Nos. 24-2838 & 24-3240

UNITED STATES COURT OF APPEALS FOR THE SEVENTH CIRCUIT

AUTUMN CORDELLIONÉ,
Plaintiff-Appellee,
v.
LLOYD ARNOLD,
Commissioner of the Indiana Department of Correction,
Defendant-Appellant.

On Appeal from the U.S. District Court for the
Southern District of Indiana, No. 3:23-cv-00135-RLY-CSW

BRIEF OF ALABAMA AND 23 OTHER STATES AS *AMICI CURIAE* SUPPORTING APPELLANT AND REVERSAL

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CORPORATE DISCLOSURE STATEMENT

As governmental parties, amici are not required to file a certificate of interested persons. Fed. R. App. P. 26.1(a).

TABLE OF CONTENTS

CORPORATE DISCLOSURE STATEMENT i

TABLE OF CONTENTS ii

TABLE OF AUTHORITIES iv

INTRODUCTION AND INTERESTS OF AMICI CURIAE 1

SUMMARY OF ARGUMENT 3

ARGUMENT 5

I. The District Court Upended The Status Quo To Grant Permanent Relief Based On An Incomplete Evidentiary Record 5

II. The District Court Relied On WPATH For Its Decision, But WPATH Is Unreliable 7

A. WPATH Crafted SOC-8 As a Political and Legal Document 8

1. WPATH Used SOC-8 to Advance Political and Legal Goals 9

2. WPATH Changed Its Treatment Recommendations Based on Political Concerns 12

B. WPATH Did Not Follow the Principles of Evidence-Based Medicine It Said It Followed 18

1. WPATH Failed to Properly Manage Conflicts of Interest 18

2. WPATH Was Not Transparent in How It Used GRADE 21

3. WPATH Hindered Publication of Evidence Reviews 24

4. WPATH Recommends Castration as "Medically Necessary" for "Eunuchs." 26

CONCLUSION 28

CERTIFICATE OF COMPLIANCE 30

CERTIFICATE OF SERVICE 31

TABLE OF AUTHORITIES

CASES

Am. Hosp. Ass'n v. Harris,
625 F.2d 1328 (7th Cir. 1980) 4, 5

Bell v. Wolfish,
441 U.S. 520 (1979) 1

Boe v. Marshall,
2:22-cv-184 (M.D. Ala. Mar. 27, 2023) 8, 9, 15, 19, 20, 27, 28

Doran v. Salem Inn, Inc.,
422 U.S. 922 (1975) 6

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603 F. Supp. 3d 1131, 1139 (M.D. Ala. 2022), *rev'd sub nom.*
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80 F.4th 1205 (11th Cir. 2023), *reh'g en banc denied*,
114 F.4th 1241 (11th Cir. 2024) 7

Gibson v. Collier,
920 F.3d 212 (5th Cir. 2019) 2

Gonzales v. Carhart,
550 U.S. 124 (2007) 2

Heller v. Doe,
509 U.S. 312 (1993) 2

K.C. v. Individual Members of Med. Licensing Bd. of Indiana,
121 F.4th 604 (7th Cir. 2024) 2, 3

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774 F.3d 63 (1st Cir. 2014) 1

O Centro Espirita Beneficiente Uniao Do Vegetal v. Ashcroft,
389 F.3d 973 (10th Cir. 2004) 5

Pyles v. Fahim,
771 F.3d 403 (7th Cir. 2014) 1

Starbucks Corp. v. McKinney,
602 U.S. 339 (2024) 5

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582 U.S. 571 (2017) 5

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895 F.2d 352 (7th Cir. 1990) 3

