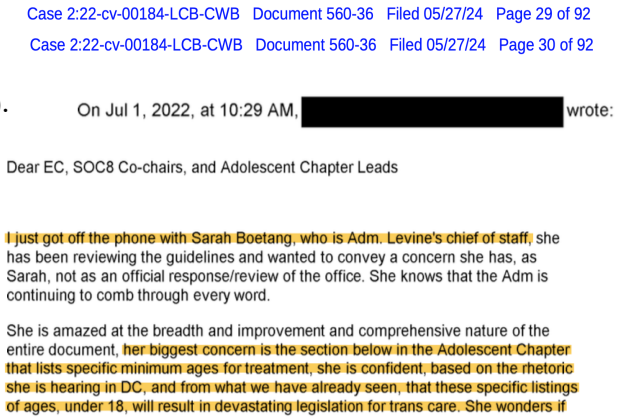
Admiral Levine, Assistant Secretary of Health and Human Services, interferes with the development of WPATH's Standards of Care, version 8

A trustworthy clinical practice guideline must be based on the best available scientific and medical evidence. It must also manage conflicts of interests and limit bias. These conflicts might be financial, reputational or academic in nature. Political, legal and ideological conflicts should never enter into the development process.

Admiral Levine was given an advance copy of WPATH's SOC-8, was asked to comment on it, and inappropriately asked that any age restrictions on youth transition be eliminated from the document. This request was motivated by political, legal and ideological reasons, and not based on evidence, ethics or patient safety. WPATH leadership complied with Admiral Levine's request and had all age limits no youth transition removed from SOC-8.

July 1, 2022



Case 2:22-cv-00184-LCB-CWB Document 560-36 Filed 05/27/24 Page 29 of 92
Case 2:22-cv-00184-LCB-CWB Document 560-36 Filed 05/27/24 Page 30 of 92

On Jul 1, 2022, at 10:29 AM, [redacted] wrote:

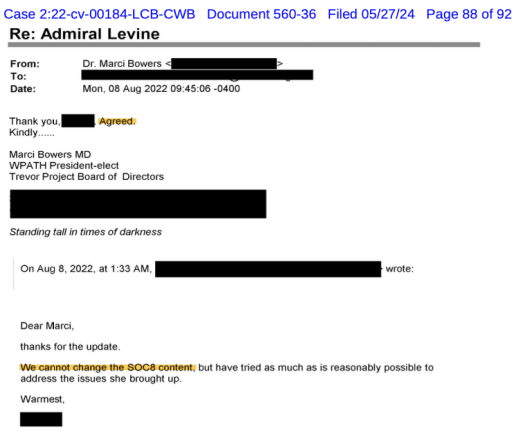
Dear EC, SOC8 Co-chairs, and Adolescent Chapter Leads

I just got off the phone with Sarah Boetang, who is Adm. Levine's chief of staff, she has been reviewing the guidelines and wanted to convey a concern she has, as Sarah, not as an official response/review of the office. She knows that the Adm is continuing to comb through every word.

She is amazed at the breadth and improvement and comprehensive nature of the entire document, her biggest concern is the section below in the Adolescent Chapter that lists specific minimum ages for treatment, she is confident, based on the rhetoric she is hearing in DC, and from what we have already seen, that these specific listings of ages, under 18, will result in devastating legislation for trans care. She wonders if

This is redacted email between what are probably WPATH members writing the Standards of Care 8th. This is in regards to the Adolescent (minors' chapter). This is 10 weeks before the document is published on September 15, 2022. Admiral Levine, Assistant Secretary of Health and Humans Services, through Levine's chief of staff Sarah Boetang, asks for all age limits to be removed. These age limits are in the draft document and in the SOC8 when it was published on September 15, 2022. By the evening of September 15, an "adjunct document," as requested by Boetang, was published as a correction. That correction with the age removals is included at the end of this chronological document.

August 8, 2022 –



Case 2:22-cv-00184-LCB-CWB Document 560-36 Filed 05/27/24 Page 88 of 92

Re: Admiral Levine

From: Dr. Marci Bowers <[redacted]>
To: [redacted]
Date: Mon, 08 Aug 2022 09:45:06 -0400

Thank you, [redacted] Agreed.
Kindly.....

Marci Bowers MD
WPATH President-elect
Trevor Project Board of Directors

[redacted]

Standing tall in times of darkness

On Aug 8, 2022, at 1:33 AM, [redacted] wrote:

Dear Marci,

thanks for the update.

We cannot change the SOC8 content, but have tried as much as is reasonably possible to address the issues she brought up.

Warmest,

[redacted]

These are emails between Marci Bowers, a trans-identified male (biological female) and WPATH members. Bowers is a surgeon that specializes in genital surgeries. Other names are redacted but likely WPATH leadership. Bowers is president elect of WPATH when this email and the Zoom invite are received from Admiral Levine. This is 5 weeks before Standards of Care version 8 is released. Subject is "Adm Levine" and Bowers is told "We cannot change the SOC8 content." Later, the contents of SOC8 are changed, just as Admiral Levine requested.

Admiral Levine, Assistant Secretary of Health and Human Services,
interferes with the development of WPATH's Standards of Care, version 8

September 3, 2022

This is 12 days before SOC8 is released. Subject is "Concerns about Standards of Care 8." Bowers lets WPATH executive committee (WPATH EC) know that a conversation will be happening this weekend with Admiral Levine and asks if that is acceptable.

Re: Concerns About Standards of Care 8

From: Dr. Marci Bowers [redacted]
To: [redacted]
Cc: [redacted] WPATH EC 2022 <wpathec2022@wpath.org>
Date: Sat, 03 Sep 2022 14:24:01 -0400

hi all—
i've also been asked to speak again with Admiral Levine this weekend. i can do so with your blessing but will only reiterate our position and find out what they are asking, if that is acceptable?

Kindly.....

Marci Bowers MD
WPATH President-elect
[redacted]
Standing tall in times of darkness

September 3, 2022

The Zoom invite between Bowers, Levine and Boetang. This is for the September 3, 2002 meeting, 12 days before release. It is a ZoomGov meeting.

Touch Base

Where: https://www.zoomgov.com/j/1611937840?pwd=SUZBMWZGekN4SXYyS2JJK1pkR0FJQT09
When: Sat Sep 03 19:00:00 2022 -04:00
Until: Sat Sep 03 19:30:00 2022 -04:00
Organisers Common Name=Boateng, Sarah (HHS/OASH) mailto:[redacted]
Required Attendees: ROLE=REQ-PARTICIPANT PARTSTAT=NEEDS-ACTION RSVP=TRUE Common Name=Levine, Rachel (HHS/OASH) mailto[redacted]
ROLE=REQ-PARTICIPANT PARTSTAT=NEEDS-ACTION RSVP=TRUE Common Name=Keene, Jamie D. EOP/WHO mailto:[redacted]
ROLE=REQ-PARTICIPANT PARTSTAT=NEEDS-ACTION RSVP=TRUE Common Name=Dr. Marci Bowers mailto:[redacted]m

Sarah Boateng is inviting you to a scheduled ZoomGov meeting.

Join ZoomGov Meeting
https://www.zoomgov.com/j/1611937840?pwd=SUZBMWZGekN4SXYyS2JJK1pkR0FJQT09

Meeting ID: 161 193 7840
Passcode: 102067
One tap mobile
+16692545252,,1611937840# US (San Jose)
+16468287666,,1611937840# US (New York)

It is important to understand that there are standards set for how to write clinical practice guidelines. The 2 most important standards are that clinical guidelines be

1) based on the best scientific evidence that is available (systematic evidence reviews)

   and

2) that the process is transparent with biases and conflicts of interests disclosed and managed properly. The request to remove ages is not evidence based, as Johns Hopkins found "little to no evidence" for youth and adolescents.

There is no role for politics and ideology in the development of clinical practice guidelines like WPATH's SOC8.

Admiral Levine, Assistant Secretary of Health and Human Services,
interferes with the development of WPATH's Standards of Care, version 8

September 15, 2022 – in the morning

This is the release of SOC8, on September 15, 2022. The first version had age restrictions. Later that same day, a correction, or "adjunct document" was released with all ages for transition removed. The original version has been scrubbed from the internet. A highly unusual step as usually original publications still remain available when corrections occur. I have copies of the correction page and the drafts that include age restrictions.

Pages S1-S259 | Published online: 15 Sep 2022

International Journal of Transgender Health

ISSN: (Print) (Online) Journal homepage: www.tandfonline.com/journals/wijt21

Standards of Care for the Health of Transgender and Gender Diverse People, Version 8

E. Coleman, A. E. Radix, W. P. Bouman, G. R. Brown, A. L. C. de Vries, M. B. Deutsch, R. Ettner, L. Fraser, M. Goodman, J. Green, A. B. Hancock, T. W. Johnson, D. H. Karasic, G. A. Knudson, S. F. Leibowitz, H. F. L. Meyer-Bahlburg, S. J. Monstrey, J. Motmans, L. Nahata, T. O. Nieder, S. L. Reisner, C. Richards, L. S. Schechter, V. Tangpricha, A. C. Tishelman, M. A. A. Van Trotsenburg, S. Winter, K. Ducheny, N. J. Adams, T. M. Adrián, L. R. Allen, D. Azul, H. Bagga, K. Başar, D. S. Bathory, J. J. Belinky, D. R. Berg, J. U. Berli, R. O. Bluebond-Langner, M.-B. Bouman, M. L. Bowers, P. J. Brassard, J. Byrne, L. Capitán, C. J. Cargill, J. M. Carswell, S. C. Chang, G. Chelvakumar, T. Corneil, K. B. Dalke,

September 15, 2022 – in the evening

This is the "adjunct document" that Adm Levine had requested back on July 1, 2022 due to her concerns about "the rhetoric she is hearing in DC" and concerns about "devastating legislation." This removal was not based on the best available evidence (Johns Hopkins found "little to no evidence" for children and youth. This removal was done for political and legal reasons.

INTERNATIONAL JOURNAL OF TRANSGENDER HEALTH
2022, VOL. 23, NO. S1, S259–S261
https://doi.org/10.1080/26895269.2022.2125695

Taylor & Francis
Taylor & Francis Group

Check for updates

Correction

Article title: Standards of Care for the Health of Transgender and Gender Diverse People, Version 8

Authors: E. Coleman, A. E. Radix, W. P. Bouman, G. R. Brown, A. L. C. de Vries, M. B. Deutsch, R. Ettner, L. Fraser, M. Goodman, J. Green, A. B. Hancock, T. W. Johnson, D. H. Karasic, G. A. Knudson, S. F. Leibowitz, H. F. L. Meyer-Bahlburg, S. J. Monstrey, J. Motmans, L. Nahata … J. Arcelus

Journal: *International Journal of Transgender Health*

Bibliometrics: Volume 23, no. S1, pp. S1-S258

DOI: https://doi.org/10.1080/26895269.2022.2100644

Some sections of text have been removed or added. Please see below.

- On page S258, the following text was removed:
  - "The following are suggested minimal ages when considering the factors unique to the adolescent treatment time frame for gender-affirming medical and surgical treatment for adolescents, who fulfil all of the other criteria listed above.
    - Hormonal treatment: 14 years
    - Chest masculinization: 15 years
    - Breast augmentation, Facial Surgery: 16 years
    - Metoidioplasty, Orchiectomy, Vaginoplasty,
    - Hysterectomy, Fronto-orbital remodeling: 17 years
    - Phalloplasty: 18 years"

June 25, 2024

The NY Times did cover the removal of ages. The reporter did not cover the fact that Johns Hopkins discovered "little to no evidence" or that WPATH suppressed Johns Hopkins and would not allow them to publish these findings.

https://www.nytimes.com/2024/06/25/health/transgender-minors-surgeries.html

By Azeen Ghorayshi

June 25, 2024 Updated 9:54 p.m. ET

The New York Times

Biden Officials Pushed to Remove Age Limits for Trans Surgery, Documents Show

Newly released emails from an influential group issuing transgender medical guidelines indicate that U.S. health officials lobbied to remove age minimums for surgery in minors because of concerns over political fallout.

Listen to this article · 8:53 min Learn more

Share full

Gmail

LCS Committees <committees.lcs.ga@coleg.gov>

Re: Problems testifying SB25-129

1 message

Huck Wach <huck.wach@gmail.com> Wed, Mar 5, 2025 at 10:25 AM
To: LCS Committees <committees.lcs.ga@coleg.gov>

Dear lawmakers,

It is very sad and disappointing to see the direction Colorado is going with its all-out assault on the unborn in the form of bills like **SB25-129**. For all the talk about equal protection and equal justice, your actions tell a different story. They tell the truth that you and those who support abortion do not care about equality at all. You believe that people of a certain size, in a certain location and at a certain level of development are somehow not human which is against all scientific knowledge. The leading cause of death in the US is murder in the womb. 1.5M US lives were lost in all of the US wars combined....we kill that many babies in just over 12 months here in the US. Billions are spent on trying to cure diseases and take away our guns while the solution to over 1M deaths a year is right there in front of us. And don't think you can hide behind "the will of the people." Just because something is legal does not make it morally right (take a lesson from slavery and Nazi Germany). The unjust killing of innocent human beings may be legal in Colorado but it is morally evil and you all know it. It is disgusting. History will judge our nation and especially our wicked state. God will pour out his judgment on those who wield the sword of justice for evil rather than good. This bill is just another slash of evil with the sword of justice and **I urge you NOT to support this bill** which is an additional step towards destruction. Repent. Change your ways and rescue the boys and girls, the future husbands and wives, mothers and fathers that are being led to death...hold them back from the slaughter.

Hans (Huck) Wach
1272 Longs Peak Ave
Longmont CO 80501

On Wed, Mar 5, 2025 at 9:57 AM LCS Committees <committees.lcs.ga@coleg.gov> wrote:

> Hi Huck -
>
> I apologize for the conflicting information. The bill was removed from the committee's calendar and will not be heard today, which is why it is no longer available to submit testimony. When the bill is rescheduled, it will again be available on the registration website. However, if you would like to send your testimony to this address, I'd be happy to share it with the committee today.
>
> Thanks,
> Elizabeth Burger
> Legislative Council Staff
>
> On Wed, Mar 5, 2025 at 9:41 AM Huck Wach <huck.wach@gmail.com> wrote:
>
> > This page says that the hearing on this is today but it is not listed as an option to submit written testimony for (see attached screenshot). It only lists 1015 and 183. Can't hear the people's voices if we can't submit testimony through the system.
> >
> > Huck
> > 1272 Longs Peak Ave
> > Longmont CO 80501

Joanna Olson-Kennedy and NIH Funded research

Joanna Olson-Kennedy is a pediatrician and adolescent medicine doctor at Los Angeles Children's Hospital. She is a principal investigator in an almost 10-million-dollar NIH funded research program. The study transitions youth and is supposed to report on the patients' outcomes. Infamously in an October 2024 New York Times article where she was interviewed, Olson-Kennedy admitted that puberty blockers did not improve outcomes for youth but she was not going to publish this data for fear it would be weaponized against her. There are many, many other scandalous things she has done. I will cover these chronologically.

August 29, 2011 – ABC News

This ABC News article was published 14 years ago. Back then she was known as Johanna Olson. She admits to using the suicide narrative to coerce parents and patients into transitioning.

> We often ask parents, Would you rather have a dead son than a live daughter? ... These kids have a suicide rate that is astronomical compared to any other group," she said.

It was unethical then and it is unethical now to threaten parents with suicide. And the suicide rates are not astronomical. The rates are elevated compared to the general teen population, but data suggests trans-identified youth have the same rate of suicide as teens with other mental health problems, such as depression, anxiety, eating disorders, etc.

She also mentions the key tenets of gender ideology. That kids are born transgender, or born in the wrong body. There is no objective data to support this dogma and her claims.

Transgender Kids Pioneer Early Changes to Identity, Body

Controversial practice rests on research positing boy brains and girl brains.

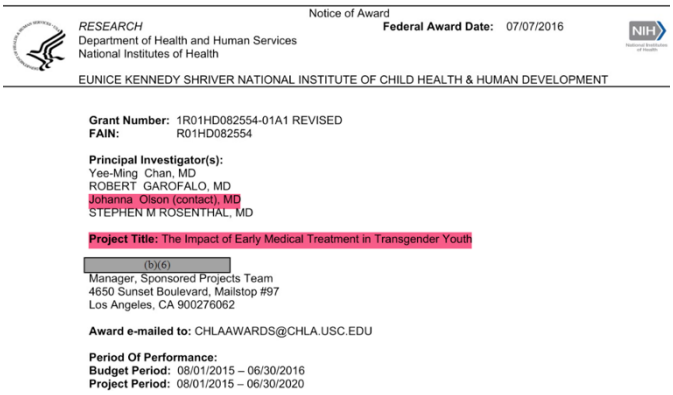
By ABC News
August 29, 2011, 10:29 AM

"We often ask parents, Would you rather have a dead son than a live daughter? ... These kids have a suicide rate that is astronomical compared to any other group," she said.

Olson says you can't force kids to be a gender they don't think they are. Gender identity isn't a choice; it's set at birth. Kids know whether they're a boy or a girl on the inside by the age of three or four.

8/1/2015 – Federal award date for Olson-Kennedy's NIH funded study

Olson-Kennedy is the principal investigator of a research project titled "The Impact of Early Medical Treatment in Transgender Youth." The funding start date is 8/1/2015. This is one of many yearly award letters.



Notice of Award

RESEARCH
Department of Health and Human Services
National Institutes of Health

Federal Award Date: 07/07/2016

EUNICE KENNEDY SHRIVER NATIONAL INSTITUTE OF CHILD HEALTH & HUMAN DEVELOPMENT

Grant Number: 1R01HD082554-01A1 REVISED
FAIN: R01HD082554

Principal Investigator(s):
Yee-Ming Chan, MD
ROBERT GAROFALO, MD
Johanna Olson (contact), MD
STEPHEN M ROSENTHAL, MD

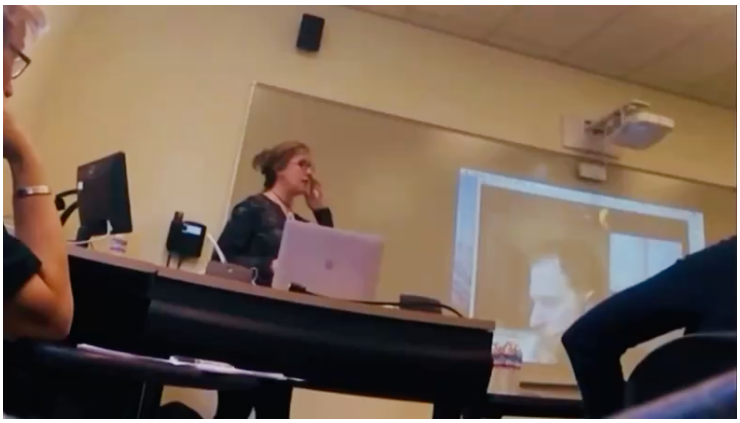
Project Title: The Impact of Early Medical Treatment in Transgender Youth

(b)(6)
Manager, Sponsored Projects Team
4650 Sunset Boulevard, Mailstop #97
Los Angeles, CA 900276062

Award e-mailed to: CHLAAWARDS@CHLA.USC.EDU

Period Of Performance:
Budget Period: 08/01/2015 – 06/30/2016
Project Period: 08/01/2015 – 06/30/2020

July 6, 2018



At a "Gender Spectrum" conference held in Moraga, Californio Olson-Kennedy says these two remarkable things. The full video is here, with the relevant quote beginning at 46:05.

> "what we do know is that adolescents actually have the capacity to make a reasoned, logical decision"

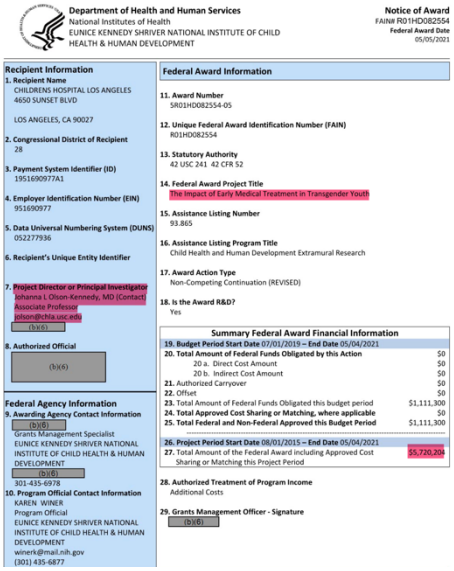
And regarding regret after double mastectomy,

> "and here is the other thing about chest surgery, if you want breasts at a later point in your life you can go and get them."

It is unconscionable for any person, let alone a physician, to readily dismiss regret over a double mastectomy done for "gender affirming care." Getting "breasts at a later point" will not return sensation or function to the person that regrets their mastectomy. They will never be able to breastfeed.

5/5/2021 – Notice of Award

This is evidence that the study "The Impact of Early Medical Treatment in Transgender Youth" has now been funded by the NIH from 8/1/2015 to 5/4/2021 to a total amount of $5,720,204.



Department of Health and Human Services
National Institutes of Health
EUNICE KENNEDY SHRIVER NATIONAL INSTITUTE OF CHILD HEALTH & HUMAN DEVELOPMENT

Notice of Award
FAIN# R01HD082554
Federal Award Date 05/05/2021

Recipient Information

1. Recipient Name
CHILDRENS HOSPITAL LOS ANGELES
4650 SUNSET BLVD

LOS ANGELES, CA 90027

2. Congressional District of Recipient
28

3. Payment System Identifier (ID)
195169077A1

4. Employer Identification Number (EIN)
951690977

5. Data Universal Numbering System (DUNS)
052277936

6. Recipient's Unique Entity Identifier

7. Project Director or Principal Investigator
Johanna L Olson-Kennedy, MD (Contact)
Associate Professor
jolson@chla.usc.edu
(b)(6)

8. Authorized Official
(b)(6)

Federal Agency Information

9. Awarding Agency Contact Information
(b)(6)
Grants Management Specialist
EUNICE KENNEDY SHRIVER NATIONAL INSTITUTE OF CHILD HEALTH & HUMAN DEVELOPMENT
(b)(6)
301-435-6978

10. Program Official Contact Information
KAREN WINER
Program Official
EUNICE KENNEDY SHRIVER NATIONAL INSTITUTE OF CHILD HEALTH & HUMAN DEVELOPMENT
winerk@mail.nih.gov
(301) 435-6877

Federal Award Information

11. Award Number
5R01HD082554-05

12. Unique Federal Award Identification Number (FAIN)
R01HD082554

13. Statutory Authority
42 USC 241 42 CFR 52

14. Federal Award Project Title
The Impact of Early Medical Treatment in Transgender Youth

15. Assistance Listing Number
93.865

16. Assistance Listing Program Title
Child Health and Human Development Extramural Research

17. Award Action Type
Non-Competing Continuation (REVISED)

18. Is the Award R&D?
Yes

Summary Federal Award Financial Information

19. Budget Period Start Date 07/01/2019 – End Date 05/04/2021	
20. Total Amount of Federal Funds Obligated by this Action	$0
20 a. Direct Cost Amount	$0
20 b. Indirect Cost Amount	$0
21. Authorized Carryover	$0
22. Offset	$0
23. Total Amount of Federal Funds Obligated this budget period	$1,111,300
24. Total Approved Cost Sharing or Matching, where applicable	$0
25. Total Federal and Non-Federal Approved this Budget Period	$1,111,300
26. Project Period Start Date 08/01/2015 – End Date 05/04/2021	
27. Total Amount of the Federal Award including Approved Cost Sharing or Matching this Project Period	$5,720,204

28. Authorized Treatment of Program Income
Additional Costs

29. Grants Management Officer - Signature
(b)(6)

11/4/2024 – House subcommittee on Health Care and Financial Services begins oversight investigation

This final item about her NIH funding is out of place chronologically. I put it here to show that Olson-Kennedy has received $9.7 million dollars of NIH grant money for her study on transitioning youth.

About Committee Activity

Press Release Published: Nov 4, 2024

McClain Probes $9.7 Million Taxpayer-Funded Study Buried by Activist Researcher on Puberty Blockers

WASHINGTON—Subcommittee on Health Care and Financial Services Chairwoman Lisa McClain (R-Mich.) is conducting oversight of the National Institutes of Health (NIH) after the results of a $9.7 million taxpayer-funded research project studying the effects of puberty blockers for transgender youth has been hidden by the project's principal investigator. In a letter to National Institutes for Health (NIH) Director Monica Bertagnolli, Subcommittee Chairwoman McClain requests documents and information related to the ongoing project and unpublished project data.

"The Committee on Oversight and Accountability is conducting oversight of the National Institutes of Health (NIH) grant of $9.7 million to an ongoing research project titled, 'The Impact of Early Medical Treatment in Transgender Youth,'" **wrote McClain.** "We are alarmed that the project's principal investigator, Dr. Johanna Olson-Kennedy, is withholding publication of the project's research findings which cast doubt on the efficacy of the 'gender affirming' model, because she believes the findings could be 'weaponized' by critics of transgender medical interventions for

January 19, 2023 – Olson-Kennedy publishes paper in the New England Journal of Medicine based on her NIH funded research

The paper is titled "Psychosocial Functioning in Transgender Youth after 2 Years of Hormones" and it states that it is "Supported by a grant (R01 HD082554) from the Eunice Kennedy Shriver National Institute of Child Health and Human Development." This is the same grant number in the above referenced documents.

The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Psychosocial Functioning in Transgender Youth after 2 Years of Hormones

Diane Chen, Ph.D., Johnny Berona, Ph.D., Yee-Ming Chan, M.D., Ph.D., Diane Ehrensaft, Ph.D., Robert Garofalo, M.D., M.P.H., Marco A. Hidalgo, Ph.D., Stephen M. Rosenthal, M.D., Amy C. Tishelman, Ph.D., and Johanna Olson-Kennedy, M.D.

It is remarkable that this paper reports that

> "The most common adverse event was suicidal ideation (in 11 participants [3.5%]); death by suicide occurred in 2 participants."

This is reported in the paper's abstract. Later in the paper's results section they report again that

> "Two participants died by suicide during the study (one after 6 months of follow-up and the other after 12 months of follow-up)."

Table 2 in the paper also reports this information.

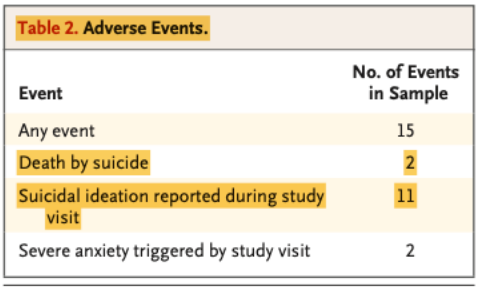


Table 2. Adverse Events.

Event	No. of Events in Sample
Any event	15
Death by suicide	2
Suicidal ideation reported during study visit	11
Severe anxiety triggered by study visit	2

These are the only times that these adverse events and deaths by suicide are mentioned in the paper. There is no discussion about these events and nothing mentioned in the paper's conclusion.

An NIH funded study has suicidal ideation as the most common adverse event, and two deaths by suicide to occur. The suicide rate was 2 out of the 315 participants in this study. That is a suicide rate of 615 per 100,000 people. The US teen suicide rate is 14 per 100,000. The fact that the authors failed to discuss these suicides and the NIH oversight of the study failed to address this is very concerning.

October 23, 2024

The New York Times

U.S. Study on Puberty Blockers Goes Unpublished Because of Politics, Doctor Says

The leader of the long-running study said that the drugs did not improve mental health in children with gender distress and that the finding might be weaponized by opponents of the care.

Protesters against a ban of gender-affirming medical care in the Texas Capitol rotunda in Austin last year. Mikala Compton/Austin American-Statesman, via Associated Press

By Azeen Ghorayshi

Published Oct. 23, 2024 Updated Oct. 24, 2024

As mentioned in introduction, the New York Times interviewed Olson-Kennedy and published that here. She admits that puberty blockers did not help the study's 95 participants but will not publish that data for fear it will be weaponized.

She also tells the reporter that the reason puberty blockers did not help was because

> "They're in really good shape when they come in, and they're in really good shape after two years," said Dr. Olson-Kennedy, who runs the country's largest youth gender clinic at the Children's Hospital of Los Angeles.
>
> That conclusion seemed to contradict an earlier description of the group, in which Dr. Olson-Kennedy and her colleagues noted that one quarter of the adolescents were depressed or suicidal before treatment.

The reporter is correct, and Olson-Kennedy is wrong. She reported in an earlier 2021 paper on these 95 youth that did not improve on puberty blockers. Before starting the puberty blockers, 28.6% had depression, 22.1% were clinically anxious, and 7.9% reported past suicide attempts.

Original article

Psychosocial Characteristics of Transgender Youth Seeking Gender-Affirming Medical Treatment: Baseline Findings From the Trans Youth Care Study

Diane Chen, Ph.D. [a,b,c,d,*], Mere Abrams, M.S.W. [e,f], Leslie Clark, Ph.D. [g,h], Diane Ehrensaft, Ph.D. [e,f], Amy C. Tishelman, Ph.D. [i,j,k], Yee-Ming Chan, M.D., Ph.D. [l,j], Robert Garofalo, M.D., M.P.H. [a,d], Johanna Olson-Kennedy, M.D. [g,h], Stephen M. Rosenthal, M.D. [e,f], and Marco A. Hidalgo, Ph.D. [g,h]

December 5, 2024

Clementine Breen filed a lawsuit against Johanna Olson-Kennedy, Children's Hospital of Los Angeles and Scott Moser. Olson-Kennedy began Clementine on puberty blockers at 12, testosterone at 13 and referred her to Scott Moser who removed her breast buds at age 14. She only had breast buds as her breasts stopped developing when puberty blockers were started and their development never progressed passed budding. I can only wonder what a surgeon is thinking when he does this to a woman who is so young. Clementine tells how her mental health deteriorated while undergoing transition in the linked podcast, but this never led Olson-Kennedy or any others to question what they were doing to her.

