Exhibit EE-1

No. 23-477

IN THE

Supreme Court of the United States

UNITED STATES,

Petitioner,

v.

JONATHAN SKRMETTI, ATTORNEY GENERAL AND REPORTER FOR TENNESSEE, *et al.*,

Respondents,

and

L.W., BY AND THROUGH HER PARENTS AND NEXT FRIENDS, SAMANTHA WILLIAMS AND BRIAN WILLIAMS, *et al.*,

Respondents in Support of Petitioner.

ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE SIXTH CIRCUIT

BRIEF OF *AMICI CURIAE* CLINICAL PRACTICE GUIDELINE EXPERTS IN SUPPORT OF PETITIONER AND RESPONDENTS IN SUPPORT OF PETITIONER

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INTEREST OF *AMICI CURIAE*[1]

Amici are adolescent medicine specialists, pediatricians, clinicians, methodologists, professors, and researchers. They have decades of experience at institutions across the country, ranging from Harvard Medical School to Stanford Medicine Children's Health.[2]

Amici have conducted and published randomized-controlled trials and observational medical studies. They also have expertise in the development and use of clinical practice guidelines across medical specialties in the United States.

Amici include:

(1) Jenifer R. Lightdale, MD, MPH, Associate Chief of the Division of Gastroenterology, Hepatology and Nutrition at Boston Children's Hospital, and Professor of Pediatrics at Harvard Medical School in Massachusetts;

(2) Neville H. Golden, MD, the Marron and Mary Elizabeth Kendrick Professor of Pediatrics, Emeritus

1. Pursuant to Supreme Court Rule 37.6, *amici curiae* state that no counsel for a party authored this brief in whole or in part, and no person or entity other than *amici curiae* and their counsel made a monetary contribution to its preparation or submission. The views expressed in this brief reflect the *amici*'s opinions as individual researchers and physicians, rather than those of the institutions that employ them. Emphasis is added and citations, internal quotations, and objections are omitted throughout this brief, unless otherwise indicated.

2. *Amici* join this brief as individuals; institutional affiliation is noted for informational purposes only and does not indicate endorsement by institutional employers of their positions.

Active, Past Division Chief of the Division of Adolescent Medicine at Stanford University School of Medicine in California;

(3) Scott E. Hadland, MD, MPH, MS, Chief of the Division of Adolescent and Young Adult Medicine, and Associate Professor of Pediatrics at Mass General for Children/Harvard Medical School in Massachusetts;

(4) Jason Nagata, MD, MSc, Associate Professor of Pediatrics in the Division of Adolescent & Young Adult Medicine at the University of California San Francisco, and affiliated faculty with the Institute for Global Health Sciences and the Center for Sexual and Gender Minority Health;

(5) Kenneth W. Goodman, PhD, Professor and Director of the Institute for Bioethics and Health Policy at the University of Miami in Florida;

(6) Melissa Brouwers, M.D., Professor and Director of the School of Epidemiology and Public Health at the University of Ottawa, Canada, who has served as principal of developers of international standards of practice guideline quality and evaluation;

(7) Mary Butler, PhD, MBA, Associate Professor at the University of Minnesota Division of Health Policy & Management and Co-Director of the Minnesota Evidence-based Practice Center of the School of Public Health;

(8) Doug Haldeman, PhD, professor and chair of the doctoral program in clinical psychology at John F. Kennedy University in California; and

(9) Jennifer Yost PhD, RN, FAAN, is a Professor at the M. Louise Fitzpatrick College of Nursing at Villanova University in Pennsylvania where she engages in research aimed at promoting the use research evidence to inform health care decisions based on best available evidence.

(10)Ian J. Saldanha, PhD, is the associate director of the Johns Hopkins Evidence-based Practice Center in Maryland, and an epidemiologist with expertise conducting evidence sytheses and clinical practice guidelines developing and advancing methods to improve them, and teaching methods for their conduct.

(11) Renata Arrington Sanders, MR, MPH, ScM, is the Chief of the Craig-Dalsimer Division of Adolescent Medicine at the Children's Hospital of Philadelphia and a Professor of Pediatrics and Medicine at the Perelman School of Medicine of the University of Pennsylvania.[3]

Amici submit this brief to address what the district court found were the "widely accepted guidelines for treating gender dysphoria," namely the World Professional Association for Transgender Health (WPATH) Standards of Care 8 (SOC8).[4] Gender dysphoria "arises from the incongruence that transgender people experience between their gender identity and [assigned] sex at birth."[5]

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3. Appendix A contains a complete listing of *amici*.

4. App. to the Petition for a Writ of Certiorari ("Pet. App.") at 178a-181a (Nov. 6, 2023); *see also* Eli Coleman, et al., *Standards of Care for the Health of Transgender and Gender Diverse People, Version 8*, International Journal of Transgender Health (2022) (SOC8).

5. SOC8, consistent with definitions from the World Health Organization and the American Psychiatric Association, defines

The district court's consideration of the evidence was correct and *amici* share a significant interest in ensuring that clinical practice guidelines—like SOC8—are reliable and evidence-based. *Amici* submit this brief to outline their concerns about governments making medical decisions in the halls of political power by banning care that is supported by reliable clinical practice guidelines. The State defendants' after-the-fact attempt to justify interfering with good medical practice based on internal communications among the clinicians who developed the guidelines compounds that concern.

Such attacks could deter subject-matter experts from participating in developing guidelines and could discourage candid, uninhibited dialogue among researchers and practitioners, which is essential to the development of reliable clinical guidelines and effective clinical practice.

SUMMARY OF ARGUMENT

The district court held—as every court to consider the issue has recognized—that a categorical ban on medical care for gender dysphoria cannot survive intermediate scrutiny under the Equal Protection Clause.[6]

While considering whether the Tennessee law was "substantially related to an important state interest," the district court made factual findings about WPATH's

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gender dysphoria as: "a state of distress or discomfort that may be experienced because a person's gender identity differs from that which is physically and/or socially attributed to their sex assigned at birth." SOC8 at S7, S15, and S252.

