

No. 25-6813

**UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT**

EMALEE WAGONER,

Plaintiff-Appellee,

v.

JENNIFER WINKELMAN,

Defendant-Appellant.

On Appeal from the United States District Court for the District of Alaska,
No. 3:18-cv-00211 (Scoble, J.)

**AMICUS BRIEF OF DR. KELLAN BAKER AND PROFESSOR
MICHAEL ULRICH AS AMICI CURIAE SUPPORTING
PLAINTIFF-APPELLEE AND AFFIRMANCE**

Luke A. Barefoot
Thomas S. Kessler
Jack Massey
Noopur Sen
Ariel Sheffey
Saifeldeen Zihiri
CLEARY GOTTlieb
STEEN & HAMILTON LLP
One Liberty Plaza
New York, NY 10006
T: (212) 225-2000
tkessler@cgsh.com

Counsel for Amici Curiae

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IDENTITY AND INTERESTS OF AMICI CURIAE¹

Dr. Kellan E. Baker (“Dr. Baker”) is the Senior Advisor for Health Policy at the Movement Advancement Project and holds academic appointments at the Johns Hopkins Bloomberg School of Public Health and the George Washington University Milken Institute School of Public Health. Dr. Baker has over twenty years of experience as an internationally recognized leader in health policy and health services research. His scholarship has appeared in prominent journals such as *The New England Journal of Medicine*, *Journal of the American Medical Association* and *American Journal of Public Health*. Between 2018 and 2021, as a research associate with Johns Hopkins University, Dr. Baker conducted systematic reviews of the scientific literature on gender dysphoria to inform the development of the WPATH Standards of Care for the Health of Transgender and Gender Diverse People, Version 8 (“SOC8”).^{2,3}

¹ Counsel for both parties consented to the filing of this brief. No counsel for a party authored this brief in whole or in part. No one other than *amici* and their counsel contributed money intended to fund the preparation or submission of this brief.

² Dr. Baker was not directly involved with drafting SOC8. His role was to contribute to the scientific reviews that informed the teams that developed SOC8. This separation between research, on the one hand, and the development of guidelines that are informed by the research, on the other hand, is standard practice in evidence-based medicine and clinical guideline development. Inst. of Med. (now Nat’l Academy of Med.) (the “IOM”), *Clinical Practice Guidelines We Can Trust* (2011), www.ncbi.nlm.nih.gov/books/NBK209539/pdf/Bookshelf_NBK209539.pdf.

Professor Michael R. Ulrich (“Professor Ulrich”) is an Associate Professor at Boston University’s School of Public Health and School of Law. His research focuses on the intersection of public health, constitutional law, and bioethics, emphasizing the role of law in the health outcomes of marginalized populations. Professor Ulrich’s scholarship has appeared in leading legal and medical journals, including *Stanford Law Review*, *The Yale Law Journal Forum*, *The New England Journal of Medicine*, and *Journal of the American Medical Association*. Professor Ulrich has also worked as a bioethicist at the National Institutes of Health.

Dr. Baker and Professor Ulrich share an interest in ensuring that medical care for people with gender dysphoria is appropriately informed by scientific research and that such research is properly understood by courts and the wider public. Given Dr. Baker’s role in conducting the systematic reviews that informed the development of SOC8, and Professor Ulrich’s expertise in bioethics and the interplay of transgender health and constitutional law, each *amicus* has a unique interest in ensuring that SOC8 is properly construed by the Court, free from Defendant-Appellant’s mischaracterizations.

³ E. Coleman et al., *Standards of Care for the Health of Transgender and Gender Diverse People, Version 8*, 23 Int’l J. Transgender Health S5 (2022).

SUMMARY OF THE ARGUMENT

Healthcare providers in many medical specialties rely extensively on clinical practice guidelines to inform their practice of medicine and to keep their knowledge current. Clinical practice guidelines provide a unique and irreplaceable value to providers by synthesizing the best and most currently available scientific evidence to provide practitioners with tangible guidance for patient care. The WPATH Standards of Care are the gold standard for clinical practice guidelines in transgender health and have been continuously maintained and regularly updated since their first publication in 1979.

The most recent iteration, SOC8, was developed through a rigorous methodology that satisfies the benchmarks established by authorities for creating reliable clinical practice guidelines. Despite this, Defendant-Appellant baselessly challenges the validity, rigor, and applicability of SOC8 to justify her preferred outcome in this case.

First, Defendant-Appellant argues that the evidence supporting WPATH's recommendations is "low quality" and therefore unreliable. This argument conflates a technical designation in evidence-based medicine with the lay concept of unreliability. In the discipline of evidence-based medicine, the term "low quality" evidence is simply a reflection of factors such as the type of study design available, not a judgment on the evidence's reliability.

Second, Defendant-Appellant points to a paucity of studies examining morbidity and mortality outcomes among transgender individuals. With respect to mortality, the scarcity of this evidence reflects only the methodological challenges inherent to studying rare outcomes like death by suicide, a type of challenge which is not unique to transgender health or WPATH’s methodology. Moreover, there is a substantial body of existing research demonstrating consistent and clinically meaningful improvements in mental health outcomes, including suicidality, from surgical interventions to treat gender dysphoria.

Third, Defendant-Appellant dismisses WPATH as an “advocacy organization,” and argues that, as a result, SOC8 can be disregarded. This characterization fundamentally misrepresents WPATH’s nature and mission. Like any medical professional association, WPATH grounds its clinical practice guidelines in peer-reviewed scientific literature and consensus-based expert opinion. The fact that WPATH’s guidelines reflect positive health outcomes in the medical fields where its members have professional expertise is not “advocacy”—it is the standard practice of medical professional associations.

