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Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS–2451–P
P.O. Box 8016
Baltimore, MD 21244-8016

Submitted electronically via http://www.regulations.gov

Re: Comments on proposed rulemakings: (1) "Medicare and Medicaid Programs: Hospital Condition of Participation: Prohibiting Sex Rejecting Procedures for Children" (Docket No. CMS-2025-1822-0001), and (2)"Medicaid Program; Prohibition on Federal Medicaid and Children's Health Insurance Program Funding for Sex-Rejecting Procedures Furnished to Children" (Docket No. CMS-2025-1823-0001).

Dear Secretary Kennedy:

On behalf of the States of Alabama, Alaska, Arkansas, Florida, Georgia, Idaho, Indiana, Iowa, Kansas, Kentucky, Louisiana, Missouri, Montana, Nebraska, North Dakota, Ohio, Oklahoma, South Carolina, South Dakota, Tennessee, Texas, Utah, West Virginia, and Wyoming, we write to comment on two proposed rules to restrict federal funding from subsidizing sex-rejecting procedures for minors. Because those procedures have not been shown to be safe or effective for treating gender dysphoria in minors—and, in fact, have been shown to carry a great risk of harm—we agree that the federal government should stop paying for them. It should also stop subsidizing hospitals that provide the treatments. We support the proposed rules.

We write to provide additional information regarding the purported "standards of care" used by some providers to justify providing sex-rejecting procedures to minors. As the proposed rules note, the organization that authors the primary treatment guideline is the World Professional Association for Transgender Health (WPATH). *See* 90 Fed. Reg. 59441, 59444-45. And as the proposed rules also note, those guidelines "are not trustworthy according to accepted standards for evaluating guideline quality," *id.* at 59445—or, frankly, any other standard.

Many of our States have learned this firsthand through litigating to defend our laws prohibiting the provision of sex-rejecting procedures to minors. For instance, in 2022, shortly after the Alabama legislature passed a law prohibiting pediatric sex-rejecting procedures, plaintiffs there sought a preliminary injunction based on the promise that WPATH used the "best available science" to develop its "standard of care." *See* Plaintiffs' PI Mem., *Boe v. Marshall*, No. 2:22-cv-184 (M.D. Ala. 2022), Doc. 8 at 12-13, 16. The district court believed them. While acknowledging that "[k]nown risks" of transitioning treatments "include loss of fertility and sexual function," the court preliminarily enjoined enforcement of Alabama's law because "WPATH recognizes transitioning medications as established medical treatments and publishes a set of guidelines for treating gender dysphoria in minors with these medications." *Eknes-Tucker v. Marshall*, 603 F. Supp. 3d 1131, 1139, 1151 (M.D. Ala. 2022), *rev'd sub nom. Eknes-Tucker v. Governor of Ala.*, 80 F.4th 1205 (11th Cir. 2023), *reh'g en banc denied*, 114 F.4th 1241 (11th Cir. 2024).

Alabama then sought and obtained discovery from WPATH to test the court's deference.[1] Doing so unveiled a tragic medical scandal. Internal documents from WPATH showed that the organization crafted its latest Standards of Care—SOC-8, published in 2022—as "a tool for our attorneys to use in defending access to care."[2] Its evidence-review team "found little to no evidence about children and adolescents."[3] Some SOC-8 authors opted *out* of the evidence-review process entirely due to "concerns, echoed by the social justice lawyers we spoke with, … that evidence-based review reveals little or no evidence and puts us in an untenable position in terms of affecting policy or winning lawsuits."[4] And Admiral Rachel Levine, the former Assistant Secretary for Health at HHS, demanded that WPATH remove from SOC-8 *all* age limits for chemical treatments, chest surgeries, and even surgeries to remove children's genitals. After some initial consternation "about allowing US politics to dictate international professional clinical guidelines,"[5] WPATH obliged. This evidence became public in 2024 and has been covered in—and substantiated by—deeply reported pieces in the *New York Times*, *The Economist*, *The Atlantic*, and elsewhere.[6]

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[1] *See* Order, *Boe*, 2:22-cv-184 (M.D. Ala. Mar. 27, 2023), Doc. 263.

[2] Defendants' Ex. 181 at 75, *Boe*, 2:22-cv-184 (M.D. Ala.), Doc. 700-10. Throughout this letter, the undersigned will reference evidence that Alabama submitted to the court in *Boe*. Citations will be by exhibit number followed by the docket entry in parenthesis and the internal page number following the colon. *E.g.*, Ex.181 (Doc.700-10):75. Exhibits are available online: https://www.alabamaag.gov/boe-v-marshall/.

[3] Ex.173(Doc.560-23):22.

[4] Ex.174(Doc.560-24):1-2.

[5] Ex.186 (Doc.700-15):32.

[6] *See, e.g.*, Azeen Ghorayshi, *Biden Officials Pushed to Remove Age Limits for Trans Surgery, Documents Show*, N.Y. TIMES (June 25, 2024), https://perma.cc/RP5L-QFD9; Nicholas Confessore, *How the Transgender Rights Movement Bet on the Supreme Court and Lost*, N.Y. TIMES (June 19, 2025), https://perma.cc/L5A6-ZVAW; *Research into Trans Medicine Has Been Manipulated*, THE ECONOMIST (June 27, 2024), https://perma.cc/A942-J2DY; Helen Lewis, *The*

The Services should have this additional information as it considers finalizing the proposed rules.