6. Pet. App. 197a-205a.

guidelines. The district court found that "WPATH [has] published widely accepted guidelines for treating gender dysphoria" "based on scientific research and clinical experience" that are the "prevailing standards of care."[7] The merits briefs here correctly explain how that conclusion was compelled by the record.[8]

Since 1979, WPATH has labored to develop evidence-based clinical guidelines for treating individuals suffering from gender dysphoria. Medical evidence has mounted for over four decades, and every major medical association now recognizes the benefits of puberty blockers and hormones for adolescents with persistent gender dysphoria.

Though WPATH and medical professionals have studied gender dysphoria for decades, some 22 States have banned or restricted medical treatments for adolescents with gender dysphoria in the last 3 years. State defendants in cases defending those bans and in opposition to certiorari here have gone beyond this record to try to rationalize the bans based on a series of methodological critiques of WPATH's clinical practice guidelines.[9] If this Court were to reconsider the district court's factual findings (and it should not), none of the State defendants' critiques—citing sources ranging from newspaper articles to YouTube videos—has merit.

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7. Pet. App. 60a, 178a, and 252a.

8. *See, e.g.*, Br. for the Petitioner United States of America, at 12 (Aug. 27, 2024); *see also* Pet. App. 183a.

9. *See, e.g.*, Br. of Respondents in Opp. to Petition for Writ of Certiorari, at 9-10 (Feb. 2, 2024); Br. of Alabama as *Amicus Curiae* Supporting Respondents in Opp. to Petition for Writ of Certiorari, at 7-24 (Feb. 2, 2024).

Based on reliable evidence, clinical experience, and expert consensus, in September 2022, WPATH issued its eighth and current version of the Standards of Care (SOC8). SOC8 summarizes the most methodologically sound medical studies on gender dysphoria, devotes a new chapter to adolescents, and makes recommendations for care.

WPATH's process for developing SOC8 was transparent, rigorous, iterative, and methodologically sound. It included a steering committee of leading clinicians and academics, an independent systematic evidence review led by a professor from Johns Hopkins University, the evaluation of over 70 pre-existing systematic reviews of evidence on a wide range of issues, and a process for achieving consensus among 119 SOC8 members and applicants who were selected to develop these guidelines. SOC8 meets or exceeds the developmental rigor of other clinical practice guidelines produced by other medical societies in the United States.

For the SOC8 chapter dedicated exclusively to adolescents, the leads were psychologists and psychiatrists practicing and teaching at institutions ranging from Emory School of Medicine to Harvard Medical School. That chapter describes the current evidence and concludes that the data "[t]aken as a whole," shows "early medical intervention" "can be effective and helpful for many."[10]

If this Court accepts State defendants' critiques of SOC8, it could undermine many thousands of clinical guidelines used by practicing physicians in almost every

10. SOC8 at S47.

field of medicine. In short, the pseudoscientific arguments made by State defendants are based on bad medicine and accepting them threatens to make medicine worse.

BACKGROUND

WPATH "is an international, multidisciplinary, professional association whose mission is to promote evidence-based care, education, research, public policy, and respect in transgender health."[11] WPATH has over 3,000 members who are health care professionals, social scientists, and legal professionals.[12] Its "evidence-based approach is not only based on the published literature (direct as well as background evidence) but also on consensus-based expert opinion."[13] SOC8, a distinct project sponsored by WPATH, totals 190 pages of text plus 68 pages of references.[14]

A. Clinical Practice Guidelines

In 2011, the Institute of Medicine of the National Academies of Sciences (IOM) published *Clinical Practice Guidelines We Can Trust*. IOM, now the National Academy of Medicine, has over 2,400 members elected by their peers in recognition of outstanding achievement.[15] IOM defines "Clinical Practice Guidelines" as "statements

11. *Id.* at S5-S258.

12. *Id.* at S5.

13. *Id.* at S247.

14. *Id.* at S178-S246.

15. National Academy of Medicine, *About the National Academy of Medicine*, https://nam.edu/about-the-nam/ (last visited Aug. 27, 2024).

that include recommendations intended to optimize patient care that are informed by a systematic review of evidence and an assessment of the benefits and harms of alternative care options."[16]

B. Methodology for SOC8[17]

Selection of Steering Committee: Members of the WPATH Board selected a Guideline Steering Committee, which oversaw the guideline development process.[18] Its Chair, Eli Coleman of the University of Minnesota Medical School, has been a frequent technical consultant to the World Health Organization (WHO) and the Centers for Disease Control and Prevention.[19] The Steering Committee also included as co-chairs a clinical associate professor of medicine at New York University and a professor of mental health and transgender health at the University of Nottingham (UK).[20]

In addition to overseeing the development of SOC8, the Steering Committee reviewed all chapters of the prior Standards of Care and the medical literature to

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16. IOM (Institute of Medicine), Clinical Practice Guidelines We Can Trust 15 (2011) (IOM Guidelines).

17. This section is based exclusively on WPATH's description of the methodology it used for the development of SOC8. *Amici* did not participate in the development of SOC8.

18. SOC8 at S247 (App. A) (SOC8 Methodology).

19. World Professional Association for Transgender Health, *Chairs of the SOC8 and Lead Evidence Team*, https://www.wpath.org/soc8/Chairs-Evidence-Leads (last visited Aug. 27, 2024).

20. *Id.*

recommend statements that needed to be updated and ensure consistency of statements across SOC8.[21]

Guideline Methodologist and Evidence Review Team: WPATH worked closely with a guideline methodologist.[22] That guideline methodologist—who also led the Evidence Review Team—is a Professor of Medicine, Epidemiology and Health Policy and Management at Johns Hopkins University.[23]

The Evidence Review Team, the Guideline Steering Committee, and the chapter leads identified the recommendation statements from the prior standards of care that needed to be updated, new areas requiring recommendation statements, and the systematic reviews required.[24]

"A systematic review attempts to collate all empirical evidence that fits pre-specified eligibility criteria in order to answer a specific research question. It uses explicit, systematic methods that are selected with a view to minimizing bias, thus providing more reliable findings from which conclusion can be drawn and decisions made."[25] For statements requiring a systematic review,

21. SOC8 Methodology at S248.

22. *Id.* at S249.