Finally, Defendant-Appellant misrepresents the evidentiary foundation of SOC8 by asserting that it is inapplicable to treatment for incarcerated individuals. In fact, WPATH’s chapter on institutional guidelines is derived from studies conducted in prisons, jails, and other carceral environments. Further, SOC8 does

not mandate any specific treatment for incarcerated individuals (or, for that matter, for non-incarcerated individuals). Rather, it provides evidence-based recommendations to help guide individualized assessments of medical necessity, consistent with well-established bioethics principles.

For these reasons, *amici* respectfully urge this Court to reject Defendant-Appellant's mischaracterizations of SOC8 and to affirm the District Court's judgment.

ARGUMENT

I. The SOC8 Clinical Practice Guidelines Are Critical to Providing Effective Healthcare to Adults with Gender Dysphoria.

WPATH is a multidisciplinary professional association comprising over 3,000 healthcare and legal professionals around the world and dedicated to advancing evidence-based clinical medicine in transgender health.⁴ WPATH maintains a peer-reviewed journal, holds biennial conferences, publishes statements on key issues in the field of transgender health, and participates in both domestic and international medical policy deliberations.

WPATH is best known for its Standards of Care, a longstanding foundational document in the field of transgender health and the gold standard for

⁴ SOC8 at S5.

international clinical practice guidelines in this field.⁵ While other publications, such as the Endocrine Society’s Clinical Practice Guidelines,⁶ also provide clinical guidance on the treatment of transgender people, no other national or international guidelines look as comprehensively at the full scope of transgender health as the WPATH Standards of Care.⁷ SOC8, released in September 2022, reflects consensus treatment recommendations developed by more than 100 global experts in transgender health. The recommendations were developed through a rigorous,

⁵ *Id.* As used in this brief, the term “Standards of Care” generally refers to the WPATH Standards of Care for the Health of Transgender and Gender Diverse People, first published in 1979 and revised several times thereafter, most recently in 2022. The term “SOC8” refers specifically to the eighth and most recent version, by E. Coleman et al., published in 2022. *See* WPATH, *History and Purpose*, <https://wpath.org/publications/soc8/soc8-history/> (last visited June 5, 2026).

⁶ Wylie C. Hembree et al., *Endocrine Treatment of Gender-Dysphoric/Gender-Incongruent Persons: An Endocrine Society Clinical Practice Guideline*, 102 J. Clinical Endocrinology & Metabolism 3869 (2017).

⁷ *See, e.g.*, Am. Coll. of Obstetricians & Gynecologists, *Health Care for Transgender and Gender Diverse Individuals*, ACOG Committee Opinion No. 823, 137 Obstetrics & Gynecology e75 (2021); Am. Psychological Ass’n, *Guidelines for Psychological Practice with Transgender and Gender Nonconforming People*, 70 Am. Psychologist 832 (2015); Pro. Ass’n for Transgender Health Aotearoa, *Guidelines for Gender-Affirming Healthcare in Aotearoa New Zealand* (2025), https://patha.nz/assets/Gender-Affirming-Healthcare_GAHC_2025_February-final.pdf; A. Tomson et al., *Southern African HIV Clinicians Society Gender-Affirming Healthcare Guideline for South Africa – Expanded Version: October 2021*, S. Afr. HIV Clinicians Soc’y (2021), [https://sahivsoc.org/Files/SAHCS%20GAHC%20guidelines-expanded%20version_Oct%202021\(3\).pdf](https://sahivsoc.org/Files/SAHCS%20GAHC%20guidelines-expanded%20version_Oct%202021(3).pdf); World Med. Ass’n, *WMA Statement on Trans People* (Oct. 2025), <https://www.wma.net/policies-post/wma-statement-on-transgender-people/>.

transparent, and iterative process informed by more than 70 systematic evidence reviews on topics ranging from cardiovascular function to bone health to psychological functioning for transgender patients.⁸ Such systematic reviews, which are designed to comprehensively collect, synthesize, and analyze available empirical evidence pertaining to pre-specified research questions, provide the evidentiary basis for SOC8, just as similar reviews do for the development of clinical practice guidelines across numerous fields of medicine.⁹

Clinical practice guidelines such as SOC8 serve a vital function: they relieve individual clinicians from the impossible task of adequately assessing and applying large, constantly evolving bodies of evidence in their routine clinical decision-making by synthesizing the best available medical evidence with practical clinical knowledge. As the IOM has recognized, such guidelines have become “fundamental to clinical practice” across medical specialties and are “ubiquitous in [the United States] healthcare system.”¹⁰

⁸ Brief of Amici Curiae Clinical Practice Guideline Experts in Support of Petitioner and Respondents in Support of Petitioner at 6, 10, *United States v. Skrmetti*, No. 23-477 (Sep. 2024).

⁹ Stefano Mancin et al., *Systematic Review of Clinical Practice Guidelines and Systematic Reviews: A Method for Conducting Comprehensive Analysis*, 12 *MethodsX* 1, 2 (2024), <https://pmc.ncbi.nlm.nih.gov/articles/PMC10788252/pdf/main.pdf>.

¹⁰ IOM, *supra* note 2, at 1–2.

II. SOC8 Is the Product of Rigorous, Reliable, and Methodologically Sound Research.

The credibility of clinical practice guidelines depends on the rigor of their development process. SOC8 was developed through a transparent and rigorous methodology that follows the standards maintained by authorities such as the World Health Organization and the IOM.

