last 3 years has occurred even though our referral base is unchanged, and our clinic has not specifically advertised its care for transgender patients."[17]

* The most familiar colloquial term used to describe the medical interventions that transform the appearance of transgender individuals may be "sex change" (or, in the case of surgery, "sex-change operation"), but this is not commonly used in the scientific and medical literature today. While no simple terms for these procedures are completely satisfactory—in the context of this article the most accurate description would be "hormonal and surgical interventions to modify secondary sex characteristics"—we employ the commonly used terms *sex reassignment* and *sex-reassignment surgery* or *procedures*, except when quoting a source that uses "gender reassignment" or some other term.

The reasons for these rising rates are unclear. It may be that increased public awareness of gender dysphoria has made parents more willing to seek medical help for their children. (We should remember that it is parents or guardians, not children themselves, who make decisions about medical care.) However, the medical treatments provided for children with apparent symptoms of gender dysphoria, including affirmation of gender expression from the earliest evidence of cross-gender behaviors, may drive some children to persist in identifying as transgender when they might otherwise have, as they grow older, found their gender to be aligned with their sex. Gender identity for children is elastic (that is, it can change over time) and plastic (that is, it can be shaped by forces like parental approval and social conditions).[18] If the increasing use of gender-affirming care does cause children to persist with their identification as the opposite sex, then many children who would otherwise not need ongoing medical treatment would be exposed to hormonal and surgical interventions.

One particular gender-affirming intervention for children and young adolescents with gender dysphoria is puberty suppression (also known as puberty blocking)—a hormone intervention that prevents the normal progression of puberty. Puberty is a turbulent time in any young person's life, and it can be terrifying for those who identify as the opposite sex. For parents of children with gender dysphoria, puberty suppression can appear very attractive. It seems like it might offer a medical solution for the anticipated confusion, anxiety, and distress by holding back the development of the most conspicuous features of their children's biological sex. Puberty suppression seems to offer an intermediate step between the social affirmation that parents can give very young children and the sex-reassignment procedures that their kids can pursue once they've grown. And it seems to offer a way to mitigate the discordance between children's beliefs about their gender and the realities of their bodily development (while acquiescing to, rather than challenging, the children's self-understanding). Puberty suppression can, in short, look like safe passage from stormy seas of childhood expressions of beliefs about gender to the secure harbor of an adulthood lived permanently as the opposite sex.

In light of the growing prominence of gender identity issues in our society, and the appeal that puberty suppression may have for parents raising children who identify as the opposite sex, it is worth examining in detail what puberty suppression is, how it works, and whether it is as safe and prudent as its advocates maintain. As we shall see, the evidence for the safety and efficacy of puberty suppression is thin, based more on the subjective judgments of clinicians than on rigorous empirical evidence. It is,

in this sense, still experimental—yet it is an experiment being conducted in an uncontrolled and unsystematic manner.

What Is Puberty?

Having experienced adolescence and the tumultuous changes it involves, most adults are familiar in a very personal way with puberty. But addressing the questions surrounding puberty-blocking interventions for gender dysphoria requires acquaintance with how puberty is defined and understood in biology and medicine. Some fundamental facts about puberty are still unknown; in the words of one medical textbook, "Initiation of the onset of puberty has long been a mystery."[19] But on the whole, the main aspects of puberty are well understood.

A textbook chapter by William A. Marshall and James M. Tanner (for whom the Tanner scale, a detailed measure of the stages of pubertal development is named) describes puberty as "the morphological and physiological changes that occur in the growing boy or girl as the gonads change from the infantile to the adult state. These changes involve nearly all the organs and structures of the body but they do not begin at the same age nor take the same length of time to reach completion in all individuals. Puberty is not complete until the individual has the physical capacity to conceive and successfully rear children."[20] The authors go on to list the principal manifestations of puberty:

> 1. The adolescent growth spurt; i.e., an acceleration followed by a deceleration of growth in most skeletal dimensions and in many internal organs.
>
> 2. The development of the gonads.
>
> 3. The development of the secondary reproductive organs and the secondary sex characters.
>
> 4. Changes in body composition, i.e., in the quantity and distribution of fat in association with growth of the skeleton and musculature.
>
> 5. Development of the circulatory and respiratory systems leading, particularly in boys, to an increase in strength and endurance.[21]

The ability to physically conceive children is made possible by the maturation of the primary sex characteristics, the organs and structures that are involved directly in reproduction. In boys, these organs and structures include the scrotum, testes, and penis while in girls they include the

ovaries, uterus, and vagina. In addition to these primary sex characteristics, secondary sex characteristics also develop during puberty—the distinctive physical features of the two sexes that are not directly involved in reproduction. Secondary sex characteristics that develop in girls include "the growth of breasts and the widening of the pelvis" and in boys "the appearance of facial hair and the broadening of shoulders," while other patterns of body hair and changes in voice and skin occur during puberty in both girls and boys.[22]

Physicians characterize the progress of puberty by marking the onset of different developmental milestones. The earliest visible event, the initial growth of pubic hair, is known as "pubarche"; it occurs between roughly ages 8 and 13 in girls, and between ages 9.5 and 13.5 in boys.[23] In girls, the onset of breast development, known as "thelarche," occurs around the same time as pubarche.[24] (The "-arche" in the terms for these milestones comes from the Greek for beginning or origin.) "Menarche" is another manifestation of sexual maturation in females, referring to the onset of menstruation, which typically occurs at around 13 years of age and is generally a sign of the ability to conceive.[25] Roughly corresponding to menarche in girls is "spermarche" in boys; this refers to the initial presence of viable sperm in semen, which also typically occurs around 13.[26]

Hormones and Puberty

Having established *what* puberty is, we now turn to *how* puberty happens.