23. World Professional Association for Transgender Health, *Establishing the SOC8 Revision Committee and Meet the Chairs and Lead Evidence Team*, https://www.wpath.org/soc8/Revision-Committee (last visited Aug. 27, 2024)

24. *Id.*

25. Toby J. Lasserson, et al., *Chapter 1.1: Why do a systematic review?*, *in* Cochrane Handbook for Systematic Reviews of Interventions (Julian Higgins, et al., eds., 2023), *available at*

the Evidence Review team drafted review questions, specifying the population, interventions, comparisons, and outcomes.[26] SOC8 chapter leads and members evaluated the review questions and provided feedback.[27]

The Evidence Review Team then conducted systematic reviews and presented the results, including evidence tables, to the members of each relevant chapter.[28] The final version of SOC8 considered evidence from over 70 systematic reviews on a huge range of topics, including the effects of puberty blockers and hormones on cardiovascular function, bone health, anxiety, depression, and psychosocial functioning.[29]

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https://training.cochrane.org/handbook/current/chapter-01; *see also* IOM Guidelines at 96.

26. SOC8 Methodology at S248.

27. *Id.*

28. *Id.*

29. *See, e.g.*, SOC8 at S215 (citing "systematic review and meta-analysis" of "[s]ex steroids and cardiovascular outcomes"); at S153 (citing "systematic review and meta-analysis on the impact of sex hormones on bone health"); at S182 (citing "systematic review" on "[h]ormone therapy, mental health, and quality of life among transgender people"); at S190 (citing "systematic review" of "[h]ormonal treatment in young people with gender dysphoria"); at S218 (citing "systematic review" of literature about "[p]revalence of anxiety symptoms and disorders in the transgender population"); at S221 (citing "systematic review and meta-analysis" of "[q]uality of life of treatment-seeking transgender adults"); at S242 (citing "systematic review of the effects of hormone therapy on psychological functioning and quality of life in transgender individuals"); at S193 (citing "systematic review" of "[i]nternational clinical practice guidelines for gender minority/trans people"); at S201 (citing "systematic review" of "[i]nterventions

Recommendations and Delphi Process: After months of debates among chapter members, chapter leads and members drafted explicit and actionable recommendation statements.[30]

WPATH then followed a rigorous Delphi process to approve the recommendation statements.[31] The Delphi process is widely-used to develop guidelines and involves "a structured solicitation of expert judgments in three rounds" relying on a panel of experts to reach formal consensus on all statements.[32] The Delphi SOC8 process used the Research and Development/UCLA Appropriateness scale ranging from 1 (strongly disagree) to 9 (strongly agree).[33]

Agreement was defined as 75 percent of the SOC8 members scoring the statement 7, 8, or 9.[34] Recommendations that did not achieve agreement were returned to chapter leads for revision based on voter comments.[35] Once modified, the revised statements went

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to improve patient comprehension in informed consent for medical and surgical procedures"); at S226 (citing "[a] systematic review of the efficacy, harmful effects, and ethical issues related to sexual orientation change efforts").

30. SOC8 Methodology at S250.

31. *Id.*

32. *See id.*

33. *Id.*

34. *Id.*

35. *Id.*

through the Delphi process again.[36] If agreement was not reached after the second round, the statement was revised again based on feedback from voters and then put through a third round of voting.[37] If a statement was not approved after 3 rounds, the statement was removed from SOC8.[38]

GRADE and Process for Formulating Recommendations: Once statements passed the Delphi process, chapter members graded each statement using a process adapted from GRADE.[39] Recommendation statements were either for or against an intervention or treatment and strength was indicated as either "we recommend" for a strong recommendation or "we suggest" for a weak recommendation.[40] The strength of the recommendation considered the "balance of potential benefits and harms," "confidence in that balance or quality of evidence," "values and preferences of providers and patients," and "resource use and feasibility."[41]

Strong recommendations were made where one or more of several conditions were met: "the evidence is of high quality"; "estimates of the effect of an intervention/

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36. *Id.*

37. *Id.*

38. *Id.*

39. *Id.* GRADE stands for "Grades of Recommendation, Assessment, Development, and Evaluation," and it assesses the statistical degree of certainty that a particular treatment will have its intended effect. *See* 45 WORLD HEALTH ORGANIZATION, HANDBOOK FOR GUIDELINE DEVELOPMENT 130 (2d ed. 2014) (WHO Handbook).

40. SOC8 Methodology at S250.

41. *Id.*

therapy/strategy (i.e., there is a high degree of certainty effects will be achieved in practice)"; "there are few downsides of therapy/intervention/strategy"; and "there is a high degree of acceptance among providers and patients or those for whom the recommendation applies."[42] Published studies, as well as expert clinical experience, were considered in determining the strength of each recommendation.[43]

After this grading process, "the Chapter Workgroups wrote the text providing the rationale or reasoning for the recommendation" including detailing "the available evidence" and any of its limitations and whether the recommendation was "strong or weak."[44] Then a separate "group of independent clinical academics working in the field of transgender health reviewed the references used in every chaper in order to validate that the references were appropriately used to support the text."[45] And, finally, the guidelines' recommended statements were circulated to renowned international advisors for review.[46]

Final Comment Period, Publication, and Plan for Updating: The draft of SOC8 was then posted online for a final six-week-long public comment period.[47] The SOC8 chair, chapter leads, and members reviewed comments

42. *Id.*

43. *Id.*

44. *Id.*

45. *Id.* at S251.

46. *Id.*

47. *Id.*

and made any necessary changes.[48] Then, WPATH disseminated the standards of care in a special edition of the International Journal of Transgender Health.[49]

SOC8 includes a plan for updating the guidelines based on new evidence or significant changes in the field.[50]

C. SOC8's Discussion of Adolescent Care

Relying on the methodology and process discussed above, several chapters in SOC8 address adolescents.[51]

SOC8 added Chapter 6 on adolescents because of "(1) the exponential growth in adolescent referral rates; (2) the increase in studies available specific to adolescent gender diversity-related care; and (3) the unique developmental and gender-affirming care issues of this age group."[52] Chapter 10 recommends adolescents receive guidance on how to disclose information to peers and support with navigating dating and sex, and delves into individualized options (including puberty blockers, and hormonal treatment) for adolescents with intersexuality.[53] And Chapter 12 and Chapter 16 focus on hormone therapy recommendations for transgender adolescents and adults.[54]

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48. *Id.*

49. *Id.*

50. *Id.*

51. *See generally* SOC8 at S9-S10.