STATUTES

Indiana Code §11-10-3-3.5(a) 3

RULES

Fed. R. App. P. 26.1(a) i

Fed. R. App. P. 32(g)(1) 30

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INTRODUCTION AND INTERESTS OF AMICI CURIAE

Amici curiae are the States of Alabama, Arkansas, Florida, Georgia, Idaho, Iowa, Kansas, Kentucky, Louisiana, Mississippi, Missouri, Montana, Nebraska, North Dakota, Ohio, Oklahoma, South Carolina, South Dakota, Tennessee, Texas, Utah, Virginia, West Virginia, and Wyoming. Like Indiana, amici States administer prison systems and are responsible for the security and healthcare of inmates. They need flexibility to do that, on a limited budget funded by taxpayers, with security concerns unique to prisons. The Constitution affords States and their prison officials just such flexibility, mandating a "wide-ranging deference" by courts. *Bell v. Wolfish*, 441 U.S. 520, 547 (1979). As the Supreme Court has recognized, "the operation of our correctional facilities is peculiarly the province of the Legislative and Executive Branches of our Government, not the Judicial." *Id.* at 548.

Federal courts should be especially reticent to second-guess state officials' decisions regarding the medical care inmates receive. Because the Eighth Amendment prohibits only "cruel and unusual *punishments*," a prisoner bringing a deliberate-indifference claim must "demonstrat[e] that the treatment he received was blatantly inappropriate"—*i.e.*, that "no minimally competent professional" could have treated the inmate as the prison did. *Pyles v. Fahim*, 771 F.3d 403, 409 (7th Cir. 2014) (quotation marks and citations omitted). That's a difficult, if not impossible, standard for an inmate to meet when the medical community is still debating how best to treat the condition at issue—here, the plaintiff's diagnosis of gender dysphoria. *E.g.*, *Kosilek v. Spencer*, 774 F.3d 63, 87, 90 (1st Cir. 2014) (en banc) (holding that a prison official

did not act with deliberate indifference by failing to provide gender dysphoric inmate sex reassignment surgery); *Gibson v. Collier*, 920 F.3d 212, 215-16 (5th Cir. 2019) ("A state does not inflict cruel and unusual punishment by declining to provide sex reassignment surgery to a transgender inmate.").

Judicial modesty is warranted for other reasons as well. As this Court recently reaffirmed, "[l]egislative enactments touching on health and welfare receive a 'strong presumption of validity.'" *K.C. v. Individual Members of Med. Licensing Bd. of Indiana*, 121 F.4th 604, 613 (7th Cir. 2024) (quoting *Heller v. Doe*, 509 U.S. 312, 319 (1993)). "And 'in areas where there is medical and scientific uncertainty,' the courts give legislatures 'wide discretion' in crafting a response." *Id.* (quoting *Gonzales v. Carhart*, 550 U.S. 124, 163 (2007)). That is just the case here: "There is no medical consensus that sex reassignment surgery is a necessary or even effective treatment for gender dysphoria." *Id.* at 611-12 (alteration omitted) (quoting *Gibson*, 920 F.3d at 223).

Medicine often proceeds in fits and starts, with promising discoveries later reassessed and refined—and sometimes abandoned—as more evidence comes to light. The medical zeitgeist is not always right, as the medical establishment's embrace of once-popular theories regarding eugenics, lobotomizing surgeries, and opioids tragically show. *E.g.*, Adam Cohen, *Imbeciles: The Supreme Court, American Eugenics, and the Sterilization of Carrie Buck* 66 (2016) (noting that "[t]he most important elite advocating eugenic sterilization was the medical establishment," which endorsed the practice "with near unanimity"). Other examples abound. *See generally* Martin A.

Makary, *Blind Spots: When Medicine Gets It Wrong, and What It Means for Our Health* (2024). And as this Court has recognized, medical organizations—even prominent ones like the American Medical Association—can and do engage in "systematic, long-term wrongdoing" that merit "doubt" about their "genuineness regarding [their] concern for scientific method in patient care." *Wilk v. American Medical Ass'n*, 895 F.2d 352, 363, 366 (7th Cir. 1990).

Accordingly, that segments of the medical establishment are once again advocating for sterilizing inmates does not mean the Constitution requires States to hop on board. Amici write to urge the Court not to "hasten to set one side of the debate into constitutional stone," preventing States "from responding to tomorrow's insights." *K.C.*, 121 F.4th at 632.