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WPATH published Standards of Care 8 (SOC-8) in September 2022.[7] Dr. Eli Coleman, a sexologist at the University of Minnesota, chaired the guideline committee, and WPATH hired an outside evidence-review team, led by Dr. Karen Robinson at Johns Hopkins University, to conduct systematic evidence reviews for authors to use in formulating their recommendations.[8] Two WPATH presidents, Dr. Walter Bouman, a clinician at the Nottingham Centre for Transgender Health in England, and Dr. Marci Bowers, a surgeon in California who has performed over 2,000 transitioning vaginoplasties, oversaw development and publication of the guideline.

A. WPATH Intentionally Used SOC-8 to Advance Political and Legal Goals.

WPATH selected 119 authors—all existing WPATH members—to contribute to SOC-8.[9] According to Dr. Bowers, it was "important" for each author "to be an advocate for [transitioning] treatments before the guidelines were created."[10] Many authors regularly served as expert witnesses to advocate for sex-rejecting procedures in court; Dr. Coleman testified that he thought it was "ethically justifiable" for those authors to "advocate for language changes [in SOC-8] to strengthen [their] position in court."[11] Other contributors seemed to concur. One wrote: "My hope with these SoC is that they land in such a way as to have serious effect in the law and policy settings that have affected us so much recently; even if the wording isn't quite correct for people who have the background you and I have."[12] Another chimed in: "It is abundantly clear to me when I go to court on behalf of TGD [transgender and gender-diverse] individuals" that "[t]he wording of our section for Version 7 has been critical to our successes, and I hope the same will hold for Version 8."[13]

Liberal Misinformation Bubble About Youth Gender Medicine, THE ATLANTIC (June 29, 2025), https://perma.cc/R4TZ-LS32; Leor Sapir, *"We're All Just Winging It": What The Gender Doctors Say in Private*, THE FREE PRESS (Dec. 3, 2025), https://www.thefp.com/p/were-all-just-winging-it-what-the; *see also* Steve Marshall, *WPATH, 'Transgender Healthcare,' and the Supreme Court*, WALL STREET J. (Dec. 2, 2024), https://perma.cc/S74A-AFAM.

[7] *See* Eli Coleman et al., *Standards of Care for the Health of Transgender and Gender Diverse People, Version 8*, 23 INT'L J. OF TRANSGENDER HEALTH (2022), https://perma.cc/Y9G6-TP3M.

[8] *Id.* at S248-49.

[9] *Id.* at S248-49; *see* Ex.21(Doc.700-3):201:2–223:24.

[10] Ex.18(Doc.564-8):121:7-11.

[11] Ex.21(Doc.700-3):158:17-25.

[12] Ex.184(Doc.700-13):24.

[13] Ex.184(Doc.700-13):15.

Perhaps for this reason—and because it knew that "we will have to argue it in court at some point"[14]—WPATH commissioned a legal review of SOC-8 and was in regular contact with movement attorneys.[15] Dr. Bouman noted the oddity: "The SOC8 are clinical guidelines, based on clinical consensus and the latest evidence based medicine; [I] don't recall the Endocrine Guidelines going through legal reviews before publication, or indeed the current SOC?"[16] The WPATH Executive Committee discussed various options for the review—"ideas; ACLU, TLDEF, Lambda Legal…"[17]—before apparently settling on the senior director of transgender and queer rights at GLAD (and counsel for plaintiffs in Alabama's case) to conduct the review.[18]

Authors were explicit in their desire to tailor SOC-8 to ensure coverage for an "individual's embodiment goals,"[19] whatever they might be. As Dr. Dan Karasic, one of the plaintiffs' experts in Alabama's case, explained to other contributors: "Medical necessity is at the center of dozens of lawsuits in the US right now";[20] "I cannot overstate the importance of SOC 8 getting this right at this important time."[21] Another author was more succinct: "[W]e need[] a tool for our attorneys to use in defending access to care."[22]

At Dr. Karasic's urging, WPATH included a whole section in SOC-8 on "medical necessity" and took to heart his advice to list the "treatments in an expansive way."[23] It assigned the designation to a whole host of interventions, including but "not limited to hysterectomy," with or without "bilateral salpingo-oophorectomy"; "bilateral mastectomy, chest reconstruction or feminizing mammoplasty"; "phalloplasty and metoidioplasty, scrotoplasty, and penile and testicular prostheses, penectomy, orchiectomy, vaginoplasty, and vulvoplasty"; "gender-affirming facial surgery and body contouring"; and "puberty blocking medication and gender-affirming hormones."[24]

One author aptly concluded of the statement: "I think it is clear as a bell that the SOC8 refers to the necessity of treatment (in its broadest sense) for their gender dysphoria (small 'd'); because it refers to the symptom of distress—which is a very very very broad category and one that any 'goodwilling' clinician can use for this purpose (or: in the unescapable medical lingo we, as physicians are