52. *Id.* at S9.

53. *See, e.g.*, *id.* at S97, S100.

54. *See, e.g.*, *id.* at S110, S157.

SOC8 states that because of "the emerging nature of knowledge regarding adolescent gender identity development, an individualized approach to clinical care is both ethical and necessary."[55] "As is the case in all areas of medicine, each study has methodological limitations, and conclusions drawn from research cannot and should not be universally applied to all adolescents."[56]

SOC8 Requires Informed Consent from Parents Before any Treatment: SOC8 is consistent with IOM's recommendations on informed consent: "Rather than dictating a one-size-fits-all approach to patient care," clinical practice guidelines "should aid clinician and patient decision making by clearly describing and appraising the evidence and reasoning regarding the likely benefits and harms related to specific clinical recommendations."[57] SOC8 specifies that "adolescents, their parents, and care providers should be informed by the nature of the evidence base."[58]

SOC8 Describes the Evidence of the Potential Benefits and Risks of Medical Interventions: For consideration by clinicians, parents, and patients, SOC8 reviews the risks and benefits of particular treatments for transgender adolescents in many chapters, including Chapter 6 (Adolescents), Chapter 10 (Intersex), Chapter 12 (Hormone Therapy) and Chapter 16 (Reproductive Health).[59]

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55. *Id.* at S45.

56. *Id.*

57. IOM Guidelines at 16.

58. *See generally* SOC8 at S9-S10, S43-S66, S110-S119, and S159.

59. *Id.* at S45.

SOC8 reviews longitudinal studies that "compared baseline psychological functioning with outcomes after the provision of medical gender-affirming treatments."[60] It concludes that "data consistently demonstrate improved or stable psychological functioning, body image, and treatment satisfaction varying from three months up to two years from the initiation of treatment."[61]

SOC8 also summarizes studies with both a cross-sectional and longitudinal component that have compared transgender adolescents at baseline to cisgender peers and then again after receiving puberty blockers. "At baseline, the transgender youth demonstrated lower psychological functioning compared with cis-gender peers, whereas when undergoing puberty blockers, they demonstrated better function than their peers."[62]

SOC8 also summarizes the results of studies of large-population surveys of transgender individuals. For example, "[i]n a large non-probability sample of transgender adults, Turban et al. (2022) found those who reported access to gender-affirming hormones in adolescence," when "compared with transgender people accessing gender-affirming hormones in adulthood," "had lower odds of past-year suicidality."[63]

SOC8 "addresses the possibility an adolescent may regret gender-affirming decisions made during

60. *Id.* at S46.

61. *Id.*

62. *Id.*

63. *Id.* at S47.

adolescence."[64] It explains "[a]t present, no clinical cohort studies have reported on profiles of adolescents who regret their initial decision or detransition after irreversible affirming treatment."[65] Even the individuals who detransitioned did "not regret initiating treatment as they experienced the start of treatment as part of understanding their gender-related care needs."[66] Nonetheless, given the possibility of regret, it directs providers to "present the full range of possible outcomes when assessing transgender adolescents" and to "be prepared to support adolescents who detransition."[67]

In sum, SOC8's recommendations for "early medical intervention" comply with the WHO and IOM recommendations in that health care professionals "only recommend gender-affirming medical treatments," such as puberty blockers, when, among other things, the adolescent has reached puberty, the parents and patient give informed consent, and the adolescent has suffered from persistent, consistent, and insistent gender dysphoria.[68]

64. *Id.*

65. *Id.*

66. *Id.*

67. *Id.*

68. *Id.* at S59-S64.

ARGUMENT

I. Reliable clinical practice guidelines, like SOC8, are essential to high quality, effective healthcare.

Every day, practicing clinicians make complex decisions about the treatments to recommend to their patients. In weighing treatment options, they must assess the strength of the available scientific evidence supporting each treatment as well as recommendations from subject matter experts based on their clinical experience. Practicing clinicians must also determine the likely risks and benefits of each treatment for a particular patient, given the patient's overall health, co-occurring conditions, values, preferences, and life circumstances.[69] And they must apply their individual clinical experience and knowledge in light of that evidence.[70] In short, familiarity with the existing evidence base, as well as recommendations from subject matter experts, is an essential component of the practice of medicine.

Because clinicians cannot realistically keep up with, let alone critically appraise, every new development in the scientific literature, evidenced-backed guidelines are essential. Every year, more than 30,000 scientific journals publish about 2 million biomedical research papers.[71] Even by 2011, "Physicians could no longer keep up with the

69. IOM Guidelines at ix.

70. *Id.* at 15.

71. Jeffrey S. Flier, *Publishing Biomedical Research: a rapidly evolving ecosystem*, 66 Perspectives in Biology & Medicine 358, 363 (2023), *available at* https://doi.org/10.1353/pbm.2023.a902032.

growing knowledge base: An internist would have to read 33 articles 365 days a year to stay up to date."[72] Given the need to also critically analyze each individual article or paper, "[t]he two situations combined to place clinicians at an increasing risk of drowning in doubtful data."[73] "Critically appraised, synthesized information such as systematic reviews and [clinical practice guidelines] became necessary tools for clinicians desiring to practice" evidence-based medicine.[74]

Clinical practice guidelines evaluate and synthesize the best available evidence for treating certain medical conditions, incorporate practical knowledge provided by subject-matter experts, and weigh other factors likely to affect patient care to formulate clinical recommendations for treatment.[75] This gives practicing clinicians access to current, evidence-based, practical guidance that they can explain to patients and parents, and apply in conjunction with their own clinical expertise.[76]

Clinical practice guidelines also reduce unnecessary variability and uncertainty in medical decision-making, which improves individual patient outcomes as well as overall healthcare quality and safety.[77] These guidelines are also used as tools for evaluating the performance of

72. IOM Guidelines at 34.

73. *Id.*

74. *Id.*

75. *Id.* at 1-2.

76. *Id.* at 15.

