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## 1. Executive summary

In 2022, the State of Alabama passed a law that restricts medical transition services for those under age 18. The state was promptly sued by the ACLU. As a result of the lawsuit, several documents had to be produced by WPATH to the court regarding their Standards of Care 8 (SOC8) procedures. Last month, the United States District Court Middle District of Alabama Northern Division put on the docket several documents regarding how WPATH SOC8 was developed—specifically, the email exchanges and documents related the relationship between WPATH and Johns Hopkins University (JHU), which was commissioned to review the evidence. Many more documents will be unsealed shortly.

The already-unsealed documents paint a troubling picture: WPATH leadership went to great lengths to suppress systematic reviews (SR) commissioned from Johns Hopkins because the reviews' conclusions did not support the WPATH plans to recommend wide access to hormones and surgeries for all those who desired them. The evidence suppression was achieved via a 2-prong strategy. First, WPATH forced JHU to withdraw the manuscripts that were already submitted for publication as they did not meet the desired conclusions. Next, WPATH instituted a new policy whereby WPATH would have to approve all future publications by JHU.

The new approval policy required that all reviews met a special WPATH checklist, which included items such as whether the review positively contributes to promoting transgender interventions, if it includes transgender people as authors, etc. WPATH required two rounds of approval—first, at the proposal stage, which had to approve the review's anticipated conclusions, and second, at the final manuscript stage. WPATH reserved the right to alter the content. The new policy also required that final publication carry the disclaimer that WPATH had no influence over the process and that the views are solely by the JHU authors.

This post-factum "approval policy" led to a heated debate between WPATH and JHU, with JHU protesting undue WPATH interference and asserting its academic freedom and contractual ability to publish. But in the end, WPATH prevailed. The offending reviews that had led to the development of the approval policy were never published. Notably, only one review was ever published after the policy was put in place: Baker et al. (2021) review of hormonal interventions. The Baker SR is problematic: it did not evaluate any physical harms (despite the protocol stating so), and its pro-medicalization conclusions contradicted the review's actual findings. The SR carries the disclaimer stating that WPATH had no role the review, ironically using exact language required by the approval policy. Internal documents confirm that Baker et al. went through the approval process.

The unsealed documents not only demonstrate that WPATH manipulated the evidence, but also show other problems (e.g., unmanaged conflicts of interest, activism-driven agendas, etc.). More documents are expected to be unsealed soon, likely containing even more damaging info about WPATH's credibility as an organization.

# 2. Key Points

- On April 1, 2018, WPATH entered a contract with Johns Hopkins University (JHU) to conduct systematic reviews [SR] of evidence for the upcoming Standards of Care 8 (SOC8). The contract negotiation throughout 2017-2018 was contentious, as WPATH tried to insert clauses that would give it permission to control the SR publications while JHU wanted to retain academic freedom and scientific integrity of the process. The negotiations were reaching an impasse and JHU nearly walked away but the contract was eventually signed in favor of the JHU position. <sup>1</sup>
  - WPATH was demanding control over publications, saying, "If we are paying for the data review through a fee for services, why wouldn't we own the results?" (Exhibit 1, p. 13/93)
  - Karen Robinson refused to allow WPATH control over the content of the publication stating: "1. First, Hopkins as an academic institution, and I as a faculty member therein, will not sign something that limits academic freedom in this manner. In other words, a sponsor cannot change or suppress publication of research. 2. Second, I will not sign off on language that goes against current standards in systematic reviews and in guideline development. It was my understanding that WPATH wanted to move toward the current standards for guideline development. To do so, the review team needs to be independent. (see IOM standards: http://www.nationalacademies.org/hmd/Reports/2011/Finding-What-Works-in-Health-

Care-Standards-for-Systematic-Reviews/Standards.aspx andhttp://www.nationalacademies.org/hmd/Reports/2011/Clinical-Practice-Guidelines-We-Can-Trust/Standards.aspx). I hope we can come to agreement."