Scientists distinguish three main biological processes involved in puberty: adrenal maturation, gonadal maturation, and somatic growth acceleration.[27] We will discuss each of these processes in turn, with a particular focus on gonadal maturation.

"Adrenarche"—the beginning of adrenal maturation—begins between ages 6 and 9 in girls, and ages 7 and 10 in boys. The hormones produced by the adrenal glands during adrenarche are relatively weak forms of androgens (masculinizing hormones) known as dehydroepiandrosterone and dehydroepiandrosterone sulfate. These hormones are responsible for signs of puberty shared by both sexes: oily skin, acne, body odor, and the growth of axillary (underarm) and pubic hair.[28]

"Gonadarche"—the beginning of the process of gonadal maturation—normally occurs in girls between ages 8 and 13 and in boys between ages 9 and 14.[29] The process begins in the brain, where specialized neurons in the hypothalamus secrete gonadotropin-releasing hormone (GnRH).[30]

This hormone is secreted in a cyclical or "pulsatile" manner[31]—the hypothalamus releases bursts of GnRH, and when the pituitary gland is exposed to these bursts, it responds by secreting two other hormones. These are luteinizing hormone (LH) and follicle-stimulating hormone (FSH), which stimulate the growth of the gonads (ovaries in women and testes in men).[32] (The "follicles" that the latter hormone stimulates are not hair follicles but ovarian follicles, the structures in the ovaries that contain immature egg cells.) In addition to regulating the maturation of the gonads and the production of sex hormones, these two hormones also play an important role in regulating aspects of human fertility[33]—but for present purposes, we will focus on their role in the development of the gonads and the production of sex hormones during puberty.

As the gonadal cells mature under the influence of LH and FSH, they begin to secrete androgens (masculinizing sex hormones like testosterone) and estrogens (feminizing sex hormones).[34] These hormones contribute to the further development of the primary sex characteristics (the uterus in girls and the penis and scrotum in boys) and to the development of secondary sex characteristics (including breasts and wider hips in girls, and wider shoulders, breaking voices, and increased muscle mass in boys). The ovaries and testes both secrete androgens as well as estrogens, however the testes secrete more androgens and the ovaries more estrogens.[35]

The gonads and the adrenal glands are involved in two separate but interrelated pathways (or "axes") of hormone signaling. These are the hypothalamic-pituitary-gonadal (HPG) axis and the hypothalamic-pituitary-adrenal (HPA) axis.[36] Though both play essential roles in puberty, it is, as just noted, the HPG axis that results in the development of the basic reproductive capacity and the external sex characteristics that distinguish the sexes.[37]

The third significant process that occurs with puberty, the somatic growth spurt, is mediated by increased production and secretion of human growth hormone, which is influenced by sex hormones secreted by the gonads (both testosterone and estrogen). Similar to the way that the secretion of GnRH by the hypothalamus provokes the pituitary gland to secrete FSH and LH, in this case short pulses of a hormone released by the hypothalamus cause the pituitary gland to release human growth hormone.[38] This process is augmented by testosterone and estrogen.[39] Growth hormone acts directly to stimulate growth in certain tissues, and also stimulates the liver to produce a substance called "insulin-like growth factor 1," which has growth-stimulating effects on muscle.[40]

The neurological and psychological changes occurring in puberty are less well understood than are the physiological changes. Men and women have distinct neurological features that may account for some of the psychological differences between the sexes, though the extent to which neurological differences account for psychological differences, and the extent to which neurological differences are caused by biological factors like hormones and genes (as opposed to environmental factors like social conditioning), are all matters of debate.[41]

Scientists distinguish between two types of effects hormones can have on the brain: organizational effects and activational effects. Organizational effects are the ways in which hormones cause highly stable changes in the basic architecture of different brain regions. Activational effects are the more immediate and temporary effects of hormones on the brain's activity. During puberty, androgens and estrogens primarily have activating effects, but long before then they have organizational effects in the brains of developing infants and fetuses.[42] (Some researchers speculate that cross-gender identification may be caused by atypical patterns of fetal exposure to sex hormones, but these theories have yet to be scientifically confirmed or even seriously tested.[43]) However, animal studies have provided some evidence that sex hormones may contribute to organizational effects (or reorganization) of the brain during puberty.[44] How, whether, and to what extent this process occurs in humans remain poorly understood.[45]

In sum: Puberty involves a myriad of complex, related, and overlapping physical processes, occurring at various points and lasting for various durations. Adrenarche and the secretion of growth hormones contribute to the child's growth and development, while gonadarche crucially leads to the maturation of sex organs that allow for reproduction, as well as the development of the other biological characteristics that distinguish males and females. The description offered here has been very simplified, of course, but it gives sufficient background to understand the workings of puberty suppression, to which we turn next.

The Origins of Puberty-Suppression Techniques

Hormone interventions to suppress puberty were not developed for the purpose of treating children with gender dysphoria—rather, they were first used as a way to normalize puberty for children who undergo puberty too early, a condition known as "precocious puberty."