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[14] Ex.182(Doc.700-11):152.
[15] Ex.4(Doc.557-4):vi.
[16] Ex.182(Doc.700-11):151.
[17] Ex.184(Doc.700-13):14.
[18] SOC-8, *supra* note 12, at S177.
[19] Ex.180(Doc.700-9):11.
[20] *Id.* at 64.
[21] Ex.181(Doc.700-10):43.
[22] *Id.* at 75.
[23] SOC-8, *supra* note 12, at S18.
[24] *Id.*

stuck with: those who fulfil a diagnosis of Gender Dysphoria and Gender Incongruence as per APA/WHO)."[25]

WPATH also made sure to sprinkle the "medically necessary" moniker throughout the guideline, even when doing so revealed it had put the cart before the horse. The adolescent chapter, for instance, notes that "[a] key challenge in adolescent transgender care is the quality of evidence evaluating the effectiveness of medically necessary gender-affirming medical and surgical treatments,"[26] but WPATH never paused to ask (or answer) how such treatments can be considered "medically necessary" if the "quality of evidence" supporting their use is so deficient. At least some authors tacitly acknowledged the question and made sure they wouldn't have to answer it—by following the advice of "social justice lawyers" to avoid conducting systematic evidence reviews lest they "reveal[] little or no evidence and put[] us in an untenable position in terms of affecting policy or winning lawsuits."[27] Others just sought to massage the guideline's language to avoid "empower[ing]" those concerned that the evidence did not support transitioning treatments,[28] all while authors and WPATH leaders raised such concerns internally.[29]

B. WPATH Changed Its Treatment Recommendations Based on Politics.

Outside political actors also influenced SOC-8. Most notably, Admiral Levine, the former Assistant Secretary for Health, met regularly with WPATH leaders, "eager to learn when SOC 8 might be published."[30] A few months before SOC-8 was to be published in September 2022 (and long after the public comment period had closed that January[31]), WPATH sent Levine an "Embargoed Copy – For Your Eyes Only" draft of SOC-8 that had been "completed" and sent to the publisher for proofreading and typesetting.[32] The draft included a departure from Standards of Care 7, which, except for so-called "top surgeries," restricted transitioning surgeries to patients who had reached the "[a]ge of majority in a given country."[33] The draft SOC-8 relaxed the age minimums: 14 for cross-sex hormones, 15 for "chest masculinization" (i.e., mastectomy), 16 for "breast augmentation, facial surgery (including rhinoplasty, tracheal shave, and genioplasty),"

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[25] Ex.181(Doc.700-10):36 (second closed parenthesis added).

[26] SOC-8, *supra* note 12, at S45-46.

[27] Ex.174(Doc.560-24):1-2.

[28] Ex.184(Doc.700-13):55.

[29] *E.g.*, Ex.176(Doc.700-5):67-68 (Dr. Bowers admitting that "no long-term studies" exist for puberty blockers); Ex.180(Doc.700-9):21 (author admitting that "most of the recommendation statements in SOC8 are not PICO format"—meaning were not supported by systematic evidence reviews—"but consensus based or based on weak evidence"); Ex.180(Doc.700-9):63 (WPATH leader: "My understanding is that a global consensus on 'puberty blockers' does not exist"); *see generally* Ex.4(Doc.557-4):i-iv.

[30] Ex.184(Doc.700-13):54.

[31] *See* Ex.187(Doc.700-16):4-5.

[32] Ex.170(Doc.700-4):61-64.

[33] E. Coleman, *Standards of Care, Version 7*, 13 INT'L J. TRANSGENDERISM 1, 25-27 (2012), https://perma.cc/T8J7-W3WC.

17 for "metoidioplasty, orchiectomy, vaginoplasty, hysterectomy and fronto-orbital remodeling," and 18 for "phalloplasty."[34]

After reviewing the draft, Levine's office contacted WPATH with a political concern: that the listing of "specific minimum ages for treatment," "under 18, will result in devastating legislation for trans care."[35] WPATH leaders met with Levine to discuss the age recommendations.[36] Levine's solution was simple: "She asked us to remove them."[37]

The authors of the adolescent chapter wrestled with how to respond to the request:

- "I really think the main argument for ages is access/insurance. So the irony is that the fear is that ages will spark political attacks on access. I don't know how I feel about allowing US politics to dictate international professional clinical guidelines that went through Delphi."[38]

- "I'm also curious how the group feels about us making changes based on current US politics.... I agree about listening to Levine."[39]

- "I think it's safe to say that we all agree and feel frustrated (at minimum) that these political issues are even a thing and are impacting our own discussions and strategies."[40]

WPATH initially told Levine that it "could not remove [the age minimums] from the document" because the recommendations had already been approved by SOC-8's "Delphi" consensus process.[41] (Indeed, Dr. Coleman said that consensus was "[t]he only evidence we had" for the recommendations.[42]) But, WPATH continued, "we heard your comments regarding the minimal age criteria" and, "[c]onsequently, we have made changes to the SOC8" by downgrading the age "recommendation" to a "suggestion."[43] Unsatisfied, Levine immediately requested—and received—more meetings with WPATH.[44]