SUPERIOR COURT OF THE STATE OF CALIFORNIA

IN AND FOR THE COUNTY OF LOS ANGELES

KAYA CLEMENTINE BREEN (a/k/a Finn Paul Breen), an individual,

Plaintiff,

v.

JOHANNA OLSON-KENNEDY, M.D., an individual; CHILDREN'S HOSPITAL LOS ANGELES, a California Corporation; CHILDREN'S HOSPITAL LOS ANGELES MEDICAL GROUP, INC., a California Corporation; SCOTT MOSSER, M.D., an

Case No.: 24STCV32096

COMPLAINT FOR:

1. MEDICAL NEGLIGENCE
2. MEDICAL NEGLIGENCE – HOSPITAL/MEDICAL GROUP

JURY TRIAL DEMANDED

Clementine tells her story on X to Billboard Chris here, and on the podcast, Gender: A Wider Lens, here. I think that Clementine might be amenable to a role in any hearings that might occur.

Lexi White
All* Above All
611 Pennsylvania Ave. SE #508
Washington, DC 20003
lexi@allaboveall.org
March 17, 2025

RE: Letter of Support for SB25-129

Dear Chair Javier Mabrey, Vice Chair Michael Carter and Members of the House Judiciary Committee,

On behalf of All* Above All, I am writing to express our strong support for **Senate Bill 25-129**, which will strengthen Colorado's existing shield law to further protect abortion and gender-affirming care providers and patients.

All* Above All was launched in 2013 as a woman of color-led effort to restore and sustain equitable coverage of abortion care. After years of bold work centering people of color working to make ends meet, All* Above All expanded its mission and scope in 2021 beyond insurance coverage of abortion to include other abortion access issues and strategies. Our goal is to fight at every level to ensure that abortion care is accessible, available, and affordable to all who seek care, and free from targeted interference or medically unnecessary threats of any kind. As a national partner to Colorado Organization for Latina Opportunity and Reproductive Rights (COLOR), we see Colorado's shield protections as a critical step in safeguarding patients and providers from the growing harms of abortion and gender-affirming care bans across the country.

SB25-129 takes necessary and strategic steps to strengthen Colorado's shield law by:

1. **Expanding the reach of Colorado's 2023 shield law** to cover all state and local entities, including but not limited to local law enforcement, public health agencies, licensed attorneys, and any entity located, headquartered, or incorporated in Colorado. This ensures that cooperation with hostile out-of-state investigations will result in penalties.

2. **Providing additional privacy and security for prescribers** of mifepristone and misoprostol by allowing them to list their practice or clinic name on prescriptions instead of their personal name. This follows similar protections established in Washington and New York and will help protect providers from harassment and targeted legal action.
3. **Strengthening legal safeguards** by requiring that any subpoena request be accompanied by an affidavit affirming that the request is unrelated to an investigation of protected health care services. Falsely submitting such an affidavit will carry penalties, helping to deter politically motivated or illegitimate legal action.
4. **Establishing civil recourse options** for Coloradans targeted by hostile out-of-state actions related to abortion and gender-affirming care. This creates a pathway for individuals and providers to seek legal remedy and protection from unjustified interference.

We commend the Colorado legislature for its commitment to protecting access to abortion and gender-affirming care at a time when many states are aggressively working to restrict these fundamental rights. Colorado stands as a beacon of care for so many people in the region, especially as surrounding states increasingly seek to criminalize access to care. In light of the current federal administration's regressive stance on reproductive justice issues — demonstrated through recent executive orders, rollbacks in access to care, and heightened threats of criminalization against abortion patients and providers — Colorado's leadership is more critical than ever.

We particularly applaud the labeling provision included in this bill and strongly recommend expanding these protections to prescribers of gender-affirming care to ensure comprehensive coverage and protection for all providers.

We urge swift passage of **SB25-129** and thank you for your leadership and advocacy in defending reproductive and gender-affirming health care. All* Above All stands ready to support this legislation and its implementation in every way possible.

Sincerely,

Lexi White
Director of State Strategies

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

Victor VOE, et al.,

Plaintiffs,

v. Case No. 1:23-cv-864

Thomas MANSFIELD, et al.,

Defendants,

Philip E. BERGER, et al.

Intervenor-Defendants

EXPERT REPORT OF
MICHAEL K. LAIDLAW, M.D.

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I, Michael K. Laidlaw, M.D., hereby declare as follows:

1. I am over the age of eighteen and submit this expert declaration based on my personal knowledge and experience.

2. I am a board-certified endocrinologist. I received my medical degree from the University of Southern California in 2001. I completed my residency in internal medicine at Los Angeles County/University of Southern California Medical Center in 2004. I also completed a fellowship in endocrinology, diabetes and metabolism at Los Angeles County/University of Southern California Medical Center in 2006.

3. The information provided regarding my professional background is detailed in my curriculum vitae. A true and correct copy of my curriculum vitae is attached as Exhibit A.

4. In my clinical practice as an endocrinologist, I evaluate and treat patients with hormonal and/or gland disorders. Hormone and gland disorders can cause or be associated with psychiatric symptoms, such as depression, anxiety, and other psychiatric symptoms. Therefore, I frequently assess and treat patients demonstrating psychiatric symptoms and determine whether their psychiatric symptoms are being caused by a hormonal issue, gland issue, or something else.

5. I have been retained by Intervenor-Defendants in the above-captioned lawsuit to provide an expert opinion on the efficacy and safety of sex reassignment treatment, including the trustworthiness of proposed standards of care or treatment guidelines promulgated by medical organizations.

6. If called to testify in this matter, I would testify truthfully and based on my expert opinion. The opinions and conclusions I express herein are based on a reasonable degree of scientific certainty.

7. I am being compensated at an hourly rate of $500 per hour plus expenses for my time spent preparing this declaration, and to prepare for and provide testimony in this matter. I am being compensated at an hourly rate of $750 for testimony at depositions or trial. My compensation does not depend on the outcome of this litigation, the opinions I express, or the testimony I may provide.

8. My opinions contained in this report are based on: (1) my clinical experience as an endocrinologist in particular dealing with hormone excess, hormone deficiency, and hormone balance; (2) my clinical experience evaluating individuals who have or have had gender incongruence including a detransitioner; (3) my knowledge of research and studies regarding the

treatment of gender dysphoria, including for minors and adults; and (4) my first-hand personal experience in human research as a physician, having been involved in two studies, one involving magnesium and bone density and the other involving ultrasound use for detecting recurrent thyroid cancer.[1] I frequently review medical studies conducted by others and have experience assessing the strengths and weaknesses of such studies.

9. I was provided with and reviewed the following case-specific materials: the plaintiffs' complaint, House Bill 808, and the documents produced by the World Professional Association of Transgender Health (WPATH) and the United States Department of Health and Human Services (HHS).

10. A true and correct copy of my CV is attached to this declaration. In the previous four years, I have provided expert testimony in the following cases: *A.B. vs. Premera Blue Cross*, No. 2:23-cv-00953-TSZ (W.D. Wash. Filed June 27, 2023); *T.D. v. Wrigley*, No. 08-2023-CV-02189 (N.D. filed Sept. 14, 2023); *Brockman v. Kaiser Foundation Hospitals, Inc.*, No. STK-CV-UMM-2023-0001612 (Cal. Sup. Ct. filed Feb. 22, 2023); *Van Garderen v. State of Montana,* No. DV 2023-0541 (Missoula Cnty. Dist. Ct. filed May 9, 2023); *Koe v. Noggle,* No. 1:23-cv-02904-SEG (N.D. Ga. filed June 29, 2023); *Poe v. Drummond,* No. 23-cv-00177-JFH-SH (N.D. Okla. filed May 2, 2023); *Doe v. Thornbury,* No. 3:23-CV-00230-DJH (W.D. Ky. filed May 3, 2023); *L.W. v. Skrmetti,* No. 3:23-cv-00376 (M.D. Tenn. filed Apr. 20, 2023); *Boe v. Marshall, No. 2:22-cv-184-LCB* (M.D. Ala. filed Apr. 19, 2022); *Dekker v. Marstiller,* No. 4:22-cv-00325-RHMAF (N.D. Fla. filed Sept. 7, 2022); *C.P. v. Blue Cross Blue Shield of Illinois,* No. 3:20-cv-06145-RJB (W.D. Wash. filed Nov. 23, 2020); *Pflag, Inc. v. Abbott,* No. D-1-GN-22-002569 (459th Dist. Ct., Travis Cnty., filed June 8, 2022); *Paoli v. Hudson,* No. 279126 (Cal. Super. Ct. Tulare Cnty. filed June 20, 2019); *Doe v. Snyder,* No. 4:20-cv-00335-SHR (D. Ariz. filed Aug. 6, 2020)*; A.M. v. Dr. F.,* No. S2011599, 2021 BCSC 32 (Can.); *A.B. v. C.D.,* [2019] No. E190334 (Can. B.C. Sup. Ct. J.); and *A.B. v. C.D.,* 2020 BCCA 11 (Can.).

[1] For the latter study I helped to design an Institutional Review Board ("IRB") approved protocol. Furthermore, I received certification in the required course "Understanding the Fundamentals: Responsibilities and Requirements for the Protection of Human Subjects in Research" at the University of Southern California in 2003.

11. In my professional opinion, treatment interventions on behalf of children and adults diagnosed with gender dysphoria must be held to the same scientific standards as other medical treatments. These interventions must be optimal, efficacious, and safe. Any treatment which alters biological development in children should be used with extreme caution. Except in the case of a fatal injury or disease, the minor will become an adult and present to the adult physician. The adult physician must be able to have a thorough understanding of any condition which alters the biological development of children and, in the case of the endocrinologist, be knowledgeable about the long-term effects of hormones on the human body, particularly when the hormones are being used in ways that alter development.

12. The following expresses my expert opinion regarding minors who present with a disparity between their biological sex and internal feeling about their gender, specifically with regard to the use of social transition, medications which block normal pubertal development, the applications of hormones of the opposite sex, and surgical procedures that alter the genitalia and/or breasts for those individuals.

I. Background

A. Biological Sex in Contrast to Gender Identity

13. A recognition and understanding of biological sex is critical to my practice as an endocrinologist because the endocrine physiology of men and women, boys and girls, differ.

14. Biological sex is the objective physical condition of having organs and body parts which correspond to a binary sex. There are only two physical sexes, male and female. The male is identified as having organs and tissues such as the penis, testicles and scrotum. The female sex is identified by having organs and tissues such as the labia, vagina, uterus, and ovaries. Biological sex is easily identified by physical observation such that adults and even young children can identify the biological sex of a newborn baby.

15. It is also noteworthy that the physical organs described above as representing biological sex have a physical genetic correlate. In other words, it is a well-established scientific fact that two X chromosomes identify the cells correlating to a female person, and an X and a Y chromosome correlate to a male person.

16. Gender identity is not a component of sex. The Diagnostic and Statistical Manual of Mental Disorders (DSM-5 TR) states that "sex and sexual refer to the biological indicators of

male and female (understood in the context of reproductive capacity), such as in sex chromosomes, gonads, sex hormones, and non-ambiguous internal and external genitalia" (DSM-5 TR, emphasis added). Note that gender identity is not a component of biological sex as defined by the DSM 5.

17. Gender identity in the DSM 5 is defined separately: "Gender identity is a category of social identity and refers to an individual's identification as male, female, or, occasionally, some category other than male or female" (DSM 5-TR). So, we can see that gender identity is not a physical entity but is described as a social identity. It is a subjective identification known only once a patient makes it known. It cannot be identified by any physical means, cannot be confirmed by any outside observer, and can change over time.

18. Gender identity is a psychological concept. It has no correlate in the human body. In the letter to the editor I wrote with my colleagues, we wrote in our critique of the Endocrine Society Guidelines that "[t]here are no laboratory, imaging, or other objective tests to diagnose a 'true transgender' child" (Laidlaw et al., 2019).

19. For example, one cannot do imaging of the human brain to find the gender identity. Likewise, there is no other imaging, laboratory tests, biopsy of tissue, autopsy of the brain, genetic testing, or other biological markers that can identify the gender identity. There is no known gene that maps to gender identity or to gender dysphoria. In other words, there is no objective physical measure to identify either gender identity or gender dysphoria.

20. This is in contrast to endocrine disorders which have a measurable physical change in either hormone levels or gland structure which can be confirmed by physical testing. Therefore, gender dysphoria is a purely psychological phenomenon and not an endocrine disorder. But as my colleagues and I wrote in our letter to the editor, it becomes an endocrine condition through gender affirmative therapy: "Childhood gender dysphoria (GD) is not an endocrine condition, but it becomes one through iatrogenic puberty blockade (PB) and high-dose cross-sex (HDCS) hormones. The consequences of this gender-affirmative therapy (GAT) are not trivial and include potential sterility, sexual dysfunction, thromboembolic and cardiovascular disease, and malignancy" (Laidlaw et al. 2019).

21. Gender identity is not determined by any known gene or set of genes. If gender identity were to be determined by genes, we would expect that identical twins would profess having the same gender identity nearly 100 percent of the time. This is not the case. In fact, the largest transexual twin study ever conducted included seventy-four pairs of identical twins

(Diamond, 2013). They were studied to determine in how many cases both twins would grow up to identify as transgender. In only twenty-one of the seventy-four pairs (28 percent) did both identical twins identify as transgender. This is consistent with the fact that multiple factors play a role in determining gender identity, including psychological and social factors. This study suggests that those factors are more important than any potential genetic contribution. Furthermore, no genetic studies have ever identified a transgender gene or genes.

22. Sex is clearly identified in 99.98% of cases by chromosomal analysis (Sax, 2002). Sex is also clearly recognized at birth in 99.98% of cases (Id.). Therefore, sex is a clear provable objective reality that can be identified through advanced testing such as karyotyping, or simple genital identification at birth by any layperson. The other 0.02% of cases have some disorder of sexual development (DSD). DSDs do not represent an additional sex or sexes, but simply a disorder on the way to binary sex development (Chan et al., 2021).

B. Human Sexual Development

1. Embryologic Development

23. Another confirmation that there are only two biological sexes comes from what is known about embryologic development and fertilization. The biologic development of the human person begins with a gamete from a female termed an ovum or egg and a gamete from a biological male which is termed sperm. The fertilization of the egg by the sperm begins the process of human biological development. The cells of the fertilized ovum then multiply and the person undergoes the incredible changes of embryologic development.

24. It is noteworthy that the male sperm comes from the biological male and the female egg comes from the biological female. There is no other third or fourth or fifth type of gamete that exists to begin the development of the human person. This is consistent with the binary nature of human sex (Alberts et al., 2002).

25. The sex binary of the human embryo is further developed between roughly weeks 8 to 12 of human development. There are two primitive structures present within the developing embryo called the Wolffian duct and Mullerian ducts (Larsen et al., 2003). The Wolffian ducts develop into substructures of the genitalia including the vas deferens and epididymis which belong exclusively to the male sex. For the female, the Mullerian ducts go on to form the uterus, fallopian tubes, cervix and upper one third of the vagina which belong exclusively to the female sex (Id.)

26. Significantly once the male structures are developed from Wolffian ducts, the Mullerian ducts are obliterated. This means that throughout the rest of embryological development the Mullerian ducts will not form into biological female structures. Likewise, in the female, the Wolffian ducts are destroyed by week 12 and will not form male structures at any point in the future (Id.).

27. Thus we can see in very early development that the sex binary is imprinted physically not only in the chromosomes, but also on the very organs that the body produces. Additionally, the potential to develop organs of the opposite sex is eliminated. Thus, in the human being there are only two physical tracts that one may progress along, the one being male and the other being female (Wilson and Bruno, 2022).

2. Pubertal Development

28. As mentioned previously, at the time of birth an infant's sex is easily identified through observation of the genitalia. Corresponding internal structures could also be confirmed through imaging if needed.

29. In early childhood, some low level of sex hormones are produced by the sex glands. The male testes produce testosterone. The female ovaries produce primarily the hormone estrogen. These sex glands remain quiescent for the most part, producing low levels of sex hormones until the time of pubertal development.

30. Puberty is an essential part of human development. Its purpose is to achieve full adult sexual function and reproductive capacity. Puberty is a time of development of the sex organs, body, and brain. There are well known changes in physical characteristics of the male such as growth of facial hair, deepening of the voice, and increasing size of the testicles and penis. Importantly, the testicles will develop sperm under the influence of testosterone and become capable of ejaculation. Because of these changes, the male will become capable of fertilizing an egg. The inability to produce sperm sufficient to fertilize an egg is termed infertility.

31. For the female, pubertal development includes changes such as breast development, widening of the pelvis, and menstruation. The female will also begin the process of ovulation which is a part of the menstrual cycle and involves the release of an egg or eggs from the ovary. Once the eggs are released in a manner in which they can become fertilized by human sperm then the female is termed fertile. The inability to release ovum that can be fertilized is infertility (Kuohong and Hornstein, 2021).

3. Tanner Stages of Development

32. From a medical perspective it is important to know the stage of pubertal development of the developing adolescent. This can be determined through a physical examination of the body. The female will have changes in breast characteristics and pubic hair development. Similarly, the male will have changes in testicular size and pubic hair development. These findings can be compared to the Tanner staging system which will allow the stage of puberty to be known.

33. Tanner stages are divided into five. Stage 1 is the pre-pubertal state before pubertal development of the child begins. Stage 5 is full adult sexual maturity. Stages 2 through 4 are various phases of pubertal development (Greenspan and Gardner, 2004).

34. Awareness of the Tanner stage of the developing adolescent is also useful to assess for maturation of sex organ development leading to fertility. For girls, the first menstruation (menarche) occurs about two years after Tanner stage 2 and will typically be at Tanner stage 4 or possibly 3 (Emmanuel and Boker, 2022). For males, the first appearance of sperm (spermarche) will typically be Tanner stages 4 (Id.). If puberty is blocked or disrupted before reaching these critical stages, the sex glands will be locked in a premature state and incapable of fertility.

4. Biological Sex Cannot Be Changed

35. It is not possible for a person to change from one biological sex to the other, and there is no technology that allows a biological male to become a biological female or vice-versa. It is not technologically possible at this time to change sex chromosomes; these will remain in every cell throughout life. It is not technologically possible to transform sex glands from one to the other. In other words, there are no hormones or other means currently known to change an ovary into a testicle or a testicle into an ovary.

36. Furthermore, as noted earlier, several of the sex specific structures (such as the epididymis of the male or uterus of the female) are produced early in embryological development from around weeks 8 to 12. The primitive ducts which lead to these organs of the opposite sex are obliterated. There is no known way to resuscitate these ducts and continue development of opposite sex structures.

37. It is also not possible to produce gametes of the opposite sex. In other words, there is not any known way to induce the testicles to produce eggs. Nor is there any known way to induce the ovaries to produce sperm. Therefore, creating conditions for a biological female to create sperm

capable of fertilizing another ovum is impossible. The induction of opposite sex fertility is impossible.

38. In fact, as I will discuss, gender affirming therapy can lead to infertility and potential sterilization.

C. Endocrine Disorders

39. Before discussing gender dysphoria and gender affirmative therapy from the perspective of an endocrinologist, it is helpful to discuss the background of endocrine diseases. This background demonstrates the difference in gender dysphoria, which is a psychological diagnosis, and other conditions treated by endocrinologists, which are physical diagnoses.

40. Endocrinology is the study of glands and hormones. Endocrine disorders can be divided into three main types: those that involve hormone excess, those that involve hormone deficiency, and those that involve structural abnormalities of the glands such as cancers.

41. It is important for the endocrinologist to determine the cause of hormone gland excess or deficiency in order to devise an appropriate treatment plan. The plan will generally be to help bring the hormones back into balance and thus bring the patient back to health.

42. To give an example of hormone excess, hyperthyroidism is a term which means overactivity of the thyroid gland. In this condition excess thyroid hormone is produced by the thyroid gland. This results in various physical and psychological changes for the afflicted patient. Examples of physical changes can include tachycardia or fast heart rate, hand tremors, and weight loss. Examples of psychological symptoms include anxiety, panic attacks, and sometimes even psychosis.

43. An endocrinologist can recognize thyroid hormone excess in part by signs and symptoms but can also confirm the diagnosis with laboratory testing that shows the thyroid hormones to be out of balance. Once this is determined and the degree of excess is known, then treatments can be given to bring these levels back into balance to benefit the patient's health and to prevent other disease effects caused by excess hormone.

44. To give another example, consider a deficiency of insulin. Insulin is a hormone which regulates blood glucose levels. If there is damage to the pancreas such that insulin levels are very low, then blood glucose levels will rise. If the glucose levels rise to a certain abnormally high level, then this is considered diabetes. In the case of type 1 diabetes, insulin levels are abnormally low and therefore blood glucose levels are abnormally high leading to a variety of

signs and symptoms. For example, the patient may have extreme thirst, frequent urination, muscle wasting, and weight loss. They may often experience lethargy and weakness.

45. In this case laboratory tests of glucose and insulin levels can confirm the diagnosis. Once diabetes is confirmed, the patient is then treated with insulin to help restore glucose balance in the body and prevent long-term complications of diabetes.

46. To give an example of a structural abnormality, a patient may have a lump on the thyroid gland in the neck. This may be further examined by an imaging test such as an ultrasound. A needle biopsy can be performed so that the cells can be examined under a microscope. A trained medical professional such as a pathologist can then examine the cells to determine if they are benign or cancerous. In the case of thyroid cancer, a surgical procedure known as a thyroidectomy may be performed to remove the diseased thyroid gland in order to treat the cancer.

47. Noteworthy in the preceding three examples is that all three disease conditions are diagnosed by physical observations. In other words, a laboratory test of a hormone, an imaging test of an organ, or an examination of cells under a microscope—or all three—may be employed in the diagnosis of endocrine disease.

D. Gender Dysphoria is a Psychological Diagnosis

48. Gender dysphoria, on the other hand, is not an endocrine diagnosis. It is a psychological diagnosis. Gender dysphoria is the persistent state of distress that stems from the feeling that one's gender identity does not align with one's physical sex (DSM-5 TR). It is diagnosed purely by psychological methods of behavioral observation and questioning. The criteria for diagnosis is found in the Diagnostic and Statistical Manual of Mental Disorders (DSM-5 TR).

49. As a practicing endocrinologist and scientist, I have made a study of GD and its treatment for two reasons: 1) I want to be sure that my colleagues and I understand the science before we treat any patients with GD; and 2) I am concerned that the medical society that claims to speak for me and other endocrinologists has abandoned scientific principles in endorsing treatments for GD that have questionable scientific support. The opinions expressed in this report are the result of my own experience, studies, education, and review of the scientific literature related to GD.

II. Gender Affirmative Therapy

50. In the section that follows I discuss four interventions (social transition, blocking normal puberty, opposite sex hormones, and surgery) that some physicians are using to treat gender dysphoria. Each intervention can lead to iatrogenic harms to the patient. The term "iatrogenic" is used in medicine to describe harms or newly created medical conditions that are the result of a treatment. These harms will be described in detail below. I speak of these harms because it is important to understand that once a patient begins GAT it is more likely the patient will continue on to surgery (de Vries et al,, 2011; de Vries et al., 2014). Thus, GAT interrupts the natural desistance process and instead places the patient on a lifetime regimen of hormonal and surgical care. A good understanding of these harms is also critical to my practice as an endocrinologist: if I did not understand these harms, I could not advise patients of the risks associated with GAT.

51. There are three general approaches to treating gender dysphoria in minors. (Zucker, 2020). One is psychosocial treatment that helps the young person align their internal sense of gender with their physical sex. Another would be to "watch and wait" and allow time and maturity to help the young person align sex and gender through natural desistance, while providing psychological support and therapy as needed and addressing comorbidities. The third option, which is the focus of that which follows, is referred to as gender affirmative therapy.

52. Gender affirmative therapy of adults and minors consists of psychosocial, medical, and surgical interventions that attempt to psychologically and medically alter the patient so that they come to believe they may become similar to the physical sex which aligns with their gender identity (but not their biological sex) and thereby reduce gender dysphoria. GAT consists of four main parts: 1) social transition, 2) blocking normal puberty or menstruation, 3) high dose opposite sex hormones, and 4) surgery of the genitalia and breasts.

53. The application of this medical therapy to minors[2] is a fairly new intervention and is associated with a number of harms both known and unknown. GAT suffers from a lack of a

[2] "[T]he US Department of Health and the Food and Drug Administration reference approximate age ranges for these phases of life, which consist of the following: (1) infancy, between birth and 2 years of age; (2) childhood, from 2 to 12 years of age; and (3) adolescence, from 12 to 21 years of age. Additionally, *Bright Futures* guidelines from the American Academy of Pediatrics identify adolescence as 11 to 21 years of age, dividing the group into early (ages 11–14 years), middle (ages 15–17 years), and late (ages 18–21 years) adolescence. The American Academy of Pediatrics has previously published a statement on the age limit of pediatrics in 1988, which was reaffirmed in 2012 and identified the upper age limit as 21 years with a note that exceptions could be made when the pediatrician and family agree to an older age, particularly in

quality evidence-base, poorly performed studies, and ongoing unethical human experimentation. As discussed below, in my professional opinion as an endocrinologist, no child should be given these treatments.

A. Social transition

54. The first stage of gender affirmative therapy is termed social transition. Social transition is a psychological intervention. The child may be encouraged to adopt the type of clothing and mannerisms or behaviors which are stereotypical of the opposite sex within a culture. For example, in the United States a boy might wear his hair long and wear dresses to socially transition. A girl may cut her hair short and wear clothes from the boys' section of a department store.

55. Social transition of the child has been noted by an expert researcher in the field of child gender dysphoria, Ken Zucker, to itself be a form of iatrogenic harm (Zucker, 2020). This is because the social transition process may solidify the young person's belief that they are in fact the sex opposite of their biological sex. The 2017 Endocrine Society Guideline states that "[s]ocial transition is associated with the persistence of GD/gender incongruence as a child progresses into adolescence" (Hembree et al., 2017). A recent study also supports the contention that children who undergo social transition are more likely to have their gender dysphoria persist into adolescence. In the 2022 article "Gender Identity 5 Years After Social Transition," which studied 317 socially transitioned youths, the authors found that "most participants were living as binary transgender youth (94.0%)" (Olson et al., 2022).

56. From an endocrine point of view, it is understandable that a child having the outward appearance of the opposite sex would believe that he or she is destined to go through puberty of the opposite sex. At this age, the child likely has only a poor understanding of the internal structures of the body, the function of the sex glands, the role of the sex glands in fertility and so forth.

57. Therefore, it would be quite frightening for a boy who believes he is a girl to be turning into a man with all of the adult features that accompany manhood. Vice versa, the girl who

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the case of a child with special health care needs. Recent research has begun to shed more light on the progression of mental and emotional development as children progress through the adolescent years into young adulthood. It is increasingly clear that the age of 21 years is an arbitrary demarcation line for adolescence because there is increasing evidence that brain development has not reliably reached adult levels of functioning until well into the third decade of life." (Hardin, 2017) (footnotes omitted).

has become convinced that she is a boy will be frightened by the physical changes brought on by womanhood.

58. In fact, it would appear that in the minds of children and adolescents that they are anticipating a sort of disease state in the future by the hormone changes that will occur as a normal and natural part of human development. Until relatively recently in human history, it has not been possible to interfere with puberty through pharmaceutical means.

B. Medications That Block Pubertal Development

1. Background

59. A second stage of gender affirmative therapy may involve blocking normal pubertal development. This may be done with puberty blocking medications (PB) that act directly on the pituitary to cause the endocrine condition known as hypogonadotropic hypogonadism (HH).

60. In order to understand what is occurring in this process, it is helpful to be aware of normal hormone function during pubertal development. There is a small pea-sized gland in the brain called the pituitary. It is sometimes referred to as the "master gland," as it controls the function of several other glands. One key function for our purposes is the control of the sex glands. There are two specific hormones produced by the pituitary referred to as luteinizing hormone (LH) and follicle stimulating hormone (FSH). These are responsible for sex hormone production and fertility. The LH and FSH act as signals to tell the sex glands to begin or to continue their function.

61. In the adult male, the production of LH will cause adult levels of testosterone to be produced by the testicles. In the adult female, the production of LH will cause adult levels of estrogen to be produced by the ovaries.

62. In early childhood, prior to the beginning of puberty, the pituitary function with respect to the sex glands is quiescent. However, during pubertal development LH will signal the testicle to increase testosterone production and this carries the boy through the stages of pubertal development into manhood. Likewise for the female, the interaction of LH with the ovaries increases estrogen production and carries the girl through the stages of development into womanhood.

63. Hypogonadotropic hypogonadism is a medical condition in which the pituitary does not send the hormonal signals (LH and FSH) to the sex glands. Therefore, the sex glands are unable to make their sex specific hormones of testosterone or estrogen.

64. If this condition occurs during puberty, the effect will be to stop pubertal development. This is a disease state which is diagnosed and treated by the endocrinologist.

65. Medications such as GnRH analogues (sometimes called puberty blockers) act on the pituitary gland to lower the pituitary release of LH and FSH levels dramatically. The result is a blockage of the signaling of the pituitary to the testicles or ovaries and therefore underproduction of the sex hormones. This will stop normal menstrual function for the female and halt further pubertal development. For the male this will halt further pubertal development. If the male had already reached spermarche, then production of new sperm will stop.