For females, precocious puberty is defined by the onset of puberty before age 8, while for males it is defined as the onset of puberty before

age 9.[46] Premature thelarche (the appearance of breast development) is usually the first clinical sign of precocious puberty in girls. For males, precocious puberty is marked by premature growth in genitalia and pubic hair.[47] In addition to the psychological and social consequences that a child might be expected to suffer, precocious puberty can also lead to reduced adult height, since the early onset of puberty interferes with later bone growth.[48]

Precocious puberty is divided into two types, central precocious puberty (sometimes labeled "true precocious puberty") and peripheral precocious puberty (sometimes labeled "precocious pseudopuberty").[49] Central precocious puberty is caused by the early activation of the gonadal hormone pathway by GnRH, and is amenable to treatment by physicians. Peripheral precocious puberty, which is caused by secretion of sex hormones by the gonads or adrenal glands independent of signals from the pituitary gland, is less amenable to treatment.[50] Precocious puberty is rare, especially in boys. A recent Spanish study of central precocious puberty estimated the overall prevalence to be 19 in 100,000 (37 in 100,000 girls affected, and 0.46 in 100,000 boys).[51] A Danish study of precocious puberty (not limited to central precocious puberty) found the prevalence to be between 20 to 23 per 10,000 in girls and less than 5 in 10,000 in boys.[52]

Treatment for precocious puberty is somewhat counterintuitive. Rather than stopping the production of GnRH, physicians actually provide patients more constant levels of synthetic GnRH (called GnRH analogues or GnRH agonists).[53] The additional GnRH "desensitizes" the pituitary, leading to a decrease in the secretion of gonadotropins (LH and FSH), which in turn leads to the decreased maturation of and secretion of sex hormones by the gonads (ovaries and testes). The first publication describing the use of GnRH analogues in children for precocious puberty appeared in 1981.[54]

The process of desensitization of the pituitary gland by synthetic GnRH is not permanent. After a patient stops taking the GnRH analogues, the pituitary will resume its normal response to the pulsatile secretion of GnRH by the hypothalamus, as evidenced by the fact that children treated for precocious puberty using GnRH analogues will resume normal pubertal development, usually about a year after they withdraw from treatment.[55]

In the time since GnRH analogues were first proposed in the early 1980s, they have become fairly well accepted as a treatment of precocious puberty, with one prominent GnRH analogue, Lupron, approved for that

use by the FDA in 1993.[56] However, there remain some questions concerning the effectiveness of treatment with GnRH analogues. A recent consensus statement of pediatric endocrinologists concluded that GnRH analogues are an effective way to improve the height of girls with onset of puberty at less than 6 years of age, and also recommended the treatment be considered for boys with onset of precocious puberty who have compromised height potential.[57] Regarding the negative psychological and social outcomes associated with precocious puberty, the authors found that the available data were unconvincing, and that additional studies are needed.[58]

It is worth noting that the use of GnRH analogues has been considered in other contexts as well—for example, in some cases of children with severe learning disabilities, to ease the difficulties that those children and their caregivers may experience with puberty.[59] Synthetic GnRH to desensitize the pituitary has also been adapted to treat a variety of other conditions related to the secretion of sex hormones in adults, including prostate cancer[60] and fertility issues.[61] This is because the natural pulsatile release of GnRH continues to play an important role beyond puberty, in that it stimulates the pituitary gland to secrete gonadotropins that trigger the gonads to secrete sex hormones from the testes and ovaries.[62]

To sum up how puberty suppression works, a thought experiment might be helpful. Imagine two pairs of biologically and psychologically normal identical twins—a pair of boys and a pair of girls—where one child from each pair undergoes puberty suppression and the other twin does not. Doctors begin administering GnRH analogue treatments for the girl at, say, age 8, and for the boy at age 9. Stopping the gonadal hormone pathway of puberty does not stop time, so the puberty-suppressed twins will continue to age and grow—and because adrenal hormones associated with puberty will not be affected, the twins receiving GnRH analogue will even undergo some of the changes associated with puberty, such as the growth of pubic hair. However, there will be major, obvious differences within each set of twins. The suppressed twins' reproductive organs will not mature: the testicles and penis of the boy undergoing puberty suppression will not mature, and the girl undergoing puberty suppression will not menstruate. The boy undergoing puberty suppression will have less muscle mass and narrower shoulders than his twin, while the breasts of the girl undergoing puberty suppression will not develop. The boy and girl undergoing puberty suppression will not have the same adolescent growth spurts as their twins. So all told, by the time the untreated twins reach maturity, look like adults, and are biologically capable of having

children, the twins undergoing puberty suppression will be several inches shorter, will physically look more androgynous and childlike, and will not be biologically capable of having children. This is only a thought experiment, but it illustrates some of the effects that puberty suppression would be expected to have on the development of a growing adolescent's body.

Advocacy and Guidelines

A number of medical associations and advocacy groups have endorsed puberty suppression as a prudent and compassionate way of helping youth with gender dysphoria. In 2009, the Endocrine Society—an international organization of professionals who deal with the body's hormones—published guidelines for the treatment of transsexual persons, recommending "that adolescents who fulfill eligibility and readiness criteria for gender reassignment initially undergo treatment to suppress pubertal development."[63]

Two years later, the Endocrine Society partnered with other organizations—the World Professional Association for Transgender Health, the European Society of Endocrinology, the European Society of Pediatric Endocrinology, and the Pediatric Endocrine Society—to circulate another set of guidelines for the treatment of transgender individuals.[64] Three observations are provided in the guidelines to justify puberty suppression. First, gender dysphoria "rarely desists after the onset of pubertal development" and additionally, "suppression causes no irreversible or harmful changes in physical development and puberty resumes readily if hormonal suppression is stopped."[65] Second, the typical physical changes of puberty are "often associated with worsening of gender dysphoria," which has "been reversed by pubertal suppression."[66] Third, the modification of secondary sex characteristics by hormonal treatments "is easier and safer when the sex steroids of the adolescent's genetic sex and their physical effects, for example, virilization of breast growth, are not present."[67]