77. *Id.* at xi, 65.

healthcare providers, creating or improving healthcare systems and processes, and educating the public about best practices.[78] Given their potential to enhance public health and their value in everyday clinical decision-making, clinical practice guidelines have become "ubiquitous in our healthcare system."[79]

II. WPATH's SOC8 are the product of a rigorous and reliable development process.

Before 2011, clinical practice guidelines involved variable and non-standardized processes, which lead to variable quality.[80] "To address the shortcomings of past guidelines," the IOM "published recommendations for trustworthy guidelines, effectively setting the gold standard for what constitutes a high-quality guideline."[81] IOM recognizes that: a systematic review is one step of the process; evidence quality is an input not the sole criterion; and clinical experience is relevant as another input.[82]

Although there are several ways to develop reliable clinical practice guidelines,[83] according to IOM, the most reliable guidelines share the following characteristics:

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78. *Id.* at 26-27.

79. *Id.* at 2.

80. Colin R. Cooke, et al., *Advancing Clinical Practice and Policy through Guidelines: The Role of the American Thoracic Society*, 182 Am. J. Respir. Crit. Care Med. No. 9, 910-914 (2013).

81. *Id.* at 910.

82. IOM Guidelines at 4-5, 20.

83. *Id.* at 68.

a) They transparently disclose their funding sources and explain the development process they followed;[84]

b) They are developed by a multidisciplinary team, including patient representatives, clinicians, subject-matter experts, and one or more methodological experts;[85]

c) They require members to disclose conflicts of interest and, if necessary, take steps to manage significant conflicts;[86]

d) Their recommendations are informed by systematic reviews of scientific literature as well as clinical experience;[87]

e) Their recommendations are approved by a consensus of members;[88]

f) They summarize the nature, quality, quantity, and consistency of the evidence concerning recommended treatments;[89]

g) They clearly explain the risks and benefits of recommended treatments and specify the role

84. *Id.* at 76-78.

85. *Id.* at 93.

86. *Id.* at 82-83.

87. *Id.* at 97.

88. *Id.* at 87.

89. *Id.* at 124-125.

played by patient preferences, values (including human rights and healthcare inequities), expert opinion, and clinical experience in developing each recommendation;[90]

h) They indicate the strength of their recommendations;[91] and

i) They are updated periodically or when new evidence suggests a need for revision.[92]

SOC8 has all these hallmarks of reliability. It provides a detailed description of its development process[93] and discloses funders in the text of the document.[94] It was developed by a diverse team of 119 subject-matter experts, healthcare professionals, researchers, and stakeholders, each of whom applied to participate and completed conflict of interest declarations.[95]

In developing SOC8, WPATH worked closely with a guideline methodologist from Johns Hopkins University—one of the top medical research universities in the United States—to assist with the planning and development of

90. *Id.* at 67.

91. *Id.* at 5.

92. *Id.* at 6-9, 26.

93. SOC8 at S247-51.

94. *Id.* at S177.

95. *Id.* at S247.

research questions and systematic reviews.[96] WPATH also contracted with Johns Hopkins' Evidence Review Team to conduct a robust review of all available evidence, including systematic reviews when direct evidence was available.[97] The SOC8 experts and the Evidence Review Team collaborated to identify the questions to be addressed through systematic reviews, and each step of the systematic review process is described in the text of SOC8.[98]

The recommendations in SOC8 were based on newly-conducted evidence reviews in addition to existing evidence reviews, expert opinion, and clinical experience.[99] Consensus on each recommendation was achieved through a widely used group facilitation tool known as the Delphi process, which encouraged rigorous debate and required approval of at least 75 percent of voting members for each recommendation.[100]

SOC8 explains the available evidence, including gaps in the literature and areas of uncertainty, and all references to scientific literature were validated by independent external reviewers before publication.[101] In addition,

96. *Id.* at S249.

97. *Id.*

98. *Id.* at S249-50.

99. *Id.* at S250.

100. *Id.*

101. *Id.* at S250-51; *see, e.g.*, *id.* at S45-47 (detailing the body of research supporting the use of puberty blockers and hormones for adolescents, identifying knowledge gaps, and identifying areas for additional research).

the explanatory text details potential risks and benefits associated with recommended interventions; provides information about implementing the recommendations; and acknowledges the values, human rights perspectives, patient preferences, and practical considerations that influenced the recommendations.[102]

Once the SOC8 membership committee reached consensus on their recommendations and the explanatory text was initially approved, WPATH distributed the document for review by an international advisory committee and for public comment.[103] Based on the feedback received, revisions to SOC8 were proposed and approved through a second Delphi process.[104] Finally, SOC8 was published, along with a plan to issue a new edition when new evidence or other changes in the field made revisions necessary.[105]

WPATH's process for developing SOC8 was transparent, rigorous, and methodologically sound, resulting in consensus between its findings and those of major medical organizations as to transgender care.[106] It meets or exceeds the developmental rigor of other clinical

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102. SOC8 at S250; *see, e.g.*, *id.* at S43-66 (adolescent chapter).

103. *Id.* at S251; *see also* IOM Guidelines at 91 (describing the benefits of allowing public comment on draft guidelines).

104. SOC8 at S251.

105. *Id.*

106. *See, e.g.,* Wylie C. Hembree, et al., *Endocrine Treatment of Gender-Dysphoric/Gender-Incongruent Persons: An Endocrine Society Clinical Practice Guideline*, 102 J. CLINICAL ENDOCRIONOL. METAB 3869-3903 (2017).

practice guidelines produced by other medical societies in the United States.[107]

III. Accepting the critiques offered by State defendants could undermine many other clinical practice guidelines.

State defendants have tried to discredit SOC8 by asserting that there were methodological flaws in its development. But these attacks have no scientific validity. They disregard or distort the applicable scientific methodologies and the practical realities of clinical practice guideline development. SOC8's development process was at least as rigorous as the process typical for clinical practice guidelines in the United States, so the State defendants' attacks would cast doubt on most guidelines used every day nationwide. We address each in turn.

1. State defendants have criticized SOC8 for failing to conduct additional systematic reviews, including a separate review to support each and every individual recommendation.[108] But SOC8 undertook "[a] separate detailed systematic review protocol . . . for each review question or topic, as appropriate" with the assistance

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107. World Professional Association for Transgender Health, *Standards of Care for Transgender and Gender Diverse People, Version 8 Frequently Asked Questions (FAQs)*, at 1-4, https://www.wpath.org/media/cms/Documents/SOC%20v8/SOC8%20FAQs%20-%20WEBSITE2.pdf (last visited Aug. 28, 2024).

