UNITED STATES DISTRICT COURT
DISTRICT OF MARYLAND

PFLAG, INC., *et al*.,	)	
	)	
Plaintiffs,	)	
	)	
v.	)	Civil No. 25-337-BAH
	)	
DONALD J. TRUMP, in his official capacity as President of the United States, *et al.*,	)	
	)	
Defendants.	)	

BRIEF OF THE STATES OF ALABAMA, ALASKA, ARKANSAS, FLORIDA, GEORGIA, IDAHO, INDIANA, IOWA, KANSAS, LOUISIANA, MISSISSIPPI, MISSOURI, MONTANA, NEBRASKA, NORTH DAKOTA, OKLAHOMA, SOUTH CAROLINA, SOUTH DAKOTA, TENNESSEE, TEXAS, VIRGINIA, WEST VIRGINIA, AND THE ARIZONA STATE LEGISLATURE AS *AMICI CURIAE* IN OPPOSITION TO PLAINTIFFS' MOTION FOR A PRELIMINARY INJUNCTION

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INTRODUCTION AND INTEREST OF *AMICI CURIAE*[1]

Plaintiffs seek a preliminary injunction based on a carefully curated factual narrative that is misleading at best. For the equities, they build their case primarily on unnamed "clinical practice guidelines" that purportedly govern how clinicians "assess, diagnose, and treat adolescents and adults with gender dysphoria." Doc. 69-1 at 3. Plaintiffs assure that the guidelines are "evidence-based," "widely accepted," and definitely "not based on 'junk' science." *Id.* at 3-4. Yet there is a reason Plaintiffs dare not name the guidelines on which they build their case. According to Plaintiffs' experts,[2] those guidelines are the "Standards of Care Version 8" by the World Professional Association for Transgender Health (WPATH)—the very guidelines the "Protecting Children" executive order correctly found "lack[] scientific integrity."[3]

The *Amici* States have seen this playbook before. In 2022, for instance, shortly after the Alabama legislature passed a law prohibiting pediatric sex-change procedures, plaintiffs there sought a preliminary injunction based on the promise that WPATH used the "best available science" to develop the "standard of care." *See* PI Mem., *Boe v. Marshall*, No. 2:22-cv-184 (M.D. Ala. 2022), ECF 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).

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[1] This brief is submitted pursuant to L.R. 105.12(a), which allows States to "file an amicus brief without the consent of the parties or leave of court."

[2] *E.g.*, Shumer Decl., Doc. 69-1 ¶¶40, 50, 52-54; Karasic Decl., Doc. 69-49 ¶¶7, 54-63.

[3] Executive Order 14187, *Protecting Children from Chemical and Surgical Mutilation*, 90 Fed. Reg. 8771, 8771 (Jan. 28, 2025).

Alabama then sought and obtained court-ordered discovery from WPATH to test the court's deference.[4] Doing so unveiled a tragic medical scandal. Internal documents from WPATH showed that the organization crafted its Standards of Care 8 as "a tool for our attorneys to use in defending access to care."[5] Its evidence-review team "found little to no evidence about children and adolescents."[6] Some SOC-8 authors opted *out* of the evidence-review process 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."[7] And Admiral Rachel Levine, the former Assistant Secretary for Health at HHS, demanded that WPATH remove *all* age limits for chemical treatments, chest surgeries, and even surgeries to remove children's genitals from SOC-8. After some initial consternation "about allowing US politics to dictate international professional clinical guidelines,"[8] WPATH obliged.

Plaintiffs tell the Court none of this, even though three of their experts—Dr. Shumer, Dr. Antommaria, and Dr. Karasic—are also witnesses in Alabama's case, and Dr. Karasic even helped create SOC-8. Nor do they mention the independent review commissioned by England's National Health Service to study the safety and efficacy of pediatric transitioning treatments.[9] The verdict? Dr. Hilary Cass, the pediatrician who led the review, put it this way: "I can't think of another area of paediatric care where we give young people a potentially irreversible treatment and have no idea what happens to them in adulthood."[10] No wonder countries in Europe are restricting minors'

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

[5] Defs' Ex. 181 at 75, *Boe*, 2:22-cv-184 (M.D. Ala.), Doc. 700-10.