2. GnRH Agonist Medication Effects Vary by Use Case

66. There are a variety of uses for GnRH agonists. The use and outcome can be very different for different applications.

67. For example, the initial development of the medication called Lupron was for the treatment of prostate cancer, the idea being that blocking pituitary hormones will block the adult male's release of testosterone from the testicles. Since testosterone will promote the growth of prostate cancer, the idea is to lower testosterone levels to a very low amount and therefore prevent the growth and spread of prostate cancer. This is a labeled use of the medication. In other words, there is FDA approval for this use.

68. Another labeled use of GnRH agonist medication is for the treatment of central precocious puberty. In the disease state of central precocious puberty, pituitary signaling is activated at an abnormally young age[3], say age four, to begin pubertal development. In order to halt puberty which has begun at an abnormally early time, a GnRH agonist may be used. Here the action of the medication on the pituitary will disrupt the signaling to the sex glands, stop early sex hormone production, and therefore stop abnormal pubertal development.

69. Then, at a more normal time of pubertal development, say age 11, the medication is stopped and puberty is allowed to proceed. The end result is to restore normal sex gland function and timing of puberty. This is a labeled use for a GnRH agonist medication.

70. What about the use of GnRH analogue medications such as Lupron in gender affirmative therapy? In these cases, we have physiologically normal children who are just beginning puberty or are somewhere in the process of pubertal development. They have healthy

[3] "The traditional definition of precocious puberty is the development of secondary sexual characteristics before 8 years of age in girls and 9 years in boys" (Kota and Ejas, 2023).

pituitary glands and sex organs. However, a puberty blocking medication is administered to stop normal pubertal development.

71. In this case the condition of hypogonadotropic hypogonadism described above (a medical disease) is induced by medication and is an iatrogenic effect of treating the psychological condition of gender dysphoria. GnRH analogue medications have not been FDA approved for this use. The use of GnRH analogue medication for this purpose in adolescents is experimental as there have been no randomized controlled trials for this specific use case.

72. In my opinion, there is not sufficient evidence to conclude that the use of puberty blockers to block natural puberty is safe when administered as part of gender affirming therapy. Nor is there sufficient evidence to conclude that the effects of puberty blockers when used in this manner are reversible.

3. Hypogonadotropic Hypogonadism

73. As described above, hypogonadotropic hypogonadism is a condition in which the pituitary fails to send signals to the gonads thereby preventing the testicle of the male from making testosterone or the ovary of the female from making estrogen.

74. As an endocrinologist I frequently evaluate patients to ascertain if they have the condition of hypogonadotropic hypogonadism. This is done by a laboratory evaluation. If the patient has this condition, I then determine the cause and the proper treatment.

75. The primary hormone of the pituitary which is abnormal in this condition is called luteinizing hormone or LH. In order to diagnose the condition, a laboratory test with reference ranges based on the person's sex and age is used to evaluate the blood sample.

76. For example, figure 1 shows the normal laboratory reference range for LH over the course of a month in an adult pre-menopausal female (0.5-76.3 mIU/mL) (Quest LH, 2023). A very low level of LH (red) with low estrogen levels indicates hypogonadotropic hypogonadism[4].

[4] Levels will be similarly low for adolescents, though the normal reference range is different.

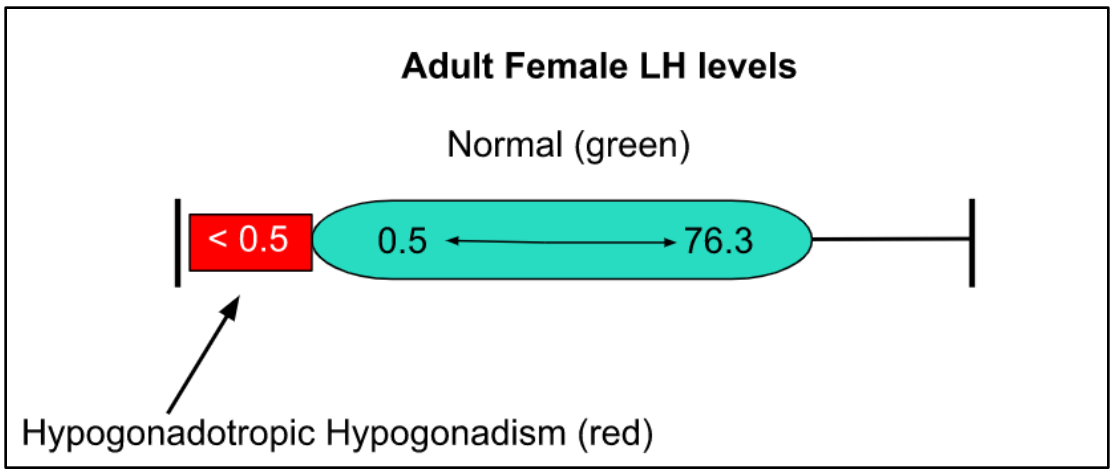

Figure 1.

77. As one can see, in hypogonadotropic hypogonadism the level of LH is below the reference range. In the female, this causes the cessation of estrogen production, and in the male it causes cessation of testosterone production. In adolescents of either sex, this will stop further pubertal development. For females in mid-puberty or beyond, this condition will also stop normal menstrual cycles and ovulation. For the male in mid-puberty or beyond, it will cause the cessation of normal sperm production.

78. As an endocrinologist, I would confirm the condition of hypogonadotropic hypogonadism based on laboratory results and then treat this medical condition.

79. What occurs to pituitary hormones and the sex hormones[5] when administering a GnRH analogue medication such as Lupron? The effect is identical to figure 1. Over time, the result of the medication is to cause very low LH levels (red) leading to low sex hormone levels thereby medically inducing the condition of hypogonadotropic hypogonadism.

80. In gender affirmative therapy, the medical condition of hypogonadotropic hypogonadism is being deliberately created by the use of medications called GnRH analogues, one of which is called Lupron.

5 The primary sex hormones being estrogen for females and testosterone for males.

4. Adverse Health Consequences of Blocking Normal Puberty

a. Infertility

81. There are a number of serious health consequences that occur as the result of blocking normal puberty. The first problem is infertility.

82. GnRHa have profound implications for fertility. The Endocrine Society Guideline recommends beginning puberty blockers as early as Tanner stage 2. As discussed earlier, this is the very beginning of puberty. Fertility development happens later, generally in Tanner stage 4. Thus, if the developing person is blocked at Tanner stage 2 or 3, as advocated by the guidelines, this is prior to the patient becoming fertile. The gonads will remain in an immature, undeveloped state.

83. If the patient remains blocked in an early pubertal stage, then even the addition of opposite sex hormones will not allow for the development of fertility. In fact, high doses of opposite sex hormones may permanently damage the immature sex organs leading to sterilization. Certainly, the removal of the gonads by surgery will ensure sterilization.

84. In a Dutch study by de Vries et al. that included seventy adolescents who took puberty blockers, all seventy decided to go on to hormones of the opposite sex (de Vries, et al. 2011). In a follow-up study by de Vries et al., the overwhelming majority went on to have sex reassignment surgery by either vaginoplasty for males or hysterectomy with ovariectomy for females (de Vries, et al. 2014). These surgeries resulted in sterilization[6]. This is why puberty blockers, rather than being a "pause" to consider aspects of mental health, are instead a pathway towards future sterilizing surgeries and potentially sterilizing hormonal treatments.

85. Even though procedures to preserve fertility are available for patients in late pubertal stages (Tanner 4 and 5), studies show that less than 5% of adolescents in North America receiving GAT even attempt fertility preservation (FP) (Nahata, 2017). Moreover, for those in early pubertal stages (Tanner 2 and 3), "ovarian tissue cryopreservation is still considered experimental in most centers and testicular tissue cryopreservation remains entirely experimental[7].

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[6] The surgeries were consequential in another important way. One person who had a vaginoplasty died of post-surgical complications of necrotizing fasciitis which is a rapidly progressive and very severe infection of the soft tissues beneath the skin and which has a high mortality (Id.).

[7] "Once testicular tissue has been cryopreserved, future options for its use may include in vitro maturation or germ cell transplant, which at this time are theoretical in nature" (Klipstein et al., 2020).

These experimental forms of FP would be the only options in children [with puberty] blocked prior to spermarche and menarche and are high in cost and limited to specialized centers. Even with FP there is no guarantee of having a child" (Laidlaw, Cretella, et al., 2019).

86. As an example, if a four-year-old child is diagnosed with precocious puberty, the abnormally early puberty may be halted by GnRH analogues (puberty blocking medication). The child will at a later time, say at age 12, have the puberty blocker discontinued and at that point normal pubertal development will be allowed to proceed. Therefore, when the child is no longer taking the medication, he or she will gain natural fertility.

87. In contrast, puberty blocking medication given to minors as a part of GAT occurs during the time for natural puberty and is—precisely the time that the adolescent person would have otherwise gained reproductive function. The effects of puberty blocker on the adolescent are to prevent sperm production in the male and ovulation in the female, which produces the infertile condition. Importantly, so long as the minor continues PB, he or she will thus remain infertile. And should the patient continue on to opposite sex hormones as part of GAT, then the patient will remain infertile. There is the additional possibility that cytotoxic effects of high dose opposite sex hormones will damage the immature gonads leading to permanent sterility.

b. Sexual Dysfunction

88. Another problem I would expect to find in youths who have HH and puberty stopped at an early stage is sexual dysfunction. The child will continue their chronological age progression toward adulthood and yet remain with undeveloped genitalia. This will lead to sexual dysfunction, including potential erectile dysfunction and inability to ejaculate and orgasm for the male. For the female with undeveloped genitalia potential sexual dysfunction may include painful intercourse and impairment of orgasm.

89. An example of the impairment of sexual function caused by stopping puberty in early development was evident in the TLC reality show "I am Jazz". This program documents Jazz Jenning's life experiences as a person with gender incongruence including Jazz's medical care. Jazz had been given puberty blockers at an early pubertal stage. In an episode of the show, Jazz, who was identified as a male at birth, visited the plastic surgeon, Christine McGinn, for a surgical evaluation for genital surgery (TLC, accessed 2022). Dr. McGinn describes her evaluation of Jazz's penis, stating it is "very, very small". In my opinion this very small penis size is consistent with beginning puberty blockers at a very early pubertal stage. Jazz also has a discussion about

sexual function with the surgeon. Jazz states: "I haven't experienced any sexual sensation." Regarding orgasm, Jazz says: "I don't know, I haven't experienced it"[8] In my opinion, these descriptions are consistent with the type of sexual dysfunction that one would expect from early blockade of normal puberty.

c. Negative Effects of Hypogonadotropic Hypogonadism on Bone Density

90. Puberty is a time of rapid bone development. This time period is critical in attaining what we call peak bone density or the maximum bone density that one will acquire in their lifetime (Elhakeem, 2019).

91. Any abnormal lowering of sex hormones occurring during this critical time will stop the rapid accumulation of bone and therefore lower ultimate adult bone density. If a person does not achieve peak bone density, they would be expected to be at future risk for osteoporosis and the potential for debilitating spine and hip fractures as adults. Hip fractures for the older patient very significantly increase the risk of major morbidity and death (Bentler, 2009). Allowing a "pause" in puberty for any period of time can lead to an inability to attain peak bone density.

92. DEXA scans are used to evaluate changes in bone density and to help evaluate risk for future fractures. In my practice I order and interpret DEXA scans for this purpose.

93. The Z-score of a DEXA scan is used to compare a patient's bone density to the same population based on age and sex. For example, a person who has a bone density similar to the average of the population would be at the 50th percentile. Those who have greater relative bone density would be above the 50th percentile. Those who have lower bone density would have a Z score below the 50th percentile.

94. Puberty blockers used in adolescence to cause HH will inhibit the normal accrual of bone density. This can be evaluated by DEXA scan. In a study in the UK, 44 patients aged 12-15 with gender dysphoria were given puberty blockers and tests of bone density were done at baseline, 12 months, 24 months and 36 months (Carmichael, 2021).

95. Figure 2 shows the Z-scores of the average age matched population percentile which is 50%. It shows the average baseline (before puberty blockers) Z-score percentile for the study participants. It also shows the bone density percentile at 12, 24, and 36 months. One can see that the average baseline z score was about 32% compared to peers of similar age and sex. At 12

[8] Jazz's age is somewhere in the mid-teens during this episode.

months this had decreased to about 15%, and by 24 months it had declined further to about 5% compared to their peers and remained at this low level.

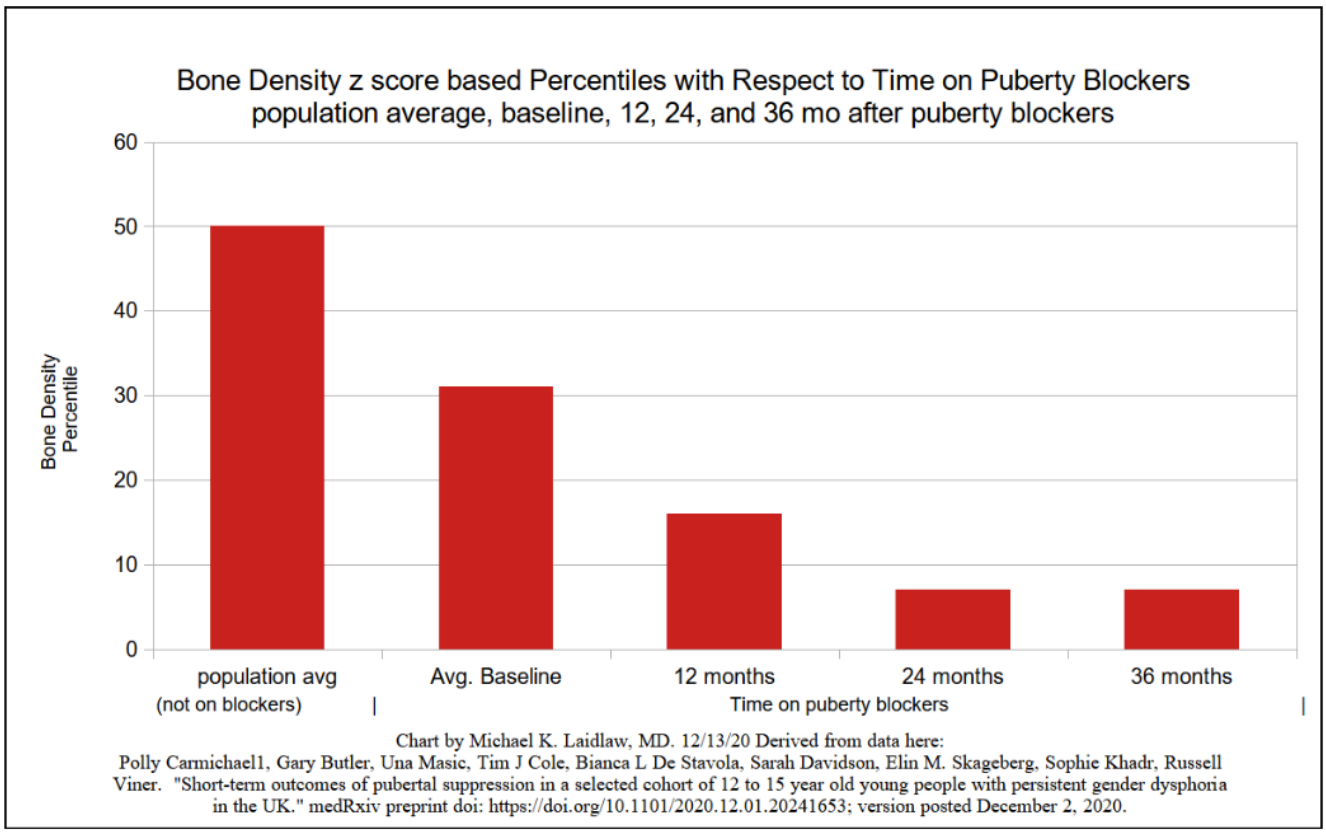

Figure 2

96. This is the same pattern of diminishing bone density compared to their peers that one would see in hypogonadotropic hypogonadism due to a pituitary injury. However, in these cases hypogonadotropic hypogonadism was caused by GnRH analogues (puberty blocking medication) that lead to greatly diminished bone density compared to their peers of the same age.

97. In natal females, hypogonadotropic hypogonadism leads to amenorrhea, meaning the absence of menstrual periods. Amenorrhea is detrimental to bone health: "In addition to this[9] important long-term consequence of amenorrhea, other problems, such as premature bone demineralization or inadequate bone formation, are likely to put amenorrheic women at high risk for osteoporosis and fracture" (Santoro, 2011) (emphasis added).

[9] "This" refers to cardiovascular disease: "Diagnosis and treatment of amenorrheic states is of increasing clinical importance because lifetime menstrual irregularities are known to be predictive of subsequent CVD in women."

98. Another consideration is the effects of HH in adolescents and late teens on the maturation of the human brain. It is known that adolescence is a crucial time of neurodevelopment and that puberty plays "a critical role in these neurodevelopmental processes" (Baxendale, 2024). Furthermore, “sex hormones including estrogen, progesterone, and testosterone can influence the development and maturation of the adolescent brain.” (Arain, 2013). It is also known that the "suppression of puberty impacts brain structure and the development of social and cognitive functions in mammals, the effects are complex and often sex specific." (Baxendale, 2024) Therefore, there are unknown, but likely negative, consequences to blocking normal puberty with respect to brain development.

d. Psychosocial Development

99. A third major problem with blocking normal puberty involves psychosocial development. Adolescence is a critical time of physical, mental, and emotional changes for the adolescent. It is important that they develop socially in conjunction with their peers.

100. While I am not a psychologist, I am familiar with and rely upon the literature in this area for the rationale of the treatment of precocious puberty[10]. It is generally accepted in endocrinology that there are psychological benefits to adolescents who go through puberty around the same time as their peers, and this is why puberty blockers (GnRH analogues) in central precocious puberty are sometimes used to delay a child’s abnormally early pubertal development to a more age-appropriate time.

101. The development of the adolescent along with their peers is also well recognized in the psychological literature: “For decades, scholars have pointed to peer relationships as one of the most important features of adolescence.” (Brown, 2009). If one is left behind for several years under the impression that they are awaiting opposite sex puberty, they will miss important opportunities for socialization and psychological development. Psychosocial development will be necessarily stunted as they are not developing with their peers. This is a permanent harm as the time cannot be regained.

102. Aside from the multiple serious problems that are iatrogenically acquired by blocking normal puberty, there appear to be independent risks of the puberty blocking medication themselves. For example, one can read the labeling of a common puberty blocking medication

[10] “The other concern often used as a rationale for treatment is negative psychosocial consequences of precocious puberty, particularly in girls” (Eugster, 2019, emphasis added).

called Lupron Depot-Ped and find under psychiatric disorders: “emotional lability, such as crying, irritability, impatience, anger, and aggression. Depression, including rare reports of suicidal ideation and attempt. Many, but not all, of these patients had a history of psychiatric illness or other comorbidities with an increased risk of depression” (Lupron, 2022). This is particularly concerning given the high rate of psychiatric comorbidity with gender dysphoria (Kaltiala-Heino, 2015).

C. Opposite Sex Hormones

103. The third stage of gender affirmative therapy involves using hormones of the opposite sex (also called cross sex hormones) at high doses to attempt to create secondary sex characteristics in the person’s body.

104. In GAT, what is termed “cross sex hormones” is the use of hormones of the opposite sex to attempt to create secondary sex characteristics. To do so, very high doses of these hormones are administered. When hormone levels climb above normal levels they are termed supraphysiologic.

1. Testosterone

105. Testosterone is an anabolic steroid of high potency. It is classified as a Schedule 3 controlled substance by the DEA: “Substances in this schedule have a potential for abuse less than substances in Schedules I or II and abuse may lead to moderate or low physical dependence or high psychological dependence” (DEA, 2022). A licensed physician with a valid DEA registration is required to prescribe testosterone.

106. I prescribe testosterone to men for testosterone deficiency. The state of testosterone deficiency can cause various problems including problems of mood, sexual function, libido, and bone density. Prescription testosterone is given to correct the abnormally low levels and bring them back into balance. The dose of testosterone must be carefully considered and monitored to avoid excess levels in the male as there are a number of serious concerns when prescribing testosterone. The use of high dose testosterone in females is experimental.

107. Contrast the FDA approved use of testosterone in males versus its experimental use females. Testosterone is FDA approved for use in adult men as well as the pediatric male population aged 12 and older (Actavis, 2018). There is no FDA approved usage of testosterone for

women or pediatric aged females.[11] The prescribing indications for adult males and pediatric males are identical and are to treat the conditions of low testosterone caused by either primary hypogonadism or secondary hypogonadism (Id.). The intent of testosterone for women and pediatric aged females in GAT is to cause severe hyperandrogenism. In this case the purpose, effects, and ultimate outcome of the FDA approved usage of testosterone for males versus the experimental use for females in GAT are very different. Therefore, the low-quality evidence guidelines of the Endocrine Society/WPATH are not an acceptable substitute for proper scientific studies including randomized controlled trials (Malone et al., 2021; Hembree et al., 2017).

108. Regarding the potential for abuse, the labeling for testosterone reads: "Testosterone has been subject to abuse, typically at doses higher than recommended for the approved indication...Anabolic androgenic steroid abuse can lead to serious cardiovascular and psychiatric adverse reactions...Abuse and misuse of testosterone are seen in male and female adults and adolescents...There have been reports of misuse by men taking higher doses of legally obtained testosterone than prescribed and continuing testosterone despite adverse events or against medical advice." (Actavis Pharma, 2018, emphasis added)

109. Adverse events with respect to the nervous system include: "Increased or decreased libido, headache, anxiety, depression, and generalized paresthesia." (Actavis Pharm, 2018)

110. With regard to ultimate height, "[t]he following adverse reactions have been reported in male and female adolescents: premature closure of bony epiphyses with termination of growth" (Actavis Pharma, Inc., 2018). What this means is that testosterone applied to the adolescent will cause premature closure of the growth plates, stopping further gains in height in the growing individual, and ultimately making the person shorter than they otherwise would have been.

111. With respect to the cardiovascular system of men using ordinary doses, "Long-term clinical safety trials have not been conducted to assess the cardiovascular outcomes of testosterone replacement therapy in men" (Actavis Pharma, 2018). No clinical safety trials have been performed for women or adolescent girls to my knowledge.

[11] "Testosterone Cypionate Injection, USP is indicated for replacement therapy in the male in conditions associated with symptoms of deficiency or absence of endogenous testosterone" (Actavis, 2018, emphasis added).

112. “There have been postmarketing reports of venous thromboembolic events [blood clots], including deep vein thrombosis (DVT) [blood clot of the extremity such as the leg] and pulmonary embolism (PE) [blood clot of the lung which may be deadly], in patients using testosterone products, such as testosterone cypionate” (Actavis Pharma, 2018).

113. A very recently published study of adverse drug reactions (ADRs) as part of gender affirming hormone therapies in France states that “[o]ur data show a previously unreported, non-negligible proportion of cases indicating cardiovascular ADRs in transgender men younger than 40 years… In transgender men taking testosterone enanthate, all reported ADRs were cardiovascular events, with pulmonary embolism in 50% of cases” (Yelehe et al., 2022).

114. There are also serious concerns regarding liver dysfunction: “Prolonged use of high doses of androgens ... has been associated with development of hepatic adenomas [benign tumors], hepatocellular carcinoma [cancer], and peliosis hepatis [generation of blood-filled cavities in the liver that may rupture] —all potentially life-threatening complications” (Actavis Pharma, 2018).

a. Hyperandrogenism

115. Hyperandrogenism is a medical condition of elevated blood androgens such as testosterone. As an endocrinologist I frequently evaluate patients to determine if they have the condition of hyperandrogenism. Hyperandrogenism in the female or male is harmful and can lead to various maladies.

116. In order to diagnose hyperandrogenism, a laboratory blood test of testosterone is done. In hyperandrogenism, one will find testosterone levels elevated above the reference range.

117. For example, for females aged 18 or older, the normal reference range is 2-45 ng/dL (Quest testosterone, 2023).[12] However, in female disease conditions these levels can be much higher. Levels above this normal reference range are considered hyperandrogenism (figure 3).

[12] For females aged 11-17 the reference range is <= 40 and below this age group, the range is even lower.

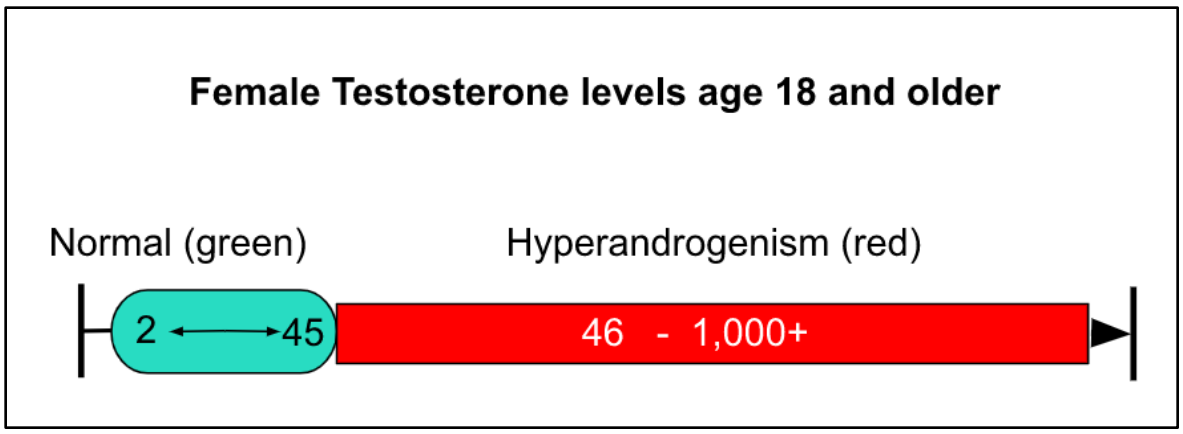

Figure 3

118. For example, in polycystic ovarian syndrome levels may range from 50 to 150 ng/dL.

119. I frequently diagnose and treat the hyperandrogen condition called polycystic ovarian syndrome (PCOS). These patients have elevated testosterone levels. These levels are mildly to moderately elevated and may range from 50-150. Hyperandrogenism found in PCOS has been associated with insulin resistance (Dunaif, 1989), metabolic syndrome (Apridonidze, 2005) and diabetes (Joham, 2014).

120. I also evaluate patients to rule out rare androgen producing tumors that generate very high levels of testosterone. These rare endocrine tumors can cause severely elevated testosterone levels in the 300-1000 range. Once the cause of a hyperandrogen condition is identified, treatments may be put in place to help bring the testosterone levels down to the normal reference range.

121. Recommendations from the Endocrine Society's clinical guidelines related to GAT are to ultimately raise female levels of testosterone to 320 to 1000 ng/dL[13] which is on the same order as dangerous endocrine tumors for women as described above (Hembree, 2017). A simple

[13] In the Endocrine Society's Guidelines there is no grading of evidence for the rationale of using such high supraphysiologic doses of opposite sex hormones for the female or male. There seems to be an underlying assumption that because the person believes to be the opposite sex then they acquire the sex specific laboratory ranges of the opposite sex. "The root cause of this flaw in thinking about diagnostic ranges was exemplified in a response letter by Rosenthal et al claiming that gender identity determines the ideal physiologic range of cross-sex hormone levels (5). Thus, a psychological construct, the 'gender identity', is imagined to affect physical reality and change a person's sex-specific laboratory reference ranges. This is clearly not the case, otherwise there would be no serious complications of high-dose androgen treatment in transgender males" (Laidlaw et al., 2021).

calculation shows this level for the adult may be anywhere from 6 to 100 times higher than native female testosterone levels. In doing so they are inducing severe hyperandrogenism. These extraordinarily high levels of testosterone are associated with multiple risks to the physical and mental health of the patient.

122. The following chart shows testosterone levels in the normal adult female range (blue), PCOS (gray), endocrine tumors (red), and gender affirmative therapy (orange) as part of female to male (FtM) transition (figure 4).

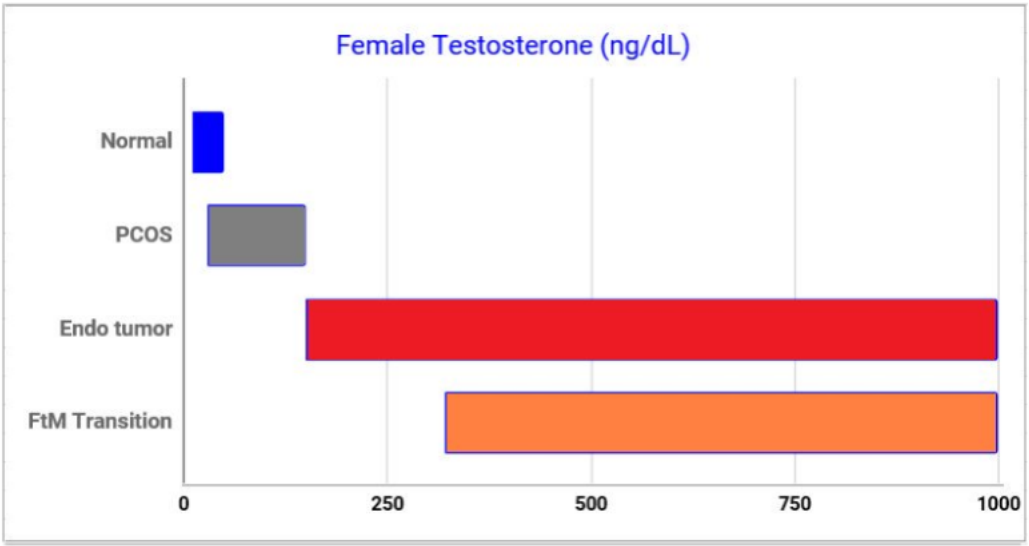

Image by Michael K Laidlaw. MD. Approximate total testosterone in ng/dL based on laboratory, etc. FtM transition from 2017 Endo Society Guidelines on Gender Dysphoria. With PCOS testosterone levels may be as high as 150. With endocrine tumors testosterone may be in the 150-1000 range. The recommendations of the Endocrine Society/WPATH are to bring levels into the 300-1000 range which is 6-100 times higher than normal endogenous adult female levels.