108. *See, e.g.*, Br. of Alabama as *Amicus Curiae* Supporting Respondents in Opp. to Petition for Writ of Certiorari, at 11-12 (Feb. 2, 2024).

of an independent Evidence Review Team under the leadership of a guideline methodologist.[109] SOC8 itself also recognizes and identifies issues that have not yet been systematically studied.[110] SOC8 was guided by its guideline methodologist and independent Evidence Review Team in developing research questions and planning systematic reviews, including determining which questions were eligible for systematic review.[111] As explained above, the final version of SOC8 also considered over 70 pre-existing "systematic reviews" on a huge range of topics, including the effects of puberty blockers and hormones on cardiovascular function, bone health, anxiety, depression, and psychosocial functioning.

In chapter 6 on adolescents, SOC8 conducts a narrative review of existing evidence rather than a systematic review. While acknowledging the limitations of that evidence base, the chapter found that "as a whole, the data show early medical intervention" "can be effective and helpful for many transgender adolescents seeking these treatments."[112]

That chapter then offers targeted recommendations supported by the best available evidence and expert consensus as determined through a rigorous Delphi

109. SOC8 at S3, S8, S41, S46.

110. *Id.*

111. *See id.* at S8, S249. Likewise, a systematic review was conducted or relied upon for other chapters addressing adolescent care. *See, e.g.*, *id.* at S120-24, S126, S247, S249-50; *see generally id.* at S178.

112. *Id.* at S45-47.

process.[113] Experts participating in a Delphi process rely on various sources of information and evidence, including their own clinical expertise, systematic reviews, observational studies, and any other relevant evidence. While in theory it might be ideal for every aspect of a clinical practice guideline to be directly supported by a systematic review, in practice this is extraordinarily rare if not impossible.[114] If courts permit the categorical banning of health care because SOC8 lacks systematic review for every single recommendation, that will cast doubt on numerous clinical practice guidelines that are similarly situated.

2. State defendants have criticized SOC8 for relying on so-called "low quality" evidence in developing some recommendations, yet almost all practice guidelines use this common and scientifically valid practice.[115]

In the medical research context, "low quality" is a technical term that refers to a rating under a methodological framework known as GRADE. GRADE assesses the statistical degree of certainty that a particular treatment will have its intended effect.[116] In

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113. *Id.* at S49-66.

114. *See, e.g.*, Shiveindra Jeyamchan, et al., *Athletes returning to play after cervical spine or neurobrachial injury*, 1 CURR. REV. MUSCULOSKELATAL MED. 175-179 (2008); Benjamin A. Lipsky, et al., *2012 Infectious Diseases Society of America clinical practice guidelines for the diagnosis and treatment of diabetic foot infections*, CLIN INFECT DIS., at 54 (2012).

115. *See* notes 119-20, below.

116. WHO Handbook at 110.

general, GRADE categorizes randomized controlled trials as "high quality" evidence and nonrandomized trials and observational studies as "low quality."[117] But evidence quality under GRADE cannot be determined mechanistically, and a study's rating can be adjusted up or down after a comprehensive review of several factors according to the raters' individual judgments.[118]

In many clinical domains, including pediatrics, there is little or no high-quality evidence.[119] It is well-established that clinical practice guidelines can make strong treatment recommendations based on so-called "low quality" evidence.[120] As the GRADE system itself

117. *Id.* at 112. Evidence quality cannot be determined mechanistically, and a study's rating can be adjusted up or down after a comprehensive review of several factors according to the raters' individual judgments. *Id.* at 113–21.

118. *Id.*

119. "A review of Cochrane systematic reviews across numerous areas of medicine showed that 86.5% of reviews reported moderate (30.8%), low (31.4%) and very-low (24%) levels of evidence. Less than 1 in 7 systematic reviews had evidence of high quality for a primary outcome and less than 1 in 5 systematic reviews had evidence of high quality of any outcome." Meredithe McNamara, et al., *An Evidence-Based Critique of "The Cass Review" on Gender-affirming Care for Adolescent Gender Dysphoria*, at 11-14 (2024), *available at* https://law.yale.edu/sites/default/files/documents/integrity-project_cass-response.pdf. *See also* IOM Guidelines at 26; WHO Handbook at 112-13; Michael L. Groff, et al., *Publication Trends of Pediatric and Adult Randomized Controlled Trials in General Medical Journals, 2005-2018: A Citation Analysis*, 7 CHILD. (BASEL) 293 (2020).

120. *See, e.g.*, Paul E. Alexander, et al., *World Health Organization recommendations are often strong based on low*

makes clear, the evidence rating is only one factor among many that affects the strength of a recommendation.[121] Other factors relevant to clinical recommendations include the degree and strength of expert consensus, the quantity and consistency of available evidence, patient preferences, and value judgments regarding the relative importance of different effects of treatment.[122] These additional factors are considered at the recommendation stage to account for the different purposes of medical research and clinical medicine.[123]

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confidence in effect estimates. 67 J CLIN EPIDEMIOL. NO. 6, 629-634 (2014) (finding that 55.4% of strong recommendations by the WHO were supported only by low quality evidence).

121. IOM Guidelines at 110; *see also* Holger J. Schünemann, et al., *Improving the use of research evidence in guideline development: 1. Guidelines for guidelines*, 4 HEALTH RSCH. POL'Y AND SYS. 21 (2006) (explaining that "'separating the judgments regarding the quality of evidence from judgments about the strength of recommendations is a critical and defining feature" of GRADE).

122. IOM Guidelines at 110 (noting quantity and consistency of evidence and value judgments, among other factors); *id.* at 111 (discussing patient preferences and value judgments); *id.* at 113 (explaining that guidelines can make a strong recommendation on low quality evidence if the guideline development group reaches an expert consensus that the benefits of a recommendation outweigh harms); WHO Handbook at 123-125, 128 (listing additional factors, including "acceptability" of a treatment to patients and other stakeholders and the "values and preferences pertain[ing] to the relative importance people assign to the outcomes associated with the intervention").