SUMMARY OF ARGUMENT

The district court abused its discretion by entering a permanent injunction and calling it "preliminary." Plaintiff Autumn Cordellioné sought an order "enjoining defendant from enforcing Indiana Code §11-10-3-3.5(a) and requiring defendant to take all steps necessary to provide plaintiff with gender affirming surgery." Compl., Dkt. 1 at 10. And that is just what Cordellioné got. The district court required "the Commissioner of the Indiana Department of Correction … to take all reasonable actions to secure plaintiff gender-affirming surgery at the earliest opportunity." SA2, SA4. The surgery is permanent and irreversible; once Cordellioné receives it, there will be no further relief the lower court can award or this Court could set aside. The case will become moot. So much for this Court's instruction that "[t]he purpose of a preliminary

injunction is to preserve the status quo pending a final hearing on the merits." *Am. Hosp. Ass'n v. Harris*, 625 F.2d 1328, 1330 (7th Cir. 1980).

The district court's award of permanent relief based on an incomplete evidentiary record was particularly unfair to the Commissioner. As the plaintiff, Cordellioné could present a carefully curated selection of evidence while moving for "emergency" relief, allowing the Commissioner to conduct only limited discovery on an expedited basis before the preliminary injunction hearing. Thus, when Cordellioné's experts extolled the virtues of the Standards of Care promulgated by the World Professional Association for Transgender Health (WPATH), the Commissioner did not have discovery from WPATH showing just how unreliable those "Standards" are. The district court then relied nearly entirely on the imprimatur of WPATH for its "preliminary" injunction.

Amici are familiar with this story, having confronted appeals to WPATH's authority in other cases. Some States like Alabama have been able to conduct discovery into the reliability of the WPATH Standards of Care and uncovered a shocking medical scandal that is still unfolding. This Court should vacate the injunction, reimpose the status quo ante, and ensure that the Commissioner can conduct similar discovery and compile a complete evidentiary record before the district court decides whether to award permanent relief.

ARGUMENT

I. The District Court Upended The Status Quo To Grant Permanent Relief Based On An Incomplete Evidentiary Record.

The purpose of a preliminary injunction "is merely to preserve the relative positions of the parties until a trial on the merits can be held." *Starbucks Corp. v. McKinney*, 602 U.S. 339, 346 (2024) (quoting *University of Tex. v. Camenisch*, 451 U.S. 390, 395 (1981)); *see Am. Hosp. Ass'n*, 625 F.2d at 1330 ("The purpose of a preliminary injunction is to preserve the status quo pending a final hearing on the merits."). At the preliminary-injunction stage, the court is tasked not with "conclusively determin[ing] the rights of the parties," but with "balanc[ing] the equities" in a way that allows the "litigation [to] move[] forward." *Trump v. Int'l Refugee Assistance Project,* 582 U.S. 571, 580 (2017). "Given this limited purpose, and given the haste that is often necessary if those positions are to be preserved," "it is generally inappropriate for a federal court at the preliminary-injunction stage to give a final judgment on the merits." *Camenisch*, 451 U.S. at 395.

There are many reasons for this limited judicial role at the preliminary-injunction stage, but one is to ensure that the court can "preserve its power to grant effectual relief by preventing parties from making unilateral and irremediable changes during the course of litigation." *O Centro Espirita Beneficiente Uniao Do Vegetal v. Ashcroft*, 389 F.3d 973, 1015 (10th Cir. 2004) (en banc) (McConnell, J., concurring); *see* Samuel L. Bray, *The Purpose of the Preliminary Injunction*, 78 Vand. L. Rev. (forthcoming 2025) (explaining that the primary purpose of a preliminary injunction "is the protection of the court's ultimate remedial options"). Preliminary injunctions

thus preserve the ability of a court to rule on the merits when "otherwise a favorable final judgment might well be useless." *Doran v. Salem Inn, Inc.*, 422 U.S. 922, 932 (1975).