Following Levine's intervention, and days before SOC-8 was to be published, pressure from the American Academy of Pediatrics (AAP) tipped the scales

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[34] Ex.170(Doc.700-4):143.
[35] Ex.186 (Doc.700-15):28.
[36] *See* Ex.186 (Doc.700-15):11, 17; Ex.21(Doc.700-3):287:5–288:6.
[37] Ex.186 (Doc.700-15):11.
[38] *Id.* at 32.
[39] *Id.*
[40] *Id.* at 33.
[41] *Id.* at 17.
[42] *Id.* at 57.
[43] *Id.* at 17.
[44] *See* Ex.18(Doc.564-8):226:8–229:18; Ex.186 (Doc.700-15):73, 88-91.

when it threatened to oppose SOC-8 if WPATH did not remove the age minimums.[45] WPATH leaders initially balked. One of the co-chairs of SOC-8 complained that "[t]he AAP guidelines … have a very weak methodology, written by few friends who think the same."[46] But the political reality soon set in: AAP was "a MAJOR organization," and "it would be a major challenge for WPATH" if AAP opposed SOC-8.[47] WPATH thus "remove[d] the ages."[48]

That is concerning enough. But perhaps even more worrisome is what the episode reveals. *First*, it shows that politicians and AAP sought, and WPATH agreed, to make changes in a clinical guideline recommending irreversible sex-rejecting procedures *for kids* based purely on political considerations. Dr. Coleman was clear in his deposition that WPATH removed the age minimums without allowing authors to vote on the change and "without being presented any new science of which the committee was previously unaware."[49]

Second, as soon as WPATH made the change, it treated the decision as "highly, highly confidential."[50] Dr. Bowers encouraged contributors to submit to "centralized authority" so there would not be "differences that can be exposed."[51] "[O]nce we get out in front of our message," Bowers urged, "we all need to support and reverberate that message so that the misinformation drone is drowned out."[52]

Having decided the strategy, Bowers then crafted the message, circulating internally the "gist of my[] response to Reuters" about the missing age minimums: "[S]ince the open comment period, a great deal of input has been received and continued to be received until the final release. [I] feel the final document puts the emphasis back on individualized patient care rather than some sort of minimal final hurdle that could encourage superficial evaluations and treatments."[53] Another leader responded: "I like this. Exactly—individualized care is the best care—that's a positive message and a strong rationale for the age change."[54] Apparently, it didn't matter that the explanation itself was "misinformation"; as Dr. Bowers explained in a similar exchange, "it is a balancing act between what i feel to be true and what we need to say."[55]

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[45] Ex.187(Doc.700-16):13-14, 109.
[46] *Id.* at 100.
[47] *Id.* at 191.
[48] *Id.* at 338.
[49] Ex.21(Doc.700-3):293:25–295:16.
[50] Ex.188(Doc.700-17):152.
[51] Ex.177(Doc.700-6):124.
[52] *Id.* at 119.
[53] Ex.188(Doc.700-17):113.
[54] *Id.*
[55] Ex.177(Doc.700-6):102.

C. WPATH Failed to Properly Manage Conflicts of Interest.

At the back of SOC-8 is an appendix with the methodology WPATH said it employed.[56] Among other things, it boasts that WPATH managed conflicts of interest and engaged an evidence-review team to conduct systematic literature reviews.[57] Discovery revealed a different story.

WPATH cites two standards it said it used to manage conflicts of interest: one from the National Academies of Medicine and the other from the World Health Organization.[58] Both standards generally recognize that the experts best equipped for creating practice guidelines are those at arm's length from the services at issue—sufficiently familiar with the topic, but *not* professionally engaged in performing, researching, or advocating for the practices under review.[59]

At the same time, the standards recognize that a guideline committee typically benefits from *some* involvement by clinicians who provide the services at issue.[60] Accordingly, they suggest ways for committees to benefit from conflicted clinicians while limiting their involvement. The standard from the National Academies recommends that "[m]embers with [conflicts of interest] should represent *not more than a minority* of the [guideline development group]."[61]

WPATH largely ignored these standards. From the get-go, it expressly limited SOC-8 authorship to existing WPATH members—clinicians and other professionals (and non) who were *already* enthusiastic about transitioning treatments.[62] As Dr. Bowers testified, it was "important for someone to be an advocate for [transitioning] treatments before the guidelines were created."[63]

Dr. Bowers's involvement in SOC-8 offers a good illustration of the lack of real conflict checks. According to the National Academies, a "conflict of interest" is "[a] divergence between an individual's private interests and his or her professional obligations such that an independent observer might reasonably question whether the individual's professional actions or decisions are motivated by personal gain, such as financial, academic advancement, clinical revenue streams, or community standing."[64] Bowers should have been subject to that standard, serving not only as a member of the Board that oversaw and approved SOC-

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[56] *See* SOC-8, *supra* note 12, at S247-51.

[57] *Id.*

[58] *Id.* at S247.

[59] *Id.*; Institute of Medicine (National Academies of Medicine), *Clinical Practice Guidelines We Can Trust* 81-93 (2011), https://perma.cc/7SA9-DAUM; World Health Organization, *Handbook for Guideline Development* 19-23 (2012).