The World Professional Association for Transgender Health (WPATH, a membership organization for health care professionals that advocates for transgender health care) also endorses puberty suppression in its *Standards of Care for the Health of Transsexual, Transgender, and Gender Nonconforming People* (2011), if the following criteria are met:

> 1. The adolescent has demonstrated a long-lasting and intense pattern of gender nonconformity or gender dysphoria (whether suppressed or expressed);

2. Gender dysphoria emerged or worsened with the onset of puberty;

3. Any coexisting psychological, medical, or social problems that could interfere with treatment (e.g., that may compromise treatment adherence) have been addressed, such that the adolescent's situation and functioning are stable enough to start treatment;

4. The adolescent has given informed consent and, particularly when the adolescent has not reached the age of medical consent, the parents or other caretakers or guardians have consented to the treatment and are involved in supporting the adolescent throughout the treatment process.[68]

The WPATH *Standards of Care* document gives the following two justifications for puberty suppression interventions: "(i) their use gives adolescents more time to explore their gender nonconformity and other developmental issues; and (ii) their use may facilitate transition [to living as the opposite sex] by preventing the development of sex characteristics that are difficult or impossible to reverse if adolescents continue on to pursue sex reassignment."[69]

In 2016, the Human Rights Campaign, an LGBT advocacy group, partnered with the American Academy of Pediatrics—the nation's most prominent professional organization for pediatricians—and the American College of Osteopathic Pediatricians to publish a guide for families of transgender children. The guide says that "to prevent the consequences of going through a puberty that doesn't match a transgender child's identity, healthcare providers may use fully reversible medications that put puberty on hold."[70] Delaying puberty, according to the guide, gives the child and family time "to explore gender-related feelings and options."[71]

Reading these various guidelines gives the impression that there is a well-established scientific consensus about the safety and efficacy of the use of puberty-blocking agents for children with gender dysphoria, and that parents of such children should think of it as a prudent and scientifically proven treatment option. But whether blocking puberty is the best way to treat gender dysphoria in children remains far from settled and it should be considered not a prudent option with demonstrated effectiveness but a drastic and experimental measure.

Experimental medical treatments for children must be subject to especially intense scrutiny, since children cannot provide legal consent to medical treatment of any kind (parents or guardians must consent for their child to receive treatment), to say nothing of consenting to become research

subjects for testing an unproven therapy. In the case of gender dysphoria, however, the safety and efficacy of puberty-suppressing hormones is not well founded on evidence—though hormone interventions used for suppressing puberty in children have undergone clinical trials, these trials were, as discussed above, for other indications, such as delaying precocious puberty. Whether puberty suppression is safe and effective when used for gender dysphoria remains unclear and unsupported by rigorous scientific evidence. This is especially worrying in light of the lack of understanding of the causes of gender dysphoria in children or adults. Conditions like precocious puberty, for instance, have a biological course that is relatively well understood. Hormone interventions that treat that condition are tailored to its causes. In the case of gender dysphoria, however, we simply do not know what causes a child to identify as the opposite sex, so medical interventions, like puberty suppression, cannot directly address it.

Some doctors who use puberty suppression to treat children with gender dysphoria argue that "the etiology does not affect the way adolescents with GD [gender dysphoria] should be treated"[72]—that is, treating gender dysphoria does not require us first to understand its causes. In an analogy offered by one anonymous psychiatrist interviewed in a study of physicians' attitudes on the subject, "even if you do not know exactly why or how [a] person has broken his leg," it is possible to "understand that it is painful and impairs function."[73] Though there are obvious differences between the importance of the etiology of incidental injuries (like a broken leg) and persistent psychological conditions (like gender dysphoria), this comparison is worth considering carefully. It is true that caring for patients is important regardless of the etiology of their conditions. However, even for an injury like a broken bone, a doctor should be interested in (for example) whether the patient has some condition that makes his or her bones more breakable. A bone fracture may be a symptom of an underlying pathology such as osteoporosis, and in such cases, different courses of treatment may be indicated; the bone may need to set for longer, and doctors will generally recommend certain lifestyle changes or extensive courses of treatment to mitigate the underlying condition and to reduce the risk of future injuries.

If we understood the underlying causes of gender dysphoria (or even factors that contribute to the risk and severity of gender dysphoria, as osteoporosis is a risk factor in bone fractures), doctors would be able to make different kinds of recommendations to patients for mitigating the underlying disconnection between the gender identity and the body of a patient, and reducing the severity of the dysphoria experienced by their

patients. All discussions of appropriate treatments for gender dysphoria in adolescents or adults are subject to the qualification that entirely new therapeutic approaches might be discovered as a result of improvements in our currently limited understanding of the etiology and course of gender dysphoria.

Puberty suppression as an intervention for gender dysphoria has been accepted so rapidly by much of the medical community, apparently without scientific scrutiny, that there is reason to be concerned about the welfare of children who are receiving it, as well as reason to question the veracity of some of the claims made to support its use—such as the assertion that it is physiologically and psychologically "reversible." To better understand the treatment options for children with gender dysphoria, it is worth examining the origins of this approach and the justifications offered for it.