The district court here applied this rule in reverse. Rather than preserving the status quo, it upended it. And rather than protecting its ability to award "favorable final judgment" to *either* party at final adjudication, the court awarded "preliminary" relief to one party—Cordellioné—that cannot be undone. By "preliminar[ily] enjoin[ing]" the Commissioner "to take all reasonable actions to secure plaintiff gender-affirming surgery at the earliest opportunity," SA4, the district court all but ensured that "favorable final judgment" will be "useless" if it turns out that judgment is due the Commissioner.

Making matters worse, the district court entered its injunction based on carefully curated evidence that Cordellioné presented about the safety and efficacy of using sex-change surgeries to treat gender dysphoria. But that record was woefully incomplete because the parties never got to conduct extensive discovery. As explained below, a robust evidentiary record would show that the foundational assumption by the district court—namely, that the WPATH "Standards of Care are credible and reliable," SA18—is wrong a thousand times over. This Court should vacate the injunction to allow the Commissioner to conduct full discovery and present a complete evidentiary record to the court before final judgment is awarded.

II. The District Court Relied On WPATH For Its Decision, But WPATH Is Unreliable.

Throughout its opinion, the district court relied on the imprimatur of the World Professional Association for Transgender Health to award Cordellioné relief. Based on representations by Cordellioné's experts, the district court found that "[t]he WPATH Standards of Care are the internationally recognized guidelines for the treatment of persons with gender dysphoria" and "are credible and reliable." SA17-18. The court expressly "rel[ied] on them in reaching its conclusions in this matter." SA18.

Amici are all too familiar with this playbook. Alabama, for instance, had enforcement of its law restricting access to sex-change procedures for minors preliminarily enjoined based on the say-so of WPATH. Following a preliminary injunction hearing in which the district court heard evidence carefully chosen by the plaintiffs (and limited evidence the State could muster in the emergency posture), the district court acknowledged that the "[k]nown risks" of providing sex-change procedures to minors "include loss of fertility and sexual function." *Eknes-Tucker v. Marshall*, 603 F. Supp. 3d 1131, 1139 (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). "Nevertheless," the court said, "WPATH recognizes transitioning medications as established medical treatments and publishes a set of guidelines for treating gender dysphoria in minors with these medications." *Id.* Accordingly, the court preliminarily enjoined enforcement of Alabama's law. *Id.* at 1151.

Alabama then obtained discovery from WPATH to test the court's deference.[1] What it discovered is nothing less than a national medical, legal, and political scandal. *See generally* Brief of Alabama as *Amicus Curiae*, No. 23-477, *United States v. Skrmetti* (U.S. Oct. 15, 2024) (discussing evidence Alabama uncovered in discovery). Here, amici discuss just a few of the episodes that cast the WPATH Standards of Care in a very different light than the one presented to the court below. While some of these episodes are necessarily more pertinent to the safety and efficacy of pediatric sex-change procedures—that was the focus of Alabama's discovery—they are useful here for two reasons. First, they show that WPATH as an institution, and the Standards of Care 8 in particular, are untrustworthy through and through. And second, they demonstrate the kind of evidence the Commissioner could uncover if given adequate time to compile a complete evidentiary record.[2]

A. 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

[1] *See* Order, *Boe v. Marshall*, 2:22-cv-184 (M.D. Ala. Mar. 27, 2023), Doc.263 (ordering WPATH to produce discovery).

[2] Throughout this brief, amici will reference evidence and briefing Alabama submitted to the district court in *Boe v. Marshall*, 2:22-cv-184 (M.D. Ala.). Citations will be by exhibit number (or brief title) followed by the docket entry in parenthesis and the internal page number following the colon. *E.g.*, Ex.173(Doc.560-23):22-23. For ease of reference, cited exhibits and briefing are available online: https://www.alabamaag.gov/boe-v-marshall/.

use in formulating their recommendations.[3] 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.

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

WPATH selected 119 authors—all existing WPATH members—to contribute to SOC-8.[4] According to Dr. Bowers, it was "important" for each author "to be an advocate for [transitioning] treatments before the guidelines were created."[5] 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."[6] 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."[7] Another chimed in: "It is abundantly clear to me when I go to court on behalf of TGD [transgender and gender-

[3] WPATH, *SOC8 Contributors*, https://perma.cc/X48V-9T8K; E. Coleman et al., *Standards of Care for the Health of Transgender & Gender Diverse People, Version 8*, 23 INT'L J. OF TRANSGENDER HEALTH S248-49 (2022), https://perma.cc/Y9G6-TP3M.