[60] Institute of Medicine, *supra* note 64, at 83.

[61] *Id.* (emphasis added).

[62] SOC-8, *supra* note 12, at S248; *see* Ex.21(Doc.700-3):201:2–223:24.

[63] Ex.18(Doc.564-8):121:7-11.

[64] Institute of Medicine, *supra* note 64, at 78.

8 but as an author of the chapter tasked with evaluating the evidence for transitioning surgeries.

So it is notable that Bowers made "more than a million dollars" in 2023 from providing transitioning surgeries, but said it would be "absurd" to consider that a conflict worth disclosing or otherwise accounting for as part of SOC-8.[65] That was WPATH's public position as well: It assured readers that "[n]o conflicts of interest were deemed significant or consequential" in crafting SOC-8.[66]

Privately, WPATH leaders knew everything was not up to par. Dr. Coleman admitted that "most participants in the SOC-8 process had financial and/or non-financial conflicts of interest."[67] Another author agreed: "Everyone involved in the SOC process has a non-financial interest."[68] Dr. Robinson, the chair of the evidence-review team, said the same: She "expect[ed] many, if not most, SOC-8 members to have competing interests."[69] She even had to inform WPATH—belatedly—that "[d]isclosure, and any necessary management of potential conflicts, should take place *prior* to the selection of guideline members."[70] "Unfortunately," she lamented, "this was not done here."[71] No matter: SOC-8 proclaims the opposite ("Conflict of interests were reviewed as part of the selection process"[72]), and Dr. Coleman testified that he did not know of any author removed from SOC-8 due to a conflict.[73]

D. WPATH Was Not Transparent in How It Used GRADE.

WPATH boasted that it used a process "adapted from the Grading of Recommendations, Assessment, Development and Evaluations (GRADE) framework" for "developing and presenting summaries of evidence" using a "systematic approach for making clinical practice recommendations."[74] According to WPATH, Dr. Robinson's evidence-review team was to conduct systematic evidence reviews, "assign[] evidence grades using the GRADE methodology," and "present[] evidence tables and other results of the systematic review" to SOC-8 authors.[75]

Chapter authors were then to grade the recommendation statements based on the evidence.[76] Per WPATH, "strong recommendations"—"we recommend"—were only for situations where "the evidence is high quality," "a high degree of

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[65] Ex.18(Doc.564-8):37:1-13, 185:25–186:9.
[66] SOC-8, *supra* note 12, at S177.
[67] Ex.21(Doc.700-3):230:17-23.
[68] Ex.174(Doc.560-24):7.
[69] Ex.166(Doc.560-16):1.
[70] *Id.* (emphasis added).
[71] *Id.*
[72] SOC-8, *supra* note 12, at S177.
[73] Ex.21(Doc.700-3):232:13-15.
[74] SOC-8, *supra* note 12, at S250.
[75] *Id.* at S249-50.
[76] *Id.* at S250.

certainty [that] effects will be achieved," "few downsides," and "a high degree of acceptance among providers."[77] On the other hand, "[w]eak recommendations"—"we suggest"—were for when "there are weaknesses in the evidence base," "a degree of doubt about the size of the effect that can be expected," and "varying degrees of acceptance among providers."[78] To "help readers distinguish between recommendations informed by systematic reviews and those not," recommendations were to "be followed by certainty of evidence for those informed by systematic literature reviews":

++++	strong certainty of evidence
+++	moderate certainty of evidence
++	low certainty of evidence
+	very low certainty of evidence[79]

The reality did not match the promise. To begin, as Dr. Coleman wrote, "we were not able to be as systematic as we could have been (e.g., we did not use GRADE explicitly)."[80] Dr. Karasic, the chair of the mental health chapter, testified that rather than relying on systematic reviews, some drafters simply "used authors … we were familiar with."[81]

WPATH also decided not to differentiate "between statements based on [literature reviews] and the rest,"[82] and ordered the removal of all notations disclosing the quality of evidence for each recommendation. A draft of the hormone chapter illustrates the change. The chapter had initially offered a "weak recommendation" ("we suggest") based on low-quality evidence ("++") that clinicians prescribe cross-sex hormones to gender dysphoric adolescents, "preferably with parental/guardian consent."[83]

At first, WPATH seemed to just remove the evidence notations. But then the recommendations themselves appeared to morph from weak ("we suggest") to strong ("we recommend"). So it was in the adolescent chapter, where all but one recommendation is now "strong"[84]—even as those recommendations are surrounded by admissions that "[a] key challenge in adolescent transgender care is the quality of evidence," with "the numbers of studies … still [so] low" that "a systematic review regarding outcomes of treatment in adolescents" is purportedly

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[77] *Id.*

[78] *Id.*

[79] WPATH, *Methodology for the Development of SOC8*, https://perma.cc/QD95-754H.

[80] Ex.190(Doc.700-18):8; *see* Ex.182(Doc.700-11):157-58.

[81] Ex.39(Doc.592-39):66:2–67:5.

[82] Ex.182(Doc.700-11):62; *see* Ex.9(Doc.700-2):¶¶29-36, 43-47.

