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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

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[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.

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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. <u>We recommend against such modifications</u> because the elements of the GRADE process are interlinked <u>because modifications may confuse some users of evidence summaries and guidelines</u>, 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

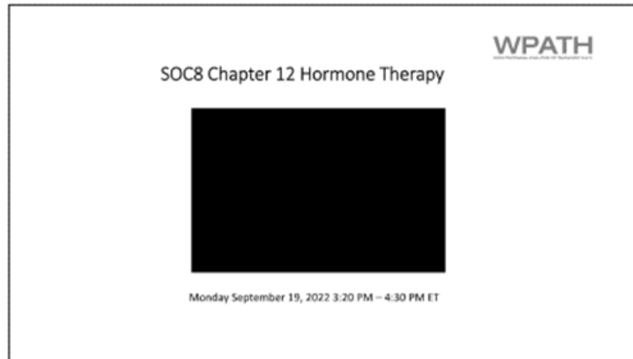
37. On May 5, 2019, Dr. Karen A. Robinson, the current director of Johns Hopkins University's Evidence-based Practice Center and the Lead of the SOC 8 Evidence Review Team, wrote in a preliminary report on "Chapter XI: Hormone Therapy for Adolescents and Adults Systematic Review to Support Development 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."



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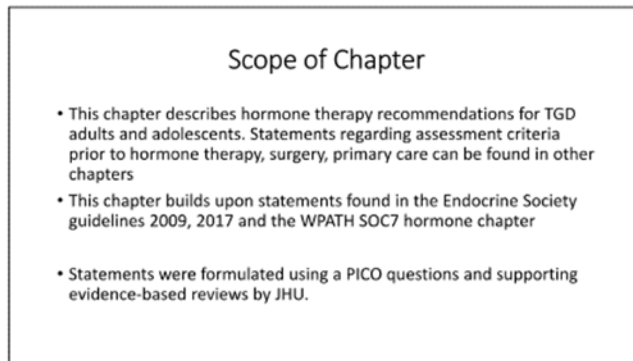

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40. It is interesting to note that the 2017 Endocrine Society Guideline (ESG) used the Grade Method as intended insofar as it published a grading (very low, low, moderate, or high) of the evidence for each recommendation.[6] An examination of the adolescent 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 <u>children</u> 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) <u>childhood, from 2 to 12 years of age</u>; and (3) <u>adolescence, from 12 to 21 years of age</u>." (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:

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• Regardless of evidence-base it is just as important to factor the ethical principles of autonomy and justice, and human rights when navigating treatment recommendations with families.

(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":

a. Ethics Chapter – this chapter will not be in the SOC8, after review and review by bioethicists, there were too many things to edit/change, we have discussed with [redacted] and will work on a standalone white paper. We will work on a draft

(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

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[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, <u>there is no current way to preserve sperm</u>" 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 <u>reverse</u> 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

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[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.

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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

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[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.

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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

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[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.)

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[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[.]" "<u>There are important lawsuits happening right now in the US</u>, one or more of which could go to the Supreme Court, on whether trans care is medically necessary vs experimental or cosmetic. <u>I cannot overstate the importance of SOC 8 getting this right at this important time.</u>" (BOEAL_WPATH_020273) (emphasis mine).

129. In a WPATH email from early January of 2022, the author wrote that "<u>we needed a tool for our attorneys to use in defending access to care here</u>. 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

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[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 <u>we had no evidence to recommend that</u>, 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

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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. <u>Not only did they say they would not endorse the SOC, they indicated</u>

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

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Michael K. Laidlaw, M.D.

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