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

[5] Ex.18(Doc.564-8):121:7-11; *Boe*.Reply (Doc.700-1):33.

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

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

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."[8]

Perhaps for this reason—and because it knew that "we will have to argue it in court at some point"[9]—WPATH commissioned a legal review of SOC-8 and was in regular contact with movement attorneys.[10] 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?"[11] When informed by Dr. Coleman that "[w]e had agreed long ago that we would send [the SOC-8 draft] … for legal review," Dr. Bouman replied that he would "check what Rachel Levine's point of view is on these issues" when he met with the Assistant Secretary for Health in the Biden Administration the following week.[12] The WPATH Executive Committee discussed various options for the review—"ideas; ACLU, TLDEF, Lambda Legal…"[13]—before apparently settling on the senior director of transgender and queer rights at GLAD (now counsel for the plaintiffs in Alabama's case) to conduct the review.[14]

Authors were also explicit in their desire to tailor SOC-8 to ensure coverage for an "individual's embodiment goals,"[15] whatever they might be. As Dr. Dan Karasic,

[8] Ex.184(Doc.700-13):15.
[9] Ex.182(Doc.700-11):152.
[10] Ex.4(Doc.557-4):vi.
[11] Ex.182(Doc.700-11):151.
[12] *Id.* at 150-51.
[13] Ex.184(Doc.700-13):14.
[14] SOC-8, *supra* note 3, at S177.
[15] Ex.180(Doc.700-9):11.

one of the plaintiffs' experts in Alabama's case, explained to other SOC-8 authors: "Medical necessity is at the center of dozens of lawsuits in the US right now,"[16] "one or more of which could go to the Supreme Court[] on whether trans care is medically necessary vs. experimental or cosmetic. I cannot overstate the importance of SOC 8 getting this right at this important time."[17] Another author was more succinct: "[W]e need[] a tool for our attorneys to use in defending access to care."[18]

WPATH thus included a whole section in SOC-8 on "medical necessity" and took to heart Dr. Karasic's advice to list the "treatments in an expansive way."[19] 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."[20]

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 stuck with: those who

[16] *Id.* at 64.
[17] Ex.181(Doc.700-10):43.
[18] *Id.* at 75.
[19] *Id.* at 66.
[20] SOC-8, *supra* note 3, at S18.

fulfil a diagnosis of Gender Dysphoria and Gender Incongruence as per APA/WHO)."[21]

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,"[22] 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."[23] Others just sought to massage the guideline's language to avoid "empower[ing]" those concerned that the evidence did not support transitioning treatments.[24]

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

Outside political actors also influenced SOC-8. Most notably, Admiral Rachel Levine, the Assistant Secretary for Health at HHS during the Biden Administration, met regularly with WPATH leaders, "eager to learn when SOC 8 might be

[21] Ex.181(Doc.700-10):36 (second closed parenthesis added).
[22] SOC-8, *supra* note 3, at S45-46.
[23] Ex.174(Doc.560-24):1-2.
[24] Ex.184(Doc.700-13):55.

published."[25] According to one WPATH member who met with Levine, "[t]he failure of WPATH to be ready with SOC 8 [was] proving to be a barrier to optimal policy progress" for the Biden Administration.[26]

A few months before SOC-8 was to be published in September 2022 (and long after the public comment period had closed that January[27]), WPATH sent Admiral 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.[28] 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."[29] 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."[30] Each recommendation was paired with a qualifier that could allow for surgery at an even earlier age.[31]

After reviewing the draft, Admiral Levine's office contacted WPATH at the beginning of July with a political concern: that the listing of "specific minimum ages for