Throughout this brief, *amici* will reference evidence 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/.

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

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

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

[9] *Cass Review* (2024), https://perma.cc/3QVZ-9Y52.

[10] Abbasi, *"Medication is Binary,"* BMJ (Apr. 2024), https://perma.cc/KUM3-XL2S.

access to the "treatments." *See* Lavietes, *Britain Bans Puberty Blockers for Transgender Minors*, NBC NEWS (Dec. 11, 2024), https://perma.cc/3Q4SNV8E; Ghorayshi, *Scotland Pauses Gender Medications for Minors*, N.Y. TIMES (Apr. 18, 2024), https://perma.cc/4YV6- FCX5 (reporting that Scotland became "the sixth country in Europe to limit" access).

Nor do Plaintiffs tell the Court what every systematic evidence review has found: only low or very-low quality evidence yielding "considerable uncertainty."[11] That conclusion is not likely to change soon. In October, the head of a large, NIH-funded study admitted to finding that "[p]uberty blockers did not lead to mental health improvements"—and then told the *New York Times* that she has not published the results because she does not want the findings "to be weaponized."[12]

Annelou de Vries, a seminal researcher in the field cited by all of Plaintiffs' experts, went further. Tacitly admitting the truth of "the critique that there is insufficient evidence," she recently wrote to "question" the "normative assumption" that the interventions "must necessarily result in 'effective' outcomes in order to be considered legitimate and essential care."[13] She suggested that the care instead be "provided and justified on the basis of personal desire and autonomy," that "effectiveness" be measured by how well the interventions "help individuals achieve their embodiment goals," and that any "experience of regret" be welcomed as "inherent to all lives."[14]

Plaintiffs echo the recasting. Showing just how far the field has come from its since-abandoned quest for "effective" and evidence-based care, Plaintiffs argue that sex-change procedures are "medically necessary" for "nonbinary" minors desiring the treatments—even though *none* of the foundational studies included nonbinary participants and *none* of Plaintiffs' experts discuss

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[11] *See* Miroshnychenko et al., *Puberty Blockers for Youth Experiencing Gender Dysphoria*, ARCH. OF DISEASE IN CHILDHOOD (Jan. 24, 2025), https://perma.cc/U3CC-MNCX; Miroshnychenko et al., *Gender-Affirming Hormone Therapy for Individuals With Gender Dysphoria*, ARCH. OF DISEASE IN CHILDHOOD (Jan. 24, 2025), https://perma.cc/6SUU-GZ7D.

[12] Ghorayshi, *U.S. Study on Puberty Blockers Goes Unpublished Because of Politics*, N.Y. TIMES (Oct. 23, 2024), https://perma.cc/8M5A-4M3W.

[13] Oosthoek, de Vries, et al., *Gender-affirming Medical Treatment for Adolescents*, 25 BMC MEDICAL ETHICS 154 (2024), https://perma.cc/8W4R-CEG7.

[14] *Id.*

research about medical interventions for such individuals. The only reference in the Endocrine Society's guideline to nonbinary patients is an admission that "[n]o evidence-based protocols are available,"[15] while WPATH's SOC-8 suggests that because "evidence is limited" doctors should be "led by a given client's personal understanding of gender as it relates to the client's gender identity, expression, *and any need for medical care*."[16] To Plaintiffs and WPATH, a medical treatment becomes "medically necessary" the moment a "client" picks it from the buffet to meet a personal "embodiment goal." No other area of pediatric medicine works like this.