123. While the goal of research is to "contribute to generalizable knowledge" by making objective findings that can be replicated, clinical practice is intended "solely to enhance the well-being of an individual patient," which requires a more thorough assessment of the patient's circumstances and a more careful consideration of

Unsurprisingly, then, it is not uncommon for clinical practice guidelines to make strong recommendations based on "low quality" evidence –including, for example, WHO's recommendations of which 55.4% were supported only by "low quality" evidence.[124] It is well established that trustworthy guidelines can be produced under these circumstances so long as they follow a transparent and rigorous process, as WPATH did in developing SOC8.[125]

In addition, in many treatment settings, including adolescent transgender care, observational studies may be more valuable than randomized controlled trials.[126] "[S]tudies of efficacy in the idealized settings of the typical randomized, controlled trial" do not always match "studies of effectiveness in real-world practice."[127] GRADE's overreliance on randomized controlled trials "often results in specialist society-based guidelines assigning inappropriately low grades to their recommendations."[128]

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subjective factors. *See* U.S. Dept. of Health and Human Services, *The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research*, at 3 (1979), *available at* https://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/index.html.

124. Alexander, note 120, at 629-34.

125. IOM Guidelines at 26.

126. Jizzo R. Bosdriesz, et al., *Evidence-based medicine–When observational studies are better than randomized controlled trials*, NEPHROLOGY (CARLTON), 25, at 737-743 (2020).

127. Cooke, note 80, at 910-914.

128. Adrian Baker, et al., *A review of grading systems for evidence based guidelines produced by medical specialties*, 10 CLINICAL MED. (LOND), at 358 (2010).

Many practice guidelines do not show the graded values for the quality of evidence for each recommendation. SOC8 is not an outlier for choosing not to publish the GRADE evidence quality ratings generated by the Evidence Review Team.[129]

Finally, and most importantly, there are ethical constraints on how randomized controlled trials could be conducted, given the current evidence base. "Clinical equipoise is widely accepted as the basis of ethics in clinical research."[130] Equipoise is "a state of genuine uncertainty on the part of the clinical investigator regarding the comparative therapeutic merits of each arm in a trial."[131] Neither providing a control group of transgender adolescents a placebo nor providing a control group any sort of conversion therapy would satisfy the ethical principal of equipoise.[132] These ethical issues also create practical barriers to randomized controlled trials (RCT) because "[r]esearchers and clinicians who are convinced of the effectiveness of gender-affirming care,

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129. *See, e.g.*, Jeyamchan, note 114, at 175; Lipsky, note 114, at 54.

130. Chunquin Deng, et al., *Challenges of clinical trial design when there is lack of clinical equipoise: use of a response-conditional crossover design*, 259 J NEUROL. 348-352 (2012).

131. Benjamin Freedman, *Equipoise and the Ethics of Clinical Research*, 317 N. ENGL. J. MED. 3 (1987).

132. WPATH "recommend[s] against" conversion therapy and gender identity change efforts "because they have been found to be ineffective and are associated with increases in mental illness and poorer psychological functioning." SOC8 at 53. Indeed, conversion therapy "has been linked to increased anxiety, depression, suicidal ideation, [and] suicide attempts." *Id.* at 53.

many of whom are leading providers in the field, are [] unlikely to accept involvement with an RCT due to ethical concerns."[133]

State defendants' criticisms of SOC8 risk undermining other clinical practice guidelines. "If high-quality evidence were a prerequisite for medical care, we would all become worse off."[134]

"All types of pediatric practices begin with a dearth of evidence and yet must deliver care to a heterogeneous population in need."[135] In neonatology care for critically care infants and pediatric critical care more generally, clinicians "routinely make hundreds (if not thousands) of high-stakes, evidence informed decisions for their patients each day."[136] "The evidence that helps answer these and other questions is rarely 'high quality' (as the term is used in GRADE).[137] "And yet, clinical outcomes are good and improving: more children leave intensive care units better off than ever before."[138] "Most aspects of neonatal and critical care became accepted clinical practice because of their immediate and short-term benefits, without

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133. Florence Ashley, et al., *Randomized-controlled trials are methodologically inappropriate in adolescent transgender healthcare*, 25 International Journal of Transgender Health No. 3, 407-418 (2024).

134. McNamara, note 119, at 4-5.

135. *Id.*

136. *Id.*

137. *Id.*

138. *Id.*

following patients into adulthood."[139] "The quest for longer and more data is never-ending, but when the answers are not available, patients cannot wait for a cure."[140]

3. WPATH also adhered to well-established best practices in identifying and managing conflicts of interest in drafting SOC8. WPATH required every person involved in the development of SOC8 to declare conflicts of interest.[141] After evaluating these declarations at the beginning and end of the development process, WPATH determined that no significant conflicts of interests existed.[142]

Critics erroneously argue that SOC8 members were conflicted and should have been excluded because they were already WPATH members; because they had previously published on the topic of gender dysphoria; or because a substantial proportion of their income was derived from providing clinical gender-transition care. None of these contentions holds water.

First, medical societies routinely restrict guideline development group membership to their own members.[143] To the extent this creates any potential conflict of interest, WPATH appropriately managed that conflict by disclosing it.[144]

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139. *Id.*

140. *Id.*

141. SOC8 at S249.

142. *Id.* at S177.

143. IOM Guidelines at 38.

144. SOC8 at S248.

Second, far from being a liability, subject-matter experts with a history of publications on a relevant topic are essential to guideline development groups. It would be illogical to exclude academics from contributing to clinical practice guidelines in a field because of their expertise in that field. To the extent experts' prior writings might be perceived as an intellectual conflict of interest, WPATH adequately managed that potential conflict by engaging a methodologist and an independent Evidence Review Team to conduct literature reviews and by selecting a multidisciplinary team of diverse members to develop SOC8.[145]

Third, concerns about financial conflicts typically arise from members' financial or research ties to sectors such as the pharmaceutical industry.[146] To the extent clinicians involved in developing SOC8 had financial conflicts of interest because they earn income from treating gender dysphoria, those conflicts are unavoidable and insignificant.[147] Indeed, it is customary for guideline

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145. *Id.* at S247, S249; *see also* WHO Handbook at 72 (explaining that commissioning a methodologist "help[s] to mitigate the effects of intellectual conflicts of interest"); *id.* at 65 (noting that subject-matter experts with intellectual conflicts of interest may be "deemed essential," and that these conflicts can be managed if "members with diverse perspectives and experiences" are included in the guideline development group).