Figure 4.

b. Medical Problems Related to Hyperandrogenism

123. With respect to cardiovascular risk, "[s]tudies of transgender males taking testosterone have shown up to a nearly 5-fold increased risk of myocardial infarction relative to females not receiving testosterone" (Laidlaw et al.,2021; Alzahrani et al., 2019).

124. Permanent physical effects of testosterone therapy involve irreversible changes to the vocal cords. Abnormal amounts of hair growth which may occur on the face, chest, abdomen, back and other areas is known as hirsutism. Should the female eventually regret her decision to take testosterone, this body hair can be very difficult to remove. Male pattern balding of the scalp may also occur. I would expect these changes to occur to the plaintiffs taking testosterone to induce

hyperandrogenism. Common sense suggests that changes of voice and hair growth could be psychologically troubling should a patient decide to detranstition and attempt to reintegrate into society as female.

125. Changes to the genitourinary system due to hyperandrogenism include polycystic ovaries, clitoromegaly and atrophy of the lining of the uterus and vagina (Hembree, 2017). The breasts have been shown to have an increase in fibrous breast tissue and a decrease in normal glandular tissue (Grynberg et al., 2010). Potential cancer risks from high dose testosterone include ovarian and breast cancer (Hembree, 2017). I would expect some or all of these effects and risks to occur to the plaintiffs taking testosterone to induce hyperandrogenism.

126. The long-term effects of starting an adolescent on puberty blockers in early puberty (Tanner stage 2 or 3) and then adding opposite sex hormones on ultimate sterility are unknown in the sense that we do not have studies showing precisely what happens, but based on what we do know, it seems safe to say that opposite sex hormones are likely cytotoxic to the immature gonads.

127. According to research, anabolic steroid abuse[14] has been shown to predispose individuals towards mood disorders, psychosis, and psychiatric disorders. The "most prominent psychiatric features associated with AAS [anabolic androgenic steroids, i.e., testosterone] abuse are manic-like presentations defined by irritability, aggressiveness, euphoria, grandiose beliefs, hyperactivity, and reckless or dangerous behavior. Other psychiatric presentations include the development of acute psychoses, exacerbation of tics and depression, and the development of acute confusional/delirious states" (Hall, 2005). Moreover, "[s]tudies... of medium steroid use (between 300 and 1000 mg/week of any AAS) and high use (more than 1000 mg/week of any AAS) have demonstrated that 23% of subjects using these doses of steroids met the DSM-III-R criteria for a major mood syndrome (mania, hypomania, and major depression) and that 3.4% — 12% developed psychotic symptoms" (Hall, 2005).

128. In an observational study of the Food and Drug Administration's Event Reporting system database for people using opposite sex hormones for the purpose of gender transition a "striking 88% were categorized as serious ADRs [adverse drug reactions]" (Gomez-Lumbreras and Villa-Zapata, 2024). Of natal females taking testosterone for transition, they found that "a substantial portion of the reports were deemed serious (72, 87.8%), with 2 deaths (2.4%) and 25

[14] Anabolic steroid abuse involves the deliberate creation of hyperandrogenism in the body as a result of high doses of testosterone or other androgens.

hospitalizations (30.5%)". These serious findings of harm underscore the dangers of high dose testosterone used for the purpose of gender transition. With respect to psychological effects, adverse reactions included anxiety, depression, affect lability, euphoric mood, self-destructive behavior, anger, aggression, anti-social behavior, and homicidal ideation. Additionally, there were reports of suicide attempts, suicidal behavior and ideation, dissociation, and emotional disorder and distress. In my opinion, these adverse mental health findings of natal females on supraphysiologic doses of testosterone are consistent with the next closest biological model, which is anabolic steroid abuse.

c. Erythrocytosis as a Result of Hyperandrogenism

129. I regularly monitor patients who are receiving testosterone to evaluate for erythrocytosis. Erythrocytosis is a condition of high red blood cell counts. Prolonged hyperandrogenism such as occurs with the use of testosterone at supraphysiologic levels can cause erythrocytosis.

130. Males and females have different reference ranges for red blood cells (measured as hematocrit). For example, the normal range of hematocrit for females over age 18 is 35.0-45.0% and males 38.5-50.0% (Quest Hematocrit, 2023). Levels above this range signify erythrocytosis (see figure 5).

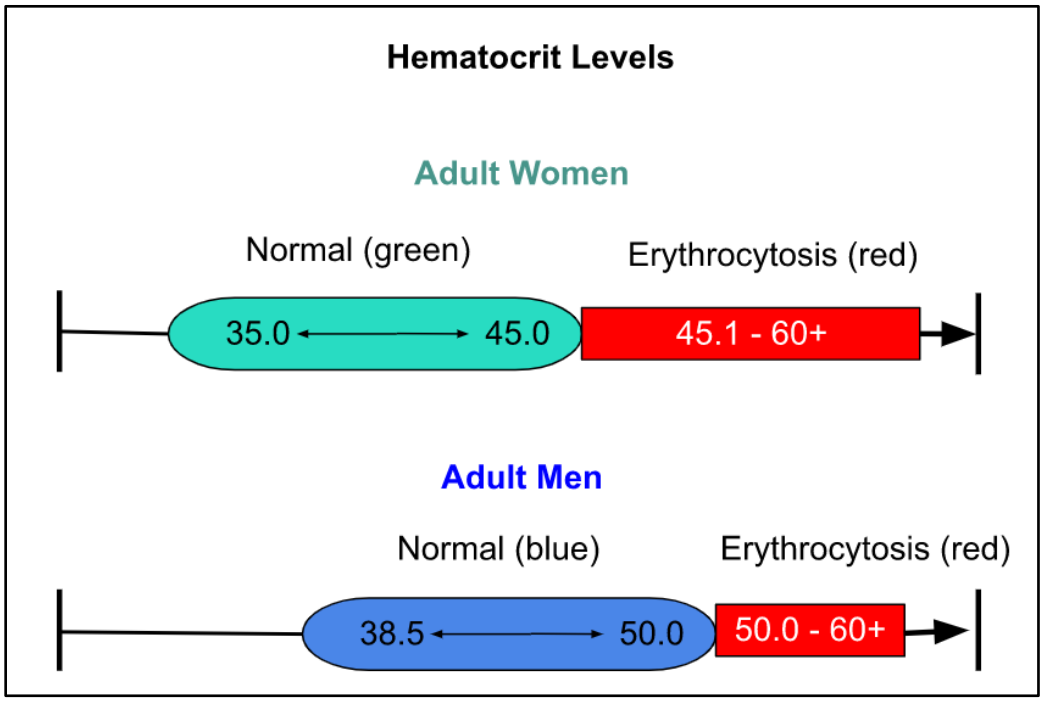

Figure 5.

131. As one can see, there is an overlap in the ranges of males and females such that levels between 45.1 and 50 are considered normal for the male. However, for the female these levels are considered erythroctotic. Levels above 50 for the male are considered erythrocytosis and for the female severe erythrocytosis.

132. The Madsen study was a "20-year follow-up study in [1,073] adult trans men who started testosterone therapy and had monitoring of hematocrit at our center" (Madsen, 2021). In this study, 24% of trans men had hematocrit levels 50% at some time which would be considered severe erythrocytosis. Unfortunately, they did not examine the hematocrit range of 45-50. However, one would presume that this would occur in at least the same percentage or higher as those who had developed severe erythrocytosis.

133. Any level of erythrocytosis in young women has been shown to be an independent risk factor for cardiovascular disease, coronary heart disease and death due to both (Gagnon, 1994).

2. Estrogen

134. Estrogen is the primary sex hormone of the female. Prescription estrogen may be used if a woman has low estrogen levels due to premature failure of her ovaries. Estrogen is prescribed to bring these levels back into a normal range for the patient's age. Another labeled use of estrogen is to treat menopausal symptoms. The use of estrogen to treat pediatric age males is experimental.

135. Hyperestogenemia is a condition of elevated blood estrogens such as estradiol. I regularly evaluate patients for hyperestrogenemia in my practice. Hyperestrogenemia in the male is harmful and can lead to various maladies.

136. In order to diagnose hyperestrogenemia, a laboratory blood test of estrogen is performed. In hyperestrogenemia, one will find estrogen levels elevated above the reference range. For example, in an adult male the normal estrogen reference range is 60-190 pg/mL (Quest Estrogen, 2023). Levels above this range are consistent with hyperestrogenemia. See figure 6.

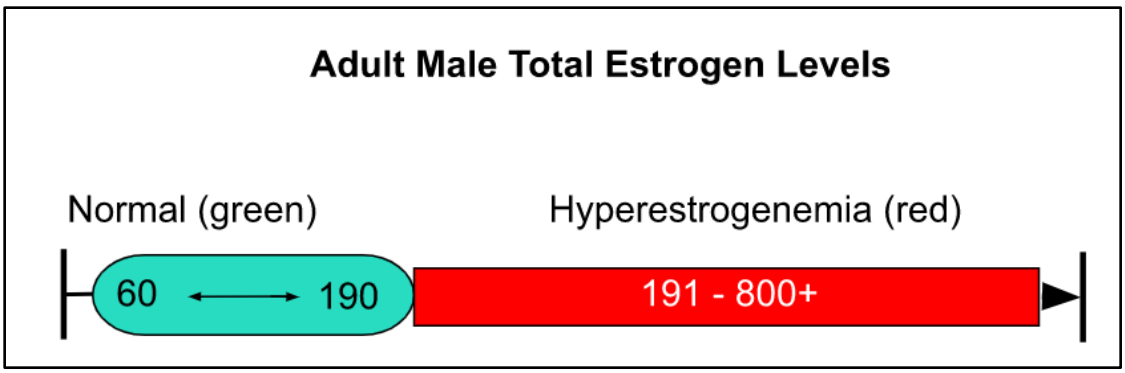

Figure 6.

137. There are medical conditions which can result in hyperestrogenemia. For example, "[t]he concentration of estrogen in cirrhotic patients is thought to increase by fourfold compared to individuals without cirrhosis" (Pagadala, 2023). Certain rare tumors for example of the adrenal gland can result in estrogen levels 3 to 10-fold higher than normal (Cavlan, 2010).

138. In gender affirmative therapy, the medical condition of hyperestrogenemia is being deliberately, medically induced by the off-label use of high doses of estrogen. The Endocrine Society guideline for treating gender dysphoria recommends raising estradiol levels to 2 to 43 times above the normal range.[15] The high doses are used in an attempt to primarily affect an increase of male breast tissue development known as gynecomastia. Gynecomastia is the abnormal growth of breast tissue in the male. I evaluate and treat patients with gynceomastia. I have prescribed medication and have referred patients for surgery for this condition.

139. Other changes of secondary sex characteristics may develop because of hyperestrogenemia such as softening of the skin and changes in fat deposition and muscle development.

140. Long-term consequences of hyperestrogenemia include increased risk of myocardial infarction and death due to cardiovascular disease (Irwig, 2018). Also "[t]here is strong evidence that estrogen therapy for trans women increases their risk for venous thromboembolism[16] over 5 fold" (Irwig, 2018).

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[15] Estradiol is a type of estrogen. The Endocrine Society Guideline recommends raising estradiol levels to 100-200 pg/mL (Hembree, 2017). The normal adult male estradiol range is 7.7-42.6 pg/mL (Labcorp Estadiol, 2023).

[16] Venous thromboembolism is a blood clot that develops in a deep vein and "can cause serious illness, disability, and in some cases, death" (CDC, 2022).

141. Breast cancer is a relatively uncommon problem of the male. However, the risk of a male developing breast cancer has been shown to be 46 times higher with high dose estrogen (Christel et al., 2019).

142. Sexual dysfunction, including decreased sexual desire and decreased spontaneous erections, is another adverse effect of hyperestrogenemia (Hembree, 2017).

D. Surgeries

143. The fourth stage of gender affirmative therapy is surgical alterations of the body of various kinds in an attempt to somehow mimic features of the opposite sex. Although endocrinologists do not typically perform surgery, we do refer patients for surgeries and need to be aware of the risks, benefits, complications, and long-term outcomes.

144. Individual surgical procedures can be a complex topic. It is helpful to first step back and consider conceptually what any surgery can and cannot accomplish.

145. In its basic form surgery is subtractive. In other words, a portion of tissue, an organ, or organs are removed in order to restore health. For example, a diseased gallbladder may be surgically removed to help the patient get back to wellness. An infected appendix may be surgically removed to prevent worsening infection or even death. In both of these cases an unhealthy body part is surgically removed in order to restore health.

146. In some cases a diseased tissue or organ is removed so that a foreign replacement part may be substituted for an unhealthy organ or tissue. For example, a diseased heart valve may be replaced with a pig valve or a prosthetic heart valve. Another example is a failed liver may be replaced by liver transplant.

147. Though modern surgical techniques and procedures are astounding, there are very noteworthy limitations. Importantly, surgery cannot de novo create new organs. If a person's kidneys fail, the surgeon has no scientific method for creating a new set of kidneys that can be implanted or grown within the patient. This conceptual background is helpful when considering various gender affirming surgeries.

148. There are a variety of gender affirming surgeries for females. These may include mastectomies, metoidioplasty, and phalloplasty.

1. Mastectomy

149. Mastectomies are the surgical removal of the breasts. The procedure is used in GAT in an attempt to make the chest appear more masculine. The surgery results in a permanent loss of

the ability to breastfeed and significant scarring of 7 to 10 inches. The scars are prone to widening and thickening due to the stresses of breathing and arm movement. Other potential complications include the loss of normal nipple sensation and difficulties with wound healing (American Cancer Society, 2022).

150. It is important to note that this operation cannot be reversed. The female will never regain healthy breasts capable of producing milk to feed a child (Mayo Clinic, Top Surgery, 2022).

151. Another important consideration is that compared to the removal of an unhealthy gallbladder or appendix, in the case of gender dysphoria the breasts are perfectly healthy and there is no organic disease process such as a cancer warranting their removal.

2. GAT Surgeries on the Male

152. GAT surgeries for the male include removal of the testicles alone to permanently lower testosterone levels. This is by nature a sterilizing procedure. Further surgeries may be done in an attempt to create a pseudo-vagina; that procedure is called vaginoplasty. In this procedure, the penis is surgically opened and the erectile tissue is removed. The skin is then closed and inverted into a newly created cavity in order to simulate a vagina. A dilator must be placed in the new cavity for some time so that it does not naturally close.

153. Potential surgical complications may include urethral strictures, infection, prolapse, fistulas and injury to the sensory nerves with partial or complete loss of erotic sensation (Mayo Clinic, Feminizing Surgery, 2022).

3. GAT Surgeries of the Female Pelvis and Genitalia

154. Other types of surgery for females include those of the genitalia and reproductive tract. For example, the ovaries, uterus, fallopian tubes, cervix and the vagina may be surgically removed. Removal of the ovaries results in sterilization.

155. Importantly, removing female body parts does not produce a male. Rather, the female has had sex-specific organs permanently destroyed with no hope of replacement, while remaining biologically female.

156. There have also been attempts to create a pseudo-penis. This procedure is known as phalloplasty. It is not possible to de novo create a new human penis. Instead, a roll of skin and subcutaneous tissue is removed from one area of the body, say the thigh or the forearm, and transplanted to the pelvis. An attempt is made to extend the urethra or urinary tract for urination through the structure. This transplanted tissue lacks the structures inherent in the male penis which

allow for erection, therefore erectile devices such as rods or inflatable devices are placed within the tube of transplanted tissue in order to simulate erection (Hembree, 2017). The labia may also be expanded to create a simulated scrotum containing prosthetic objects to provide the appearance of testicles.

157. Complications may include urinary stricture, problems with blood supply to the transplanted roll of tissue, large scarring to the forearm or thigh, infections including peritonitis, and possible injury to the sensory nerve of the clitoris (Mayo Clinic, Masculinizing Surgery, 2022). A recent systematic review and meta-analysis of 1731 patients who underwent phalloplasty found very high rates of complications (76.5%) including a urethral fistula rate of 34.1% and urethral stricture rate of 25.4% (Wang, 2022).

III. The Lack of Evidence Supporting Gender-Affirming Therapy

158. There is not a medical consensus supporting the use of puberty blockers and cross-sex hormones for the treatment of gender dysphoria. In my opinion, there is insufficient evidence to conclude that any benefit of such treatment would outweigh the harm, particularly given the evidence of a rapid rise in cases of youth gender dysphoria, the high rates of coexisting mental health comorbidities, and naturally high rates of desistance.

A. The Endocrine Society and WPATH

159. Clinical guidelines promoting GAT have been produced by medical organizations such as the Endocrine Society and social-political advocacy groups like WPATH. Here I discuss the Endocrine Society. I discuss the advocacy group WPATH's guidelines in a supplemental report.

1. Endocrine Society

160. In 2017 the Endocrine Society published its guideline titled the "Endocrine Treatment of Gender-Dysphoric/Gender-Incongruent Persons: An Endocrine Society Clinical Practice Guideline". It is notable that the Endocrine Society never claimed that its guideline should be considered standard of care. In fact, quite the opposite. The Endocrine Society states that its "guidelines cannot guarantee any specific outcome, nor do they establish a standard of care" (Hembree et al, 2017, p. 3895, emphasis added).

161. It is also notable that nine out of ten authors of the Endocrine Society Guideline were members of WPATH or worked on WPATH's scientific committees. According to

WPATH's website, seven of those nine had at some time been in WPATH leadership, including the WPATH presidency and board of directors.

162. With respect to the Endocrine Society's guideline, the quality of evidence for the treatment of adolescents is rated "very low-quality evidence" and "low quality evidence". "The quality of evidence for [puberty blocking agents] is noted to be low. In fact, all of the evidence in the guidelines with regard to treating children/adolescents by [gender affirmative therapy] is low to very low because of the absence of proper studies" (Laidlaw et al., 2019).

163. Unlike some other recommendations for adolescent GAT, the Endocrine Society's guideline does not include any grading of the quality of evidence specifically for their justification of laboratory ranges of testosterone or estrogen or for adolescent mastectomy or other surgeries.

164. Endocrinologists William Malone and Paul Hruz and other colleagues have written critically of the Endocrine Society's guideline: "Unlike standards of care, which should be authoritative, unbiased consensus positions designed to produce optimal outcomes, practice guidelines are suggestions or recommendations to improve care that, depending on their sponsor, may be biased. In addition, the ES claim of effectiveness of these interventions is at odds with several systematic reviews, including a recent Cochrane review of evidence, and a now corrected population-based study that found no evidence that hormones or surgery improve long-term psychological well-being. Lastly, the claim of relative safety of these interventions ignores the growing body of evidence of adverse effects on bone growth, cardiovascular health, and fertility, as well as transition regret" (Malone et al., 2021) (footnotes omitted).

165. In June of 2022, the Endocrine Society published "Enhancing the Trustworthiness of the Endocrine Society's Clinical Practice Guidelines" (McCartney et al., 2022). It wrote: "In an effort to enhance the trustworthiness of its clinical practice guidelines, the Endocrine Society has recently adopted new policies and more rigorous methodologies for its guideline program." (Id.) The document relates that in 2019, the ECRI Guidelines Trust "asked the Society for permission to include its guidelines in the ECRI Guidelines Trust database". However, after an evaluation by ECRI, the guideline related to osteoporosis "was the only guideline for which all recommendations were based on verifiable systematic evidence review with explicit descriptions of search strategy, study selection, and evidence summaries" (Id.). It follows that the recommendations from the ESG 2017 on Gender Dysphoria/Gender Incongruence were <u>not</u> all recommendations "based on verifiable systematic evidence review with explicit descriptions of search strategy, study selection,

and evidence summaries." Furthermore, these ESG 2017 were highly subject to conflicts of interest. Nine out of the ten authors were members or worked on the scientific committees of the advocacy group WPATH. Additionally, WPATH was a cosponsoring organization of the 2017 Guideline. The "Enhancing Trustworthiness" article recommends the opposite composition of authors for guidelines: "A majority (>50%) of non-Chair GDP members must be free of relevant C/DOI [conflict/duality of interest]" (McCartney et al., 2022).

166. Further problems with the Endocrine Society's guideline are highlighted in a recent BMJ Investigation article. It reads: "Guyatt, who co-developed GRADE, found 'serious problems' with the Endocrine Society guidelines, noting that the systematic reviews didn't look at the effect of the interventions on gender dysphoria itself, arguably 'the most important outcome.' He also noted that the Endocrine Society had at times paired strong recommendations—phrased as 'we recommend'—with weak evidence. In the adolescent section, the weaker phrasing 'we suggest' is used for pubertal hormone suppression when children 'first exhibit physical changes of puberty'; however, the stronger phrasing is used to 'recommend' GnRHa treatment. 'GRADE discourages strong recommendations with low or very low-quality evidence except under very specific circumstances,' Guyatt told the BMJ. Those exceptions are 'very few and far between'" (Block, 2023).

167. It is clear that with respect to the subject of gender dysphoria, the Endocrine Society has acted as a vassal organization of WPATH's social-political advocacy group rather than an independent medical society generating its own scientific opinions. In my opinion, the Endocrine Society's guidelines do not provide a standard of care that any physician should follow.

B. Flawed Studies Based on the Problematic 2015 US Transgender Survey

168. There is much additional evidence that questions the long-term benefits of opposite sex hormones and gender reassignment surgery and in fact suggests serious harms.

169. D'Angelo et al. have written about the 2015 USTS survey as part of the criticism of another flawed study in the journal Pediatrics by Jack Turban in 2020 titled "Pubertal Suppression for Transgender Youth and Risk of Suicidal Ideation" (Turban, 2020). They write in their critique of the USTS that it is "a convenience sampling, a methodology which generates low-quality, unreliable data. Specifically, the participants were recruited through transgender advocacy organizations and subjects were asked to 'pledge' to promote the survey among friends and family. This recruiting method yielded a large but highly skewed sample…Their analysis is compromised

by serious methodological flaws, including the use of a biased data sample, reliance on survey questions with poor validity, and the omission of a key control variable, namely subjects' baseline mental health status" (D'Angelo et al., 2021) (footnotes omitted). They also state that "[s]tigmatizing non-'affirmative' psychotherapy for GD [gender dysphoria] as 'conversion' will reduce access to treatment alternatives for patients seeking non-biomedical solutions to their distress") (Id.).

170. Other published studies of GAT have been shown to have serious errors. For example, a major correction was issued by the American Journal of Psychiatry. The authors and editors of a 2020 study, titled "Reduction in mental health treatment utilization among transgender individuals after gender-affirming surgeries: a total population study" (Bränström study, 2020) retracted their original primary conclusion. Letters to the editor by twelve authors including myself led to a reanalysis of the data and a corrected conclusion stating that in fact the data showed no improvement in mental health for transgender identified individuals after surgical treatment nor was there improvement with opposite sex hormones ("Correction", 2020; Van Mol et al., 2020).

171. The initial reports of this study claimed that the authors found treatment benefits with surgery, and this was shared widely in the media. For example, ABC News posted an article titled "Transgender surgery linked with better long-term mental health, study shows" (Weitzer, 2019). An NBC news/Reuters headline reads: "Sex-reassignment surgery yields long-term mental health benefits, study finds" (Reuters, 2019).

172. However, after twelve authors from around the world (including our team) investigated the study in detail, a number of serious errors were exposed leading to a retraction (Kalin, 2020; Anckarsäter et al., 2020).

173. In our letter to the editor, which I co-wrote with former Chairman of Psychiatry at Johns Hopkins Medical School, Paul McHugh, MD, we noted key missing evidence in the original Branstrom report when compared to the previous body of knowledge yielded from the Swedish Dhejne study. We wrote that "[t]he study supports only weak conclusions about psychiatric medication usage and nothing decisive about suicidality. In overlooking so much available data, this study lacks the evidence to support its pro gender-affirmation surgery conclusion" (Van Mol, Laidlaw, et al., 2020).

174. In another letter, Professor Mikael Landen wrote that "the authors miss the one conclusion that can be drawn: that the perioperative transition period seems to be associated with

high risk for suicide attempt. Future research should use properly designed observational studies to answer the important question as to whether gender-affirming treatment affects psychiatric outcomes" (Landen, 2020).

175. In another letter to the editor, psychiatrist David Curtis noted that "[t]he study confirms the strong association between psychiatric morbidity and the experience of incongruity between gender identity and biological sex. However, the Branstrom study does not demonstrate that either hormonal treatment or surgery has any effect on this morbidity. It seems that the main message of this article is that the incidence of mental health problems and suicide attempts is especially high in the year after the completion of gender-affirming surgery" (Curtis, 2020).

176. In yet another critical letter, Dr. Agnes Wold stated that "[w]hether these factors involve a causal relationship (i.e., that surgery actually worsens the poor mental health in individuals with gender dysphoria) cannot be determined from such a study. Nevertheless, the data presented in the article do not support the conclusion that such surgery is beneficial to mental health in individuals with gender dysphoria" (Wold, 2020).

D. High Rates of Completed Suicide and Psychiatric Complications in GAT

177. The most comprehensive study of GAT of its kind is from Sweden in 2011. The authors examined data over a 30-year time period (Dhejne, 2011). The Dhejne team made extensive use of numerous Swedish database registries and examined data from 324 patients in Sweden over 30 years who had taken opposite sex hormones and had undergone sex reassignment surgery. They used population controls matched by birth year, birth sex, and reassigned sex. <u>When followed out beyond ten years, the sex-reassigned group had nineteen times the rate of completed suicides and nearly three times the rate of all-cause mortality and inpatient psychiatric care compared to the general population of Sweden.</u>

178. The study published by Chen and Olson-Kennedy et al. confirms the inherent danger of gender affirmative therapy found in the Dhejne study. The New England Journal of Medicine published "Psychosocial Functioning in Transgender Youth after 2 Years of Hormones," for which Dr. Johanna Olson-Kennedy is the principal investigator (Chen, Olson-Kennedy, et al., 2023). This arm of her study included 315 adolescents aged 12 to 20 years old who were taking high dose hormones of the opposite sex. The study was not randomized and had no control group. The authors report that 2 out 315 subjects died by suicide. The authors also report "The most common adverse event was suicidal ideation" in 11 subjects.

179. The death by suicide of 2 out of 315 subjects equates to approximately 317 suicide deaths per 100,000 patient-years. If we compare this figure to that of the UK's largest gender identity service, Tavistock, the "annual suicide rate is calculated as 13 per 100,000" patient-years (Biggs, 2021). The death-by-suicide rate was approximately 24 times higher in Dr. Olson-Kennedy's study compared to the much larger Tavistock Clinic. In fact, Professor Biggs reports that two of the four suicide deaths from the Tavistock data were of patients who were on the waiting list and "would not have obtained treatment" (Id.). This strongly suggests that the use of high dose opposite sex hormones in Dr. Olson-Kennedy's study was associated with a much higher death rate. NIH produced the consent forms related to this study pursuant to a FOIA request my colleague submitted. I have reviewed them and provided them to counsel for the Intervenor-Defendants. Unfortunately, of the many side effects of hormone therapy listed on the study's consent forms, death by suicide (or by any cause) is not listed and was not disclosed to participants.

180. Unfortunately, unlike the Dhejne study, the Olson-Kennedy study provides little other useful data about outcomes such as psychiatric hospitalizations, suicide attempts, or rates of comorbid psychiatric illness. These facts would be useful to know to determine how high-dose opposite hormones and gender affirmative therapy affect overall health and their association with death by suicide. All of the data collected to date in Dr. Olson-Kennedy's publicly funded study the "The Impact of Early Medical Treatment in Transgender Youth" should be released to the public so that other researchers and clinicians can determine how puberty blockers, opposite sex hormones, and mastectomy surgeries affect adolescent physical and mental health.

181. While it is true that patients suffering from gender dysphoria have higher rates of suicidal ideation and completed suicide than the general population, studies have not shown that providing hormones reduces rates of suicide, and in fact those interventions may be associated with increased rates.

E. An Increase in Cases of Gender Dysphoria

182. Gender Dysphoria has been a relatively rare condition in children and adolescents. However there have been very significant increases in referrals for this condition noted around the globe.

183. For example, in the UK, "The number of referrals to GIDS [Gender Identity Development Service] has increased very significantly in recent years. In 2009, 97 children and young people were referred. In 2018 that number was 2519" (Bell v Tavistock Judgment, 2020).

There is evidence that this increase may be in part due to social contagion and fueled by social media/internet use (Littman, 2018).

184. The French National Academy of Medicine wrote recently: "Parents addressing their children's questions about transgender identity or associated distress should remain vigilant regarding the addictive role of excessive engagement with social media, which is both harmful to the psychological development of young people and is responsible for a very significant part of the growing sense of gender incongruence" (SEGM, 2022).

185. In "a study of the Finnish gender identity service, '75% of adolescents [assessed] had been or were currently undergoing child and adolescent psychiatric treatment for reasons other than gender dysphoria' (Kaltiala-Heino, 2015). In fact, '68% had their first contact with psychiatric services due to other reasons than gender identity issues.' The same study also showed that 26% percent had an autistic spectrum disorder and that a disproportionate number of females (87%) were presenting to the gender clinics compared to the past" (Laidlaw in gdworkinggroup.org, 2018).