The gold standard framework for developing clinical practice guidelines was established by the IOM (the “IOM Framework”)¹¹ to define key attributes of reliable guidelines: transparency in funding and methodology;¹² conflict of interest management;¹³ multidisciplinary expertise;¹⁴ reliance on systematic evidence reviews combined with clinical experience;¹⁵ clear articulation of the evidence foundations for each recommendation;¹⁶ precise articulation of recommendations;¹⁷ external review;¹⁸ and periodic updating.¹⁹ The IOM Framework also discusses the

¹¹ Colin R. Cooke & Michael K. Gould, *Advancing Clinical Practice and Policy through Guidelines: The Role of the American Thoracic Society*, 187 Am. J. Respiratory & Critical Care Med. 910, 910 (2013), <https://academic.oup.com/ajrccm/article-abstract/187/9/910/8510111?redirectedFrom=fulltext>.

¹² IOM, *supra* note 2, at 6, 76–78.

¹³ *Id.* at 6–7, 82–92.

¹⁴ *Id.* at 7, 93–96.

¹⁵ *Id.* at 7–8, 97–99.

¹⁶ *Id.* at 7–8, 99–127.

¹⁷ *Id.* at 8, 128–31.

¹⁸ *Id.* at 8, 131–34.

¹⁹ *Id.* at 8–9, 134–37.

importance of group processes designed to achieve broad agreement—including formal consensus methods such as the Delphi Method, which is a widely known “systematic process of forecasting using the collective opinion of panel members”²⁰ and which was used in the development of SOC8.

The development of SOC8 followed a rigorous, multi-year process that satisfies each component of the IOM Framework. First, the WPATH Board of Directors appointed a “Guideline Steering Committee” responsible for overseeing and managing the development of SOC8.²¹ The Guideline Steering Committee then assembled the “SOC8 Review Committee,” a diverse team of more than 100 experts and clinicians including surgeons, endocrinologists, psychiatrists, psychologists, and primary care physicians.²² The SOC8 Review Committee was responsible for writing, developing, and voting on each clinical guideline recommendation ultimately included in SOC8.²³ In parallel, the WPATH Board of Directors engaged the “Evidence Review Team,” an independent team of academic researchers at Johns Hopkins University that included Dr. Baker.²⁴ The Evidence

²⁰ *Id.* at 86–93; *see also id.* at 81, 124–25; Prashant Nasa, Ravi Jain & Deven Juneja, *Delphi Methodology in Healthcare Research: How to Decide Its Appropriateness*, 11 World J. of Methodology 116, 116 (2021), <https://www.wjgnet.com/2222-0682/full/v11/i4/116.htm>.

²¹ SOC8 at S248–49.

²² *See id.*

²³ *Id.* at S247–250.

²⁴ *Id.* at 249.

Review Team was responsible for conducting systematic literature reviews and serving as an impartial evidence-gathering body to aid the SOC8 Review Committee's development of the guidelines.²⁵ The members of the SOC8 Review Committee and the Evidence Review Team were vetted for any potential conflicts of interest,²⁶ and the names, institutional affiliations, and biographies of the SOC8 Review Committee members are available to the public.²⁷

The SOC8 Review Committee began by developing a list of key research topics for the systematic reviews of the relevant scientific literature. Then, following standard evidence review procedures, the SOC8 Review Committee developed specific review questions iteratively with the Evidence Review Team. The Evidence Review Team developed and registered the review protocols, which minimized bias and ensured transparency and reproducibility by pre-specifying the review questions, eligibility criteria, and other methods.²⁸ Once each review was underway, the Evidence Review Team adhered strictly to these rigorous

²⁵ *Id.* at 249–250.

²⁶ SOC8 at S247.

²⁷ *Id.* at S1–2, S177; WPATH, *Chairs of the Soc8 and Lead Evidence Team*, <https://wpath.org/publications/soc8/chairs-evidence-leads/> (last visited June 15, 2026); WPATH, *SOC8 Contributors* (July 26, 2021), <https://wpath.org/wp-content/uploads/2024/11/SOC8-Full-Contributor-List-FINAL-UPDATED-09232021.pdf>.

²⁸ SOC8 at 249; *see also* David Moher et al., *Preferred Reporting Items for Systematic Review and Meta-analysis Protocols (PRISMA-P) 2015 Statement*, 4 *Systematic Reviews* 1 (2015), <https://doi.org/10.1186/2046-4053-4-1>.

protocols.²⁹ The resulting evidence was presented to the members of the SOC8 Review Committee, who evaluated the findings in light of their clinical expertise—synthesizing rigorous evidence with practical clinical knowledge, as the IOM Framework envisions.³⁰

To draft clinical recommendations based on the evidence presented, the SOC8 Review Committee considered the full spectrum of IOM-recommended factors—evidence, balance of benefits and harms, patient values and preferences, resource requirements and cost-effectiveness, equity, feasibility, and acceptability.³¹ In addition, the SOC8 Review Committee employed a modified version of the “GRADE” framework (Grading of Recommendations, Assessment, Development, and Evaluation) to describe each recommendation’s evidentiary support, as assessed by the Evidence Review Team.³² Importantly, GRADE distinguishes between the “certainty” of underlying evidence and the strength of the resulting recommendations—a critical distinction that Defendant-Appellant elides.³³ *See* Appellant Opening Br. at 10. GRADE expressly recognizes that strong recommendations may be warranted despite low-certainty evidence,

²⁹ SOC8 at 248–49.

³⁰ *Id.*

³¹ *Id.*

³² *Id.* at S250.