Plaintiffs also mislead when it comes to the evidence that *does* exist. For instance, they claim that "puberty-delaying medication" has "no impact on fertility," Doc. 69-1 at 27, but they fail to inform the Court that nearly all children who start on puberty blockers to treat gender dysphoria then take cross-sex hormones—and the combination *can* permanently impair fertility, as Plaintiffs' expert Dr. Shumer admits.[17] And how could it not? As Dr. Shumer said, "progressing through natural puberty is a requirement for fertility."[18]

Then there is the risk of suicide, which Plaintiffs argue requires granting relief. *E.g.*, Doc. 69-1 at 26. But as Plaintiffs' own attorney recently told the Supreme Court, "there is no evidence … that this treatment reduces completed suicide." Tr.88, *United States v. Skrmetti*, No. 23-477 (U.S. Dec. 4, 2024).[19] Too many parents are familiar with the threat, though, having "consented" to sex-change procedures after being told that "You can either have a living son or a dead daughter."[20] Given the vulnerability of this young patient population, it's a wonder these suggestions

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[15] Hembree et al., *Endocrine Treatment of Gender-Dysphoric/Gender-Incongruent Persons*, 102 J. CLIN. ENDOCRINOL. METAB. 3869, 3888 (2017)

[16] E. Coleman et al., *Standards of Care for the Health of Transgender & Gender Diverse People, Version 8*, 23 INT'L J. OF TRANSGENDER HEALTH S84, S81 (2022) (emphasis added), https://perma.cc/Y9G6-TP3M.

[17] *See* Ex.39(Doc.564-25):121:5-20, 153:13–158:15.

[18] Ex.39(Doc.564-25):150:1-7.

[19] *See also Cass Review*, *supra* note 9, at 33 ("It has been suggested that hormone treatment reduces the elevated risk of death by suicide in this population, but the evidence found did not support this conclusion.").

[20] Affidavit of Jamie Reed ¶39 (Feb. 7, 2023), https://perma.cc/QE9Q-K2QP.

haven't already become self-fulfilling prophecy—which cynical advocates would then use to further "affect[] policy" and "win[] lawsuits."

Minors suffering from gender dysphoria deserve better. *Amici* States submit this brief to tell the Court just some of what they learned about WPATH after peeking behind the curtain. Plaintiffs' reliance on WPATH is reason to reject their request for relief, not reason to grant it.

ARGUMENT

I. WPATH Crafted SOC-8 As A Political And Legal Document.

WPATH published Standards of Care 8 (SOC-8) in September 2022. 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.[21] 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 the development and publication of the guideline.

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

WPATH selected 119 authors—all existing WPATH members—to contribute to SOC-8.[22] According to Dr. Bowers, it was "important" for each author "to be an advocate for [transitioning] treatments before the guidelines were created."[23] Many authors regularly served as expert witnesses to advocate for sex-change 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."[24] 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

[21] SOC-8, *supra* note 16, at S248-49.

[22] SOC-8, *supra* note 16, at S248-49; *see* Ex.21(Doc.700-3):201:2–223:24.

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

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

background you and I have."[25] 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."[26]

Perhaps for this reason—and because it knew that "we will have to argue it in court at some point"[27]—WPATH commissioned a legal review of SOC-8 and was in regular contact with movement attorneys.[28] 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?"[29] The WPATH Executive Committee discussed various options for the review—"ideas; ACLU, TLDEF, Lambda Legal…"[30]—before apparently settling on the senior director of transgender and queer rights at GLAD to conduct the review.[31]

Authors were explicit in their desire to tailor SOC-8 to ensure coverage for an "individual's embodiment goals,"[32] whatever they might be. As Plaintiffs' expert Dr. Dan Karasic explained to other contributors: "Medical necessity is at the center of dozens of lawsuits in the US right now";[33] "I cannot overstate the importance of SOC 8 getting this right at this important time."[34]

At Dr. Karasic's urging, WPATH thus included a whole section in SOC-8 on "medical necessity."[35] It 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

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[25] Ex.184(Doc.700-13):24.
[26] Ex.184(Doc.700-13):15.
[27] Ex.182(Doc.700-11):152.
[28] Ex.4(Doc.557-4):vi.
[29] Ex.182(Doc.700-11):151.
[30] Ex.184(Doc.700-13):14.
[31] SOC-8, *supra* note 16, at S177.
[32] Ex.180(Doc.700-9):11.
[33] *Id.* at 64.
[34] Ex.181(Doc.700-10):43.
[35] SOC-8, *supra* note 16, at S18.