F. Desistance

186. Desistance is a term indicating that the child, adolescent, or adult who initially presented with gender incongruence has come to experience a realignment of their internal sense of gender and their physical body. "Children with [gender dysphoria] will outgrow this condition in 61% to 98% of cases by adulthood. There is currently no way to predict who will desist and who will remain dysphoric" (Laidlaw et al., 2019; Ristori & Steensma, 2016).

187. Because there is no physical marker to diagnose gender dysphoria, and because it is not possible to predict which child or adolescent will desist, it is not possible to know which young person will remain transgender identified as adults. Also, because the rate of desistance is so high, gender affirmative therapy will necessarily cause serious and irreversible harm to many children and adolescents who would naturally outgrow the condition if not affirmed.

188. Puberty, which pertains to the physical development of the reproductive tract, breasts, and associated secondary sex characteristics, can begin as early as age 8 in girls and age 9 in boys. The studies which have examined desistance involved adolescents and children aged twelve and under. For example, table 1 in Ristori and Steensma 2016 shows multiple studies involving minors. For the three most recent—Singh (2012), Wallien & Cohen-Kettenis (2008),

and Drummond et al. (2008)—these involved age ranges from 3 to 12years old[17]. The desistance rate varied from 61 to 88%. Since the upper age was twelve this would include children in the age range of 8-12 years old, many of whom were already adolescents going through puberty based on a knowledge of the ages of initiation of puberty and were therefore not pre-pubertal.[18] Therefore we can see that a high proportion of adolescents do in fact desist.

G. Mastectomy Surgery for Minors

189. Any serious look at long-term effects of surgical treatment would follow subjects out at least ten years. For example, a study was published examining patients who had mild calcium disorders due to a gland called the parathyroid. They compared a group of patients who had surgical removal of the parathyroid to a control group who had not. They examined data ten years after surgery was completed and concluded that parathyroid surgery in this group "did not appear to reduce morbidity or mortality" in that patient group (Pretorius, 2022).

190. To my knowledge there exists no comparable studies of minors with gender dysphoria comparing those who had mastectomy surgery to a control group who had not. There are also no known studies of minors followed for 10 years or more to determine the long-term risks and benefits of mastectomy for gender dysphoria.

191. Good quality studies specifically showing that mastectomy surgery is safe, effective, and optimal for treating minors with gender dysphoria do not exist. For example, there is a study titled "Chest Reconstruction and Chest Dysphoria in Transmasculine Minors and Young Adults Comparisons of Nonsurgical and Postsurgical Cohorts" (Olson-Kennedy, 2018). The study authors conclude that "[c]hest dysphoria was high among presurgical transmasculine youth, and surgical intervention positively affected both minors and young adults." However, there are a

[17] "This study provided information on the natural histories of 25 girls with gender identity disorder (GID). Standardized assessment data in childhood (mean age, 8.88 years; range, 3-12 years)" (Drummond et al., 2008). "We studied 77 children who had been referred in childhood to our clinic because of gender dysphoria (59 boys, 18 girls; mean age 8.4 years, age range 5-12 years)" (Wallien et al., 2008). "Standardized assessment data in childhood (mean age, 7.49 years; range, 3–12 years) and at follow-up (mean age, 20.58 years; range, 13–39 years) were used to evaluate gender identity and sexual orientation outcome. At follow-up, 17 participants (12.2%) were judged to have persistent gender dysphoria" (Singh, 2012).

[18] To my knowledge the desistance literature does not examine Tanner stages of puberty as part of their studies. However, one can infer based on the ages that many children had at least begun puberty (Tanner stage 2) or were at a more advanced stage of puberty.

number of problems with this study. First, the term "chest dysphoria" is a creation of the study authors and is not found as a diagnosis or even referenced in the DSM-5. Second the "chest dysphoria scale" is a measuring tool created by the authors, but which the authors state "is not yet validated." (*Id*., p. 435) Third, the mastectomies were performed on girls as young as 13 and 14 years old and who thereby lacked the maturity and capacity of good judgment for truly informed consent for this life altering procedure. For this reason, in my professional opinion, the research and surgeries performed were flawed and unethical.

192. There exists another poorly designed study which suffers from similar methodological and ethical problems as the Olson-Kennedy study. A 2021 study published in Pediatrics examined females aged 13-21 recruited from a gender clinic. Thirty young females had mastectomy procedures and sixteen had not. The average age at surgery was 16.4 years (Mehringer, 2021). The follow up time after surgery was only 19 months and no data is provided or analyzed about key psychiatric information such as comorbid psychological illnesses, self-harming behaviors, psychiatric hospitalizations, psychiatric medication use, or suicide attempts.

193. Information returned from the study surveys were all qualitative and included responses such as "[My chest dysphoria] made me feel like shit, honestly. It made me suicidal. I would have breakdowns". Another respondent stated, "I've been suicidal quite a few times over just looking at myself in the mirror and seeing [my chest]. That's not something that I should have been born with" (Mehringer, 2021). The omission of psychiatric data is a major flaw in the study and also irresponsible given the obviously dangerous psychological states that some of these young people were in.

194. Since such a high proportion of subjects were using testosterone (83%), some of the responses could be attributed to adverse effects of testosterone. For example, as related earlier, high dose testosterone can manifest in irritability and aggressiveness. One study subject responded, "I get tingly and stuff and it kind of makes me want to punch something" (Mehringer, 2022).

195. The testosterone labeling also indicates nausea and depression as adverse reactions which are described by another study subject "There's a feeling of hopelessness, of desperation, of—almost makes me feel physically sick" (Actavis Pharma, Inc., 2018; Mehringer, 2022).

196. The study appears to have been designed, at least in part, to justify insurance companies paying for mastectomy procedure for minors with GD, even though they have provided no long-term statistical evidence of benefit: "These findings...underscore the importance of

insurance coverage not being restricted by age" (Mehrniger, 2021). This also appears to be part of the aim of the flawed Olson-Kennedy study, which stated that "changes in clinical practice and in insurance plans' requirements for youth with gender dysphoria who are seeking surgery seem essential" (Olson-Kennedy, 2018). So these two studies, rather than being a thorough examination of the psychological and physical risks and benefits of mastectomy surgery over the long-term appear instead to exist, at least in part, to validate the need for insurance companies to insure the costs of these dubious procedures for minors.

H. Centers for Medicare and Medicaid Services

197. The Centers for Medicare and Medicaid Services ("CMS") has found "inconclusive" clinical evidence regarding gender reassignment surgery. Specifically, the CMS Decision Memo for Gender Dysphoria and Gender Reassignment Surgery (CAG-00446N) (June 19, 2019) states: "The Centers for Medicare & Medicaid Services (CMS) is not issuing a National Coverage Determination (NCD) at this time on gender reassignment surgery for Medicare beneficiaries with gender dysphoria because the clinical evidence is inconclusive for the Medicare population" (CMS.gov, 2016).

I. Nations and States Question and Reverse Course on GAT

198. Numerous nations are questioning and reversing course on the WPATH/Endocrine Society's low quality gender affirmative therapy guidelines. For example, in the *Bell v. Tavistock* Judgment in the UK, regarding puberty blockers in GAT, the court concluded that "there is real uncertainty over the short and long-term consequences of the treatment with very limited evidence as to its efficacy, or indeed quite what it is seeking to achieve. This means it is, in our view, properly described as experimental treatment" (*Bell v. Tavistock* Judgment, 2020, emphasis added). The case was appealed and although the medical decision making was returned to clinicians (rather than the courts), it was noted that great pains should be taken to ensure that the child and parents are properly informed before embarking on such treatments.

199. In the bulletin of the Royal College of Psychiatrists in 2021, in a reevaluation of the evidence, Griffin and co-authors write, "As there is evidence that many psychiatric disorders persist despite positive affirmation and medical transition, it is puzzling why transition would come to be seen as a key goal rather than other outcomes, such as improved quality of life and reduced morbidity. When the phenomena related to identity disorders and the evidence base are uncertain, it might be wiser for the profession to admit the uncertainties. Taking a supportive,

exploratory approach with gender-questioning patients should not be considered conversion therapy“ (Griffin et al., 2021).

200. In 2020, Finland recognized that “[r]esearch data on the treatment of dysphoria due to gender identity conflicts in minors is limited,” and recommended prioritizing psychotherapy for gender dysphoria and mental health comorbidities over medical gender affirmation (Council for Choices in Healthcare in Finland, 2020). Additionally, “[s]urgical treatments are not part of the treatment methods for dysphoria caused by gender-related conflicts in minors”.

201. In 2021, Sweden’s largest adolescent gender clinic announced that it would no longer prescribe puberty blockers or cross-sex hormones to youth under 18 years outside clinical trials (SEGM, 2021). “In December 2019, the SBU (Swedish Agency for Health Technology Assessment and Assessment of Social Services) published an overview of the knowledge base which showed a lack of evidence for both the long-term consequences of the treatments, and the reasons for the large influx of patients in recent years. These treatments are potentially fraught with extensive and irreversible adverse consequences such as cardiovascular disease, osteoporosis, infertility, increased cancer risk, and thrombosis. This makes it challenging to assess the risk / benefit for the individual patient, and even more challenging for the minors or their guardians to be in a position of an informed stance regarding these treatments” (Gauffen and Norgren, 2021).

202. In the nation of Norway, a report from the Norwegian Healthcare Investigation Board (Ukom) was released in March of this year. The report found “there is insufficient evidence for the use of puberty blockers and cross sex hormone treatments in young people, especially for teenagers who are increasingly seeking health services and being referred to specialist healthcare. Ukom defines such treatments as utprøvende behandling, or ‘treatments under trial,’ said Moen” (Block, “Norway”, 2023).

203. Dr Hilary Cass “was appointed by NHS England and NHS Improvement to chair the Independent Review of Gender Identity Services for children and young people in late 2020” (The Cass Review website, 2022). In her interim report dated February 2022, it states that “[e]vidence on the appropriate management of children and young people with gender incongruence and dysphoria is inconclusive both nationally and internationally” (Cass, 2022). This led to the shutting down of their Tavistock child gender identity clinic.

204. In April 2024, the “Independent review of gender identity services for children and young people: Final report” , commissioned by NHS England, was published. With respect to

comorbid psychological moribidities and distress in gender dysphoria, they recommend that "[s]tandard evidence based psychological and psychopharmacological treatment approaches should be used to support the management of the associated distress and cooccurring conditions" (Cass, 2024, p. 31). With respect to puberty blocking medication they opine that "[t]he rationale for early puberty suppression remains unclear, with weak evidence regarding the impact on gender dysphoria, mental or psychosocial health. The effect on cognitive and psychosexual development remains unknown." (Cass Final Report Web Page, 2024) With regards to opposite sex hormones for the treatment of youth gender dysphoria they state that "[t]he use of masculinising / feminising hormones in those under the age of 18 also presents many unknowns...The lack of long-term follow-up data on those commencing treatment at an earlier age means we have inadequate information about the range of outcomes for this group." (Id) The final Cass report leaves unchanged the recommendation that surgical treatments for gender dysphoria are reserved for those eighteen years of age or older (Cass, 2024, p. 166).

205. These recent decisions by the medical authorities of other nations demonstrate that a number have reversed course and reduced or eliminated their reliance on the low-quality gender affirmative therapy guidelines put forth by WPATH and the Endocrine Society.

VI. Conclusion

206. The gender affirmative therapy model suffers from serious deficiencies in logic and lacks scientific foundation. The deep error hidden in this model is that one cannot in fact change sex. One cannot acquire the deep characteristics of biological sex in order to gain the complete sexual and reproductive functions of the opposite sex. This is not technologically possible.

207. Children and adolescents are of such immature minds that they are likely to believe that it is possible. In fact they may come to believe that their inherent, biologically necessary puberty is "terrifying" or needs to be stopped. Social transition serves to convince the child or adolescent that they can be the opposite sex. Puberty blockers sustain this state of mind by retaining a childlike state with respect to the genitalia and body habitus. High dose opposite sex hormones then cause medical conditions such as hirsutism and irreversible damage to the vocal cords in females and gynecomastia in males. These conditions serve to convince the young person that they are going through puberty of the opposite sex when in fact they are not developing sexually and are likely infertile.

208. There are known risks from GAT for both adults and minors, some of which I have described above, including cardiovascular disease, cancer, deficiencies in ultimate bone density, harms to sexual function, infertility, and for some permanent sterility. The child or adolescent cannot consent (or assent) to these harms when they are not mature enough to fully comprehend what they mean. Long-term studies regarding the treatment effects specifically for minors with hormones and surgeries, using randomized controlled studies or even proper observational studies do not exist.

209. WPATH's SOC 8 should not be followed by any physician, mental health care provider, or other medical professional.

210. For the reasons set forth above and in my supplemental report, in my professional opinion as an endocrinologist, no child or adolescent should receive puberty blockers to block normal puberty, nor should they receive supraphysiologic doses of opposite sex hormones to attempt to alter secondary sex characteristics, nor should they have surgeries to remove or alter the breasts, genitalia or reproductive tracts as part of GAT. There exists insufficient evidence of benefit, but serious concerns for risk of harm. Therefore, I believe that North Carolina's House Bill 808 is based on sound medical principles for the protection of minors.

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House Judiciary

03/19/2025 02:30 PM

SB25-129 Legally Protected Hlth-Care Activity Protections

Typed Text of Testimony Submitted

Name, Position, Representing	Typed Text of Testimony
Jeany Rush Against themself	TO: SENATE JUDICIARY COMMITTEE HOUSE JUDICIARY COMMITTEE RE: SB25-129 Protected Health-Care Activity Protections Sponsors: Cutter, F. Winter, Joseph, McCormick FROM: Jeany Rush Colorado Springs Constituent 3-19-25 VOTE: NO WHEN DID CHOPPING OFF HEALTHY BODY PARTS BY MUTILATING CHILDREN, RIPPING OUT OF THE WOMB FULLY GROWN BABIES, STERILIZING MINORS FOR LIFE BECOME A PROTECTED HEALTH CARE ACTIVITY OR A PROTECTED REPRODUCTIVE HEALTH CARE EVENT, MUCH LESS A PRIVILEGE? NONE of this will EVER create another human being! REMIND ME NOT ASK YOU FOR ANY PROTECTION IN MY LIFE! In a State where it's already legal to STERILIZE, (NEUTERED FOR LIFE),MUTILATE, AND DRUG MINORS both in state, and visitors, YOU as supposed' Defenders of Citizens, want to make it more difficult for anyone to hold accountable from liability, medical personnel, providers who may give in-humane services, and malpractice on another human, or child? Your Protected Class gives no recourse, or defense to Victims, trans kids or anyone! IT'S MALPRACTICE ON THEIR HUMANITY! WHAT COULD GO WRONG HERE? This bill insults all intelligence! It's travesty that is the legacy of this body! You all could'nt even pass a bill to protect abortion clinics from substandard practices. You're not protecting children from known experimental, pseudo science & ideological rape of our children’s minds and bodies. You have hogtied the legal system, give an attorney general rights to decide in this, circumventing peoples rights under the law & constitution. Violating both God’s laws, and the Nations? HAVE YOU LOST YOUR MINDS? WHO MADE YOU THE JUDGE, JURY, AND GOD ? “January 28, Presidential Executive Order An order to protect children with gender dysphoria while Protecting Children from Chemical and Surgical Mutilation, hospitals across the country will be required to suspend any gender interventions on individuals under the age of 19. No funds to

	sponsor, promote, assist, nor support medical interventions: puberty blockers or surgeries meant to “so-called transition” a child to the opposite sex”
Steve McKenna Against themself	Please vote NO on SB-25-129, “Legally Protected Health-Care Activity Protections.” As a trial lawyer with over 25 years in private practice and for the US government, I cannot fathom why we would want a law that exempts providers of abortions or gender-affirming care (controversial medical treatments) from liability for any possible harm they might cause. Further, providing legal “protections” for “legally protected health-care activity” is nonsensical. This bill is not simply a pander to abortion activists and the TQ+ community, it is dangerous and will strip legal recourse from women and children who are harmed.

TO: JUDICIARY COOMMITTEE

RE: SB25-129 Legally Protected Health Care Activity Protections

DATE: 3/19/2025 2:30 P.M.

SPONSOR: Senator Lisa Cutter

Seator Faith Winter

House Representative Junie Joseph

House Representative Karen McCormick

My name is Jody Nickerson from Jefferson County, and I represent myself.
Thank you for this opportunity .

This bill jumped out at me, being a concerned mother and grandmother and having a granddaughter fighting the challenges of identity who had been influenced by adult contacts in her school years.

Why are you having to conceal a doctor's identify on a prescription to minors? Is it because you do realize that the procedures you are allowing minors to have may be truly detrimental in many situations and you have a need to protect these doctors that are not keeping their oath which is being challenged by courts and insurance companies today? This bill seems to be opening pandora's box not only challenging the Medical Board but Medicaid and personal insurance companies that underwrite in this state. I truly want to understand the logic.

Even speaking to my granddaughter, she doesn't approve of child trafficking or grooming which she can admit has occurred. She's 21 today and still battling identity due to the ideology and pressure she was exposed to in school. So why are you allowing it to happen by permitting all those minors having to come here to get anonymous prescriptions.

Then there is the concern that Medicaid is being challenged as well as personal insurance companies overseen by the Colorado Division of Insurance (DOI), part of the Department of Regulatory Agencies (DORA),

who are seeing more cases of the misuse of the health care industry covering minors. The funds appropriated would seem to have much higher priorities than to encourage minor medications that lead to minor's abortions and transgender procedures especially in wholesome family environments without parental consent. We already have numerous successful agencies that help minors in destructive family environments. Are you not using those agencies? These cases and challenges are increasing by thousands. This misuse of funds in these agencies is being investigated and increasing so to have to account for their appropriations. One phone call answered that question. So why would you put more pressure on the facilities and the doctors. This bill will not keep cases against the doctors or facilities from occurring on numerous civil court levels, as Dr. Fauci himself is experiencing involving minors. No one is above the law especially Federal law. It would seem any facility supporting this bill would be trying to hide something but willing to jeopardize funding for their more important cases, like psychological support. Funding that taxpayers pay for.

This bill would pivot these doctors, the facilities and Medicaid in a dangerous direction which due to the presentation of this bill will support more of those investigations. Please reconsider evaluating the ramifications. By presenting this bill there are those already taking notes.

I want to see Colorado as a safe state which this bill would promote potential illegal activities on our minors and make our children unsafe from being kidnapped, raped or groomed.

I heard a statement made today that good legislators are ones that put successful bills that you can count on one hand. Be one of those good legislators and devote more time to not the statistics, but the ramifications and factors.

Please pull this bill or vote NO.

Doc. 557-9
Defendants' Summary Judgment Exhibit 9 (Redacted)

IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF ALABAMA
NORTHERN DIVISION

BRIANNA BOE, *et al.*,	)	
	)	
Plaintiffs,	)	
	)	
UNITED STATES OF AMERICA,	)	
	)	
Intervenor Plaintiff,	)	
	)	
v.	)	Civil Action No. 2:22-cv-184-LCB
	)	
HON. STEVE MARSHALL, in his Official capacity as Attorney General, of the State of Alabama, *et al.*,	)	
	)	
Defendants.	)	

SUPPLEMENTAL EXPERT REPORT OF
MICHAEL K. LAIDLAW, M.D.

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I, Michael K. Laidlaw, M.D., hereby declare as follows:

1. I am over the age of eighteen and submit this expert declaration based on my personal knowledge and experience.

2. In addition to the cases listed in my initial report, I have since provided expert testimony in the following cases: L.B. v. Premera Blue Cross, Case No. 23-cv-00953-TSZ (W.D. Wash.); T.D. v. Wrigley, Case No. 08-2023-CV-02189 (S.C.D. ND); Garderen v. State of Montana, Cause No. DV 2023-0541 (Mont. D. Ct.); Emma Koe v. Noggle, Case No. 23-cv-02904-SEG (N.D. Ga); Poe v. Drummond, Case No. 23-cv-00177-JFH-SH (N.D. Okla.); Doe 1 v. Thornbury, Case No. 3:23-CV-00230-DJH (W.D. Ky.); L.W. v. Skrmetti, Case No. 3:23-cv-00376 (M.D. Tenn.).

3. Since my last report in this case on May 19, 2023, I have been given access to documents received in discovery from the World Professional Association for Transgender Health (WPATH) and the U.S. Department of Health and Human Services (HHS).[1] I understand that these documents are subject to the Court's protective order. I also had access to Defendants' Motion to Compel the United States to Designate Admiral Levine as a Custodian (Doc. 302). I have been asked by Defendants to review and opine on the WPATH and HHS documents as they relate to the safety and efficacy of sex reassignment treatments for minors and the reliability and trustworthiness of the WPATH Standards of Care 8.

4. The bases for my opinions expressed in this report are my review of the aforementioned documents, my professional experience as a practicing endocrinologist, and my knowledge of the pertinent scientific literature, including those publications cited in this report.

5. Specifically, I have first-hand personal experience in human research as a physician, having been involved in two studies—one involving magnesium and bone density and the other involving ultrasound use for detecting recurrent thyroid cancer. For the latter study I helped to design an Institutional Review Board ("IRB") approved protocol. Furthermore, I received certification in the required course "Understanding the Fundamentals: Responsibilities

[1] Specifically, I was provided access to documents bates stamped BOEAL_WPATH_000001 through BOEAL_WPATH_101726, HHS_0012038-40, HHS_0028597-602, HHS_0028603-04, HHS_0028624-28, HHS_0029067-73, HHS_0084445-46, HHS_0084456-61, and HHS_0144565 through HHS_017022.

and Requirements for the Protection of Human Subjects in Research" at the University of Southern California in 2003.

6. In what follows I will discuss the serious flaws in WPATH's Standards of Care 8 (SOC 8) with respect to the guidelines' methodology; the faulty recommendations of SOC 8 based on a lack of transparency with respect to quality of studies, a lack of significant long term research, an unwillingness to acknowledge known harms, an unwillingness to examine pertinent ethical considerations, and deliberate changes to recommendations without regard to underlying evidence; the deliberate crafting of the SOC 8 to both help insure medical necessity for their proposed treatments and also to protect clinicians from liability; and finally the strong political influence placed on WPATH by HHS and the American Academy of Pediatrics (AAP) to make serious last-minute alterations to the SOC 8 that removed the vast majority of recommended age minimums for transitioning hormones and procedures against the advice of WPATH's own experts.

I. WPATH's Methodology for Producing Standards of Care 8

7. WPATH's Standards of Care 8 (SOC 8) were published on Sep. 6, 2022 and endorsed by the plaintiff's expert Dr. Shumer as representing an "expert consensus for clinicians related to medical care for transgender people, based on the best available science and clinical experience." (Coleman et al., 2022) (Shumer Decl, p. 16).

8. WPATH has made claims about the nature of evidence in their SOC 8 document. In their FAQ document, they state that "[t]his version [8] of the Standards of Care uses an enhanced evidence-based approach to include recommendations intended to optimize patient care that are informed by a systematic review of evidence and an assessment of the benefits and possible harms of alternative care options." (WPATH FAQ, 2024).

9. The lead author of SOC 8, Eli Coleman, claims, "WPATH followed a rigorous, multi-year process and was based on the best available scientific evidence and weighing all risks and benefits to arrive at the recommendations in our Standards of Care 8 guidelines...WPATH stands behind our process and conclusions." (Bowers, 2023).

10. Admiral Rachel Levine, a highly positioned and influential, politically appointed administrator within HHS, serving as assistant secretary of health, has made numerous statements attesting to the purported validity, importance, and scientific integrity of WPATH's guidelines.

11. With respect to how the SOC 8 was generated, Admiral Levine stated that "[r]ather than relying on a few cherry-picked reports to make a political argument, WPATH assesses the

full state of the science and provides substantive, rigorously analyzed, peer-reviewed recommendations to the medical community on how best to care for patients who are transgender or gender non-binary." (Levine, 2022).

12. With respect to the SOC 8's recommendations, Admiral Levine stated that "[t]here is nothing one-sided about their approach." Admiral Levine claimed that: 1) "It is founded on a vast body of medical literature." 2) "It is free of any agenda other than to ensure that medical decisions are informed by science." 3) "This is the way medicine is supposed to be practiced, and it is the way doctors are supposed to care for their patients." (Id.)

13. It is apparent from email exchanges among WPATH members that Dr. Levine is particularly important to maintaining WPATH's credibility and promoting its SOC 8. As WPATH states in one email, "she's our best cheerleader." (BOEAL_WPATH_062621).

14. Admiral Levine has stated that "we need to lead with real data and compassion rather than slander and stigmatization" (ADM Rachel Levine, Twitter/X @HHS_ASH Jul 19-2022), and I agree. Ironically, however, Dr Levine has also implied that criticism of gender affirmative therapy is "politicized" and shows "the spirit of intolerance and discrimination," and that "it is unconscionable that evidence-based care is being politicized." (ADM Rachel Levine, Twitter/X @HHS_ASH Feb 24-2022).

15. Additionally, Dr. Levine has made statements seeming to imply that suicides or potential suicides of gender dysphoric youth are somehow related to legitimate criticisms of gender affirmative therapy. Levine stated: "The language of medicine and science is being used to drive people to suicide. The mantle of concern for children is being claimed to destroy children's lives." (ADM Rachel Levine, Twitter/X @HHS_ASH Apr 30-2022).

16. The current president of WPATH, Marci Bowers, stated that any criticism of the SOC 8 is by nature an assault on minority groups, women, religious organizations, and humanity itself, stating: "An attack on trans care is an attack on women. It is an attack on black people, brown people, and Asian people. It is an attack on Jewish, Muslim, Hindi, Sikh, and true Christian communities. It is an attack on diversity and all of the ideals that diversity holds. It is an attack on us all." (Bowers, 2023).

17. Given that Admiral Levine is a highly influential member of HHS whose opinions and recommendations affect millions of American's lives, and that Admiral Levine has relied on WPATH to form judgements about what constitutes the best treatment for children and adolescents

with gender dysphoria, physicians and the public at large should expect that these opinions and recommendations are based on a very high level of intellectual and ethical integrity and a thorough knowledge of the subject matter.

18. Accordingly, I investigated the claims of both WPATH and Dr. Levine based on what is known about the SOC 8 document. I relied on the published SOC 8 document and its correction, as well as the claims and opinions of the creators of WPATH as revealed in what they have written and spoken both in private and in public. The ultimate goal for everyone should be to provide minor patients with the best evidence-based care for their health and welfare, both now and into the future.

19. The SOC 8 is a document of consensus produced by a narrow, ideologically homogenous group of experts and stakeholders who have two primary aims: 1) ensure the reimbursement of Gender Affirmative Therapy (GAT) related medical visits, medications, surgeries, and procedures; and 2) protect clinicians and others involved in GAT from liability.

20. As a practicing endocrinologist, I use clinical guidelines to help determine the proper diagnosis and care of individual patients. However, it is incumbent upon me as a physician specialist to assess the validity, evidence base, and methodology used to generate such guidelines.

21. The first concern I had when SOC 8 was published was what methodology did WPATH use to generate the guidelines. What were the specific steps involved taken to produce the recommendations?[2]

22. WPATH's Standards of Care 8 document claims that the authors used two types of processes to make recommendations. One was the Delphi technique or method and the second was the GRADE system or method. (Coleman et al, 2022, p. S247) These are two different processes for generating recommendations and are not intended to be used together.

A. Delphi

23. First let's examine the Delphi technique. The Delphi technique is a method of generating recommendations based on expert consensus. This technique was developed in the 1950s by the Rand Corporation to use a panel of experts to "forecast the effect of technology on

[2] I went through an identical process with Endocrine Society guidelines of 2017. My coauthors and I wrote about our serious concerns in a letter to the editor of the Endocrine Society's flagship Journal, JCEM, in 2019. (Laidlaw, Van Meter, et al., 2019).

warfare." (Rand Corporation, 2024). The process involves selecting a group of experts and posing a series of questions. (McGeary, 2009). The experts then submit answers anonymously. The answers are collated and ranked and these statements are voted upon. This process of voting and ranking may go through two to four or more iterations. At that point, a consensus statement is produced based on the highest ranked choice. This technique has also been used in many other disciplines including healthcare but is not without criticism.

24. It is important to understand that this technique is not evidence based, but solely consensus based. Recommendations are generated solely based on expert opinion without evidentiary support. In fact, "[in] health sciences, the Delphi technique is primarily used by researchers when the available knowledge is incomplete or subject to uncertainty and other methods that provide higher levels of evidence cannot be used. The aim is to collect expert-based judgments and often to use them to identify consensus." (Niederberger et al., 2020). Additionally, "[i]n intervention research in health sciences, surveys of experts are considered subordinate to evidence-based methods because they do not take account of any reliable findings on observed cause-effect relationships." (Id.)

25. One problem that can occur when employing the Delphi method is selection bias with respect to the composition of expert groups because there is no standard of how to compose an expert group. (Id.) It stands to reason that a narrow selection of experts with similar opinions makes for biased recommendations. This is exactly what happened with the WPATH SOC 8's Delphi process. Lead author Eli Coleman stated, "We had 119 experts from around the world" involved in producing SOC 8. (Bowers, 2023). However, all of the expert developers of SOC 8 were members of WPATH. In fact, with respect to the criteria used for the selection of the Co-chairs on the SOC 8 Revision committee and Chapter Leads, one had to be a "[l]ongstanding WPATH Full Member in good standing" and a "[w]ell recognized advocate for WPATH and the SOC." (WPATH Revision Committee, accessed 2024). A chapter Workgroup Member had to be a "WPATH Full Member in good standing." (Id.)