³³ Jeffrey C. Andrews et al., *GRADE Guidelines: 15. Going From Evidence to Recommendation—Determinants of a Recommendation’s Direction and Strength*, 66 J. Clinical Epidemiology 726 (2013).

including in situations where randomized trials would be unethical or infeasible and where the balance of benefits and harms, patient values, and other factors support a clear course of action.³⁴ SOC8 transparently reports the grading (i.e., strength) of its recommendations, allowing clinicians, patients, and other stakeholders to understand both the nature and limitations of the supporting evidence—satisfying the IOM Framework’s call for clear articulation of the foundations of evidence.³⁵

After chapter divisions of the SOC8 Review Committee drafted individual recommendation statements based on the evidence, the Committee convened as a whole and employed the Delphi methodology—a well-established technique for achieving expert consensus that the IOM Framework specifically endorses—to determine which recommendation statements should be approved for SOC8.³⁶ This structured process required a pre-specified level of at least 75 percent agreement between all members of the SOC8 Review Committee before any recommendation could be included in SOC8.³⁷ Statements failing to achieve consensus were revised based on feedback from members of the SOC8 Review Committee and resubmitted; those that failed to generate consensus after three

³⁴ SOC8 at S250.

³⁵ *Id.*

³⁶ *Id.* at S250.

³⁷ *Id.*

rounds of revision were excluded.³⁸ This process ensured that every recommendation in SOC8 represents a genuine professional consensus, not merely a majority view. Contrary to Defendant-Appellant’s arguments, such consensus was achieved precisely because the recommendations were supported by methodologically sound research; the recommendations did not, in any sense, replace the research itself.³⁹ *See* Appellant Opening Br. at 10 (incorrectly asserting that “WPATH declares support for its guidance on a supposed consensus of the medical communities rather than evidence-based research of their effectiveness.”) (internal quotations omitted).

After the guidelines were developed, but before they were published, SOC8 underwent multiple layers of additional, external scrutiny—another requirement of the IOM Framework. First, the “WPATH International Advisory Group,” a body of experts distinct from the SOC8 Review Committee, reviewed the draft guidelines and provided input.⁴⁰ WPATH then opened a six-week public comment period, inviting critique from the broader medical and scientific community.⁴¹ Additionally, a separate group of independent clinical academics validated that

³⁸ *Id.*

³⁹ Indeed, SOC8 contains meticulous references for every recommendation, and the resulting bibliography is 68 pages long.

⁴⁰ SOC8 at S251.

⁴¹ *Id.*

every cited reference appropriately supported the accompanying text.⁴² These safeguards ensured that SOC8 reflects not just internal consensus but robust external validation as well.⁴³ SOC8 also contains a detailed appendix describing each step of this development methodology, from the process for selecting members of each relevant committee through the final publication and plan for future updates—demonstrating the IOM Framework’s emphasis on methodological transparency.⁴⁴

Finally, recognizing that medical knowledge evolves, WPATH committed to revising SOC8 as warranted by new evidence or significant developments in the field.⁴⁵ This commitment to periodic updating ensures that the Standards of Care remain current with the best available science.⁴⁶

In sum, SOC8 was developed through a process that satisfies the most demanding standards for clinical practice guidelines: transparency in funding and methodology; conflict of interest management; independent systematic reviews; marriage of evidence reviews with clinical expertise; deliberation by multidisciplinary experts; structured consensus; transparent and independent grading of evidence and recommendation strength; external peer review and public

⁴² *Id.*

⁴³ *Id.*

⁴⁴ *Id.* at S247–51.

⁴⁵ *Id.* at S251.

⁴⁶ *Id.*

comment; and a commitment to ongoing revision. Defendant-Appellant makes the unsupported (and unsupportable) assertion that WPATH's standards are somehow lacking.⁴⁷ Given that WPATH's rigorous process hews to the IOM standards in all respects, Defendant-Appellant's claim is effectively an attempt to invalidate the IOM standards themselves, which would require disposing of clinical guidelines in dozens of medical fields and upend medical practice globally. Otherwise, and in the absence of any articulation of what standard SOC8 fails to meet, Defendant-Appellant's accusations are simply empty rhetoric. As outlined above, the methodology through which SOC8 was developed places it firmly on equal footing to other clinical practice guidelines across diverse fields of medicine.

III. Defendant-Appellant's Attacks on the Evidence Underlying SOC8 Are Meritless.

Defendant-Appellant advances two principal arguments in her attempt to doubt ^{SOW} regarding "the quality of evidence supporting the WPATH standards."

Appellant Opening Br. at 11. *First*, Defendant-Appellant argues that the evidence

⁴⁷ Defendant-Appellant points to a recent study that argued that courts and clinicians should exercise "caution in uncritically adopting or endorsing" SOC8's recommendations. Yuan Zhang et al., *Quality of the World Professional Association for Transgender Health Guidelines Standards of Care 8: An Appraisal Using the Agree II Instrument*, Archives of Sexual Behav. (Feb. 2026), perma.cc/4XDX-2F66. But clinical practice guidelines are never intended for "uncritical" adoption; by design, they provide evidence-based recommendations that clinicians must apply using their own expertise and each patient's individual needs and circumstances.

supporting WPATH’s recommendations has been characterized as “low quality.” *Id.* at 10-11. *Second*, Defendant-Appellant points to what it describes as a “relative scarcity of studies showing a reduction in morbidity and mortality” from gender-affirming medical care. *Id.* at 11, 27, 33, 47. Both arguments rest on fundamental, unscientific misunderstandings of how clinical evidence is evaluated and how clinical practice guidelines are developed.