Blocking Puberty for Gender Dysphoria

During the 1980s, at about the same time that GnRH-based treatments for precocious puberty were being developed, another use of the technique was being tested: to suppress the normal physiological production of male sex hormones among adult males who identify as females. This form of hormonal sex reassignment was first described in 1981, when Canadian doctors reported their use of GnRH analogues to suppress androgen production in four transsexual males, ages 18 to 29.[74] GnRH analogues continue to be used as part of sex-reassignment procedures for some adult male-to-female sex reassignment patients.[75]

It was only in the 1990s that GnRH analogues came to be used for the first time to suppress puberty in children who identify as the opposite sex. In 1998, Peggy Cohen-Kettenis and Stephanie van Goozen, psychologists at a Dutch gender clinic, described the case of a 13-year-old female gender-dysphoria patient. GnRH analogue was used to suppress puberty before she received a definitive diagnosis of gender identity disorder at age 16. (Gender identity disorder was then the generally accepted term for what is now more often called gender dysphoria, although the two are not identical.) At age 18, she underwent sex-reassignment surgery.[76] The clinic's scientists and physicians went on to develop an influential protocol for using puberty suppression as part of a gender-affirming therapeutic approach to gender dysphoria and gender identity issues in adolescents. A description of the protocol was published in the *European Journal of Endocrinology* in 2006,[77] with another paper describing "changing insights" into the use

of puberty suppression in adolescents published in the *Journal of Sexual Medicine* in 2008.[78]

The protocol, often referred to as the "Dutch protocol," calls for puberty suppression to begin at age 12 after a diagnosis of gender identity disorder. The protocol stipulates that the diagnosis should be made by both a psychologist and a psychiatrist, after information is "obtained from both the adolescent and the parents on various aspects of general and psychosexual development of the adolescent, the adolescent's current functioning and functioning of the family."[79] The researchers' method for suppressing puberty was to inject 3.75 milligrams of the GnRH analogue triptorelin every four weeks.[80] With this regimen, "there was no progression of the pubertal stage," and "regression of the first stages of the already developed sex characteristics." This meant that, in girls, "breast tissue will become weak and may disappear completely," and in boys, "testicular volume will regress to a lower volume."[81]

Then, starting at age 16, cross-sex hormones are administered while GnRH analogue treatment continues, in order to induce something like the process of puberty that would normally occur for members of the opposite sex. In female-to-male patients, testosterone administration leads to the development of "a low voice, facial and body hair growth, and a more masculine body shape" as well as to clitoral enlargement and further atrophying of breast tissue.[82] In patients seeking a male-to-female transition, the administration of estrogens will result in "breast development and a female-appearing body shape." Cross-sex hormone administration for these patients will be prescribed for the rest of their lives.[83]

Surgery is prescribed for patients once they reach 18 years of age, though "if the patient is not satisfied with, or is ambivalent about, the hormonal effects or surgery, the applicant is not referred for surgery."[84] Male-to-female surgery involves the construction of "female-looking external genitals" (which involves the removal of the testes), in addition to breast enlargement if estrogen therapy has not resulted in satisfactory breast growth.[85] For female-to-male patients, the first surgery is often mastectomy; some female-to-male patients elect not to undergo the phalloplasty (the surgical construction of a penis), since the quality and functionality of such surgically constructed "neopenises" vary.[86] Removal of the uterus and ovaries are also common surgical procedures for female-to-male patients.[87] After the surgical removal of the gonads (testes in male-to-female patients or ovaries in female-to-male), the patients then discontinue GnRH analogue treatment, since the signaling pathway from GnRH to the pituitary gland will no longer result in the production

of sex hormones once the gonads are removed.[88] Some of the surgical operations involved in sex reassignment, such as breast augmentation, are primarily cosmetic; others, such as the removal of gonads, have significant biological effects in that they impair or eliminate the individual's natural reproductive capacities and ability to produce important sex hormones. However, none of the surgeries or hormone treatments currently possible confer the reproductive capacities of the opposite sex.

According to researchers at the Dutch clinic, some of the known effects of puberty suppression on physiologically normal children are what you would expect from alterations made to that critical stage of human development. It has a significant negative effect on the height growth rates of both male-to-female and female-to-male patients.[89] The female-to-male patients subsequently experienced a growth spurt when androgens were administered, whereas for male-to-female patients, estrogen treatment "may result in a more appropriate 'female' final height."[90] The development of normal bone-mineral density is another concern for children and adolescents treated with puberty-suppressing hormones. Early reports suggested that the patients may have experienced reduced development of bone-mineral density while on puberty-suppressing treatments, though density increased when cross-sex hormone treatments began.[91] Other more recent reports are mixed; one paper found that, although bone mass did not decline during puberty suppression, the children undergoing puberty suppression fell behind the average rates of bone-density growth for their age,[92] while another reported that puberty suppression resulted in decreased bone growth in adolescents with gender dysphoria.[93]

In the United States, the treatment of gender dysphoria is not yet an FDA-approved use for GnRH analogue drugs (although treatments for precocious puberty, prostate cancer, and other conditions are approved).[94] This means that puberty suppression relies on the "off-label" prescription of GnRH analogue treatments; doctors are permitted to use these drugs in treating children with gender dysphoria, but the lack of FDA approval means that pharmaceutical companies selling the drugs cannot market them for treating gender dysphoria. Off-label status reflects that the use has not been proven in clinical trials to be safe and effective.

Weak Justifications

Modifying biologically normal development in 12-year-olds to treat a psychiatric condition is a serious step, one that the scientists who developed the Dutch protocol attempt to justify with a number of arguments.