• Eventually, however, contract was signed without the control WPATH desired.<sup>2</sup>

<sup>&</sup>lt;sup>1</sup> Exhibit 167 (Document 560-17) page 27of 93. Email from Karen Robinson at JHU to WPATH, March 6th 2018, objecting to WPATH demands to control publications.

<sup>&</sup>lt;sup>2</sup> Exhibit 167 (Document 560-17) pages 17-26 of 93. "Sponsored Research Agreement Johns Hopkins University".

- In addition to conducting evidence synthesis, JHU also served as a consultant to the WPATH guideline development process overall (e.g., developing special COI forms, educating WPATH on how to structure the research questions/PICOs, etc.).
- As JHU engaged with WPATH, they became concerned about unmanaged WPATH <u>COIs in the process that was already well underway</u>. JHU noted in their email communications: "We would expect many, if not most, SOC8 members to have competing interests. Disclosure, and any necessary management of potential conflicts, should take place prior to the selection of guideline members. Unfortunately, this was not done here but the decision was made to adhere as much as possible to best practice for guideline development." WPATH guideline authors objected to the process of COI disclosures, noting: "Unlike other medical guidelines, trans health care is a socially and politically charged issue, and often subject to laws and policies outside the authors' control. These also can change anytime in the future, prior or after the SOC8 are published. The question about the author now or in the future subject to being in conflict to the SOC8 recommendations is impossible for many of use to answer "no" to." In the end, it does not appear that there was any meaningful management of COIs.<sup>3</sup>
- The WPATH team, likewise, developed major reservations about the Johns Hopkins team and the evidence-based process JHU was devising. At one point, a senior WPATY leader stated, "Might I jump in and ask about the research review team (Johns Hopkins) – would it make sense for us to meet with them at least once to provide some context? Do they deeply understand gender care and the broad gender spectrum? <sup>4</sup> Another senior WPATH leader wrote, ahead of a planning meeting stated that he "would not like that this recommendation graded as insufficient or inadequate." <sup>5</sup>
- The communications show that the WPATH team does not appear to understand Evidence-Based Medicine (EBM). The Johns Hopkins team must explain key aspects such as PICOs, systematic reviews, and other EBM terms and concepts multiple times. Finally, one of the senior WPATH leaders concedes that what they thought was "evidence" is actually at best "indirect evidence" and would not generate the strength of the recommendations they hoped for: "what our committee has felt (and continues to feel) is evidence based (questions on stigma in community, family acceptance/rejection tied with outcomes, question on the role of mental health professional/assessment prior to medical interventions, gender identity change efforts/conversion therapies etc.) is thought of as indirect evidence."<sup>6</sup>
- Eventually, at least 15 questions were identified as needing a systematic review (SR), and at least 6 chapters had completed reviews. According to the documents, there were at least 15 PICOs (population, intervention, comparator, outcome)

<sup>&</sup>lt;sup>3</sup> Exhibit 166 (document 560-16), pages 2-4 of 29. December 2018. Email from Karen Robinson (JHU) to WPATH (December 21 2018) and reactions from WPATH chapter authors.

<sup>&</sup>lt;sup>4</sup> Exhibit 168 (document 560-18) page 168 of 297

 $<sup>^{\</sup>scriptscriptstyle 5}$  Exhibit 168 (document 560-18), page 47 of 297

<sup>&</sup>lt;sup>6</sup> Exhibit 168 (document 560-18), page 116 of 297

questions that were planned to be evaluated in a systematic reviews, including, "what are the benefits of harms of social transition, puberty blockers, cross-sex hormones, mastectomy, breast augmentation, genital surgery" and others (See a more complete list at the end of this document.)<sup>7</sup> At one point, likely around 2020, the following six SOC8 chapters had systematic reviews had been completed: "Assessment, Primary Care, Endocrinology, Surgery, Reproductive Medicine, and Voice Therapy."<sup>8</sup>