A. Evidence Labelled “Low” Certainty or Quality Is Not Inherently Deficient.

Defendant-Appellant asserts that WPATH’s guidance relies on “supposed consensus” rather than “evidence-based research” because the supporting evidence is “low quality.” Appellant Opening Br. at 10. This argument conflates a technical designation in evidence-based medicine with the lay concept of unreliability. In fact, “low quality” evidence (more commonly called low certainty evidence) is simply a reflection of factors such as the type of study design available—not a judgment about the evidence’s reliability or the soundness of clinical recommendations based upon it.

Evidence-based medicine tools assess the certainty of evidence according to specific evidence-rating scales, which usually include four levels of evidence: high, moderate, low, and very low or insufficient. Though the ratings can be adjusted up or down according to various factors, evidence that comes from randomized controlled trials starts with a presumptive “high” rating, while

evidence from observational studies starts with a presumptive “low” rating.⁴⁸

These presumptive ratings are applied even before a given body of evidence is fully assessed because of the emphasis these tools place on randomized controlled trials.

In transgender health research, as in many other medical fields, randomized controlled trials often are not possible. All else being equal, randomized controlled trials are considered the “gold standard” in terms of the certainty of scientific evidence they produce, but many areas of medicine routinely cannot use them for ethical and practical reasons.⁴⁹ This is because randomized controlled trials typically involve withholding the relevant treatment from a subset of the study population and comparing that group’s outcomes with the group that does receive treatment. This type of study can only be performed ethically in the context of true clinical equipoise—i.e., where researchers do not know at the outset of the trial whether the treatment is effective or superior to the existing standard of care. If there is existing evidence that the treatment is effective, particularly when that

⁴⁸ Gordon H. Guyatt et al., *GRADE: An Emerging Consensus on Rating Quality of Evidence and Strength of Recommendations*, 336 BMJ 924 (2008), <https://www.bmj.com/content/336/7650/924>.

⁴⁹ R. Lawrence Moss et al., *The Role of Prospective Randomized Clinical Trials in Pediatric Surgery: State of the Art?*, 36 J. of Pediatric Surgery 1182, 1194 (2001); Jeremy Howick, Ashley Graham Kennedy & Alexander Mebius, *The Philosophy of Evidence-Based Medicine*, Oxford Bibliographies (2011), https://www.researchgate.net/publication/272679119_The_Philosophy_of_Evidence-Based_Medicine.

form of treatment is considered the standard of care, clinical equipoise does not exist, and running a randomized controlled trial that withholds treatment altogether, or provides a treatment known to be deficient, would be contrary to medical ethics. As a result, for treatments that have previously shown effectiveness, researchers must typically use study designs that are labelled “lower quality” or “lower certainty,” but do not involve withholding medical treatment from patients where medical science has already established the treatment to be beneficial.

The study of transgender health presents many such instances. The body of scientific evidence and clinical expertise available in the field today indicates that the standard of care for the treatment of gender dysphoria is associated with clinically meaningful improvements in measurable indicators of mental and physical health for transgender patients, while withholding treatment often causes harm.⁵⁰ As a result, longstanding principles of medical research ethics generally

⁵⁰ In 2018, for instance, Dr. Baker reviewed all peer-reviewed articles published in English between 1991 and 2017 that assessed the effects of medical treatment reflecting the expert clinical consensus on various health-related outcomes among transgender people. This 2018 review identified 55 primary research studies on this topic, of which 51 (93%) found that these treatments improve outcomes for transgender people, while 4 (7%) reported mixed or null findings. The review found *no studies* concluding that treatment according to the widespread standard of care causes harm. Further research has supported that withholding treatment is harmful. See, e.g., Kyle K.H. Tan et al., *Unmet Need for Gender Affirming Care as a Social Determinant of Mental Health Inequities for Transgender Youth in Aotearoa/New Zealand*, 45 J. Pub. Health e225 (2023).

do not support the use of randomized controlled trials to test gender-affirming care for transgender populations.⁵¹ As discussed below, that does not diminish the analytic weight or scientific value of the sizeable body of evidence on the treatment of gender dysphoria.

In addition to being unethical, randomized controlled trials for studies of transgender health treatments are also often infeasible. Most randomized controlled trial designs require that study participants be unaware of which treatment arm they are randomly assigned to. This is typically impossible in the context of gender-affirming treatments, such as hormone interventions or surgeries, that create visible physical effects, as it becomes obvious to study participants even over short periods of time whether they are assigned to the treatment or control group. The expert testimony cited by Defendant-Appellant herself⁵² highlights this problem:

[L]ow evidence does not equate with poor evidence. So this has often been weaponized, this idea that there's no evidence. But in order to have high evidence, you have to have randomized controlled trials. And it would be impossible to have that, for example, without the [gender-affirming] surgery, because it would mean you'd have two groups. One group would have

⁵¹ Theodore E. Schall, Kaitlyn Jaffe & Jacob D. Moses, *Roles of Randomized Controlled Trials in Establishing Evidence-Based Gender-Affirming Care and Advancing Health Equity*, 26 AMA J. Ethics E684 (2024), <https://doi.org/10.1001/amajethics.2024.684>; Florence Ashley et al., *Randomized-Controlled Trials Are Methodologically Inappropriate in Adolescent Transgender Healthcare*, 25 Int'l J. Transgender Health 407 (2023).