[83] Ex.182(Doc.700-11):5; *see id.* at 1-40; Ex.9(Doc.700-2):¶¶29-36, 43-47.

[84] SOC-8, *supra* note 12, at S48.

"not possible."[85] And so it was in the hormone chapter, where the final version of the above statement transformed into a strong "we recommend."[86]

While this mismatch may not seem like a big deal, the difference between a "strong" and "weak" recommendation is important, particularly when it comes to life-altering interventions like cross-sex hormones. Under GRADE, "low" or "very-low" quality evidence means, respectively, that the true effect of the medical intervention may, or is likely to be, "substantially different" from the estimate of the effect based on the available evidence.[87] Thus, given that the estimated effect is therefore likely to be *wrong* for very low-quality evidence, it is imperative for clinicians to know the quality of evidence supporting a treatment recommendation—and why, with certain exceptions not applicable here, evidence-based medicine warns against "strong" recommendations based on low-quality evidence.[88] So it is a big deal indeed that WPATH promised clinicians that it followed this system when it actually eschewed transparency and made "strong" recommendations no matter what the evidence said.

E. WPATH Hindered Publication of Evidence Reviews.

Though the SOC-8 authors and their advocacy allies didn't seem to have much use for them, the Johns Hopkins evidence-review team "completed and submitted reports of reviews (dozens!) to WPATH" for SOC-8.[89] The results were concerning. In August 2020, the head of the team, Dr. Robinson, wrote to the Agency for Healthcare Research and Quality at HHS about their research into "multiple types of interventions (surgical, hormone, voice therapy…)."[90] She reported: "[W]e found little to no evidence about children and adolescents."[91]

Dr. Robinson also informed HHS that she was "having issues with this sponsor"—WPATH—"trying to restrict our ability to publish."[92] Days earlier, WPATH had rejected Robinson's request to publish two manuscripts because her team failed to comply with WPATH's policy for using SOC-8 data.[93] Among other things, that policy required the team to seek "final approval" of any article from an SOC-8 leader and then from the WPATH Board of Directors.[94] It also mandated that authors "use the Data for the benefit of advancing transgender health in a positive manner" (as defined by WPATH) and "involve[] at least one member of

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[85] *Id.* at S46-47.

[86] *Id.* at S111.

[87] Howard Balshem *et al.*, *GRADE Guidelines*, 64 J. CLINICAL EPIDEMIOL. 401, 404 (2011), https://perma.cc/2KDY-6BW5.

[88] Liang Yao *et al.*, *Discordant and Inappropriate Discordant Recommendations*, BMJ (2021), https://perma.cc/W7XN-ZELX.

[89] Ex.173 (Doc.560-23):22-25.

[90] *Id.* at 24.

[91] *Id.* at 22.

[92] *Id.*

[93] Ex.167(Doc.560-17):86-88.

[94] *Id.* at 37-38, 75-81.

the transgender community in the design, drafting of the article, and the *final approval* of the article."[95] Once those boxes were checked, the WPATH Board of Directors had final authority on whether the manuscript could be published.[96]

This is an alarming amount of editorial control over publication of a systematic review, the entire purpose of which is to provide an objective and neutral review of the evidence. But WPATH justified its oversight by reasoning that it was of "paramount" importance "that any publication based on WPATH SOC8 data [be] thoroughly scrutinized and reviewed to ensure that publication does not negatively affect the provision of transgender healthcare in the broadest sense" (as WPATH defined it).[97] But to make the process *appear* neutral, WPATH imposed one last requirement: Authors had to "acknowledge[]" in their manuscript that they were "solely responsible for the content of the manuscript, and the manuscript does not necessarily reflect the view of WPATH."[98]

WPATH eventually allowed the Johns Hopkins team to publish two of its manuscripts. (It's still unclear what happened to the others.[99]) The team dutifully reported that the "authors"—not WPATH—were "responsible for all content."[100]

F. WPATH Recommends Castration as "Medically Necessary" for "Eunuchs."

As if to drive home how unscientific the SOC-8 enterprise was, WPATH included an entire chapter on "eunuchs"—"individuals assigned male at birth" who "wish to eliminate masculine physical features, masculine genitals, or genital functioning."[101] Because eunuchs "wish for a body that is compatible with their eunuch identity," WPATH recommends "castration to better align their bodies with their gender identity."[102] That's not an exaggeration. When asked at his deposition whether "in the case of a physically healthy man with no recognized mental health conditions and who presents as a eunuch seeking castration, but no finding is made that he's actually at high risk of self-castration, nevertheless, WPATH's official position is that that castration may be a medically necessary procedure?", Dr. Coleman confirmed: "That's correct."[103]

Dr. Coleman also admitted that no diagnostic manual recognizes "eunuch" as a medical or psychiatric diagnosis.[104] And other SOC-8 authors criticized the

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[95] *Id.* at 37 (emphasis added).

[96] *Id.* at 38.

[97] *Id.* at 91.

[98] *Id.* at 38.

[99] *Cf.* Ex.167(Doc.560-17):91.