First, they argue that blocking puberty may mitigate the psychosocial difficulties experienced by adolescents with gender dysphoria by lessening the growing incongruity between the adolescent patient's gender identity and sex.[95] They also argue that mitigating the early development of secondary sex characteristics during puberty can make the eventual transition (both medical and social) to living as the opposite sex easier.[96]

For patients and doctors who are committed to the view that the young person's gender dysphoria represents a persistent and real problem that can best be solved by transitioning the patient to living as the opposite sex, puberty suppression can seem like a desirable approach. But most children who identify as the opposite sex will not persist in these feelings and will eventually come to identify as their biological sex: According to the *Diagnostic and Statistical Manual of Mental Disorders*, "In natal [biological] males, persistence [of gender dysphoria] has ranged from 2.2% to 30%. In natal females, persistence has ranged from 12% to 50%."[97] (As noted earlier, there is some evidence that cross-gender identification becomes more persistent if it lasts into adolescence.[98]) The relatively low levels of persistence pose a challenge for those who would use puberty-suppressing treatments for young children—and for those who recommend encouraging and affirming children in their cross-gender identification. The epidemiologically low persistence rates suggest that puberty suppression would not be wise for all children who experience gender dysphoria, since it would be an unnecessary treatment for those children whose gender dysphoria would not persist if they received no intervention, and it is generally considered best, in clinical practice, to avoid unnecessary medical interventions. And beyond *unnecessary*, the interventions could, in some cases, be *harmful*, if they lead children whose gender dysphoria may have resolved in adolescence to instead persist in a dysphoric condition.

In a 2008 article, the Dutch scientists respond to this concern—the possibility that young adolescents might undergo medical interventions that could ultimately be unnecessary or worse—by arguing that adolescents who continue to identify as the opposite sex and who continue to desire sex reassignment into early puberty rarely come to identify as their biological sex; they also note that none of their own patients who were found eligible for sex reassignment decided against it.[99] But the fact that none of the patients for whom they recommended sex reassignment decided against the procedure may either indicate that their recommendations were based on a sound diagnosis of persistent gender dysphoria, *or* that their diagnosis—along with the course of treatment that followed

from it, including gender-affirmative psychotherapy and puberty suppression—may have solidified the feelings of cross-gender identification in these patients, leading them to commit more strongly to sex reassignment than they might have if they had received a different diagnosis or a different course of treatment.

The criteria used by the Dutch scientists to ensure that puberty-suppressing drugs are used only in appropriate cases do little to alleviate the concern that such treatments might make feelings of cross-gender identification more persistent:

> i) a presence of gender dysphoria from early childhood on; (ii) an increase of the gender dysphoria after the first pubertal changes; (iii) an absence of psychiatric comorbidity that interferes with the diagnostic work-up or treatment; (iv) adequate psychological and social support during treatment; and (v) a demonstration of knowledge and understanding of the effects of GnRH, cross-sex hormone treatment, surgery, and the social consequences of sex reassignment.[100]

It is worth closely examining some of these criteria. The first criterion, that gender dysphoria is present from early childhood on, seems to assume that a patient's identification as the other gender will endure if the patient has felt that way for a long time. But signs of gender dysphoria in children are even more vague and unreliable than signs of gender dysphoria in adolescents and adults; diagnoses of gender dysphoria in children rely more on gender-atypical behaviors (for example, boys playing with dolls or girls preferring to play with boys) than on a committed belief on the part of the patients that they "really are" the opposite sex. While an increasing severity of gender dysphoria around the onset of puberty (the second criterion) may be associated with the long-term persistence of gender dysphoria, it is difficult to separate this from the possibility that the "psychological and social support" for the child's cross-gender feelings, behaviors, and identification (the fourth criterion) may have contributed to the persistence of the child's gender dysphoria. And regarding the fifth and final criterion, it seems difficult to expect that a 12-year-old would have an understanding of the effects of these complex medical interventions and of the "social consequences of sex reassignment" when these are matters that are poorly understood by doctors and scientists themselves. Furthermore, whether children as young as 12 fully understand their gender identity and whether they can be diagnosed reliably as having persistent gender dysphoria are difficult psychological questions that cannot be separated from medical judgments about the appropriateness of puberty suppression.

In the same 2008 paper, the authors write that providing pubertal suppression allows patients to avoid the "alienating experience of developing sex characteristics, which they do not regard as their own" and it "is also proof of solidarity of the health professional with the plight of the applicant."[101] Though it is important for physicians to establish a relationship of trust and compassion with their patients, for physicians to offer "proof of solidarity" to patients by acceding to their wishes, regardless of whether the patients' wishes are in their best medical interests, is far from the Hippocratic tradition and surrenders the physician's responsibility to treat patients with their ultimate benefit in mind.

Claims of "Reversibility"

A major selling point for puberty suppression is the claim that the procedure is "fully reversible."[102] This assertion allows advocates to make puberty suppression seem like a prudent compromise between two extremes: not providing any medical treatment for young patients diagnosed with gender dysphoria, which would seem negligent, and immediately and permanently medically altering the sexual characteristics of children, which would seem reckless.