146. IOM Guidelines at 61-62.

147. As WHO recognizes, "[i]ndividuals selected for their technical expertise in a guideline's subject area are critically important" to guideline development groups and should be included along with other members with "a range of expertise and institutional and professional affiliations." WHO Handbook 26; *see also id.* at 67

development groups to be comprised of clinicians who are involved in providing the care or treatment in question. Excluding the perspectives of practicing clinicians would severely undercut or even eliminate the utility of the guideline. In any event, WPATH adequately managed any financial conflicts related to clinical practice by publicly disclosing all members' names and affiliations and by selecting a multidisciplinary guideline development group.[148]

(indicating that "conflicts of interest represent a spectrum; they are not absolute situations"); *id.* at 67-69 (listing those with substantial ties to industry—and not clinicians—among those who have conflicts of interest that must be managed "at the individual level" through exclusion or other means – indicating that any financial COIs of clinicians do not require exclusion and can be managed at the group level); IOM Guidelines at 80 (focusing on concerns raised by authors' financial ties to commercial entities, including "pharmaceutical and medical device companies," while noting that clinicians "may provide valuable insight" on a guideline and "may simply be without substitutes").

148. *See* SOC8 at S1-S2 (listing names and affiliations of all members); *see also* WORLD PROFESSIONAL ASSOCIATION FOR TRANSGENDER HEALTH, *SOC8 Contributors*, https://www.wpath.org/media/cms/Documents/SOC%20v8/SOC8%20Full%20Contributor%20List%20-%20FINAL%20UPDATED%2009232021.pdf (last visited Aug. 29, 2024) (providing biographies of all members); WHO Handbook at 70 (noting that "physicians tend to recommend procedures that they personally deliver, whereas multidisciplinary groups tend to be more conservative in their recommendations"); IOM Guidelines at 61-62 (87 percent of individual authors across 37 guidelines "had a financial relationship with industry and 59 percent had financial relationships with companies whose products were considered," yet "[t]he majority of respondents reported no discussion or disclosure of financial relationships with industry among panel participants during the guideline development process."); *see also id.* at 81 (noting that "COI policies vary with regard to the specific types of information that must be disclosed").

4. State defendants have also sought to undermine SOC8 not with reference to any scientific evidence but, rather, based on internal documents obtained from WPATH. There is nothing remarkable about SOC8 members communicating internally about scientific evidence and outcomes relating to treatments. The State defendants' reliance on cherry-picked statements isolated from thousands of pages of internal correspondence would chill the development of reliable clinical practice guidelines and is irrelevant in light of the widely-accepted evidence supporting the SOC8 recommendations.

First, any evaluation of SOC8's trustworthiness must begin with its 190 pages of text plus 68 pages of references and end well short of any speculation about the SOC8 members' states of mind. As the IOM explains: "An explicit statement of how evidence, expertise, and values were weighed by the guideline writers helps users to determine the level of confidence they should have in any individual recommendation."[149] As explained above, SOC8 itself describes its weighing process in great detail and that process was transparent, rigorous, iterative, and included the Delphi process for achieving at least 75 percent agreement on its included recommendations. Scrutinizing what a few members wrote in emails says nothing about the reliability of SOC8.

Second, scrutinizing internal communications for evidence of bias is not administrable. Understanding the meaning and context of each communication often will require medical expertise, intimate familiarity with the guideline development process, and a comprehensive

149. IOM Guidelines at 77.

understanding of the timing, nature, and purpose of the communication as related to that process. Furthermore, to evaluate the significance of each communication, courts would have to consider other communications expressing different perspectives; attempt to determine the relative weight each perspective was given at each stage of the process; and extrapolate from that whether and how the communication in question influenced the final guideline recommendations. The diversity of perspectives represented in SOC8's membership and the sheer volume of communications exchanged in the development of SOC8 make this next to impossible. Assessments of guideline development processes are better left to scientific experts using objective measures.

Third, experts and clinicians should be free to do their jobs and advocate for their patients without fear that their written communications will be taken out of context and misused in court to harm the patient population they have dedicated their careers to serving. Indeed, IOM recognizes that greater granularity is counterproductive: "The desire to have public access to [guideline development group] deliberations and documents must be blanced with resource and time constraints as well as the need for [guideline development group] members to engage in frank discussion."[150] If SOC8 members' internal communications are subject to judicial scrutiny, it would compromise the ability to engage in robust scientific exchange to ensure best outcomes for patients. Subject-matter experts could be deterred from volunteering to develop future clinical practice guidelines. And members of guideline development groups could be

150. IOM Guidelines at 76.

fearful of engaging in the candid, uninhibited dialogue that is integral to the development of reliable guidelines. They will likely communicate less, and less freely.

* * *

Today, State defendants offer results-oriented, methodological critiques of SOC8, but those critiques are grounded in politics rather than science. Accepting those critiques would have grave consequences for many other fields of medicine, with a chilling effect on clinicians' vital participation in the process of developing clinical guidlelines. Such a result would undermine the accuracy of clinical practice guidelines and the thoroughness of their development process. Ultimately, it could lead to the development of fewer high-quality clinical practice guidelines in the United States, which could mean less guidance for clinicians; lower awareness of scientific evidence supporting particular treatments; less informed clinical judgments; worse patient outcomes; and diminished public health.

CONCLUSION

This Court should reject State defendants' after-the-fact justifications for disregarding SOC8 in an attempt to support categorical bans on medical treatment, in part because accepting those attacks could compromise clinical guidelines essential to public health and deter future development of reliable guidelines.

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APPENDIX

TABLE OF APPENDICES

APPENDIX A — LIST OF *AMICI CURIAE*

List of *Amici Curiae*

1. Melissa Brouwers, MD.
2. Mary Butler, PhD, MBA.
3. Neville H. Golden, MD.
4. Kenneth W. Goodman, PhD.
5. Scott E. Hadland, MD, MPH, MS.
6. Doug Haldeman, PhD.
7. Jenifer R. Lightdale, MD, MPH.
8. Jason Nagata, MD, MSc.
9. Ian J. Saldanha, PhD
10. Renata Arrington Sanders, MD, MPH, ScM
11. Jennifer Yost PhD, RN, FAAN.