[100] Kellan Baker *et al.*, *Hormone Therapy, Mental Health, and Quality of Life*, 5 J. ENDOCRINE SOC'Y 1, 3 (2021); L. Wilson, *Effects of Antiandrogens on Prolactin Levels Among Transgender Women*, 21 INT'L J. TRANSGENDER HEALTH 391, 392 (2020).

[101] SOC-8, *supra* note 12, at S88.

[102] *Id.* at S88-89.

[103] Ex.21(Doc.700-3):172:19–173:25.

[104] *Id.*

chapter as "very high on speculation and assumptions, whilst a robust evidence base is largely absent."[105] Dr. Bowers even admitted that not every board member read the chapter before approving it for publication.[106] No matter: The guideline still recommends castration for men and boys who identify as "eunuch."

And how did WPATH learn that castration constitutes "medically necessary gender-affirming care"?[107] From the internet—specifically a "large online peer-support community" called the "Eunuch Archive."[108] According to SOC-8 itself, the "Archive" contains "the greatest wealth of information about contemporary eunuch-identified people."[109] The guideline does not disclose that part of the "wealth" comes in the form of the Archive's fiction repository, which hosts thousands of stories that "focus on the eroticization of child castration" and "involve the sadistic sexual abuse of children."[110] "The fictional pornography" "includes themes such as Nazi doctors castrating children, baby boys being fed milk with estrogen in order to be violently sex trafficked as adolescents, and pedophilic fantasies of children who have been castrated to halt their puberty."[111]

Despite all this, advocates regularly promise that the WPATH Standards were developed using well-accepted processes and similar to other treatment guidelines. Let's hope not.

G. WPATH Acts Like an Advocacy Organization, Not a Medical One.

As is clear by now, though WPATH cloaks itself in the garb of evidence-based medicine, its heart is in advocacy. (Indeed, in its attempt to avoid discovery into its "evidence-based" guideline, WPATH told the district court in Alabama it was just a "nonparty advocacy organization[]."[112]) That was evident after SOC-8 was published, when Dr. Coleman circulated an internal "12-point strategic plan to advance gender affirming care."[113] He began by identifying "attacks on access to trans health care," which included (1) "academics and scientists who are naturally skeptical," (2) "parents of youth who are caught in the middle of this controversy," (3) "continuing pressure in health care to provide evidence-based care," and (4) "increasing number of regret cases and individuals who are vocal in their retransition who are quick to blame clinicians for allowing themselves to transition despite an informed consent process."[114]

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[105] Ex.182(Doc.700-11):96.

[106] Ex.18(Doc.564-8):147:9–148:4; *Boe*.MSJ(Doc.619):16.

[107] SOC-8, *supra* note 12, at S88.

[108] *Id.*

[109] *Id.*

[110] Genevieve Gluck, *Top Trans Medical Association Collaborated with Castration, Child Abuse Fetishists*, REDUXX (May 17, 2022), https://perma.cc/5DWF-MLRU.

[111] *Id.*

[112] Mot. to Quash at 3, *Boe*, 2:22-cv-184 (M.D. Ala. Dec. 27, 2022), Doc.208.

[113] Ex.190(Doc.700-18):5 (capitalization altered).

[114] *Id.*; *see* Ex.16(Doc.557-16):¶103.

To combat these "attacks" from "evidence-based medicine" and aggrieved patients, Dr. Coleman encouraged WPATH to ask other medical organizations to formally endorse SOC-8. He noted that the statement "that the SOC has so many endorsements has been an extremely powerful argument" in court, particularly given that "[a]ll of us are painfully aware that there are many gaps in research to back up our recommendations."[115] Problem was, Dr. Coleman "ha[d] no idea how it was ever said that so many medical organizations ha[d] endorsed" the standards.[116] He suspected that organizations had only "referenced" the guideline but "never formally endorsed" it.[117]

So Dr. Coleman and other WPATH leaders made a concerted effort to obtain formal endorsements from other organizations. At his deposition in May 2024, Dr. Coleman knew of only two organizations that had endorsed SOC-8: the World Association for Sexual Health and the International Society for Sexual Medicine.[118] The AAP, Dr. Coleman said, rejected WPATH's request.[119] So did the American Medical Association, which told WPATH that it "does not endorse or support standards of care—that falls outside of our expertise."[120] The response caused Dr. Bouman to complain that the AMA is run by "white cisgender heterosexual hillbillies from nowhere."[121]

Then there is WPATH's response to the Cass Review. Rather than embracing one of "the most comprehensive, evidence-based reviews of a medical service from the long history of such independent investigations" in the UK,[122] WPATH seems to view NHS England and the Cass Review as simply more "attacks on access to trans health care." In its public "comment on the Cass Review," for instance, WPATH defends SOC-8 against the Review's harsh assessment by boasting that its guideline was "based on far more systematic reviews tha[n] the Cass Review."[123] That may or may not be true—Dr. Robinson did say her team had conducted "dozens!" of reviews—but it's a rich claim for WPATH to make given that it went to such great lengths to restrict its own evidence review team from publishing its findings, WPATH did not otherwise make a *single* review or evidence table from SOC-8 available to the public, and SOC-8 states that WPATH found insufficient evidence to even conduct a systematic review for the adolescent chapter. By contrast, the six systematic evidence reviews and two appraisals of international clinical guidelines conducted through an open procurement process

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[115] Ex.190(Doc.700-18):5-6.