- The collaborative spirit between WPATH and JHU seems to have evaporated abruptly, when on July 27, 2020, WPATH learned of 2 systematic reviews that JHU submitted for publication, and which WPATH found problematic as they did not support the WPATH-desired conclusions. WPATH demanded that JHU withdraw the two manuscripts from publication, and insisted that JHU follow a new approval policy for any future publications.
  - On August 20, WPATH notified JHU that that the reviews submitted by JHU raised "many concerns noted regarding these papers by our Board of Directors and SOCv8 Chairs and Co-Chairs".<sup>9</sup> While one of the three reviews had already been published,<sup>10</sup> WPATH instructed JHU not publish the remaining two reviews (we do not know the topics for those reviews). Further, WPATH notified JHU of a new approval policy that JHU had to publish going forward (more on the new policy below).
  - A similar letter was sent by WPATH to its SOC8 chapter authors three months later, in October 2020. The letter, "*Dear SOC8 Working Group Members*," letter stated that WPATH was "*caught on the wrong foot*" by JHU wanting to publish 3 systematic reviews.<sup>11</sup> WPATH explains that subsequently, WPATH developed a new approval policy <sup>12</sup> "to ensure that publication does not negatively affect the provision of transgender healthcare in the broadest sense."<sup>13</sup>

<sup>&</sup>lt;sup>7</sup> Exhibit 168 (document 560-18), page.19-32 of 297 . List of PICOs (population, intervention, comparator, outcome) questions.

<sup>&</sup>lt;sup>8</sup> Exhibit 167 (document 560-16), page 38 of 93. Background for the new approval process, which outlined reviews already completed. Note: completed systematic reviews does not mean the same thing as completed manuscripts ready for publications; it could mean just the evidence tables of Grade evidence. <sup>9</sup> Exhibit 1 (document 523-1), pages 2 -3 of 15, August 26, 2020. This is an email from WPATH leadership to Karen Robinson at JHU.

<sup>&</sup>lt;sup>10</sup> Wilson LM, Baker KE, Sharma R, Dukhanin V, McArthur K, Robinson KA. Effects of antiandrogens on prolactin levels among transgender women on estrogen therapy: A systematic review. *International Journal of Transgender Health*. 2020;21(4):391-402. doi:<u>10.1080/15532739.2020.1819505</u>

<sup>&</sup>lt;sup>11</sup> Exhibit 1 (document 523-1), page 14 of 15, October 20, 2020. The "Dear SOC8 Working Group Members" email detail WPATH objections to the systematic review content. It was an attachment to an internal email WPAPTH email.

<sup>&</sup>lt;sup>12</sup> Exhibit 1 (document 523-1), pages 4-11 of 15. This the detailed approval policy instituted by WPATH for any future publications by JHU.

<sup>&</sup>lt;sup>13</sup> Exhibit 1 (document 523-1), page 14 of 15, October 20, 2020. The "Dear SOC8 Working Group Members" email detail WPATH objections to the systematic review content. It was an attachment to an internal email WPAPTH email. The email itself and JHU Karen Robinsons' response to it are on pages 12 and 13 of 15.

- The new approval process,<sup>12</sup> developed by WPATH in response to the "problematic" review conclusions by JHU, required 2 levels of WPATH approval and WPATH ability to later content—while also insisting that any final publication carry a disclaimer the manuscript content does not reflect WPATH views and that "the authors are solely responsible for the content of the manuscript".
  - WPATH developed an approval checklist, which required that the authors must have the "intention to use the Data for the benefit of advancing transgender health in a positive manner," the content approval must involve SOC8 chapter leads, and the review must include "at least one member of the transgender community in the design, drafting of the article, and the final approval of the article."
  - Two levels of WPATH approval were required before JHU could submit a publication: first, the proposal which <u>includes the conclusion</u> had to be approved; and then, the actual manuscript draft, with WPATH retaining the rights to alter content.
  - Only the reviews passing both levels of approval could be submitted by JHU for publication—and they had to carry a specific disclaimer that "the authors are solely responsible for the content of the manuscript, and the manuscript does not necessarily reflect the view of WPATH in the publication." <sup>14</sup>
- At first, JHU vehemently objected to this—but later succumbed to WPATH pressures, withdrawing the 2 reviews and subjecting the only review that was published later to the invasive WPATH vetting.
  - At first, JHU protested WPATH assertions that JHU cannot publish the reviews and must subject to the approval policy. Karen Robinson from JHU stated, "We have the right to publish and any JHU publications arising out of the work conducted as part of this contract are not subject to approval by WPATH nor subject to any policy of WPATH." <sup>15</sup> Karen Robinson reminded WPATH of the earlier disagreement before the contract was signed, where stated clearly that JHU would never enter into an agreement that restrained their academic freedom and unduly influenced the process (see earlier discussion).<sup>16</sup> She also stated that JHU is not obligated to follow a policy unilaterally instituted by WPATH post-factum.