Some claims of reversibility:

- The Dutch scientists who developed the protocol for puberty suppression describe it as "fully reversible."[103]
- Pediatric endocrinologist Daniel Metzger says that "the effect of the puberty-blocking drugs is reversible."[104]
- Norman Spack, a physician at Boston's Children Hospital who treats gender dysphoria, describes puberty-suppressing drugs as "totally reversible."[105]
- In a review of the research on puberty-blocking drugs for an LGBT advocacy group, Laura E. Kuper, a researcher focused on transgender health, describes puberty blocking as "fully reversible."[106]
- Transgender journalist Mitch Kellaway, writing for the website Advocate.com about how "blocking puberty is beneficial for transgender youth," describes puberty blocking as "fully reversible."[107]
- In another Advocate.com story about puberty blocking, transgender activist Andrea James writes that "the treatment is reversible."[108]

- Bioethicist Arthur Caplan has described puberty blocking as reversible, saying that "if it's decided to stop the treatment, puberty will resume."[109]

- Pediatric endocrinologists Christopher P. Houk and Peter A. Lee write that puberty suppression in children with gender dysphoria is "reversible."[110]

A twist on the theme of reversibility appears in the guide for supporting and caring for transgender children published in 2016 by the Human Rights Campaign. The document highlights how "extremely distressing" the development of secondary sex characteristics can be for transgender youth, and even notes that "some of these physical changes, such as breast development, are *irreversible* or require surgery to undo" (emphasis added).[111] Similar language is used by the scientists who developed the Dutch protocol, who write that "the child who will live permanently in the desired gender role as an adult may be spared the torment of (full) pubescent development of the 'wrong' secondary sex characteristics"[112] and elsewhere write that puberty suppression is important because the development of secondary sex characteristics that cause a transgender person to look "like a man (woman) when living as a woman (man)…is obviously an enormous and lifelong disadvantage."[113] This turns the normal language of reversibility on its head, speaking of the natural process of biological development as an irreversible series of problems that medicine should seek to prevent, while presenting the intervention—puberty suppression—as benign and reversible.

One common argument based on the idea that puberty suppression is a reversible and prudent first step is that it can, as the Dutch scientists put it, "give adolescents, together with the attending health professional, more time to explore their gender identity, without the distress of the developing secondary sex characteristics. The precision of the diagnosis may thus be improved."[114] There is much that is strange about this argument. It presumes that natural sex characteristics interfere with the "exploration" of gender identity, when one would expect that the development of natural sex characteristics might contribute to the natural consolidation of one's gender identity. It also presumes that interfering with the development of natural sex characteristics can allow for a more accurate diagnosis of the gender identity of the child. But it seems equally plausible that the interference with normal pubertal development will influence the gender identity of the child by reducing

the prospects for developing a gender identity corresponding to his or her biological sex.

Given its potential importance in the lives of the affected children, it is worth carefully examining these claims about reversibility. In developmental biology, it makes little sense to describe anything as "reversible." If a child does not develop certain characteristics at age 12 because of a medical intervention, then his or her developing those characteristics at age 18 is not a "reversal," since the sequence of development has already been disrupted. This is especially important since there is a complex relationship between physiological and psychosocial development during adolescence. Gender identity is shaped during puberty and adolescence as young people's bodies become more sexually differentiated and mature. Given how little we understand about gender identity and how it is formed and consolidated, we should be cautious about interfering with the normal process of sexual maturation.

Rather than claiming that puberty suppression is reversible, researchers and clinicians should focus on the question of whether the physiological and psychosocial development that occurs during puberty can resume in something resembling a normal way after puberty-suppressing treatments are withdrawn. In children with precocious puberty, this does appear to be the case. Puberty-suppressing hormones are typically withdrawn around the average age for the normal onset of gonadarche, at about age 12, and normal hormone levels and pubertal development gradually resume. For one common method of treating precocious puberty, girls reached menarche approximately a year after their hormone treatments ended, at an average age of approximately 13, essentially the same average age as the general population.[115]

However, the evidence for the safety and efficacy of puberty suppression in boys is less robust, chiefly since precocious puberty is much more rare in boys. Although the risks are speculative and based on limited evidence, boys who undergo puberty suppression may be at greater risk for the development of testicular microcalcifications, which may be associated with an increased risk of testicular cancer, and puberty suppression in boys may also be associated with obesity.[116]

Most critically, unlike children affected by precocious puberty, adolescents with gender dysphoria do not have any physiological disorders of puberty that are being corrected by the puberty-suppressing drugs. The fact that children with suppressed precocious puberty between ages 8 and 12 resume puberty at age 13 does not mean that adolescents suffering from gender dysphoria whose puberty is suppressed beginning at

age 12 will simply resume normal pubertal development down the road if they choose to withdraw from the puberty-suppressing treatment and choose not to undergo other sex-reassignment procedures. Another troubling question that has been largely uninvestigated is what psychological consequences there might be for children with gender dysphoria whose puberty has been suppressed and who later come to identify as their biological sex.

Though there is very little scientific evidence relating to the effects of puberty suppression on children with gender dysphoria—and there certainly have been no controlled clinical trials comparing the outcomes of puberty suppression to the outcomes of alternative therapeutic approaches—there are reasons to suspect that the treatments could have negative consequences for neurological development. Scientists at the University of Glasgow recently used puberty-suppressing treatments on sheep, and found that the spatial memory of male sheep was impaired by puberty suppression using GnRH analogues,[117] and that adult sheep that were treated with GnRH analogues near puberty continued to show signs of impaired spatial memory.[118] In a 2015 study of adolescents treated with puberty suppression, the authors claimed that "there are no detrimental effects of [GnRH analogues] on [executive functioning]."[119] but the results of their study were more ambiguous and more suggestive of harm than that summary indicates.[120] (It is also worth noting that the study was conducted on a small number of subjects, which makes the detection of significant differences difficult.)