26. The Delphi technique has also been criticized from a sociological perspective because it raises "questions about [the recommendations'] validity, the dominance of possible thought collectives, and the reproduction of possible power structures." (Niederberger et al., 2020). Because of a collective group bias, another problem is "possibly failing to take new impetus and scientific findings sufficiently into account" (Id.)

27. It appears from emails and drafts of SOC 8 that the Delphi process itself was misused or ignored. For example, the published SOC 8 contains this recommendation: "12.21- We recommend health care professionals maintain existing hormone therapy if the transgender and gender diverse individual's mental health deteriorates and assess the reason for the deterioration, unless contraindicated." (Coleman et al., 2022). However, a draft comment indicates that the words "unless contraindicated" was added after the Delphi process had completed. The reviewer placed a strikethrough on the words "unless contraindicated" and made the comment that the phrase "changes the [Delphi] statement which has already been voted on." (BOEL_WPATH_024545). Nevertheless, the altered statement, containing "unless contraindicated," remains in the final version of SOC 8.

28. If WPATH authors were more open to the public, explicitly describing that they used the Delphi technique to gather a consensus within their own narrowly defined group and also admitting that they used the Delphi technique because "the available knowledge is incomplete" and "subject to uncertainty," and "other methods that provide higher levels of evidence" could not be used, then clinicians could use this honest admission to understand they are reading a highly biased document of opinions. WPATH did not do that.

B. GRADE

29. The SOC 8 developers used a second system for generating recommendations known as GRADE—"Grading of Recommendations, Assessment, Development, and Evaluations." In the GRADE system, a clinical question is asked and then evidence is systematically gathered using a specific method for conducting a systematic literature review. The evidence is then weighed and assigned one of four values: very low, low, moderate, or high. (Guyatt et al., 2011). These values are sometimes represented as +, ++, +++, and ++++, respectively. After the evidence is graded, then a recommendation may be made for or against a particular medical intervention. This is classified as either a "strong" or "weak" recommendation. (Id.)

30. The lead author of SOC 8, Eli Coleman stated, "[we] used a consensus-based approach (Delphi) involving all committee members to arrive at our conclusions and then graded the strength of our recommendations."[3] (Bowers, 2023)

31. Coleman and WPATH claim to have used a process adapted from the GRADE framework in SOC 8. (Coleman et al., 2022, s250). But, among other issues, they failed to incorporate the quintessential GRADE component in their final published document, which is to show the graded values pertaining to quality of evidence for each recommendation. This omission was not merely a minor modification of GRADE; it was a very deliberate decision on the part of leadership to not include the grading of evidence. This was made clear in an internal email:

> This is a question for [redacted] I noticed that your chapter says: "Statements supported by systematic literature reviews are rated as follows: ++++ strong certainty of evidence, +++ moderate certainty of evidence, ++ low certainty of evidence, + very low certainty of evidence". My understanding is that we were not going to make a difference between statements based on [literature reviews] and the rest, is that right [redacted]? If so, we will need to remove the +, ++, +++, ++++

(BOEAL_WPATH_024233) (emphasis mine).

The response to this email stated, "If there is no grading of statements, you can remove the +, ++ but I will leave them in for now since we spend a good amount of time grading the statements." (BOEAL_WPATH_024238). In a follow up e-mail, the author replied, "That is correct—but my understanding is that they have a number of statements based upon systematic reviews." (BOEAL_WPATH_024302).

32. This intentional omission of the ranking of the quality of evidence in the final versions of SOC 8 and other failures to use GRADE properly were highlighted in the British

[3] "Once the statements passed the Delphi process, chapter members graded each statement using a process adapted from the Grading of Recommendations, Assessment, Development and Evaluations (GRADE) framework. This a transparent framework for developing and presenting summaries of evidence and provides a systematic approach for making clinical practice recommendations (Guyatt et al., 2011). . . .The statements were classified as:

- Strong recommendations ('we recommend') are for those interventions/therapy/strategies where:
  - the evidence is of high quality. . . .
- Weak recommendations ('we suggest') are for those interventions/therapy/strategies where:
  - there are weaknesses in the evidence base"

(Coleman et al., 2022, s250).

Journal of Medicine: "WPATH's recommendations lack a grading system to indicate the quality of the evidence—one of several deficiencies." (Block, 2023). The article goes on to highlight further criticisms by one of the developers of GRADE, Dr. Gordon Guyatt: "Both Guyatt and Helfand noted that a trustworthy guideline would be transparent about all commissioned systematic reviews: how many were done and what the results were. But Helfand remarked that neither was made clear in the WPATH guidelines and also noted several instances in which the strength of evidence presented to justify a recommendation was 'at odds with what their own systematic reviewers found.'" (Id.)

33. This pattern of removing crucial aspects of the guidelines and ignoring systematic reviews of evidence because they were detrimental to the advocacy role of WPATH is a pattern in the development of the SOC 8. It shows that the goal of SOC 8 was not to present guidelines with a transparent view of the evidence so that clinicians can make decisions for their patients who have questions about their gender identity; rather, it was a way to ensure medical necessity so that medications and procedures can be paid for and to protect clinicians from liability—as I discuss below.

34. In my opinion, the aberrant use of GRADE could easily confuse users of SOC 8 into believing that the SOC 8 authors made recommendations to patients based on high-quality evidence, when in fact the evidence was either not graded at all or any grades were discarded when it came time to make treatment recommendations. We know this because WPATH did not fully disclose the quality assessments of their collected studies to the public.

35. Dr. Guyatt, the GRADE co-developer, expressly warned against the misuse or modification of GRADE in this way: "Some organizations have used modified versions of the GRADE approach. We recommend against such modifications because the elements of the GRADE process are interlinked because modifications may confuse some users of evidence summaries and guidelines, and because such changes compromise the goal of a single system with which clinicians, policy makers, and patients can become familiar." (Guyatt et al., 2011) (emphasis mine).

36. To conclude this section about methods, I do not believe the GRADE system was used in any meaningful way other than as an attempt to imply that the SOC 8 has strong evidence for many of its recommendations. Had the SOC 8 simply relied on the Delphi method alone, it would be clear that the recommendations were made solely or primarily on the basis of the opinions

of WPATH's homogenous group of experts rather than a systematic review of the evidence of outcomes. WPATH evaded that honesty. The end result can easily confuse readers that "strong" recommendations are necessarily linked with high-quality evidence and "weak" recommendations with low quality evidence. And the all-important ranking of the actual evidence is missing from the SOC 8 text, rendering it impossible for clinicians and other users to understand how the SOC 8 arrived at its conclusions. (Coleman et al., 2022, p. S250). In my opinion, this muddled, non-transparent, and sloppy approach to generating recommendations only serves to confuse users of the SOC 8 into thinking that the WPATH recommendations are based on a robust evidentiary foundation when that is not the case.

II. The SOC 8's Hormone Therapy Chapter Draft, Final Version, and Presentation

A. Background

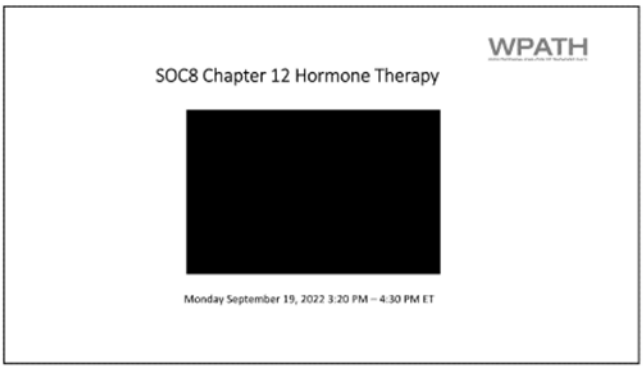
37. On May 5, 2019, Dr. Karen A. Robinson, the current director of Johns Hopkins University's Evidence-based Practice Center and the Lead of the SOC 8 Evidence Review Team, wrote in a preliminary report on "Chapter XI: Hormone Therapy for Adolescents and Adults Systematic Review to Support Development of WPATH SOC 8" that "[t]wo Reviewers will independently grade the strength of evidence by adapting the GRADE methodology." (BOEAL_WPATH_096345). However, the strength of the evidence (very low, low, moderate, or high) was never presented in the SOC 8 for the hormone chapter or indeed any chapter.

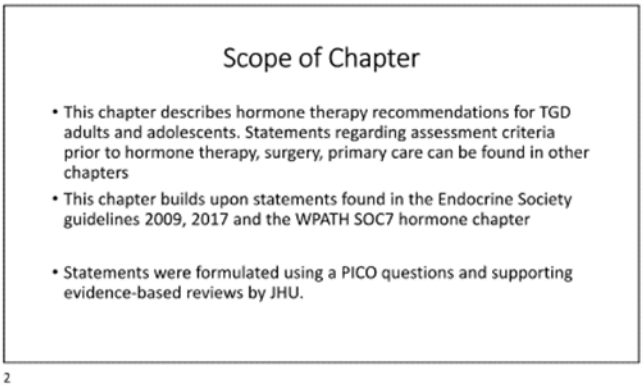
38. While the Johns Hopkins Evidence Review Team was meant to provide chapter leads and authors with systematic reviews of the evidence to use to inform their recommendations and explanations, communications from WPATH reveal that the chapter authors and reviewers cherrypicked the studies they liked and discarded the studies they did not like. This may be because the literature review, according to Dr. Robinson, "found little to no evidence about children and adolescents."[4] (HHS-0153484).

39. In 2022, WPATH leaders commissioned presentations to discuss SOC 8 at their symposium in Montreal. (BOEAL_WPATH_087219). One presentation was entitled "SOC8

[4] In fact, an email from Dr. Robinson to HHS shows Dr. Robinson's frustration with WPATH interfering with her work. She stated that she had "been having issues with this sponsor [WPATH] trying to restrict our ability to publish." (HHS-0153484).

Chapter 12 Hormone Therapy."[5] (BOEAL_WPATH_087239). It stated that "[t]his chapter builds upon statements found in the Endocrine Society Guidelines 2009, 2017."





40. It is interesting to note that the 2017 Endocrine Society Guideline (ESG) used the Grade Method as intended insofar as it published a grading (very low, low, moderate, or high) of the evidence for each recommendation.[6] An examination of the adolescent chapter from the ESG

[5] As best as I can tell based on WPATH's publicly available symposium schedule, the presenters for this presentation are listed in the following excerpt:

> "Session A - Grand Salon SOC8 SESSION Hormone Therapy Vin Tangpricha, MD, PhD (Lead); Martin den Heijer, MD, PhD; Michael Irwig, MD; Stephen Rosenthal, MD; Joshua Safer, MD; Colt St. Amand, MD, PhD; Guy T'Sjoen, MD, PhD."

Note also that Admiral Rachel Levine is listed as the keynote speaker for this event. (WPATH.org, Schedule, 2022).

[6] My May 19, 2023 report in this case outlines the serious flaws of the Endocrine Society guidelines. (Laidlaw 2023 ¶¶192-199). The co-developer of the GRADE system also "found 'serious problems' with the Endocrine Society guidelines, noting that the systematic reviews didn't look at the effect of the interventions on gender dysphoria itself, arguably 'the most important outcome.'" (Laidlaw 2023 ¶200).

shows that all evidence for adolescents is low to very low quality or in some cases there is no evidence at all such as recommendations for hormone ranges. (Hembree et al., 2017; Laidlaw et al., 2019).

41. However, rather than building and expanding on the ESG, WPATH removed the essential pillar of evidence grading and failed to provide the strength of the evidence that was supposed to have come from the systematic reviews that Johns Hopkins was to conduct. What was the reason for this? I can only conclude that the evidence was so thin, weak, low quality, or absent that WPATH chose not to include the grading of evidence in their final document.

42. I will next examine the SOC 8's treatment of puberty blockers, opposite sex hormones, ethical considerations, fertility, cardiovascular risks, and bone development. I will also look at the type of research being used as evidence to support the SOC 8.

B. Puberty Blockers and Opposite Sex Hormones

43. The published SOC 8 states:

> "We recommend healthcare professionals begin pubertal hormone suppression in eligible transgender and gender diverse adolescents after they first exhibit physical changes of puberty."

(Coleman et al., 2022).

As a reminder, WPATH stated in its methods section that "Strong recommendations ('we recommend')" are reserved "for those interventions/therapy/strategies where" "the evidence is of high quality," "there is a high degree of certainty effects will be achieved in practice," "there are few downsides of therapy/intervention/strategy," and "there is a high degree of acceptance among providers and patients or those for whom the recommendation applies." (Coleman et al., 2022).

44. In WPATH's earlier draft, this recommendation had a specific grade of "+++" indicating a moderate level of quality evidence. (BOEAL_WPATH_024500). However, no such specific grading of evidence is found in the final SOC 8 product. Furthermore, in the final text of SOC 8, the authors admit that they did not do (or did not recognize) a systematic review of the outcomes for youths because they claimed conducting such a review was "not possible." (Coleman et al., S46). Yet, according to GRADE co-developer Guyatt, "'systematic reviews are always possible,' even if few or no studies meet the eligibility criteria"; making "a recommendation without one" would "'be violating standards of trustworthy guidelines.'" (Block, 2023).

45. Also, there is an admission on the part of one WPATH email author that he or she believes there is not a global consensus regarding puberty blockers: "My understanding is that a global consensus on 'puberty blockers' does not exist." (BOEAL_WPATH_022856).

46. These alterations of evidence reporting and admission about puberty blockers are of great concern because in the final SOC 8 document, the authors made a "strong" recommendation in favor of puberty blockers, thus implying to clinicians that such a recommendation resulted from high quality evidence. As I discussed in my initial report, this strong recommendation (without high quality evidence from a systemic review) has extreme health consequences for children receiving puberty blockers at this earliest pubertal stage. (Laidlaw 2023, Sec. II.B.). Among those health consequences are 1) infertility without the possibility of storing sperm or ovum as fertility preservation at this stage requires experimental preservation of ovarian and testicular tissue; 2) an inability to accrue normal bone density leading to future risk of osteoporosis and fractures; and, 3) "unknown effects on brain development" with possible effects on cognitive function. (Hembree et al., pp. 3882-83).

47. What is even more remarkable is that WPATH is making this puberty blocker recommendation for girls as young as age seven and boys as young as age eight without high quality evidence found in systematic reviews. (BOEAL_WPATH_087242). Although the authors of SOC 8 claim that "[t]he effects of GnRHa are considered to be fully reversible," they provide no evidence that this is true when puberty blockers are given to stop naturally timed puberty. (BOEAL_WPATH_087243).

48. For example, when puberty blockers are prescribed for the FDA approved indication of treating precocious puberty, puberty is indeed paused from a time of early childhood (age 4 as an example) until a more typical time of natural puberty (age 11 or 12 as an example). Then natural puberty is allowed to proceed by stopping the puberty-blocking medication. After, the patient will proceed through the natural stages of sexual development until finally reaching full adult sexual development.

49. By contrast, in GAT, natural puberty is stopped and, under the prescribed course of treatment, never allowed to resume. This is because the addition of opposite sex hormones continues to prevent the normal signaling of the pituitary gland to the gonads. The end effect is that the patient's endogenous (internally produced) sex hormones are never allowed to be released in sufficient quantity to allow natural puberty to continue. Thus, the person never reaches full adult

sexual development. This has profoundly negative effects on fertility as I have discussed in my previous report and will discuss further (Laidlaw 2023, Sec. II.4.A).

50. SOC 8 authors were intentionally vague about just how young the patients are receiving hormones and puberty blockers. Most people would consider an eight-year-old to be a child, even if she had started the beginnings of pubertal development. But because the idea of treating young children with powerful hormones in an attempt to change their sex is shocking to most of the public, SOC 8 authors sought to refer to such children as "adolescents"—even though adolescence is generally defined as beginning at age 12 and stretching to age 21.[7]

51. In one communication from WPATH, the author wrote: "I would avoid children and hormones, and stick to medical definitions: when a young person reaches Tanner 2, they are by definition reaching puberty, and therefore classed as adolescents (whether they are 9 or 12). So: children are not in puberty and therefore do not qualify for hormones and blockers; and adolescents do." (BOEAL_WPATH_037245). In my opinion, this redefinition of the age of adolescence to suit WPATH's needs confuses the public as to what properly defines who is a child and who is an adolescent (and thus whether WPATH intends for children to receive hormonal treatments).

52. The WPATH presentation on Hormone Therapy discussed the SOC 8 recommendation regarding stopping normal menstrual periods for gender dysphoric natal females without grading the quality of evidence for such a recommendation. (BOEAL_WPATH_087248).

53. SOC 8 provides: "12.7-We recommend health care professionals prescribe progestogens or a GnRH agonist for eligible* transgender and gender diverse adolescents with a uterus to reduce dysphoria caused by their menstrual cycle when gender-affirming testosterone use is not yet indicated." (Coleman et al., 2022).

54. As I described in my initial report (Laidlaw 2023 ¶¶ 101-13), stopping normal menstrual function in females is detrimental to bone health. "In addition to this important long-term consequence of amenorrhea [cardiovascular risk], other problems, such as premature bone

[7] From The American Academy of Pediatrics Policy Statement on the Age Limit of Pediatrics from Sep 1, 2017: "In the guidelines for choosing pediatric experts for advisory panels, the US Department of Health and the Food and Drug Administration reference approximate age ranges for these phases of life, which consist of the following: (1) infancy, between birth and 2 years of age; (2) childhood, from 2 to 12 years of age; and (3) adolescence, from 12 to 21 years of age." (Hardin and Hackell, 2017) (citations omitted).

demineralization or inadequate bone formation, are likely to put amenorrheic women at high risk for osteoporosis and fracture." (Santoro, 2011).

55. One of the methods advocated to stop normal menstrual periods for natal females is the use of progesterone. However, a different chapter of SOC 8 describes general problems associated with progestin medications including "weight gain, depression, and lipid changes." (Colemen et al., 2022, p. S122).

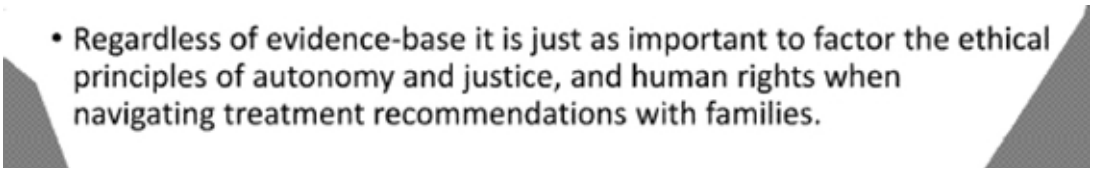
56. In a discussion regarding combined use of estrogen and progesterone for natal males, SOC 8 states: "To date, there have been no quality studies evaluating the role of progesterones in hormone therapy for transgender patients." (Id.)

57. With respect to adding progesterone to estrogen treatment for natal males identifying as transgender, the SOC 8 describes attempting a systematic review of evidence and finding that there isn't any notable evidence of benefit and that the literature in fact "suggest[s] a potential harm of some progestins." (Colemen et al., 2022, p. S122). But rather than using this as the basis of caution or even recommending *against* this use of progestins, the SOC 8 actually recommends prescribing progesterone in collaboration with the patient's desire. This is to be followed by an evaluation of the (apparently not completely understood, but harmful) response: "If, after a discussion of the risks and benefits of progesterone treatment, there is a collaborative decision to begin a trial of progesterone therapy, the prescriber should evaluate the patient within a year to review the patient's response to this treatment." (Id.)

58. In an email, a WPATH author writes about this addition: "[We could] [a]dd a small paragraph that there is no good quality evidence on progesterone and cite that we asked for a systematic review on this topic and there was only one study that was insufficient to provide enough data to make a recommendation. We can state that we acknowledge that some people use progesterone but there needs to be a risk/benefit discussion." (BOEAL_WPATH_045666).

C. Ethical Considerations

59. While it is self-evident that children and adolescents do not have the maturity, knowledge, and life experience to truly understand fertility or parenthood, the published SOC 8 pays little attention to this as an ethical concern. Rather, WPATH's presentation on SOC 8's adolescent chapter considered autonomy, justice, and human rights to be "just as important" as the evidence base for interventions:



(BOEAL_WPATH_087227).

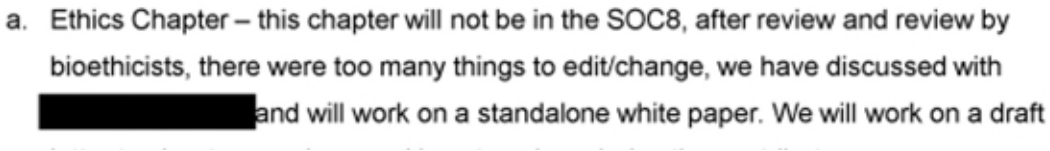
60. Privately, however, ethical concerns about GAT's impact on fertility were acknowledged. For example, in a September 4, 2022 WPATH email about its Ethics Course at the Montreal WPATH Symposium, the author opines that "[m]aking decisions about [puberty] blockers is a major challenge to families and clinicians—how do we propose puberty blockers (presumably leading to hormones and later surgery) to parents and their child in an informed way that considers aspects of future life that are almost unimaginable at age 9-10-11-12? Sex, reproduction, intimacy, aging, etc." (BOEAL_WPATH_076562).

61. In an educational session titled "Foundations in Gender Affirming Hormone Therapy: Adults and Adolescents," WPATH member Dr. Daniel Metzger, replied to a question about fertility concerns when blocking puberty at the earliest stage like this:

> I think that's the hardest part of what I do, because, of course, it is not in what is in the mind of a 13-year old, or 15-year old, or even a 17-year old... kids have zero idea about their fertility, right?

(Brock 2024).

62. WPATH meeting minutes from May 2022 indicate SOC 8 was to include an Ethics chapter, but "there were too many things to edit/change":



(BOEAL_WPATH_062948).

63. Indeed, SOC 8 does not even include a chapter on ethics with accompanying ethics statements that had, at minimum, been through their biased Delphi process. This fact did not seem particularly concerning to the SOC 8 creators: "Since the Ethics chapter is not going to be included in SOC8, we do not have to worry about the Ethics statements." (BOEAL_WPATH_073277).

64. The published SOC 8 does have a subsection in the "Adolescents" chapter titled "Ethical and human rights perspectives." However, concern about the ethics of puberty blockers and fertility is nowhere to be found. Rather, there is a focus on how *natural* puberty may have

"harmful effects." (Colemen et al., p. S48). This contention about the alleged harmful effects of natural puberty has no accompanying grading of evidence.

65. There is also a statement in the chapter prioritizing autonomy of the young person to receive GAT: "From a human rights perspective, considering gender diversity as a normal and expected variation within the broader diversity of the human experience, it is an adolescent's right to participate in their own decision-making process about their health and lives, including access to gender health services (Amnesty International, 2020)." (Id.)

66. There is no grading of evidence for this assertion, and the opinion is not based on a journal of medicine or ethics, but rather a human rights organization's press release about puberty blockers.[8] This statement ignores young people's limited knowledge, judgement, maturity, and life experiences with which to make decisions about impairments to fertility, sexual function and breast feeding that occur with GAT.

D. Fertility Preservation

67. The WPATH presentation on hormone therapy displays the very minimal evidence from studies regarding fertility preservation for natal females taking testosterone. It discusses a solitary case of a trans identifying person who had an egg retrieval while taking testosterone. However, the presenters relate that they have "[n]o data for comparison with what might have happened without exogenous testosterone." (BOEAL_WPATH_087253).

68. Within the same presentation slide an admission is made as to how truly little has been studied with respect to fertility preservation for youths receiving puberty blockers. In fact, in North America, the use of fertility preservation among minors undergoing GAT is reported to be very low, less than 5%. (Nahata et al., 2017; Chen et al., 2017). The presentation discusses briefly a single case of a natal female whose puberty was blocked at the earliest stage (which again may be as young as age 7 according to WPATH) and went through the deeply invasive procedure of

[8] The press release is a joint statement of Amnesty International UK and an organization called "Liberty" commenting on the UK's High Court ruling about puberty blockers: "Joint statement following High Court ruling that children under 16 are unlikely to be able to give informed consent to undergo treatment with puberty-blocking drug." Amnesty International UK, Dec. 2020, https://www.amnesty.org.uk/press-releases/amnesty-international-uk-and-liberty-joint-statement-puberty-blockers.

oocyte retrieval.[9] (BOEAL_WPATH_087253). With respect to that case, the presenters wrote about the lack of high-quality data as there was "[n]o data comparison for what might have happened without GnRH [puberty blocker] prescription." (Id.) There is also no discussion that pregnancy actually occurred in that case.

69. Comments from a citecheck review for the draft of the Reproductive Health chapter show the same problems of a lack of systematic evidence and dependence on single cases: "There are a number of citations that reference a single case study, but do not actually reference a study or clear evidence that would justify some of the statements...many [comments] flag issues with citing editorials or single case studies." (BOEAL_WPATH_018761).

70. The hormone therapy presentation also admits that "[i]f GnRH [is] instituted before spermatogenesis, there is no current way to preserve sperm" other than stopping puberty blockers to allow normal puberty to proceed. (BOEAL_WPATH_087254) (emphasis mine).

71. In the educational session referenced earlier with Dr. Metzger, he discusses the difficulty of attempting this very process for natal males who have had puberty blocked at the earliest stage and were then prescribed estrogen. Dr. Metzger said that in order to retrieve viable sperm, doctors would need to attempt to reverse the GAT process by having the child proceed through natural puberty: "[T]hey [the patients] would have to go off their estrogen, to back into male puberty to the point they are producing sperm, which would be a lot of virilization, so that is something we have to talk about." (Brock 2024).

72. With respect to natal females who have puberty blocked, take testosterone, and then attempt fertility by pausing GAT, Dr. Metzger states: "So, you can freeze eggs and then later use them but that's still a very early kind of technology that's quite expensive." With respect to natal females who have puberty blocked, Dr. Metzger states that the closest analogy relates to cancer treatment: "You know, a little bit of what we know is from, like, little girls who get cancer, right?...I don't, I don't think that lots is known about that still, for a, say a 10-year old assigned female. I don't think we know." (Id.)

73. Examples of the WPATH Hormone Therapy chapter failing to acknowledge known problems with fertility preservation can be found by comparing the review of the chapter draft to

[9] The SOC 8 describes the fertility preservation procedure in general as "often physically and emotionally uncomfortable" (Coleman et al., 2022, S159). In my opinion, these procedures would in all likelihood be even more uncomfortable for children and adolescents.

the final SOC 8 document. In the published SOC 8, on p. S156, WPATH claims that "[r]esearch protocols for ovarian and testicular tissue cryopreservation have also been developed and studied," citing the following: "Borgström et al., 2020; Nahata et al., 2019; Rodriguez-Wallberg, et al., 2019)." However, the reviewer of the chapter had struck the "Borgström et al." citation, noting: "Technically, this was a study on viability sampling, not a publication of an established protocol for harvesting pre pubertal sperm for FP." (BOEAL_WPATH_026219). Nevertheless, the citation remains in the published SOC 8.

74. With respect to the Rodriguez-Wallberg citation, the reviewer stated: "Similar to the Borgstrom article, this includes a study on harvesting eggs from cis women and girls, but are not a descriptor of a protocol." (Id.) Again, no clarification regarding this distinction is found in the published SOC 8.

75. On p. S160, SOC 8 states, "other studies have reported some positive experiences [of transgender identifying individuals] during pregnancy as well (Fischer, 2021; Light et al., 2014)." However, the chapter reviewer noted that the Light et al. article also "speaks to the issue of isolation and depression as a result of pregnancy, in addition to noting some positive experiences." (BOEAL_WPATH_026230). This was not disclosed in the final text.

76. Each of these examples indicate that reviewers' criticisms and recommendations were ignored, likely in order to place gender affirmative therapy in a more positive light.

E. Other Risks

77. With respect to estrogen, WPATH admits that there are increased risks for venous thromboembolism, which are blood clots which may be deadly. (BOEAL_WPATH_087258). In a review by Irwig in 2018, the general risk was found to be five times above the typical risk for natal males. (Irwig, 2018). The WPATH presentation claims that the transdermal patch has the "[l]owest risk"; however, this is based on "cis F" (meaning studies on natal females) (BOEAL_WPATH_087258). This appears to be an admission that they have only studies for natal females to rely on and do not have any studies for the use of transdermal estrogen for natal males with gender dysphoria, either as adults or adolescents.

78. In an American Heart Association (AHA) position statement from 2021, "Assessing and Addressing Cardiovascular Health in People Who Are Transgender and Gender Diverse: A Scientific Statement from the American Heart Association," the AHA confirms the thromboembolism risk of estrogen in GAT:

> In analyses assessing the effects of hormone therapy on cardiovascular outcomes, data consistently demonstrate elevated risk for venous thromboembolism among people who are transgender receiving estrogen-based hormone therapy.

(Streed et al., 2021) (emphasis mine).

79. WPATH's Hormone Therapy presentation claimed that "less well established concerns include CAD [coronary artery disease]." (BOEAL_WPATH_087255). This is stunning given that the same review paper by Irwig had concluded that risks of myocardial infarction and death due to cardiovascular disease were increased in natal males and females receiving opposite sex hormones (Irwig, 2018).

80. Additionally, the AHA's scientific statement stated:

> A growing body of research demonstrates that TGD populations may be at disproportionate risk for poor cardiovascular outcomes. Within the Behavioral Risk Factor Surveillance System (BRFSS), multivariable analyses of cross-sectional self-reported data revealed that men who are transgender had a >2-fold and 4-fold increase in the prevalence of myocardial infarction compared with men who are cisgender and women who are cisgender, respectively. Conversely, women who are transgender had >2-fold increase in the prevalence of myocardial infarction compared with women who are cisgender but did not have a significant increase in comparison with men who are cisgender.