⁵² Appellant Opening Br. at 10.

surgery, and they wouldn't know if they had surgery or not. So you can see the absurdity of that. Only one out of ten medical and surgical interventions have high levels of certainty. Tonsillectomy, rotator cuff surgery, arthroscopic knee surgery all have low quality of evidence, as do aspirin and Vitamin D.⁵³

Therefore, much of the highest quality research evidence in transgender health is, according to the framework of ethical evidence-based medicine, designated as “low” certainty on the basis of the underlying types of study designs.⁵⁴ But this is a relative designation, not an absolute one. As Defendant-Appellant’s own evidence shows, the majority of medical evidence across a wide variety of fields, including “state of the art” evidence in many fields, is based on study designs other than randomized controlled trials (such as prospective cohort studies and other observational studies).⁵⁵ If this Court finds “low quality” evidence to be an appropriate basis for denying treatment to incarcerated individuals, states could just as easily deny life-saving treatments for cancer or

⁵³ 2-ER-117:21-118:8; *cf.* Appellant Opening Br. at 10.

⁵⁴ A small number of randomized controlled trials using innovative study designs (i.e., not placebo-controlled) have been conducted in transgender health. The findings of these randomized controlled trials align with the overall conclusions of systematic reviews in this field. *See* Brendan J. Nolan et al., *Early Access to Testosterone Therapy in Transgender and Gender-Diverse Adults Seeking Masculinization: A Randomized Clinical Trial*, 6 JAMA Network Open, no. 9, 2023, at 1, <https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2809058>.

⁵⁵ Luis H. Braga et al., *Randomized Controlled Trials - The What, When, How and Why*, 21 J. of Pediatric Urology 397, 403 (2024); Thomas R. Frieden, *Evidence for Health Decision Making - Beyond Randomized, Controlled Trials*, 377 NEJM 465 (2017).

cardiovascular disease. Indeed, an assessment of systematic reviews across 52 areas of medicine, including anesthesia, cancer, and cardiovascular disease, showed that only 13.5 percent reported evidence deemed “high” quality, while more than half are based on evidence whose quality was rated “low” (31.7%) or “very low” (24%).⁵⁶ Similarly, fewer than one in six systematic reviews across medical sectors found “high” quality evidence for a primary health outcome of interest, and fewer than one in five reported “high” quality evidence for any health outcome.⁵⁷

There exists no research demonstrating a relationship between evidence scoring highly in quality grading systems and improved patient care, nor is there an expectation or requirement that clinical guidelines and treatment protocols be based solely or chiefly on “high” certainty evidence.⁵⁸ As the Supreme Court has acknowledged, “medical professionals and researchers do not limit the data they consider to the results of randomized controlled trials or to statistically significant evidence.” *Matrixx Initiatives, Inc. v. Siracusano*, 563 U.S. 27, 41 (2011) (citations omitted).

⁵⁶ Padhraig S. Fleming et al., *High Quality of the Evidence for Medical and Other Health-Related Interventions Was Uncommon in Cochrane Systematic Reviews*, 78 J. of Clinical Epidemiology 34 (2016).

⁵⁷ *See id.* at 39.

⁵⁸ Brian P. Kavanagh, *The GRADE System for Rating Clinical Guidelines*, 6 PLoS Med., no. 9, 2009, at 1, <https://journals.plos.org/plosmedicine/article?id=10.1371/journal.pmed.1000094>.

Moreover, though evidence from medical research at large is a core component of the development and application of clinical practice guidelines, clinical care always requires consideration of multiple factors, including patient need, values, and preferences, expert clinical judgment and individualized evaluations and assessments of patient need. In the context of “low quality” evidence, these other factors become more important—not less. Dr. Gordon Guyatt, the “father of evidence-based medicine,” has expressed serious concerns about the growing misuse of concepts from evidence-based medicine to support restrictions on care for transgender people. He and his coauthors have written:

It is profoundly misguided to cast health care based on low-certainty evidence as bad care or as care driven by ideology, and low-certainty evidence as bad science. Many of the interventions we offer are based on low certainty evidence, and enlightened individuals often legitimately and wisely choose such interventions. Thus, forbidding delivery of gender-affirming care and limiting medical management options on the basis of low certainty evidence is a clear violation of the principles of evidence-based shared decision-making and is unconscionable.⁵⁹

Contrary to Defendant-Appellant’s assertion, WPATH’s usage of “low quality” evidence in developing SOC8 is not an indication that its recommendations are not based on evidence. The evidence underlying SOC8 is as

⁵⁹ Gordon Guyatt et al., *Systematic Reviews Related to Gender-Affirming Care*, McMaster U. (2025), <https://hei.healthsci.mcmaster.ca/systematic-reviews-related-to-gender-affirming-care>.

reliable as the evidence supporting the vast majority of medical and surgical interventions.

B. The Scarcity of Morbidity and Mortality Studies Is a Natural Result of the Rarity of These Outcomes and Does Not Signal Evidentiary Weakness.

Defendant-Appellant argues that the “relative scarcity of studies showing a reduction in morbidity and mortality,” particularly suicide and suicidality, undermines the reliability of WPATH’s recommendations. *See* Appellant Opening Br. at 11, 27, 33, 47. Defendant-Appellant highlights two studies that she wrongly characterizes as supporting the argument that sex-reassignment surgeries do not improve patient outcomes. *See* Appellant Opening Br. at 32–33. But Defendant-Appellant fundamentally misinterprets both studies, how clinical evidence is evaluated, and why certain outcomes are more amenable to study than others.