[25] Ex.184(Doc.700-13):54.
[26] Ex.184(Doc.700-13):54.
[27] *See* Ex.187(Doc.700-16):4-5.
[28] Ex.170(Doc.700-4):61-64.
[29] Coleman, *Standards of Care, Version 7*, 13 INT'L J. OF TRANSGENDERISM 1, 25-27 (2012), https://perma.cc/T8J7-W3WC.
[30] Ex.170(Doc.700-4):143.
[31] *Id.*

treatment," "under 18, will result in devastating legislation for trans care."[32] Admiral Levine's chief of staff suggested that WPATH hide the recommendations by removing the age limits from SOC-8 and creating an "adjunct document" that could be "published or distributed in a way that is less visible."[33] WPATH leaders met with Levine and HHS officials to discuss the age recommendations.[34] According to a WPATH participant, Levine "was very concerned that having ages (mainly for surgery) will affect access to health care for trans youth … and she and the Biden administration worried that having ages in the document will make matters worse."[35] Levine's solution was simple: "She asked us to remove them."[36]

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."[37]
- "I need someone to explain to me how taking out the ages will help in the fight against the conservative anti trans agenda."[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]

[32] Ex.186 (Doc.700-15):28.
[33] *Id.* at 29.
[34] *See* Ex.186 (Doc.700-15):11, 17; Ex.21(Doc.700-3):287:5–288:6.
[35] Ex.186 (Doc.700-15):11.
[36] *Id.*
[37] *Id.* at 32.
[38] *Id.*
[39] *Id.*

- "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 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

[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; *Boe*.MSJ(Doc.619):20; Ex.186 (Doc.700-15):73, 88-91.
[45] Ex.187(Doc.700-16):13-14, 109 ("The AAP comments asked us to remove age[s]").
[46] *Id.* at 100.

"it would be a major challenge for WPATH" if AAP opposed SOC-8.[47] WPATH thus caved and "agreed to remove the ages."[48]

Thanks to the Biden Administration and AAP, SOC-8 does not contain age minimums for any transitioning hormonal or surgical intervention except for one: phalloplasty, the surgical creation of a neopenis. WPATH considers all other surgeries and interventions "medically necessary gender-affirming medical treatment[s] in adolescents."[49]

That is concerning enough. But perhaps even more worrisome is what the episode reveals. *First*, it shows that both the Biden Administration 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 being presented any new science of which the committee was previously unaware."[50] In fact, despite assuring that "formal consensus for *all* statements was obtained using the Delphi process (a structured solicitation of expert judgments [of its contributing

[47] *Id.* at 191.

[48] *Id.* at 338. SOC-8 was initially published with the age minimums intact, so WPATH had to quickly issue a "correction" to remove them. *See Correction*, 23 INT'L J. OF TRANSGENDER HEALTH S259 (2022), https://perma.cc/4342-KFEN. Remarkably, WPATH then had the correction itself removed. *See Statement of Removal*, https://bit.ly/3qSqC9b.

[49] *See* SOC-8, *supra* note 3, at S66.

[50] Ex.21(Doc.700-3):293:25–295:16.

authors] in three rounds),"[51] WPATH did not send the last-minute change through Delphi.[52] Instead, it treated its decision as "highly, highly confidential."[53]

Second, as soon as WPATH made the change, it began covering it up. Rather than explaining what *actually* happened, WPATH leaders promptly sought for "all [to] get on the same exact page, and PRONTO."[54] Dr. Bowers encouraged contributors to submit to "centralized authority" so there would not be "differences that can be exposed."[55] "[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."[56]

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."[57] 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."[58] Apparently, it didn't matter

[51] SOC-8, *supra* note 3, at S250 (emphasis added).
[52] Ex.21(Doc.700-3):293:25–295:16 (Dr. Coleman: "[W]e did not submit that change to Delphi at the end.").
[53] Ex.188(Doc.700-17):152.
[54] *Id.* at 120.
[55] Ex.177(Doc.700-6):124.
[56] *Id.* at 119.
[57] Ex.188(Doc.700-17):113.
[58] *Id.*

that the explanation itself could be considered "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."[59]

B. 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.[60] Among other things, the appendix states that WPATH managed conflicts of interest, used the GRADE framework to tailor recommendation statements based on the strength of evidence, and engaged the Johns Hopkins evidence review team to conduct systematic literature reviews and create evidence tables for use in SOC-8.[61] Discovery revealed a different story.