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,"[36] 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 evidence reviews.[37]

B. WPATH Changed Its Treatment Recommendations Based on Political Concerns.

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."[38] A few months before SOC-8 was to be published in September 2022 (and long after the public comment period had closed that January[39]), 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.[40] 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."[41] 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)," 17 for "metoidioplasty, orchiectomy, vaginoplasty, hysterectomy and fronto-orbital remodeling," and 18 for "phalloplasty."[42]

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[36] *Id.* at S45-46.

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

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

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

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

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

[42] Ex.170(Doc.700-4):143.

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."[43] WPATH leaders met with Levine to discuss the age recommendations.[44] Levine's solution was simple: "She asked us to remove them."[45]

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.[46] (Indeed, Dr. Coleman said that consensus was "[t]he only evidence we had" for the recommendations.[47]) 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."[48] Unsatisfied, Levine immediately requested—and received—more meetings with WPATH.[49]

Following Levine's intervention, and days before SOC-8 was to be published, pressure from the American Academy of Pediatrics (AAP) tipped the scales when it threatened to oppose SOC-8 if WPATH did not remove the age minimums.[50] 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."[51] 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.[52] WPATH thus "remove[d] the ages."[53]

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[43] Ex.186 (Doc.700-15):28.

[44] *See* Ex.186 (Doc.700-15):11, 17; Ex.21(Doc.700-3):287:5–288:6.

[45] Ex.186 (Doc.700-15):11.

[46] *Id.* at 17.

[47] *Id.* at 57.

[48] *Id.* at 17.

[49] *See* Ex.18(Doc.564-8):226:8–229:18; Ex.186 (Doc.700-15):73, 88-91.

[50] Ex.187(Doc.700-16):13-14, 109.

[51] *Id.* at 100.

[52] *Id.* at 191.

[53] *Id.* at 338.

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-change 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."[54] Remarkably, WPATH *still* tells this Court the exact opposite. *See* Doc. 79-1 at 10 (assuring that "[e]ach recommendation" went through Delphi).

Second, as soon as WPATH made the change, it treated the decision as "highly, highly confidential."[55] Dr. Bowers encouraged contributors to submit to "centralized authority" so there would not be "differences that can be exposed."[56] "[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."[57]

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."[58] 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."[59] 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."[60]

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[54] Ex.21(Doc.700-3):293:25–295:16.
[55] Ex.188(Doc.700-17):152.
[56] Ex.177(Doc.700-6):124.
[57] *Id.* at 119.
[58] Ex.188(Doc.700-17):113.
[59] *Id.*
[60] Ex.177(Doc.700-6):102.

II. WPATH Did Not Follow The Principles Of Evidence-Based Medicine It Said It Followed.

At the back of SOC-8 is an appendix with the methodology WPATH said it employed.[61] It proclaims that WPATH managed conflicts of interest, used the GRADE framework to tailor recommendation statements based on strength of evidence, and engaged an evidence-review team to conduct systematic literature reviews for SOC-8.[62] Discovery revealed a different story.

A. WPATH Failed to Properly Manage Conflicts of Interest.

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.[63] 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.[64]

At the same time, the standards recognize that a guideline committee typically benefits from *some* involvement by clinicians who provide the services at issue.[65] 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]."[66]

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

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[61] *See* SOC-8, *supra* note 16, at S247-51.