(Streed et al., 2021) (citations omitted). These important American Heart Association's positions are not found in the SOC 8, nor is the paper cited. (Streed et al., 2021).

81. In my opinion, in an abundance of caution, one must conclude, until proven otherwise, that the cardiovascular risks are increased while taking opposite sex hormones in GAT, at least in part, because of the effects of the high doses recommended by WPATH and the ESG.

82. I have discussed the problems with youths acquiring optimal bone density during natural puberty when progression is blocker by medication and the subsequent increased risk for osteoporosis in my report (Laidlaw 2023, Sec II.4.c, Fig 2).

83. Dr. Metzger echoed this problem in the same educational presentation referenced earlier. He said: "Normally puberty is the time of putting the calcium into your piggy bank. This is how I explain it to families. You've got a piggy bank for your calcium and you better get it all in by 25 because at 25 you're going to live off that piggy bank." He continued:

> The puberty blockers slow that calcium accrual back into the bones quite a bit, back to the prepubertal level. We do know that even if you look at people now age 22, if you've done all of this and you've gone off and then you go back on the hormones' that you want to have, you have not caught up by age 22. Which is

> about the time you need to fill up your piggy bank. This is a concern that not everybody is getting their piggy bank completely filled up with calcium.

(Brock, 2024)

84. With respect to hormones levels being sufficient for "good bone health" and "not supraphysiologic," the "Hormone Therapy" chapter internal reviewer suggested to the authors: "Perhaps mention that this is still expert opinion, and no one has looked at evidence surrounding hormone levels and health." (BOEAL_WPATH_021733). Once again, the authors rejected the suggestion and it was not incorporated into the final version of SOC 8.

F. [redacted]

85. [redacted]

86. [redacted]

[redacted]

[redacted]

[redacted]

87. [redacted]

88. [redacted]

[12] [redacted]

[13] [redacted]

[redacted]

III. SOC 8's "Sexual Health" Chapter Draft and Final Version

89. In the published version of SOC 8, chapter 17 examines "Sexual Health." On p. S164, one can read eight statements that were allegedly approved by the Delphi process. All eight received the admonition to recommend to healthcare professionals. Again, according to the methodology section of SOC 8, these "recommendations" typically meant that there was "high quality" evidence to support them. However, an examination of the draft and comments for this chapter tells a different story. In the draft, six out of seven statements instead used the word "suggest" (indicating low quality evidence) rather than "recommend."

90. It becomes clear that the internal reviewers (rather than the Delphi process) sought to ensure that these changes were made. In fact, there is a tacit admission by the internal reviewer that "most of the chapters have used 'recommend' in their recommendations even if they have a lack of literature based on clinical expertise." (BOEAL_WPATH_018866) (emphasis mine). The reviewer goes on to say, "having a chapter that mainly says 'suggest'…may suggest (sorry) that sexual health is less important." (Id.)

[14] The FDA also wrote that "[p]atients with psychosis or suicidal ideation within the last 30 days will be required to undergo thorough counselling before being re-considered for enrollment." (Id.)

91. In another example, the draft statement read: "We suggest HCPs [health care professionals] who provide care to trans and gender diverse patients counsel adolescents and adults regarding prevention of sexually transmitted infections." (BOEAL_WPATH_018869). The reviewer commented, "in view of the evidence and the importance, I wonder whether this is 'recommend.'" (Id.)

92. The final statement was indeed changed from "suggest" to "recommend": "17.6. We recommend health care professionals who provide care to transgender and gender diverse people counsel adolescents and adults regarding prevention of sexually transmitted infections."

93. In yet another example, the draft states: "The mechanism for how hormone therapy can effect changes in the many aforementioned aspects of sexual function remain poorly understood." (BOEAL_WPATH_19476). However, the reviewer commented: "not sure if this adds anything, as this imply the low evidence so it will question as to why we 'recommend' and not 'suggest.'" (Id.) The sentence does not appear in the published SOC 8 (Statement 17.5). (S166-67).

94. In still another example, a recommendation was made before complete evidence was available to support it. In an email regarding the sexual health chapter, cc'd to sexualhealthosc8@wpath.org, the author wrote: "The section at the end supporting the recommendation is work in progress, still finding literature" (BOEAL_WPATH_046248) (emphasis mine).

95. The modifications to this chapter and the previous examples show that the SOC 8 did not accurately reflect the evidence base and that its authors knew that. WPATH claims that the Standards of Care 8 recommendations were grounded in evidence-based medicine and that the studies which they relied upon are of high quality evidence, but the authors knew this was not true. I discuss the possible reasons for this deception later in this report.

IV. SOC 8's Use of Studies Associated with Youth Suicides

96. One study author, WPATH member and President-elect of USPATH[15] Johanna Olson-Kennedy, was referenced nearly a dozen times in the SOC 8 for her work with GAT in adolescents. In an interview with PBS news hour, Olson-Kennedy related that "[w]ithout support and [gender affirmative] treatment,...trans kids are a risk for almost everything: depression, self

[15] USPATH Board of Directors, https://www.wpath.org/uspath.

harm, substance abuse, homelessness, HIV and suicide." (PBS News Hour, 2016) (emphasis mine). Elsewhere, Olson-Kennedy described GAT treatments, including hormones and surgeries, like this: "Many of my patients have described the opportunity [to undergo GAT] to align their physical body with their gender as life-saving." (Olson-Kennedy Expert Affidavit, Loe v. Texas, Para. 61) (emphasis mine). In an expert report she stated, "The denial of gender-affirming care, on the other hand, is harmful to transgender people. It exacerbates their dysphoria and may cause anxiety, depression, and suicidality, among other harms."[16] (Olson-Kennedy report, Van Garderen v. MT, Para. 75) (emphasis mine).

97. In my prior report, I wrote about my grave concerns about this author's claims because of her unethical study involving adolescents, as young as age 13 and 14, receiving mastectomies for gender dysphoria.[17] (Laidlaw 2023, ¶¶ 209-12, 230-35). Mastectomy surgery is an irreversible procedure after which the patient is unable to regain the ability to breast feed. In my professional opinion, minors lack the maturity, life experience, and capacity of good judgment for truly informed consent for this life altering procedure.

98. My colleague and I wrote a letter to the Inspector General of Health & Human Services in 2019 recommending an investigation of Olson-Kennedy's mastectomy study. Among the many concerns we described, we stated, "it would seem that the authors were anxious to get a study published in the literature in order to insure that surgeons would be reimbursed for the resection of the healthy breasts of minor girls." (Laidlaw Horvath 2019). This compulsion to help ensure medical necessity for reimbursements is a theme in the creation of the SOC 8, as I will

[16] One WPATH member described the issues with the claim that GAT improves mental health: "Interesting but highlights the difficulty in picking an endpoint for therapeutic efficacy and use of early puberty blockade—is it... A. Reduction in suicidality? Difficult to prove B. Improvement in psychosocial functioning? Easier to prove but at what cost.... As we learn more about the difficulties associated with confirming surgeries, adulthood and longterm happiness." (BOEAL_WPATH_064859).

[17] The study is titled "Chest Reconstruction and Chest Dysphoria in Transmasculine Minors and Young Adults Comparisons of Nonsurgical and Postsurgical Cohorts" (Olson-Kennedy, 2018). There are a number of serious problems with this study. First, the term "chest dysphoria" is a creation of the study authors and is not found as a diagnosis or even referenced in the DSM-5. Second, the "chest dysphoria scale" is a measuring tool created by the authors, but which the authors state "is not yet validated." (Id., p. 435). Third, the mastectomies were performed on girls as young as 13 and 14 years old, who necessarily lacked the maturity and capacity of good judgment for truly informed consent for this life altering procedure. For this reason, in my professional opinion, the research and surgeries performed were flawed and unethical.

describe later in this report. Note also that the mastectomy study was published in 2018. The SOC 8's original minimum age for mastectomy (before deleting the age minimums, as I will also later discuss) was 15. So even compared to the majority of experts who developed the SOC 8, Olson-Kennedy was more extreme with respect to being willing to advise performing irreversible surgeries on minors.

99. I am also deeply concerned because of Olson-Kennedy's multi-year, NIH funded study involving youths taking opposite sex hormones. In a 2017 progress report to NIH, Olson-Kennedy disclosed that she and her team of researchers reduced the age-minimum criteria for youths taking opposite sex hormones as part of the study from thirteen to eight. (HHS-0162821). Reducing the age minimum so that children as young as eight years old could be included in the study to take opposite sex hormones and undergo irreversible bodily changes is an indicator of the extreme nature of Olson-Kennedy's research.

F.2 ACTUAL OR ANTICIPATED CHALLENGES OR DELAYS AND ACTIONS OR PLANS TO RESOLVE THEM

In order to completely capture the impact on all youth undergoing treatment with GnRH agonists, recruitment will be expanded to include those youth in Tanner 4 of development. In addition, the minimum age for the cross-sex hormone cohort inclusion criteria was decreased from 13 to 8 to ensure that a potential participant who could be eligible for cross-sex hormones based on Tanner Staging would not be excluded due to age alone. The Principal Investigators assert that this will not impact the data analysis and results of the research study.

(HHS-0162821).

100. Another indicator came in 2023, when, contrary to Olson-Kennedy's claims that GAT is "life-saving," her team disclosed in the New England Journal of Medicine that two deaths by suicide were associated with the study. (Chen at al., 2023). Two preliminary articles about this study are a part of the evidence base of SOC 8.[18] Stunningly, rather than describe important medical information related to these deaths in the published study so that fatalities could be

[18] They are referenced in SOC 8 as:
Olson-Kennedy, J., Chan, Y.-M., Garofalo, R., Spack, N., Chen, D., Clark, L., Ehrensaft, D., Hidalgo, M., Tishelman, A., & Rosenthal, S. (2019). Impact of early medical treatment for transgender youth: Protocol for the longitudinal, observational Trans Youth Care Study. JMIR Research Protocols, 8(7), e14434. https://doi.org/10. 2196/14434
and
Chen, D., Abrams, M., Clark, L., Ehrensaft, D., Tishelman, A. C., Chan, Y.-M., Garofalo, R., Olson-Kennedy, J., Rosenthal, S. M., & Hidalgo, M. A. (2021). Psychosocial characteristics of transgender youth seeking gender-affirming medical treatment: Baseline findings from the trans youth care study. Journal of Adolescent Health, 68(6), 1104–1111. https://doi.org/10.1016/j.jadohealth.2020.07.033.

understood and prevented, the authors chose to conclude that GAT improved psychosocial functioning. (Id.)

101. One wonders how this allegedly "life saving" treatment can be associated with two deaths in a study population of only a few hundred young people. Nevertheless, an NBC News headline from January 2023 claimed, "Hormone therapy improves mental health for transgender youths, a new study finds." (NBC News, 2023). Medpage Today's headline claimed: "Gender-Affirming Hormones Boost Mental Health for Transgender Youth." (Medpage Today, 2023). It appears that Olson-Kennedy's attempt to "flip the script" has led to confusion in the public by making headlines that high-dose hormones improved overall mental health when two youths actually died.

102. Because of the powerful effects of high doses of opposite sex hormones on the human mind (as seen in studies of anabolic steroid abuse), including by inducing problems with mood disorders and even psychosis, it is of the utmost importance that any deaths that occur in a GAT study receive a thorough medical investigation.[19] For example, one should expect to know the age and sex of the patients, blood levels of hormones both preceding and after death, psychotropic medications taken (if any), other psychiatric treatments and hospitalizations, other medical and psychiatric history, and to review autopsy reports.

103. My colleagues and I wrote a letter about this study as well in 2019 to the Office for Human Research Protections of the Department of Health and Human Service. (HHS-0029070). In our letter we concluded, "Because this study poses irreversible medical harms (including infertility) to children, we request an immediate moratorium and investigation." (Id.)

[19] Anabolic steroid abuse has been shown to predispose individuals toward mood disorders, psychosis, and psychiatric disorders. The "most prominent psychiatric features associated with AAS [anabolic androgenic steroids, i.e., testosterone] abuse are manic-like presentations defined by irritability, aggressiveness, euphoria, grandiose beliefs, hyperactivity, and reckless or dangerous behavior. Other psychiatric presentations include the development of acute psychoses, exacerbation of tics and depression, and the development of acute confusional/delirious states." (Hall, 2005). Moreover, "[s]tudies... of medium steroid use (between 300 and 1000 mg/week of any AAS) and high use (more than 1000 mg/week of any AAS) have demonstrated that 23% of subjects using these doses of steroids met the DSM-III-R criteria for a major mood syndrome (mania, hypomania, and major depression) and that 3.4% — 12% developed psychotic symptoms." (Hall, 2005).

104. Unfortunately, our concerns were dismissed. In a response letter from Diana W. Bianchi, M.D., Director of the NIH's National Institute of Child Health and Human Development, she wrote: "Notably, these research participants and their parents sought and obtained the hormonal therapies independent of the protocol. Therefore, termination of the protocol would not end the treatments; rather, it would only end the compilation of data needed to advance scientific understanding of the risks and likely outcomes of those treatments." (HHS-0028603). Furthermore, as part of the rationale for the HHS's decision, Dr. Bianchi looked to the Endocrine Society Guideline (ESG) of 2017 (of which nine out of ten authors of the Endocrine Society Guideline were members of WPATH or worked on WPATH's scientific committees)[20] as supporting their determination not to issue a moratorium. She stated that "[p]hysicians at the funded academic centers follow current guidelines for the therapy of trans gender youth," and referenced the 2017 ESG as apparently a justification for continuing the unethical study. This was in spite of the fact that the ESG stated in its disclaimer that their "guidelines cannot guarantee any specific outcome, nor do they establish a standard of care." (Hembree et al, 2017, p. 3895).

105. Subpoenaed documents from HHS discuss only one of the two deaths. Dr. Olson-Kennedy wrote to the NIH's Lisa Freund: "On 11/21/17 I was notified that a study participant died by suicide [redacted]. She continued: "Dr. [redacted] and he deemed that the death by suicide was not related to the study and was due to an underlying psychological condition." (HHS-0162852).

106. Rather than investigating further, the death was dismissed with the alleged justification being "[t]his is not a clinical trial and the IRB [redacted] determined this was not related to the study." (Id.). Dr. Bianchi never informed the public about the 2017 death by suicide in her HHS response letter.

107. Part of the problem with the response letter from Dr. Bianchi is that she and HHS have wrongly separated the gathering of the study participants' data from the underlying treatments. Dr. Bianchi wrote, "Notably, these research participants and their parents sought and obtained the hormonal therapies independent of the protocol. Therefore, termination of the protocol would not end the treatments; rather, it would only end the compilation of data needed to advance scientific understanding of the risks and likely outcomes of those treatments." (HHS_0028603). Dr. Bianchi makes a distinction without a difference. It is simply not possible to

[20] See additional information in my May 19, 2023 report Section III.A.2.

gather research data without study participants. The NIH is culpable of funding unethical research by virtue of the fact the research gathers data from the unethical treatments of minors.

108. The first principle of the Nuremberg code, a document pertaining to the ethical principles of human research, states, "The voluntary consent of the human subject is absolutely essential. This means that the person involved should have legal capacity to give consent; should be so situated as to be able to exercise free power of choice, without the intervention of any element of force, fraud, deceit, duress, overreaching, or other ulterior form of constraint or coercion; and should have sufficient knowledge and comprehension of the elements of the subject matter involved as to enable him to make an understanding and enlightened decision." (Shuster, 1997).

109. I contend that the underlying treatments in Olson-Kennedy's study are unethical due to the minor participants being unable to give proper informed consent or assent for health risks such as infertility and death because of their age and immaturity. The parents also cannot provide informed consent on behalf of their children as they have often been coerced by the fear that their child might be suicidal (as per Olson-Kennedy) without such treatment. Neither the child nor the parents "have sufficient knowledge and comprehension of the elements of the subject matter involved as to enable him to make an understanding and enlightened decision" because of the dearth of available long-term evidence (or even basic animal studies) with respect to the hormonal and surgical treatments. It follows that if the underlying treatments are unethical, then the gathering of data from such a study is also unethical. Therefore, the NIH has funded and continues to fund unethical research with respect to this study.

110. [redacted]

111. [redacted]

[redacted]

112. I have not seen any documents related to the second suicide death in the Olson-Kennedy study, but I remain deeply concerned that high dose hormones may have contributed to the deaths of these two youths. There appears to be an unwillingness on the part of HHS to investigate the ethical and potential legal problems with this study further or to intervene to prevent further medical harms. This is not surprising given the close relationship between some members of HHS and WPATH, as will be discussed later in this report.

113. To summarize, in my opinion, the SOC 8 has relied on unethical research in which permanent harms have occurred to minors who were not of sufficient age to consent or assent to the body and mind-altering medications and medical procedures that are an integral part of GAT. The research, rather than proving with long term data that GAT is safe for minors, instead raises serious concerns about the possibility of lifelong regret due to irreversible procedures, and the possibility of mental health deterioration and death associated with high dose opposite sex hormones.

V. Political Influence on SOC 8

114. In the following I will examine how WPATH authors included, excluded, and altered content in the SOC 8 based on obvious political considerations rather than evidence-based scientific considerations. Specifically, I will discuss how the SOC 8 were designed to support insurance coverage for GAT medications and procedures and also to be used as a "tool" in litigation. I will also detail how the heavy political influence on the SOC 8 creators culminated in the age recommendations to be first downgraded to suggestions and then deleted altogether.

A. Medical Necessity

115. In general, any medication, office visit or surgical procedure in the United States needs to be paid for in some manner, and these costs may be substantial. Payers may include insurance companies, government agencies, individuals, or some combination of the three. Particularly for gender affirmative therapy, medications such as puberty blockers or surgical procedures can be very costly. Insurance companies follow a concept called "medical necessity" to determine if a particular medication or procedure has a sufficient benefit to risk ratio compared to the cost in order to justify their coverage. Government entities make similar evaluations.

116. Generally, to establish medical necessity, there must be sufficient published medical research ensuring scientific validity with respect to safety and efficacy.[21] Clinical guidelines may assist insurers and government agencies to know which medications and procedures provide the highest benefit to cost ratio with the minimum risks. As healthcare funds are not infinite, crucial decisions need to be made with respect to coverage.

117. Naturally, the production of clinical guidelines could be slanted and biased in such a way as to convince insurance companies and government entities that particular medications and procedures should be covered. In my opinion, a review of the SOC 8 and the emails and comments regarding its development show this to be the case with SOC 8.

118. An internal WPATH email dated Aug 26, 2021 and cc'd to mentalhealthsoc8@wpath.org stated:

> I hope SOC 8 can incorporate some language about medical necessity for insurance coverage or governmental provision of care. This was an omission in SOC 7 and the WPATH Board had to release a separate Medical Necessity Statement

[21] Alabama's Medicaid Provider Manual defines medical necessity as: any health care service, intervention, or supply (collectively referred to as 'service') that a physician (or psychologist, when applicable), exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing, or treating an illness, [including mental illnesses and substance use disorders], injury, disease, condition, or its symptoms, in a manner that is:

- in accordance with generally accepted standards of medical practice;
- • clinically appropriate in terms of type, frequency, extent, site and duration, and considered effective for the patient's illness, injury, disease, or condition;
- in accordance with medical necessity 'guidelines/references' in Agency's Administrative Code, State Plan, and Provider Manual;
- not primarily for the convenience of the patient or Provider;
- not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury, disease, or condition.
- the service is not contraindicated; and
- the Provider's records include sufficient documentation to justify the service. For these purposes, "generally accepted standards of medical practice" means:

• Standards that are based on credible scientific evidence published in peer reviewed medical literature generally recognized by the relevant medical community are required when applicable; or

- Alternatively, may consider physician specialty society recommendations [clinical treatment guidelines/guidance] and/or the general consensus of physicians practicing in relevant clinical areas."

(National Academy for State Health Policy, 2021) (emphasis mine).

> afterwards. I do independent medical reviews for people appealing their insurance denials to state regulatory bodies and clear language is important for this. The State of California at least looks to WPATH as the authority for determining medical necessity, and this is critical for facial feminization surgery especially, but coverage of any needed surgery, so the language is important. We don't want SOC 8 to take us backwards on this.

(BOEAL_WPATH_020166) (emphasis mine).

119. The email reply is in agreement, even going so far as to say it would be easy to simply "put it through Delphi very quickly (no one is going to disagree with it)" in order to incorporate it as a part of SOC 8. (BOEAL_WPATH_020279).

120. On August 27th, 2021, an email discusses incorporating a medical necessity statement for minors: "On a related note, medical necessity for youth care-- puberty blockers and chest surgery for transmasculine youth-- is often challenged by US insurance companies. I wonder whether [redacted] and the Adolescent committee might consider adding a medical necessity statement for care for minors?" (BOEAL_WPATH_020279).

121. An email from Jan 25, 2022, indicates that progress was made with respect to the goal of generating a medical necessity statement and that it could be quickly published: "I am pleased to hear the medical necessity statement is being updated...I am happy to publish this medical necessity statement separately in IJTH—that will take only a few weeks and then it can be added to the SOC8 as an appendix." (BOEAL_WPATH_036391)

122. On Jan 6, 2022, a WPATH email stated: "I had a first stab at re-drafting a Medical Necessity Statement...Would you be interested in helping make a final draft, which we can then run past the Board of Directors and SOC8 Chair and Co-Chairs please...let's get this done ASAP." (BOEL_WPATH_037203).

123. Initially, the thought was to try to publish the statement of medical necessity in the International Journal of Transgender Health (IJTH), which wasn't considered to be difficult:[22] "Once everybody is happy with it [the draft], I can publish it in IJTH - that should take no longer than 1 week." (Id.)

[22] One likely reason that publishing in the International Journal of Transgender Health (IJTH) was not deemed to be a difficult or long process (unlike most journal article submissions) is that SOC 8's lead author, Eli Coleman, is a cofounding editor, and because WPATH is the IJTH's "partner organization." (IJTH Editorial Board; IJTH Journal Overview).

124. A follow up email shows that authors even developed a statement to be easily put through the Delphi process: "We had a meeting yesterday with the chairs and decide that we need to create a recommendation for medical necessity that goes through delphi and is approved by everyone. It is then in the SOC-8 as a recommendation, possible in the introduction as the first recommendation. So far we have this. We recommend that healthcare systems should provide medically necessary gender affirming psychological, medical and surgical treatments for trans and gender diverse children, adolescents and adults." (BOEL_WPATH_037201).

125. A decision was made to include the statement directly into chapter two of SOC 8 entitled "Global Applicability." The published statement reads: "2.1- We recommend health care systems should provide medically necessary gender-affirming health care for transgender and gender diverse people." (Coleman et al., 2023). Note again that, according to WPATH's methods, any statement beginning with "We recommend" is supposed to be backed by strong evidence. However, as in the rest of SOC 8, no grading of evidence was provided. In spite of this reluctance to provide evidence, a fairly comprehensive list of possible procedures and medical treatments for GAT are included in the published chapter: "Medically necessary gender-affirming interventions are discussed in SOC-8. These include but are not limited to":

> hysterectomy +/- bilateral salpingo-oophorectomy; bilateral mastectomy, chest reconstruction or feminizing mammoplasty, nipple resizing or placement of breast prostheses; genital reconstruction, for example, phalloplasty and metoidioplasty, scrotoplasty, and penile and testicular prostheses, penectomy, orchiectomy, vaginoplasty, and vulvoplasty; hair removal from the face, body, and genital areas for gender affirmation or as part of a preoperative preparation process; gender-affirming facial surgery and body contouring; voice therapy and/or surgery; as well as puberty blocking medication and gender-affirming hormones; counseling or psychotherapeutic treatment as appropriate for the patient and based on a review of the patient's individual circumstances and needs.

(Coleman et al., 2022, s18). This blanket statement is obviously unscientific. In one fell swoop, the vast majority of types of procedures and medical treatments in GAT were given a strong recommendation without regard to supporting evidence and without regard for the age of the persons receiving such treatments.

126. This appears to be a blatant attempt to ensure that every type of medication or procedure that WPATH proposed would be covered by private and government health plans or by socialized health systems outside of the United States.

B. The Standards of Care 8 were Written as Protection from Litigation

127. Closely tied to medical necessity is WPATH's perceived need to ensure victories in lawsuits involving their comprehensive list of treatments just listed. This is made abundantly clear in email communications.

128. From a WPATH email in late August of 2021: "The concept of medical necessity is so critical for provision of healthcare to trans people in the US[.]" "There are important lawsuits happening right now in the US, one or more of which could go to the Supreme Court, on whether trans care is medically necessary vs experimental or cosmetic. I cannot overstate the importance of SOC 8 getting this right at this important time." (BOEAL_WPATH_020273) (emphasis mine).

129. In a WPATH email from early January of 2022, the author wrote that "we needed a tool for our attorneys to use in defending access to care here. I have long wanted this (and many of our other policy statements) to become part of the SOC because that gives them greater force." (BOEAL_WPATH_037220) (emphasis mine).

130. On May 2, 2022, a WPATH author wrote that "[e]stablishing medical necessity is central to all healthcare provision in the US—and currently there are lawsuits in the US trying to reverse the provision of trans healthcare by asserting that it is categorically not medically necessary." (BOEAL_WPATH_061843).

131. There was also concern that using accurate language in SOC 8 to describe the paucity of evidence in this field would affect the legal outcome of cases in the United States: "I am concerned about language such as 'insufficient evidence,' 'limited data,' etc. … I say this from the perspective of current legal challenges in the US."

> 1. I am concerned about language such as "insufficient evidence," "limited data," etc...I say this from the perspective of current legal challenges in the US. Groups in the US are trying to claim that gender-affirming interventions are experimental and should only be performed under research protocols (this is based on two recent federal cases in which I am an expert witness). In addition, these groups already assert that research in this field is low quality (ie

(BOEAL_WPATH_020387).

132. The authors went as far as to recommend a legal review of SOC 8 before publication to help with litigation: "My thoughts are to ask for a legal (broad) review regarding basic human rights...and then have a global open, on-line consultation period for a few weeks...and then - assuming there are no very contentious issues emerging - move to publish." (BOEAL_WPATH_019432). One reply is in agreement regarding SOC content, "[W]e will have

to argue it in court at some point. We should know what those potentially problematic items are before we publish." (BOEAL_WPATH_019432).

133. There is even a concern in one response that a similar process did not take place before the Endocrine Society's guideline publication: "I don't recall Endocrine Guidelines going through legal review before publication." (BOEAL_WPATH_019430).

VI. On the Removal of Ages Minimums for GAT Treatments for Minors

134. The single most telling act on the part of leadership of the WPATH Standards of Care 8 that shows that prioritizing advocacy efforts with respect to medical necessity, minimizing litigation, and advancing their political cause over ensuring the health and safety of minors was the last-minute decision to remove the age minimums for medications and surgeries for minors receiving GAT.

135. In a correction to the SOC 8, recommendations for minimum age of opposite sex hormones were removed (Correction IJTH, 2022).[23] Nearly all recommendations for minimum age of surgery were also removed, meaning a minor of any age could be referred for nearly any of the GAT surgeries listed previously (Id.)[24]

136. The correction reads: "On page S258, the following text was removed: 'The following are suggested minimal ages when considering the factors unique to the adolescent treatment time frame for gender-affirming medical and surgical treatment for adolescents, who fulfil all of the other criteria listed above. – Hormonal treatment: 14 years – Chest masculinization: 15 years – Breast augmentation, Facial Surgery: 16 years – Metoidioplasty, Orchiectomy, Vaginoplasty, – Hysterectomy, Fronto-orbital remodeling: 17 years – Phalloplasty: 18 years" (WPATH SOC 8 Correction, p. S261).

137. Of great concern is that the minimum age recommendations were deleted in contradiction to the recommendation of their own expert consensus: "On page S66, the following text was removed: 'Age recommendations for irreversible surgical procedures were determined by

[23] The correction notice has since been removed from the International Journal of Transgender Health. (Statement of Removal (2022), International Journal of Transgender Health, 23:sup1, S259, DOI: 10.1080/26895269.2022.2125695.)

[24] The authors left one caution about phalloplasty surgery in the published text: "Given the complexity of phalloplasty, and current high rates of complications in comparison to other gender-affirming surgical treatments, it is not recommended this surgery be considered in youth under 18 at this time." (Coleman et al., 2022, p. S66)

a review of existing literature and the expert consensus of mental health providers, medical providers, and surgeons highly experienced in providing care to TGD adolescents.'" (WPATH SOC 8 Correction, p. S260) (emphasis mine).

138. One of the key figures involved in removing the age minimums in the SOC 8 was Admiral Rachel Levine of HHS. A WPATH email dated August 12, 2021 reveals the political pressure on WPATH as it tried to publish SOC 8: "I just got off a very productive call with Rachel Levine. The failure of WPATH to be ready with SOC 8 is proving a barrier to optimal policy progress and she was eager to learn when SOC 8 might be published." (BOEAL_WPATH_018924). The person who met with the Admiral explained that WPATH had received "a charge from the United States government to do what is required to complete the project immediately." (Id.) (emphasis mine).

139. A WPATH email dated a week later reiterates the pressure: "I am meeting with Rachel Levine and her team next week, as the US Department of Health is very keen to bring the trans health agenda forward." (BOEAL_WPATH_019314).