1. WPATH Failed to Properly Manage Conflicts of Interest.

WPATH cites two international 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.[62] 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.[63]

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[59] Ex.177(Doc.700-6):102.

[60] *See* SOC-8, *supra* note 3, at S247-51.

[61] SOC-8, *supra* note 3, at S247-50.

[62] *Id.* at S247.

[63] *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).

At the same time, the standards recognize that a guideline committee typically benefits from *some* involvement by clinicians who provide the services at issue.[64] Accordingly, they suggest ways for committees to benefit from conflicted clinicians while limiting their involvement. The standard from the National Academies, for instance, recommends that "[m]embers with [conflicts of interest] should represent *not more than a minority* of the [guideline development group]."[65]

Yet aside from citing them in its methodology section, it appears that 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.[66] Dr. Coleman testified that it was "not unusual at all" "for participants in the SOC-8 process to have many published articles already on topics relating to gender dysphoria."[67] Dr. Bowers agreed 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

[64] Institute of Medicine, *supra* note 63, at 83 (recognizing that "a [guideline development group] may not be able to perform its work without members who have [conflicts of interest], such as relevant clinical specialists who receive a substantial portion of their incomes from services pertinent to the [clinical practice guidelines]")

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

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

[67] Ex.21(Doc.700-3):228:14-19.

[68] Ex.18(Doc.564-8):121:7-11; *Boe.*Reply(Doc.700-1):34.

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 at his deposition that "most participants in the SOC-8 process had financial and/or nonfinancial conflicts of interest."[72] Another author agreed: "Everyone involved in the SOC process has a non-financial interest."[73] Dr. Robinson, the chair of the Johns Hopkins evidence review team, said the same: She "expect[ed] many, if not most, SOC-8 members to have competing interests."[74] Robinson even had to inform WPATH—belatedly—that "[d]isclosure, and any necessary management of potential

[69] Institute of Medicine, *supra* note 63, at 78.
[70] Ex.18(Doc.564-8):37:1-13, 185:25–186:9; *Boe*.Reply(Doc.700-1):34-35.
[71] SOC-8, *supra* note 3, at S177.
[72] Ex.21(Doc.700-3):230:17-23.
[73] Ex.174(Doc.560-24):7.
[74] Ex.166(Doc.560-16):1.

conflicts, should take place *prior* to the selection of guideline members."[75] "Unfortunately," she lamented, "this was not done here."[76] No matter: SOC-8 proclaims the opposite ("Conflict of interests were reviewed as part of the selection process"[77]), and Dr. Coleman testified that he did not know of any author removed from SOC-8 due to a conflict.[78]

2. 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."[79] 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.[80]

Chapter authors were then to grade the recommendation statements based on the evidence.[81] 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

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

among providers."[82] 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."[83] 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[84]

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)."[85] 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."[86]

WPATH also decided not to differentiate "between statements based on [literature reviews] and the rest,"[87] and ordered the removal of all notations disclosing the quality of evidence for each recommendation. A draft of the hormone chapter illustrates the change and its import. The chapter had initially offered a "weak

[82] *Id.*
[83] *Id.*
[84] WPATH, *Methodology for the Development of SOC8*, https://perma.cc/QD95-754H (last visited Oct. 13, 2024).
[85] Ex.190(Doc.700-18):8; *see* Ex.182(Doc.700-11):157-58.
[86] Ex.39(Doc.592-39):66:2–67:5.
[87] Ex.182(Doc.700-11):62; *see* Ex.9(Doc.700-2):¶¶29-36, 43-47.

recommendation" ("we suggest") based on low-quality evidence ("++") that clinicians prescribe cross-sex hormones to gender dysphoric adolescents, "preferably with parental/guardian consent."[88]

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"[89]—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."[90] And so it was in the hormone chapter, where the final version of the above statement transformed into a strong "we recommend."[91]