The first study cited by Defendant-Appellant, *Long-Term Follow-Up of Transsexual Persons Undergoing Sex Reassignment Surgery: Cohort Study in Sweden* by Cecilia Dhejne et al. (2011), *see* Appellant Opening Br. at 32–33, does not show that sex-reassignment surgeries fail to improve patient outcomes. The study team compared post-surgery transgender adults with matched cisgender individuals from the general population. The study did not compare post-surgery transgender adults with transgender individuals who either (i) elected not to undergo surgery, or (ii) sought surgery but did not receive it. In the absence of

either such comparison, a study cannot—and this study did not even purport to—“address whether sex reassignment is an effective treatment or not.”⁶⁰ As the lead author herself noted in a 2015 interview, “[p]eople who misuse the study always omit the fact that the study clearly states that it is not an evaluation of gender dysphoria treatment. If we look at the literature, we find that several recent studies conclude that WPATH Standards of Care compliant treatment decrease[s] gender dysphoria and improves mental health.”⁶¹

The second study cited by Defendant-Appellant is *Examining Gender-Specific Mental Health Risks After Gender-Affirming Surgery: A National Database Study* by Joshua E. Lewis et al. (2025). See Appellant Opening Br. at 33. This study excluded patients with a pre-existing mental health diagnosis from evaluation, and therefore plainly did not, and could not, address whether surgery improves mental health among transgender patients who enter treatment with depression, anxiety, or other psychiatric conditions.

In light of these serious limitations, these two studies—particularly set against the sizeable body of evidence supporting SOC8—simply do not provide

⁶⁰ Cecilia Dhejne et al., *Long-Term Follow-Up of Transsexual Persons Undergoing Sex Reassignment Surgery: Cohort Study in Sweden*, 6 PLoS one, no. 2, 2011, at 1, 2, <https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0016885>.

⁶¹ Cristan Williams, *Fact check: study shows transition makes trans people suicidal*, TransAdvocate (Nov. 2, 2015), https://www.transadvocate.com/fact-check-study-shows-transition-makes-trans-people-suicidal_n_15483.htm.

support for Defendant-Appellant’s contention that “the State had legitimate reasons to doubt the appropriateness of sex-reassignment surgery for prisoners.” *See* Appellant Opening Br. at 32.

By contrast, the systematic reviews that informed SOC8 assessed all available evidence regarding mental health outcomes such as quality of life, depression, and anxiety in relation to gender-affirming treatments, and observed that surgical interventions had consistently positive effects, including “a decrease in active mental health conditions, including depression, anxiety, drug or alcohol misuse, and suicidal ideation and self-harm.”⁶² Though the certainty of the assessed evidence was judged to be “low” (meaning it came from observational studies rather than randomized controlled trials, as explained *supra* Section III(A)), SOC8 concludes that “data consistently demonstrate improved or stable psychological functioning, body image, and treatment satisfaction” from the use of surgical interventions.⁶³ Research published after SOC8 reaffirms the positive

⁶² Lee H. Kilner et al., *Gender-Affirming Surgery Improves Mental Health Outcomes and Decreases Antidepressant Use in Patients with Gender Dysphoria*, 154 J. Plastic & Reconstructive Surgery 1142, 1147 (2024); *see also, e.g.*, SOC8 at S46; Andrea Nobili, Colin Glazebrook & Jon Arcelus, *Quality of Life of Treatment-Seeking Transgender Adults: A Systematic Review and Meta-Analysis*, 19 Rev. Endocrine & Metabolic Disorders 199 (2018) (finding that gender-affirming treatment, including surgical interventions, was associated with improved quality of life among transgender adults).

⁶³ SOC8 at S46.

effects of surgical interventions.⁶⁴

SOC8 does not draw definitive conclusions about death by suicide or other causes because such outcomes are, fortunately, rare, and studying rare outcomes requires either extraordinarily large sample sizes or extended follow-up periods—neither of which have been consistently available thus far in the field of transgender health. This is not a deficiency unique to transgender health or to SOC8’s methodology; it is a methodological reality across medicine.

With respect to suicidal ideation among individuals with gender dysphoria, however, the literature indicates a clear relationship between surgical interventions and decreases in suicidal ideation. Multiple peer-reviewed studies have found that patients with gender dysphoria who receive surgical treatment experience significantly lower odds of adverse mental health outcomes, including suicidal ideation.⁶⁵

⁶⁴ See Inês Rafael Marques et al., *The Impact of Gender-Affirming Surgeries on Suicide-Related Outcomes: A Systematic Review*, 5 J. Psychosexual Health 134 (2023); Lucas Shelemy et al., *Systematic Review of Prospective Adult Mental Health Outcomes Following Affirmative Interventions for Gender Dysphoria*, 26 Int’l J. Transgender Health 480 (2025); Keith A. Yeo, Yi Jie Yeo & Cyrus Su Hui Ho, *Impact of Gender-Affirming Surgery on Psychiatric Outcomes and Quality of Life in Transgender Individuals: A Systematic Review of Longitudinal Cohort Studies*, 15 J. Clinical Med., no. 6, 2026, at 1, <https://pmc.ncbi.nlm.nih.gov/articles/PMC13026213/pdf/jcm-15-02213.pdf>.

⁶⁵ Alina N. Almazan & Alex S. Keuroghlian, *Association Between Gender-Affirming Surgeries and Mental Health Outcomes*, 156 JAMA Surgery 611 (2021) (finding that individuals who had undergone gender-affirming surgery had lower

The available evidence on mental health outcomes—including quality of life, depression, and suicidality—consistently supports the conclusion that gender-affirming treatment, including surgical interventions, benefits individuals with gender dysphoria. These findings align with the expert clinical consensus reflected in SOC8 and the recommendations of every major medical organization that has examined the evidence.