140. According to the WPATH's Executive Committee minutes of Sep 1, 2021, Admiral Levine "offered to help WPATH in any way she could," including by (1) helping with either a SOC 8 White House launch or, if not possible, then a launch at the Department of Health and Human Services and (2) "mak[ing] an introduction to WHO and suggest[ing] they endorse/ratify SOC8." Admiral Levine was also "invited to be the Keynote Speaker for WPATH 2022 in Montreal." (BOEAL_WPATH_020658).

141. Another email from Oct 27, 2021 discusses that someone with ties to the "US State Department for Health" wanted to ensure SOC 8 gets published and is used in "national policies": "[We] are in regular contract with [redacted] who has taken a personal interest in ensuring that the SOC8 gets completed and published at the earliest convenience, so that the US State Department for Health can use the SOC8 for its national policies." (BOEAL_WPATH_023924).

142. According to a Nov 11, 2021, WPATH email: "funding for the dissemination of SOC8 in North America and beyond" was discussed with Admiral Levine. Admiral Levine also accepted the invitation "to give the plenary lecture" on the opening day of the WPATH symposium in Montreal and "would explore the option of a White House launch," and if that was not possible "promise[d] to have the launch at the State Department for Health." (BOEAL_WPATH_026664).

143. In a WPATH email from Apr 24, 2022, the author wrote: "Let's get going with finalizing the SOC8...I have just spoken to Admiral Levine today, who—as always is extremely supportive of the SOC8, but also very eager for its release—so to ensure integration in the US health policies of the Biden government. So, let's crack on with the job!!!" (BOEAL_WPATH_061521).

144. In a May 2022 email, a Fox news reporter made an inquiry to WPATH about Admiral Levine's statement suggesting that there "is no argument" among medical experts regarding GAT for young people. (BOEAL_WPATH_062621). One email author admitted internally in WPATH that "there is a subtlety" not present in Admiral Levine's argument that the outlet "would love to hear." Another email respondent replied: "I would also not do anything to debate what Dr. Levine has said, she's our best cheerleader." Another contributor agreed with that sentiment, suggesting that WPATH "[a]bsolutely not" engage with the report because "[w]e can regain the narrative later in other ways, not undermining her [Admiral Levine's] credibility."

145. In a May 31st, 2022, WPATH email, the author wrote, "[W]e count on you as a US Department for Health to assist us to disseminate the SOC8 as widely as is humanly possible in North America." (BOEAL_WPATH_062943).

146. It is clear that WPATH was relying on Admiral Levine (and by extension HHS) to partner with it in several important ways WPATH leaders deemed crucial with respect to the advocacy, publicizing, and legitimizing of SOC 8. I believe that this dependence on the assistance and approval of Dr. Levine led to WPATH's decision to initially alter the language regarding minimum age requirements for GAT for minors against the recommendations of WPATH SOC 8's own expert opinion.

147. In a July 2022 email entitled, "Some Feedback from Member of Adm Levine's Staff," the author wrote: "I just got off the phone with Sarah Boetang [*sic*] who is Adm Levine's chief of staff." With respect to Ms. Boateng's opinion regarding age minimums, the email author writes that "these specific listings of ages, under 18, will result in devastating legislation for trans care. She [Ms. Boateng] wonders if the specific ages can be taken out." (BOEAL_WPATH_071455).

148. It seems there was internal debate amongst WPATH members regarding this consideration. One author in favor of keeping at least some age minimums did not seem to take the safety, efficacy, and evidence into account for keeping the age minimums, but rather insurance

coverage, writing: "My concern…is that without specific age requirements, insurers may not grant authorization." (BOEAL_WPATH_071457).

149. The debate about how to handle Dr. Levine's recommendation continued. In a WPATH email dated July 1, 2022, the author wrote about several concerns: how to ensure that insurance companies cover treatments for those under 18 years old; how to delete the age minimums from the SOC 8 final without putting these major changes back through the Delphi process; wishing that Admiral Levine's office had read the age minimums earlier in December so that they could presumably collaborate on what they considered to be the best age minimums; and concerns about the "messaging and marketing" of SOC 8. The author wrote: "If we don't put ages, the insurance companies specify 18 years old, hence the main reason to list the ages. I don't see how we can simply remove something that important from the document—without going through a Delphi—at this final stage of the game. I wish that Adm Levine's office read this when they were posted for public review in December.… We should be focusing on all the criteria, and then after that can say 'after meeting all of these strict criteria, kids need to be of X age to access X treatment.' It's all about messaging and marketing." (BOEAL_WPATH_071466).

150. In another email, it seems that at least one WPATH member was ready to reject this major change, stating "[I] just read the email trail, which I found disturbing for a number of reasons.… It is not appropriate to take any feedback from a nonmedical professional seriously. Nothing is going to change in the SOC8. It is done!" (BOEAL_WPATH_071476).

151. In a July 29th, 2022 email, the author writes about the age minimums, stating that Admiral Levine "asked us to remove them." (BOEAL_WPATH_ 072114). The author goes on to explain the close communication between the WPATH's executive committee and Admiral Levine, being in the same meeting, and how they could alter the SOC 8 at a late stage to please Dr. Levine and HHS: "We have the WPATH executive committee in this meeting and we explained to her that we could not just remove them [the age minimum] at this stage. So we have been thinking of solutions. You may remember that ages in the document were a 'suggestion' not a 'recommendation' as we had no evidence to recommend that, but in the document it has become a 'recommendation' as it is part of the criteria. What is clear is that we don't want to remove the ages from the whole document." (Id.) (emphasis mine).

152. In an internal WPATH discussion, a workgroup member voiced concern about how this change would undermine WPATH's statements about SOC 8's methodology. The member

wrote that if they make such a change then "we can never say that the adolescent chapter passed through Delphi." (BOEAL_WPATH_072147-49). From the communications it appears that politics were the overriding consideration, not scientific and intellectual rigor or the best interests of children and adolescents:

> *recommendation with room for adjusting in unique circumstances? I need someone to explain to me how taking out the ages will help in the fight against the conservative anti trans agenda. Maybe I'm missing something.*

(BOEAL_WPATH_072148) (highlighting mine).

> *My understanding is that the suggestion from the chairs is to leave the ages in but have them as suggestions and not criteria/recommendations for start of treatment? That seems like an ok compromise to me.*
>
> *I agree that changing to "suggest" is a good compromise. And yes, it is frustrating to have to have politics in our brains as we make these decisions. But it is what it is!*

(BOEAL_WPATH_072149) (highlighting mine).

153. It seems that Admiral Levine and staff were ultimately successful in persuading WPATH to change recommendations regarding age minimums in the SOC 8 to suggestions. In a WPATH email from August 2022 the author wrote, "Given that the recommendations for minimal ages for the various gender affirming medical and surgical evidence are consensus based, we could not remove them from the document. Therefore we have made changes as to how the minimal changes are presented in the document. They are now not a recommendation from the SOC-8 anymore, but they have been written only as suggested minimal ages." (BOEAL_WPATH_072964).

154. Admiral Levine and HHS departmental staff were successful in making a substantial change to the SOC 8 document. However, it was ultimately a threat from a medical/political organization, the American Academy of Pediatrics, to remove its endorsement that was the proverbial straw to break the camel's back. This political threat caused WPATH to make the drastic, last-minute change to their SOC 8 document with respect to minors against the advice of their own expert's recommendations.

155. On Sept 9, 2022, in a WPATH email, the author wrote: "The American Academy of Pediatrics (AAP) – a MAJOR organization in the United States that is typically very pro-transhealth/gender affirming care- voiced its opposition to the SOC8, specifically due to aspects of the Adolescent chapter. Not only did they say they would not endorse the SOC, they indicated

that they would actively publicly oppose it. They had several concerns, one of which was the age criteria for minors (they believe that surgery of any type should not happen until the patient is age of majority).… Clearly, if AAP were to publicly oppose the SOC 8, it would be a major challenge for WPATH, SOC8, and trans youth access to care in the U.S." (BOEAL_WPATH_079974) (emphasis mine). It goes on to say that an "urgent taskforce" was being assembled to decide next steps.

156. Admiral Levine's opinion and influence continued to be a factor leading to a delay in the release of SOC 8. In another WPATH email from the same day, the author states, "I also want to inform you that I am going to inform the entire WPATH Board of Directors as to why the SOC8 online publication has been halted since [redacted] spoke to Rachel Levine last Saturday." (BOEAL_WPATH_080018). There is also an admission that to change the SOC 8 based on the AAP's opinions would be against their own process, procedure, and methodology. (Id).

157. Finally, after a meeting with the AAP's Jeff Hudson, and a WPATH internal meeting, WPATH made a decision to remove the age minimums for children and adolescents against the advice of their own experts. A September 10th, 2022 WPATH email reads: "Dear jeff [Hudson of AAP]: … We have just finished our meeting and we have agreed to remove the ages and to add the sentence we agreed. I hope that by doing this AAP will be able to endorse the SOC8 or at least to support it." (BOEAL_WPATH_ 080863).

158. There can be no doubt that the WPATH first altered the SOC 8's age minimums for youths because of the political opinion of their "biggest cheerleader" Admiral Rachel Levine and HHS staff, not because of a shift in the scientific evidence that necessitated the last-minute change. It is also clear that the age minimums for GAT hormones and surgeries were ultimately removed entirely because of political pressure from the influential US medical/political organization the AAP.

159. These actions by WPATH contradict Admiral Levine's statement that the SOC 8 "is free of any agenda other than to ensure that medical decisions are informed by science." (Levine, 2022). And these actions and the preceding examples of modifying the SOC 8 to put it in the best possible light belie lead author Eli Coleman's claim that SOC 8 "uses an enhanced evidence-based approach to include recommendations intended to optimize patient care that are informed by a systematic review of evidence and an assessment of the benefits and possible harms of alternative care options." (WPATH FAQ).

VII. Conclusion

160. In my opinion, the SOC 8 document along with the subpoenaed WPATH and HHS communications make it abundantly clear that WPATH prioritized their advocacy efforts with respect to medical necessity, minimizing litigation, and advancing their political cause over ensuring the health and safety of minors.

161. In addition, the decision to remove age limits was not merely done in opposition to WPATH's own experts, but also because of external political pressure on the part of United States government officials and a medical organization with a political agenda to advance GAT for minors despite the paltry evidence base and considerable risks to the developing bodies and minds of children and adolescents.

162. For these reasons, the SOC 8 do not represent high-quality, evidence-based medical guidelines, but are instead a prime example of activist-based recommendations for this condition.

163. I have written in my prior report and stand by my opinion that WPATH SOC 8 represents a grave and immediate danger to minors, young adults, and adults. It should not be followed by any physician, mental health care provider, or other medical professional.

Executed February 2, 2024

_____
Michael K. Laidlaw, M.D.

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Good afternoon members of the committee, my name is Indra Lusero, I am an attorney and nationally recognized expert on human rights during pregnancy and birth. I am the founder and director of Elephant Circle. We are asking for your yes vote on Senate Bill 129.

At Elephant Circle we field calls from people in the perinatal period all over Colorado and the country, through our network we have heard from thousands. People are being turned away when seeking emergency care, yes, even in Colorado. People are being denied care they need. People are coming to Colorado specifically to flee hostile places. People are being targeted and discriminated against in the perinatal period, related to their own reproductive health care decisions or those of people they love. And the people we hear from come from all walks of life, including religiously conservative, anti-abortion, and apolitical.

We are in favor of this policy because at its core this bill is about infrastructure for support. Humans, like the elephants who inspire us, need a circle of support during the dynamic process that is the perinatal period.

Indeed, every human culture has this infrastructure. When my great grandmother was pregnant as a teenager in Huerfano county 125 years ago she had this infrastructure, if she faced a perinatal emergency she would call the midwife. And every community had their parteras and parteras were protected.

This infrastructure had pros and cons. Perinatal care wasn't political, it was private, and existed in a realm attuned to pregnancy as a process with multiple potential outcomes. But some communities had access to more and better tools, and some could be excluded and discriminated against.

This very local system was replaced in the middle of the last century with another kind of infrastructure: a specialized workforce, hospitals where anyone could go, and roads to get there. And this infrastructure was built with 28 billion dollars of public money so that everyone, regardless of resources, regardless of race, color, or creed could get care. The infrastructure also included laws and policies that account for differences between states and facilitate our freedom of movement across them, recognizing our interconnectedness.

Today we are at a crossroads with this infrastructure, it needs a 21st century update, not just to account for eroded local capacity, the need for midwives, or health industry fragmentation, but to account for the fact that the legal infrastructure itself is under attack and so are some of us.

People who are endeavoring to form a protective circle, as is our innate human drive, are at risk. They feel vulnerable personally, professionally, physically and economically. Which makes our infrastructure vulnerable too. This bill is part of creating the infrastructure for support that we need to confront the realities of today.

Submitted by:

Indra Lusero, Esq., Director at Elephant Circle
indra@elephantcircle.org, 303-902-9402

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WPATH muzzle Johns Hopkins researchers

In 2018, WPATH hired Johns Hopkins University researchers to conduct systematic evidence reviews. From the very beginning, WPATH sought to control Johns Hopkins, limit their academic freedom, and control what the public learned about the quality of evidence that exist in the field of gender medicine.

This control violates the editorial independence and fails to control biases and conflicts of interest. As a result, WPATH's clinical practice guidelines or "standards of care" cannot be trusted. Ideological, political and legal concerns were paramount, and not the medical and scientific evidence, nor the safety and well being of trans-identified youth.

This timeline describes WPATH control and corruption, citing what was discovered by the Alabama attorney general's office.

December 17, 2017

WPATH and Johns Hopkins University (JHU) are negotiating a contract for JHU to do systematic evidence reviews for WPATH's 8th version of their "Standards of Care." WPATH has promised the public and medical community that this 8th version will be the most evidence-based version.

Karen Robinson is the Director of JHU Evidence-based Practice Center. Donna Kelly is an executive with WPATH. This email is clear that from the outset WPATH wanted to have control over what JHU found and how that information would be disseminated

"Our board has very specific thoughts around having approval for all uses…"

From: Karen Robinson
To: Donna Kelly
Subject: RE: Any update?
Date: Thursday, December 21, 2017 9:25:00 AM

Donna --
I have asked for a contact at research office to review and provide advice on wording. We then may need to discuss on phone.
In general, my understanding is that the university will not sign off on a contract that allows a sponsor to stop an academic publication.
Also, just to be clear, the "data" we are talking about is our review of existing publications.
I will be back in touch when I have heard from lawyer on this end.
Thanks for your persistence in this, Donna!
Happy holidays and best wishes for a happy and healthy new year,
Karen

-----Original Message-----
From: Donna Kelly [mailto:donna@veritasmeetingsolutions.com]
Sent: Wednesday, December 20, 2017 5:29 PM
To: Karen Robinson < REDACTED
Subject: RE: Any update?

Thanks Karen.
Please define "other than for education, academic or research purposes" in 9.2.
Our board has very specific thoughts around having approval for all uses, they are not likely to want to grant use of the data for academic research purposes without approval of the context.
Happy to discuss this more by phone if that is easier.
Donna

August 31, 2020 – "no evidence about children and adolescents"

Two and a half years later JHU has completed all of the systematic evidence reviews for WPATH. This is an email from JHU's Karen Robinson to Dr. Christina Chang. Dr. Chang is with the Agency for Healthcare Research and Quality, which is an agency within Health and Human Services. Dr. Chang's webpage is no longer active on the AHRQ/HHS website, but here is an achieved version of it.

JHU's Karen Robinson says two very important things to AHRQ/HHS's Christine Chang.

From: Karen Robinson <krobin@jhmi.edu>
Sent: Monday, August 31, 2020 4:57 PM
To: Chang, Christine (AHRQ/CEPI) [redacted]; Ritu Sharma <rsharma6@jhu.edu>; Lisa Wilson <LisaWilson@jhmi.edu>
Subject: Re: Ongoing review on gender-affirming surgeries: duplication with EPC program nomination

Christine -

I'm sorry I failed to get back to you. I have been distracted and I am not sure what we will end up publishing in a timely manner as we have been having issues with this sponsor trying to restrict our ability to publish.

I don't think any of the planned manuscripts would be an overlap. This is not because the review questions were different but we found little to no evidence about children and adolescents.

1) **"we have been having issues with this sponsor (WPATH) trying to restrict out ability to publish."**

2) **"we found little to no evidence about children and adolescents.**

August 2020

These are 3 screen shots of the WAPTH policy created to restrict Johns Hopkins academic freedom and control what was published. It is clear that the "Aim of the Policy" is "for the benefit of advancing transgender health in a positive manner."

This policy violates the principles necessary for the development of trustworthy clinical practice guidelines. Guidelines must be based on 1) the best available evidence, and JHU researchers "found little to no evidence," and 2) transparency, which includes managing conflicts of interests and allowing for editorial independence. This policy injects conflicts of interest into the development process and imposes editorial control over JHU. The flow diagram shows that WPATH imposed control over the publication process at several steps.

WPATH
WORLD PROFESSIONAL ASSOCIATION FOR TRANSGENDER HEALTH

Policy & Procedures Regarding the Use of WPATH SOC8 Data
Revised August 2020

This policy will be shared with every SOC8 member in order to inform them of the process of SOC8 Data Use and to allow each SOC8 member to apply to access the existing SOC8 data as described below

Background to the Policy

In April 2018 WPATH commissioned John Hopkins University (JHU) to support the development of the 8th edition of the Standards of Care for the Health of Transsexual, Transgender, and Gender Nonconforming People (SOC8). WPATH entered into a Sponsored Research Agreement with John Hopkins University on behalf of its School of Medicine with Dr Karen A. Robinson, Director at JHU Evidence-based Practice Center as principal investigator in conducting the research for WPATH. WPATH contracted Dr Robinson and her team to perform systematic literature reviews and other activities to support the development of the 8th edition of SOC.

Aim of the Policy

WPATH commissioned and financed an update and the development of the SOC8 for the benefit of transgender healthcare in order to promote health, research, education, respect, dignity, and equality for trans people globally.

Therefore, the aim is of this policy is to develop and to describe a process to ensure that any manuscripts developed from the systematic literature reviews commissioned by WPATH benefit transgender healthcare and promote health, research, education, respect, dignity, and equality for transgender people globally.

A decision-making process to give access to the Data should be underpinned by a number of good practice directives. Hence, WPATH grants access to the data to any interested party, which:

a. has the intention to use the Data for the benefit of advancing transgender health in a positive manner and;
b. has the intention to publish the Data in reputable, academic, peer-reviewed journals and;
c. involves the Work Group Leader of the Chapter or, alternatively, a designated representative of that specific SOC8 Chapter, or alternatively the Chair or Co-Chairs of the SOC8 in the design, drafting of the article, and the final approval of the article and;

Pathway to approval for use of WPATH Data

WPATH grants approval to use the Data for publication to any interested party, when:

a. the directives outlined under the aim of this policy have been fulfilled and;
b. the author(s) have acknowledged that WPATH has sponsored the acquisition of the data in the publication and;
c. the author(s) have acknowledged that the authors are solely responsible for the content of the manuscript, and the manuscript does not necessarily reflect the view of WPATH in the publication and;
d. The publication ("manuscript") has been approved by WPATH via a designated approval process.

Designated approval process for publication of Data (see Figure 1)

Figure 1 - Designated approval process for publication of Data

October 20, 2020

John Hopkin's Karen Robinson complains directly to WPATH's executive committee (WPATH EC) and to Drs. Arcelus, Coleman and Radix. These three are the lead authors for SOC8.

She complains that JHU

1) "institutional policies on academic freedom and intellectual property prohibit such restrictions/approvals regarding publication"

   and

2) "We have the right to publish and any JHU publications arising out of the work conducted as part of this contract are not subject to approval of WPATH nor subject to any policy of WPATH."

She goes on to say that she has "made these statements several times in email and phone conversations, beginning when the contract was being negotiated in 2018."

The August 2022 WPATH policy that is mentioned directly above is what Karen Robinson is complaining about.

From: Karen Robinson
Sent: October 20, 2020 8:23 PM
To: WPATH EC <wpathec@wpath.org>; Jon Arcelus <Jon.Arcelus@nottingham.ac.uk>; Eli Coleman <dreli@umn.edu>; Asa Radix <asa.radix@gmail.com>; Blaine Vella <blaine@wpath.org>
Cc: Stephen Fisher REDACTED ; Stefanie Gregory REDACTED
Subject: FW: Letter from Your WPATH EC and SOC8 Co-Chairs - re: SOC8 Data
Importance: High

All –

I am concerned about this message sent to the members of SOC8 Working Group Members as it suggests that there continues to be incorrect interpretation regarding data ownership and publications. WPATH approval for our publications is not required under the terms of the agreement, the WPATH policy was not incorporated into the executed agreement so it is not binding on us, and the JHU institution policies on academic freedom and intellectual property prohibit such restrictions/approvals regarding publication.

It seems as though the misunderstanding may be based on the sentence in section 7 of contract that states that WPATH "retains the unrestricted right to use to Project Data … including the publication of the Project Data and the communication of Project Data to third parties." Retains the right is not the same as ownership, and it also does not preclude JHU from also having those same rights in the Project Data.

We have the right to publish and any JHU publications arising out of the work conducted as part of this contract are not subject to approval by WPATH nor subject to any policy of WPATH. We will continue to send draft manuscripts to WPATH for review and will give any comments received due regard.

I feel like I have made these statements several times in email and phone conversations, beginning when the contract was being negotiated in 2018. I suggest that a call might be useful and I have copied in individuals from our Office of Research Administration and Office of General Counsel.

Thanks,
Karen

Karen A. Robinson, PhD
Professor of Medicine, Epidemiology, and Health Policy & Management
Director, Johns Hopkins University Evidence-based Practice Center
Johns Hopkins University
REDACTED

September 15, 2022

WPATH SOC8 is released, and later that same day the "correction" is published that removes all age limits for youth transition. This is done for political and legal strategy. There is no evidence to support these ages limits to begin with, let alone evidence of support their removal, as JHU found "little to no evidence."

INTERNATIONAL JOURNAL OF TRANSGENDER HEALTH
2022, VOL. 23, NO. S1, S259–S261
https://doi.org/10.1080/26895269.2022.2125695

Correction

Article title: Standards of Care for the Health of Transgender and Gender Diverse People, Version 8

Authors: E. Coleman, A. E. Radix, W. P. Bouman, G. R. Brown, A. L. C. de Vries, M. B. Deutsch, R. Ettner, L. Fraser, M. Goodman, J. Green, A. B. Hancock, T. W. Johnson, D. H. Karasic, G. A. Knudson, S. F. Leibowitz, H. F. L. Meyer-Bahlburg, S. J. Monstrey, J. Motmans, L. Nahata … J. Arcelus

Journal: *International Journal of Transgender Health*

Bibliometrics: Volume 23, no. S1, pp. S1-S258

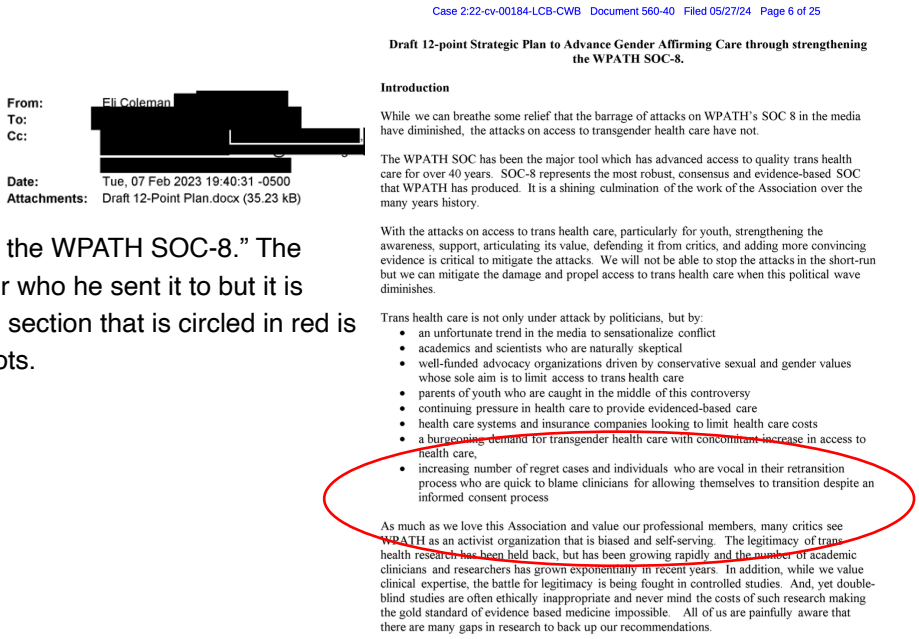
DOI: https://doi.org/10.1080/26895269.2022.2100644

Some sections of text have been removed or added. Please see below.

- On page S258, the following text was removed:
  - "The following are suggested minimal ages when considering the factors unique to the adolescent treatment time frame for gender-affirming medical and surgical treatment for adolescents, who fulfil all of the other criteria listed above.
    - Hormonal treatment: 14 years
    - Chest masculinization: 15 years
    - Breast augmentation, Facial Surgery: 16 years
    - Metoidioplasty, Orchiectomy, Vaginoplasty,
    - Hysterectomy, Fronto-orbital remodeling: 17 years
    - Phalloplasty: 18 years"

February 7, 2023

Dr. Eli Coleman, the first author of SOC8, sends out his "Draft 12-point Strategic Plan to Advance Gender Affirming Care through strengthening the WPATH SOC-8." The document is redacted so it is not clear who he sent it to but it is assumed it is leaders in WPATH. The section that is circled in red is highlighted in the next two screen shots.



From: Eli Coleman [redacted]
To: [redacted]
Cc: [redacted]
Date: Tue, 07 Feb 2023 19:40:31 -0500
Attachments: Draft 12-Point Plan.docx (35.23 kB)

Draft 12-point Strategic Plan to Advance Gender Affirming Care through strengthening the WPATH SOC-8.

Introduction

While we can breathe some relief that the barrage of attacks on WPATH's SOC 8 in the media have diminished, the attacks on access to transgender health care have not.

The WPATH SOC has been the major tool which has advanced access to quality trans health care for over 40 years. SOC-8 represents the most robust, consensus and evidence-based SOC that WPATH has produced. It is a shining culmination of the work of the Association over the many years history.

With the attacks on access to trans health care, particularly for youth, strengthening the awareness, support, articulating its value, defending it from critics, and adding more convincing evidence is critical to mitigate the attacks. We will not be able to stop the attacks in the short-run but we can mitigate the damage and propel access to trans health care when this political wave diminishes.

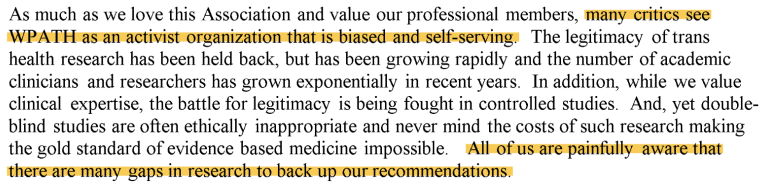
Trans health care is not only under attack by politicians, but by:

- an unfortunate trend in the media to sensationalize conflict
- academics and scientists who are naturally skeptical
- well-funded advocacy organizations driven by conservative sexual and gender values whose sole aim is to limit access to trans health care
- parents of youth who are caught in the middle of this controversy
- continuing pressure in health care to provide evidenced-based care
- health care systems and insurance companies looking to limit health care costs
- a burgeoning demand for transgender health care with concomitant increase in access to health care,
- increasing number of regret cases and individuals who are vocal in their retransition process who are quick to blame clinicians for allowing themselves to transition despite an informed consent process

As much as we love this Association and value our professional members, many critics see WPATH as an activist organization that is biased and self-serving. The legitimacy of trans health research has been held back, but has been growing rapidly and the number of academic clinicians and researchers has grown exponentially in recent years. In addition, while we value clinical expertise, the battle for legitimacy is being fought in controlled studies. And, yet double-blind studies are often ethically inappropriate and never mind the costs of such research making the gold standard of evidence based medicine impossible. All of us are painfully aware that there are many gaps in research to back up our recommendations.

February 7, 2023 – Coleman's strategic plan

In this first screen shot Coleman says "many critics see WAPTH as an activist organization that is biased and self-serving." Their actions prove this description is indeed accurate. And he writes that "All of us are painfully aware that there are many gaps in research to back up our recommendations." Here, the first author of SOC8, admits that he knew what Karen Robinson and Johns Hopkins had discovered. There was "little to no evidence for children and adolescents."



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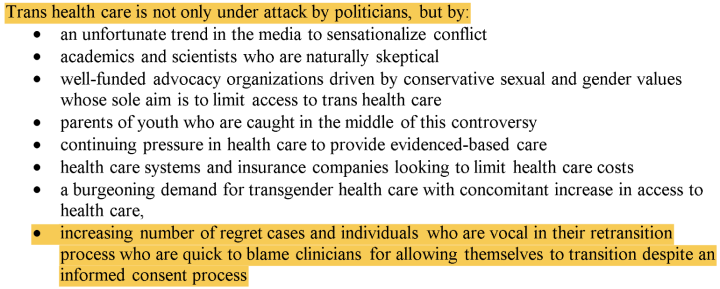
This second screen shot shows that Coleman blames detransitioners – he calls them retransitioners—for attacking trans health care and WPATH. He says they have "allowed themselves to transition despite an informed consent process."

An ethical, truly informed consent is not possible, for many reasons. The foremost reason being that patients would have to be told that there is "little to no evidence" to support transition. And can a teen consent to loss of fertility? Loss of sexual function? Do they have the capacity, knowledge, and full understanding what they are consenting to, and losing? Teens have the right to an "open future" and not to foreclose on things they cannot possibly understand. They cannot understand what they are losing and what that might mean to their future self.



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