<sup>&</sup>lt;sup>14</sup> Exhibit 1 (document 523-1), pages 4-11 of 15, presumably attached to email from August 26, 2020. This the detailed approval policy instituted by WPATH for any future publications by JHU.

<sup>&</sup>lt;sup>15</sup> Exhibit 1 (document 523-1), page 13 of 15. Email from Karen Robinson to WPATH, Oct 20, 2020.

<sup>&</sup>lt;sup>16</sup> Exhibit 167 (Document 560-17) page 27of 93. Email from Karen Robinson at JHU to WPATH, March 6th 2018, March 6, 2018 stating, "1. *First, Hopkins as an academic institution, and I as a faculty member therein, will not sign something that limits academic freedom in this manner. In other words, a sponsor cannot change or suppress publication of research.* 

<sup>2.</sup> Second, I will not sign off on language that goes against current standards in systematic reviews and in guideline development. It was my understanding that WPATH wanted to

- However, in the end WPATH appears to have prevailed. The two offending reviews were withdrawn from publication. Only one review (Baker et al., 2021) was published, and it carries all the markings of a systematic review that went through the required approvals (see next).
- <u>The only SR published after the new WPATH approval policy suffers from</u> <u>demonstrable bias</u>. There was only one review that was published after the policy was put in place (Baker et al, 2021). It was an SR of hormonal interventions.
  - The review "passed" the WPATH new approval policy with flying colors (the conclusions were positive; the author was transgender; and the WPATH chapter leads were involved in shaping the SR). See the WPATH checklist specific to the Baker et al review. <sup>17</sup>
  - The Baker et al. review's highly positive conclusions of the benefits hormonal interventions are markedly disconnected from the review's actual findings (low to very low certainty to "insufficient" evidence).
  - The Baker SR only looked at the domains where benefits are expected (i.e., psychological domains) and never evaluated health domains where harms are expected (i.e., physical health).
  - The Baker SR carries the WPATH-required disclaimer that WPATH disclaimer that the JHU authors have full responsibility for the content, and that the views do not necessarily reflect WPATH (ironically, using the language that was required by the WPATH new approval policy *verbatim*)
  - Of note, there are more signs of unprofessionalism and evidence suppression associated with Baker that is beyond the documents in the Alabama discovery but available upon request. There are further communications between community researchers and the primary author (Baker), which show Baker is highly ideologically oriented, personally conflicted (transgender man researcher stating that he is an activist first and researcher second, and that policy goals trump research), and unprofessional when responding to questions about his research.
    - There is also correspondence with the Editor in Chief of the journal that published the Baker SR where the editor refuses multiple letters to the editor that point out problems in the Baker review, going as far as stating that that the journal is contractually obligated by the sponsor not to correct any errors in the review, and that any corrections have to come from the authors themselves.

http://www.nationalacademies.org/hmd/Reports/2011/Finding-What-Works-in-Health-Care-Standards-for-Systematic-Reviews/Standards.aspx and http://www.nationalacademies.org/hmd/Reports/2011/Clinical-Practice-Guidelines-We-Can-

move toward the current standards for guideline development. To do so, the review team needs to be independent. (see IOM standards:

*Trust/Standards.aspx*). *I hope we can come to agreement.* 

<sup>&</sup>lt;sup>17</sup> Exhibit 167 (Document 560-17) page 41 of 93. The WPATH "checklist" for the Baker et al. SR.