[62] *Id.*

[63] *Id.* at S247.

[64] *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).

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

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

already enthusiastic about transitioning treatments.[67] As Dr. Bowers testified, it was "important for someone to be an advocate for [transitioning] treatments before the guidelines were created."[68]

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."[69] Bowers should have been subject to that standard, serving not only as a member of the Board that oversaw and approved SOC-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.[70] 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.[71]

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 nonfinancial conflicts of interest."[72] 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."[73] She even had to inform WPATH—belatedly—that "[d]isclosure, and any necessary management of potential conflicts, should take place

[67] SOC-8, *supra* note 16, at S248; *see* Ex.21(Doc.700-3):201:2–223:24.
[68] Ex.18(Doc.564-8):121:7-11.
[69] Institute of Medicine, *supra* note 64, at 78.
[70] Ex.18(Doc.564-8):37:1-13, 185:25–186:9.
[71] SOC-8, *supra* note 16, at S177.
[72] Ex.21(Doc.700-3):230:17-23.
[73] Ex.166(Doc.560-16):1.

prior to the selection of guideline members."[74] "Unfortunately," she lamented, "this was not done here."[75] No matter: SOC-8 proclaims the opposite ("Conflict of interests were reviewed as part of the selection process"[76]), and Dr. Coleman testified that he did not know of any author removed from SOC-8 due to a conflict.[77]

B. 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."[78] 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.[79]

Chapter authors were then to grade the recommendation statements based on the evidence.[80] Per WPATH, "strong recommendations"—"we recommend"—were only for situations where "the evidence is high quality," "a high degree of certainty [that] effects will be achieved," "few downsides," and "a high degree of acceptance among providers."[81] 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."[82] To "help readers distinguish between recommendations

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[74] *Id.* (emphasis added).
[75] *Id.*
[76] SOC-8, *supra* note 16, at S177.
[77] Ex.21(Doc.700-3):232:13-15.
[78] SOC-8, *supra* note 16, at S250.
[79] *Id.* at S249-50.
[80] *Id.* at S250.
[81] *Id.*
[82] *Id.*

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[83]

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)."[84] 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."[85]

WPATH also decided not to differentiate "between statements based on [literature reviews] and the rest,"[86] 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."[87]

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"[88]—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 "not possible."[89]

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

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

[85] Ex.39(Doc.592-39):66:2–67:5.

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

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

[88] SOC-8, *supra* note 16, at S48.

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

And so it was in the hormone chapter, where the final version of the above statement transformed into a strong "we recommend."[90]

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 evidence available.[91] 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.[92] WPATH promised clinicians that it followed this system when it actually eschewed transparency and made "strong" recommendations regardless of the evidence.

C. 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.[93] 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…)."[94] She reported: "[W]e found little to no evidence about children and adolescents."[95]

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[90] *Id.* at S111.

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

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

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

[94] *Id.* at 24.

[95] *Id.* at 22.

Dr. Robinson also informed HHS that she was "having issues with this sponsor"—WPATH—"trying to restrict our ability to publish."[96] 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.[97] 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.[98]

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).[99] 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."[100]

WPATH eventually allowed the Johns Hopkins team to publish two of its manuscripts. (It's still unclear what happened to the others.[101]) The team dutifully reported that the "authors"—not WPATH—were "responsible for all content."[102]

CONCLUSION

These vignettes are necessarily incomplete. Much more could be said. But the point is simply this: Plaintiffs have come to this Court seeking preliminary injunctive relief based on a carefully constructed narrative that is, in fact, not true. The Court should deny Plaintiffs' motion.

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[96] *Id.*

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

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

[99] *Id.* at 91.

[100] *Id.* at 38.

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

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

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CERTIFICATE OF SERVICE

I certify that on February 25, 2025, I electronically filed the foregoing with the Clerk of Court using the CM/ECF system, which will send notification of such filing to any CM/ECF participants.

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