While this mismatch may not seem like a big deal, the difference between a "strong" and "weak" recommendation is extremely 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.[92] Thus, given that the estimated effect is

[88] Ex.182(Doc.700-11):5; *see id.* at 1-40; Ex.9(Doc.700-2):¶¶29-36, 43-47.
[89] SOC-8, *supra* note 3, at S48.
[90] *Id.* at S46-47.
[91] SOC-8, *supra* note 3, at S111.
[92] Balshem, *GRADE Guidelines*, 64 J. CLINICAL EPIDEMIOL. 401, 404 (2011), https://perma.cc/2KDY-6BW5.

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.[93] 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 regardless of the evidence.

3. 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.[94] 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…)."[95] She reported: "[W]e found little to no evidence about children and adolescents."[96] HHS wrote back: "Knowing that there is little/no evidence about children and adolescents is helpful."[97]

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

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[93] Yao, *Discordant and Inappropriate Discordant Recommendations*, BMJ (2021), https://perma.cc/W7XN-ZELX.
[94] Ex.173 (Doc.560-23):22-25.
[95] *Id.* at 24.
[96] *Id.* at 22.
[97] *Id.*
[98] *Id.*

rejected Robinson's request to publish two manuscripts because her team failed to comply with WPATH's policy for using SOC-8 data.[99] Among other things, that policy required the team to seek "final approval" of any article from an SOC-8 leader.[100] 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 the transgender community in the design, drafting of the article, and the *final approval* of the article."[101] Once those boxes were checked, the WPATH Board of Directors had final authority on whether the manuscript could be published.[102]

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" (again, as WPATH defined it).[103] 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."[104]

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[99] Ex.167(Doc.560-17):86-88.
[100] *Id.* at 75-81.
[101] *Id.* at 37 (emphasis added).
[102] *Id.* at 38.
[103] *Id.* at 91.
[104] *Id.* at 38.

WPATH eventually allowed the Johns Hopkins team to publish two of its manuscripts. (It's still unclear what happened to the others.[105]) The team dutifully reported that the "authors"—not WPATH—were "responsible for all content."[106]

4. 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."[107] 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."[108] 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."[109]

Dr. Coleman also admitted that no diagnostic manual recognizes "eunuch" as a medical or psychiatric diagnosis.[110] And other SOC-8 authors criticized the chapter

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

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

[107] SOC-8, *supra* note 3, at S88.

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

[109] Ex.21(Doc.700-3):172:19–173:25.

[110] *Id.*

as "very high on speculation and assumptions, whilst a robust evidence base is largely absent."[111] Dr. Bowers even admitted that not every board member read the chapter before approving it for publication.[112] No matter: The guideline the district court here relied on as establishing the Eighth Amendment standard of care officially recommends castration for men and boys who identify as "eunuch."

And how did WPATH learn that castration constitutes "medically necessary gender-affirming care"?[113] From the internet—specifically a "large online peer-support community" called the "Eunuch Archive."[114] According to SOC-8 itself, the "Archive" contains "the greatest wealth of information about contemporary eunuch-identified people."[115] 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."[116] "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."[117]

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[111] Ex.182(Doc.700-11):96.
[112] Ex.18(Doc.564-8):147:9–148:4; *Boe*.MSJ(Doc.619):16.
[113] SOC-8, *supra* note 3, at S88.
[114] *Id.*
[115] *Id.*
[116] Gluck, *Top Trans Medical Association Collaborated With Castration, Child Abuse Fetishists*, REDUXX (May 17, 2022), https://perma.cc/5DWF-MLRU.
[117] *Id.*

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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[]."[118]) Contra the district court's conclusion, the WPATH Standards are not "credible and reliable," and they should not be relied on to constitutionalize a standard of care under the Eighth Amendment. The Commissioner should be allowed the opportunity to conduct discovery and compile an evidentiary record that shows just that.

CONCLUSION

The Court should reverse.

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

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CERTIFICATE OF COMPLIANCE

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Dated: January 28, 2025

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CERTIFICATE OF SERVICE

I certify that on January 28, 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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