- Of further note, other attempts learn about the fate of the shelved reviews were met with silence.
  - When Health and Human Services (HHS) AHRQ department tasked with conducting SRs in the United States contacted the JHU team about the status of the reviews in the registered protocols, the lead researcher (Robinson) stated that the "sponsor" (i.e., WPATH) would not allow them to publish. This came out through another lawsuit discovery. <sup>18</sup>
  - Anecdotally, at least one major medical organization evaluating its guidance was told that they will not be allowed to see the results (they may or may not be willing to go on record).
  - When other researchers, journalists, or administrators contacted WPATH or JHU about the state of the referenced evidence in WPATH, the response was silence (evidence available upon request).
- Another issue is the WPATH abandonment of the SR process for the Adolescent chapter. The initial plan was to do systematic reviews of the benefits of hormonal treatments and of adolescent decisional capacity to consent—but the intention for the latter was promptly abandoned when it became clear that the data would not support the desired conclusion.
  - There was a stated expectation by WPATH Adolescent Chapter leads that these were the two areas where a systematic review would support the medicalization of minors through evidence-based recommendations: *hormone use*, and *capacity to consent*. <sup>19-20</sup>
  - The email by a Chapter Lead Scott Leibowitz stated:

"As you all know, the Adolescent chapter is going to be one of the most scrutinized chapters in the entire standards of care. We are a unique chapter when it comes to the evidence-based review because we do feel that there is a justification to do a literature review on what we postulate will be evidence-based statements about the interventions (even though we expect the evidence to be graded low). Essentially the literature reviews on some of our statements- as we plan on submitting once I edit them to incorporate the feedback from our workgroup- are important for the following reasons:

- Studies that demonstrate the psychological effectiveness of some of the interventions (blockers, hormones) in adolescence all included cohorts who went through a rather rigorous psychological assessment. We would like to talk this through as a group because it's a very important point.
- There is also literature on adolescent decision making and capacity to make informed decisions that carry lifelong ramifications. Since our chapter is a new chapter for the standards of care, and it focuses in on a developmental age group/assessment, (as opposed to other chapters that are more

<sup>&</sup>lt;sup>18</sup> https://donoharmmedicine.org/wp-content/uploads/2024/05/email.pdf

<sup>&</sup>lt;sup>19</sup> Exhibit 168 (document 560-18) pages 43-44 of 297. Email from Scott Leibowitz (WPATH Adolescent Chapter lead).

<sup>&</sup>lt;sup>20</sup> Exhibit 168 (document 560-18), page 116 of 297

*intervention specific), we are going to want to justify certain statements with graded evidence in terms of looking at the literature on decision making in the developmental cohort (adolescence) in general.*"<sup>19</sup>

- "Adolescent medical decision-making literature is something that the Johns Hopkins team is able to help out in terms of a literature review and grading."<sup>20</sup>
- Another chapter lead, de Vries, provided Karen Robinson with "some articles on decision making in teens; these are review articles, but show that there is some evidence. I think we need this sort of evidence base on decision making capacity in adolescents, regarding medical affirming treatment. Hope this is of help and clarifies what we mean."<sup>21</sup>
- After the review of documents of literature on adolescent consent, Karen Robinson from JHU notified WPATH that a systematic review of the hormones is already being taken care of in the Endocrine chapter, while the review of the consent literature does not suggest the evidence is promising.<sup>22</sup> The plan to conduct an adolescent decisional capacity SR was subsequently abandoned. <sup>23</sup> Likewise, another planned systematic review of "family acceptance" and "social acceptance" <sup>24</sup> was also subsequently abandoned.
- At one point, Scott Leibowitz summarizes WPATH decisions in regard to evidence evaluation as, "Very little is happening in terms of systematic reviews for our chapter." <sup>25</sup>
- While the decision not to do SRs as they would only generate undesirable "low certainty" ratings was WPATH's, personal communications indicate with SOC 8 authors suggest that the Adolescent section authors were told by WPATH leadership that it was JHU who asserted that systematics reviews relating to adolescents were not possible (the person may or may not wish to go on record) and that the team would have to use consensus and not expect any reviews.
- The final language in the final WPATH SOC8 Adolescent section confirms this, as the authors stated: "Despite the slowly growing body of evidence supporting the effectiveness of early medical intervention, the number of studies is still low, and there are few outcome studies that follow youth into adulthood. Therefore, a systematic review regarding outcomes of treatment