[116] *Id.*

[117] *Id.* at 6 (spelling corrected).

[118] Ex.21(Doc.700-3):261:5-12, 262:4-8; *see* Ex.190(Doc.700-18):6.

[119] Ex.21(Doc.700-3):261:20-23; Ex.188(Doc.700-17):152.

[120] Ex.189(Doc.560-39):15.

[121] *Id.* at 13; Ex.21(Doc.700-3):259:4-10.

[122] C. Ronny Cheung et al., *Gender Medicine and the Cass Review: Why Medicine and the Law Make Poor Bedfellows*, ARCH. DIS. CHILD 1-2 (Oct. 2024), https://perma.cc/X7CH-NM7U.

[123] WPATH and USPATH Comment on the Cass Review (May 17, 2024), https://perma.cc/B2TU-ALSR.

by the University of York for the Cass Review are freely available in the peer-reviewed *Archives of Disease in Childhood*.[124] WPATH's critique of the Cass Review is simply not serious.

It is also not unusual. WPATH has long sought to ensure that only one side of the story is told, and it critiques or silences those who offer opposing viewpoints to the public.[125] For instance, at its inaugural conference in 2017, USPATH—WPATH's U.S. affiliate—bowed to the demands of trans-activist protestors and cancelled a panel presentation by a respected researcher, Dr. Ken Zucker, who attempted to present research showing that most children with gender dysphoria will have the dysphoria "desist" by adulthood.[126] A few years later, USPATH formally censured its president, Dr. Erica Anderson, for publicly discussing concerns about "sloppy" care resulting from gender dysphoric youth being "[r]ushed through the medicalization" of transitioning treatments.[127] WPATH even issued a formal statement "oppos[ing] the use of the lay press … as a forum for the scientific debate" over "the use of puberty delay and hormone therapy for transgender and gender diverse youth."[128] As Dr. Bowers explained it: "[T]he public … doesn't need to sort through all of that."[129]

The result of WPATH's flavor of advocacy has been predictable. One of the authors of SOC-8's adolescent chapter was prescient in her concern: "My fear is that if WPATH continues to muzzle clinicians and relay the message to the public that they have no right to know about the debate, WPATH will become the bad guy and not the trusted source."[130]

* * *

Much more could be said about how untrustworthy WPATH is. But it is worth emphasizing that WPATH's insistence on advocacy over patient welfare has a human cost that its own leaders have seen firsthand. As Dr. Bowers recounted in a private email to other WPATH leaders (apologizing for going public with concerns about puberty blockers):

> Like my [female genital mutilation] patients who had never experienced orgasm, the puberty blockaded kids did not know what orgasm might feel like and most experienced sensation to their genitalia

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[124] And online: https://adc.bmj.com/pages/gender-identity-service-series.

[125] *See generally* Ex.16(Doc.557-16).

[126] *See* Ex.16(Doc.557-16):¶¶9-13; Ex.39(Doc.592-39):187:23–188:5; Ex.178(Doc.700-7):5.

[127] Ex.176(Doc.700-5):107, 113-14; Ex.16(Doc.557-16):¶¶14-17; Abigail Shrier, *Top Trans Doctors Blow the Whistle on "Sloppy" Care*, THE FREE PRESS (Oct. 4, 2021), https://perma.cc/R7M3-XTQ3.

[128] Joint Letter from USPATH and WPATH (Oct. 12, 2022), https://perma.cc/X7ZN-G6FS.

[129] Ex.18(Doc.564-8):287:18-22; *Boe*.MSJ(Doc.619):22.

[130] Ex.176(Doc.700-5):152.

> no differently than if it had been a finger or a portion of their thigh.... My concern culminated during a pre-surgical evaluation on a young trans girl from a highly educated family whose daughter responded when I asked about orgasm, "what is that?" The parents countered with, "oh honey, didn't they teach you that in school?" I felt that our informed consent process might not be enough.... It occurred to me that how could anyone truly know how important sexual function was to a relationship, to happiness? It isn't an easy question to answer....[131]

So it isn't. That is why States routinely set age limits on risky endeavors, be it driving a car, buying a beer, or consenting to a hysterectomy. Undergoing sex-rejecting procedures is no different. As Dr. Coleman privately recognized, "at their age – they would not know what they want."[132]

We thus commend the Services work in this area and support the proposed rules that would stop subsidizing sex-rejecting procedures for minors.

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[131] Ex.176(Doc.700-5):68.
[132] Ex.180(Doc.700-9):59.

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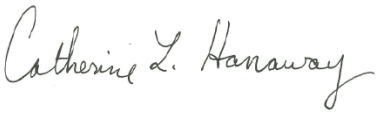

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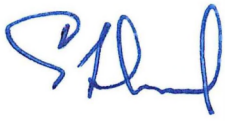

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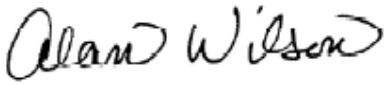

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