In addition to the reasons to suspect that puberty suppression may have side effects on physiological and psychological development, the evidence that something like normal puberty will resume for these patients after puberty-suppressing drugs are removed is very weak. This is because there are virtually no published reports, even case studies, of adolescents withdrawing from puberty-suppressing drugs and then resuming the normal pubertal development typical for their sex. Rather than resuming biologically normal puberty, these adolescents generally go from suppressed puberty to medically conditioned cross-sex puberty, when they are administered cross-sex hormones at approximately age 16. During this time, as per the Dutch protocol, puberty-suppressing GnRH analogues continue to be administered to prevent the initiation of gonadarche; the sex hormones that are normally secreted by the maturing gonads are not produced, and physicians administer sex hormones normally produced by the gonads of the opposite sex. This means that adolescents undergoing cross-sex hormone treatment circumvent the most fundamental form of

sexual maturation—the maturation of their reproductive organs. Patients undergoing sex reassignment discontinue GnRH treatment after having their gonads removed, since the secretion of sex hormones that the treatment is ultimately intended to prevent will no longer be possible.

Today's medical technology does not make it possible for a patient to actually grow the sex organs of the opposite sex. Instead, doctors focus on preventing the maturation of primary sex characteristics and manipulating secondary sex characteristics through the administration of hormones. Infertility is therefore one of the major side effects of the course of treatment that runs from puberty suppression through cross-sex hormones to surgical sex reassignment.

After the surgical removal of ovaries or testes, which the Dutch protocol recommends for young adults with gender dysphoria at around age 18, the possibility of normal pubertal development becomes impossible, since it is these organs that normally produce the androgens and estrogens responsible for the development of secondary sex characteristics. Even though the secretion of GnRH by the hypothalamus may continue to stimulate the pituitary to secrete gonadotropins, if the gonads themselves are physically removed from the body, these hormonal signals become virtual "dead letters."

Because the major studies of puberty suppression have not reported results of patients who have withdrawn from treatment and then resumed the puberty typical of their sex, we also do not know how normally the primary and secondary sex characteristics will develop in adolescents whose puberty has been artificially suppressed beginning at age 12. And so the claim that puberty suppression for adolescents with gender dysphoria is "reversible" is based on speculation, not rigorous analysis of scientific data.

The lack of data on gender dysphoria patients who have withdrawn from puberty-suppressing regimens and resumed normal development raises again the very important question of whether these treatments contribute to the persistence of gender dysphoria in patients who might otherwise have resolved their feelings of being the opposite sex. As noted above, most children who are diagnosed with gender dysphoria will eventually stop identifying as the opposite sex. The fact that cross-gender identification apparently persists for virtually *all* who undergo puberty suppression could indicate that these treatments increase the likelihood that the patients' cross-gender identification will persist.

As philosopher Ian Hacking has argued, many psychological conditions are subject to what he calls a "looping effect," wherein the classification of

people as belonging to certain "kinds" can change how those people think of themselves and how they behave.[121] Children and adolescents who are experiencing confusion about gender roles, their sexuality and behavior, and the changes caused by puberty may be especially likely to take up the way of life provided for by a "kind" like "transgender" as a way to make sense of their confusing circumstances, especially when they are subjected to the pressure of being labeled as such by adults in positions of authority, including parents, teachers, psychologists, and physicians.

What We Don't Know Can Hurt Us

The use of puberty suppression and cross-sex hormones for minors is a radical step that presumes a great deal of knowledge and competence on the part of the children assenting to these procedures, on the part of the parents or guardians being asked to give legal consent to them, and on the part of the scientists and physicians who are developing and administering them. We frequently hear from neuroscientists that the adolescent brain is too immature to make reliably rational decisions,[122] but we are supposed to expect emotionally troubled adolescents to make decisions about their gender identities and about serious medical treatments at the age of 12 or younger. And we are supposed to expect parents and physicians to evaluate the risks and benefits of puberty suppression, despite the state of ignorance in the scientific community about the nature of gender identity.

The claim that puberty-blocking treatments are fully reversible makes them appear less drastic, but this claim is not supported by scientific evidence. It remains unknown whether or not ordinary sex-typical puberty will resume following the suppression of puberty in patients with gender dysphoria. It is also unclear whether children would be able to develop normal reproductive functions if they were to withdraw from puberty suppression. It likewise remains unclear whether bone and muscle development will proceed normally for these children if they resume puberty as their biological sex. Furthermore, we do not fully understand the psychological consequences of using puberty suppression to treat young people with gender dysphoria.

More research is needed to resolve these unanswered questions. At the same time, research into how and why gender dysphoria occurs, persists, and desists must also continue, as it could elucidate new ways to help people cope with gender dysphoria with less permanent and drastic treatments than sex reassignment.

In light of the many uncertainties and unknowns, it would be appropriate to describe the use of puberty-blocking treatments for gender dysphoria as experimental. And yet it is not being treated as such by the medical community. Over the course of decades, experimental medicine has developed many norms, standards, and protocols, including human subjects protections, the use of institutional review boards, and carefully controlled clinical trials, as well as long-term follow-up studies. These longstanding practices are meant to make experimental medicine more rigorous and to serve the interests of patients, physicians, and the community. But when it comes to the use of puberty-blocking treatments for gender dysphoria, these standards and protocols seem to be almost entirely absent—a fact that ill serves patients, physicians, the community, and the search for truth. Physicians should be cautious about embracing experimental therapies in general, but especially those intended for children, and should particularly avoid any experimental therapy that has virtually no scientific evidence of effectiveness or safety. Regardless of the good intentions of the physicians and parents, to expose young people to such treatments is to endanger them.

While there is much that is not known with certainty about gender dysphoria, there is clear evidence that patients who identify as the opposite sex often suffer a great deal. They have higher rates of anxiety, depression, and even suicide than the general population. Something must be done to help these patients, but as scientists struggle to better understand what gender dysphoria is and what causes it, it would not seem prudent to embrace hormonal treatments and sex reassignment as the foremost therapeutic tools for treating this condition.

Notes

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