<sup>&</sup>lt;sup>21</sup> Exhibit 168 (document 560-18) pages 42 (and page 106) of 297. Email from de Vries (WPATH Adolescent Chapter lead).

<sup>&</sup>lt;sup>22</sup> Exhibit 168 (document 560-18) page 106 of 297. Email from Karen Robinson (JHU) to Annalou de Vires (WPATH) explaining why the consent literature de Vries shared is not impressive

<sup>&</sup>lt;sup>23</sup> Exhibit 168 (document 560-18) page 116. Email from Karen Robinson.

<sup>&</sup>lt;sup>24</sup> Exhibit 168 (document 560-18) page 115 (Email from Scott Leibowitz); page 118 (Email from de Vries).

<sup>&</sup>lt;sup>25</sup> Exhibit 168 (document 560-18) page 116 of 297 Email from Scott Leibowitz.

*in adolescents is not possible. A short narrative review is provided instead*" (Coleman et al., 2022, p. 46).

• Notably, SOC8 asserted that adolescents can consent, and the hormonal and surgical interventions are beneficial and should be provided with no minimum age requirements—all based on "consensus."

In summary, it appears that WPATH strong-armed JHU into not publishing the evidence, and the JHU at first resisted this, but later succumb to the pressure. To date, no evidence for adolescents has been published—either for interventions themselves (PB, CSH, Surgery) or the decision capacity. However, WPATH continues to insist its recommendations are evidence-based, as it continues to stonewall all requests to see the suppressed reviews.

The same leadership engaged in WPATH SOC8 is also now leading the World Health Organization's transgender guideline, promising the worlds another "evidence-based guideline".

## 3. Planned WPATH SOC8 PICOs / guideline questions

- Specific to the topic of systematic reviews for social transition, the following questions were identified as needing a systematic review of evidence as of May 2018 (see Exhibit 168, pp.18-31, also reproduced below).
  - What are the benefits and harms of social transition?
  - At what age should social transition be stated [sic]?
- Specific to the topic of systematic reviews for endocrine interventions (puberty blockers and cross-sex hormones) for adolescents, it appears that the following questions were identified as needing a systematic review of evidence, as of May 2018 (see Exhibit 168, pp.18-31, also reproduced below).
  - For adolescents assigned male at birth, what are the benefits and harms of puberty- suppressing hormones?
  - For adolescents assigned female at birth, what are the benefits and harms of puberty- suppressing hormones
  - What is the optimal timing of monitoring [the effects of puberty-suppressing hormones]?
  - What are the appropriate tests for monitoring [the effects of puberty-suppressing hormones]?
  - At what stage of development should gender-affirming hormones be initiated?
  - For adolescents with male genitalia, what are the benefits and harms of feminizing hormone therapy?
  - For adolescents with female genitalia, what are the benefits and harms of masculinizing hormone therapy?

In addition, these questions were identified as relevant to anyone prescribed crossed-sex hormones, which would include adolescents (even though they were not specific to the Adolescent section:

- What is the optimal timing of monitoring [clinical response to testosterone]?
- What is the optimal timing of monitoring [clinical response to estrogen]?
- What is the optimal test for monitoring [clinical response to testosterone]?
- What is the optimal test for monitoring [clinical response to estrogen]?

In reviewing the published systematic reviews, I find only 2 reviews (Baker et al., 2020; Wilson et al., 2021) [1, 2]. Wilson et al. does not address any of the questions above, whereas Baker et al., only partially address some of the above questions, and does not fully address any of the above questions (e.g., the effects of physical health are not addressed; the population of adolescents is not clearly separated from adults, etc.)

- Specific to the topic of systematic reviews for surgical interventions, the following questions were identified as needing a systematic review of evidence, as of May 2018 (see Exhibit 168, pp.18-31, also reproduced below).
- What are the benefits and harms of breast augmentation?
- What are the benefits and harms of a mastectomy?
- What are the benefits and harms of genital surgical procedures?
- What are the benefits and harms of other[gender-affirming] surgical procedures?

# 4. Pathway to WPATH Approval, with disclaimer of "independence" from WPATH:

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#### Pathway to approval for use of WPATH Data

WPATH grants approval to use the Data for publication to any interested a. the directives outlined under the aim of this policy have been fulfilled

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

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



Figure 1 - Designated approval process for publication of Data

# 5. Notification to WPATH Guideline Committee of the "New Approval" process

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#### Dear SOC8 Working Group Members,

Thank you very much for your hard work on the SOC8. Many of the chapters are going through Delphi at present whilst many chapters also are finalizing the text of their chapters and/or recommendation statements. This is an exciting accomplishment! We are hoping to see completed chapters in early 2021.

We are writing you today to inform you of an update of our Policies & Procedures regarding the WPATH SOC8 Data. As you know, WPATH commissioned a number of systematic reviews to be conducted by John Hopkins University. These systematic reviews are the property of WPATH. We would like to see as many systematic review manuscripts as possible to be published (ideally in our official journal, International Journal of Transgender Health). We want to let you know that if you or any other of your chapter members are interested in contributing a manuscript based on one of the systematic reviews, there is a policy on how to request a copy of the reviews and permission to publish these reviews. Please see the attached policy approved by the WPATH board that provides the details on how to initiate this process.

As a final note, we offer our apologies regarding the tardiness of this message and the recently developed Policy & Procedures Regarding the Use of WPATH SOC8 Data. We were caught on the wrong foot when the John Hopkins University Team informed us of wanting to publish 3 papers based on the SOC8 data.

Subsequently, we developed the attached Policy, which was ratified by the Board of Directors and the SOC8 Chair and Co-Chairs.

One paper from the John Hopkins University Team has recently been published online in the International Journal of Transgender Health, whilst two papers have not received the green light to be published. It is paramount that any publication based on the WPATH SOC8 data is thoroughly scrutinized and reviewed to ensure that publication does not negatively affect the provision of transgender healthcare in the broadest sense.

We hope that you find the Policy & Procedures Regarding the Use of WPATH SOC8 Data helpful. We thank you very much again for your support of the SOC8 revision.

Sincerely,

Vin Tangpricha Gail Knudson Randi Ettner

JHU\_000012046

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EXHIBIT 1

### 6. The evidence reviews that were definitely completed:

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Since the start of the contract between WPATH and JHU Dr Robinson and her team have provided systematic literature reviews for the development of statements of the following chapters: Assessment, Primary Care, Endocrinology, Surgery, Reproductive Medicine, and Voice Therapy. Dr Robinson and team have also provided guidance regarding the methodology of the SOC8 and feedback for some of the statements.

## 7. Bibliography

Baker KE, Wilson LM, Sharma R, Dukhanin V, McArthur K, Robinson KA. Hormone Therapy, Mental Health, and Quality of Life Among Transgender People: A Systematic Review. *Journal of the Endocrine Society*. 2021;5(4):bvab011. doi:10.1210/jendso/bvab011

Taylor J, Hall R, Heathcote C, Hewitt CE, Langton T, Fraser L. Clinical guidelines for children and adolescents experiencing gender dysphoria or incongruence: a systematic review of guideline quality (part 1). *Archives of Disease in Childhood*. Published online April 9, 2024. doi:<u>10.1136/archdischild-2023-326499</u>

Wilson LM, Baker KE, Sharma R, Dukhanin V, McArthur K, Robinson KA. Effects of antiandrogens on prolactin levels among transgender women on estrogen therapy: A systematic review. *International Journal of Transgender Health*. 2020;21(4):391-402. doi:10.1080/15532739.2020.1819505