C. Defendant-Appellant’s Characterization of WPATH as an “Advocacy” Organization Is Baseless.

Defendant-Appellant dismisses SOC8 on the baseless and inflammatory assertion that WPATH is “an advocacy group, not a neutral scientific organization.” Appellant Opening Br. at 8–9. Defendant-Appellant relies on dicta from other courts suggesting that “WPATH aspires to be both a scientific organization and an advocacy group” and that its guidelines are “not a politically neutral document.” *See* Appellant Opening Br. at 9 (quoting *Kosilek v. Spencer*, 774 F.3d 63, 78 (1st Cir. 2014) (*en banc*)). These characterizations fundamentally

odds of psychological distress, smoking, and suicidal ideation than those who desired surgery but had not received it); *see also, e.g.*, Raymond P. Tucker et al., *Hormone Therapy, Gender Affirmation Surgery, and Their Association with Recent Suicidal Ideation and Depression Symptoms in Transgender Veterans*, *Psychol. Med.* 1 (2018), https://www.researchgate.net/publication/322492790_Hormone_therapy_gender_affirmation_surgery_and_their_association_with_recent_suicidal_ideation_and_depression_symptoms_in_transgender_veterans (reporting association between gender-affirming surgery and lower levels of recent suicidal ideation and depression among transgender veterans).

misrepresent WPATH’s nature and mission, and the rigorous methodology underlying SOC8.

First, as described *supra* Section I, WPATH is a multidisciplinary professional association comprising medical practitioners, legal experts, and scientific researchers—not politicians or activists. *Contra* Appellant Opening Br. at 3–4. The extensive, rigorous, multi-year process described above does not comport with the practice of an advocacy organization; instead, it is the methodology of rigorous, evidence-based clinical science conducted by a professional medical body. *See supra* Section II.

Second, medical professional societies in all specialties routinely participate in public discussions of matters of concern to their members. The American Medical Association, the American Heart Association, the American Cancer Society, and numerous other professional medical associations frequently write *amicus* briefs, provide legislative testimony, file regulatory comments, and release public statements in support of policies that they believe reflect the expertise and values of their members and their mission to advance patient health.⁶⁶ Even if

⁶⁶ *See, e.g.,* Am. Med. Assoc., *Policy H-185.927, Health insurance coverage for gender-affirming care of transgender patients* (reaffirmed 2024), <https://www.ama-assn.org/system/files/transgender-coverage-issue-brief.pdf>; Am. Med. Assoc., *AMA reinforces opposition to restrictions on transgender medical care* (June 15, 2021), <https://www.ama-assn.org/press-center/ama-press-releases/ama-reinforces-opposition-restrictions-transgender-medical-care> (“The

these are characterized as “advocacy” functions, in no other area of medicine are they viewed as discounting these organizations’ clinical and scientific work. If these “advocacy” functions were considered disqualifying as Defendant-Appellant suggests, no professional medical association’s guidelines would be admissible as a clinical standard of care, and any association that takes clear positions on clinical questions would be classified merely as an “advocacy” organization by Defendant-Appellant’s definition.

IV. The SOC8 Guidelines Regarding Surgical Management of Gender Dysphoria Apply to Incarcerated Individuals.

Defendant-Appellant incorrectly asserts that SOC8 “does not wrestle with the unfortunate and unavoidable realities of custodial care” and instead “collapses” carceral settings into the same category as other residential treatment centers. *See* Appellant Opening Br. at 9; *see also, e.g., id.* at 11, 22-23, 48-52. This misrepresents the foundation of WPATH’s guidance relating to institutionalized settings. *First*, WPATH’s guidelines with respect to healthcare in institutionalized

AMA opposes the dangerous intrusion of government into the practice of medicine and the criminalization of health care decision-making Gender-affirming care is medically necessary, evidence-based care that improves the physical and mental health of transgender and gender-diverse people.”); Am. Psych. Assoc., *Policy Statement on Affirming Evidence-Based Inclusive Care for Transgender, Gender Diverse, and Nonbinary Individuals* (Feb. 2024), <https://www.apa.org/about/policy/transgender-nonbinary-inclusive-care.pdf> (affirming “APA’s support for unobstructed access to healthcare and evidence-based clinical care for transgender, gender-diverse, and nonbinary children, adolescents, and adults”).

settings are not merely adapted to carceral settings—they are substantially derived from carceral settings. As SOC8 explicitly acknowledged in its section on institutionalized settings, “[m]uch of the evidence in support of proper care of [transgender] persons comes from carceral settings,” and the “majority of the available literature related to institutions . . . focuses on those who are incarcerated in jails, prisons, or other carceral environments.”⁶⁷ Far from ignoring the realities of prisons, SOC8’s guidelines on institutionalized settings are based on treatment standards derived from carceral settings, which were subsequently applied to other residential treatment centers—not the other way around.

Second, Defendant-Appellant’s contention that medical necessity should be evaluated differently for incarcerated individuals fundamentally conflicts with basic principles of bioethics. *See, e.g.*, Appellant Opening Br. at 51 (attacking Plaintiff-Appellee’s experts’ conclusions regarding the medical necessity of surgical intervention because those experts were not “correctional practitioner[s]”).

⁶⁷ SOC8 at S104; *see also id.* at S105 (“The majority of the available literature related to institutions focuses on those who are incarcerated in jails, prisons, or other carceral settings.”); George R. Brown & Everett McDuffie, *Health Care Policies Addressing Transgender Inmates in Prison Systems in the United States*, 15 J. Correctional Health Care 280 (2009), https://www.researchgate.net/publication/26698949_Health_Care_Policies_Addressing_Transgender_Inmates_in_Prison_Systems_in_the_United_States (cited at S104); Douglas Routh et al., *Transgender inmates in prisons*, Int’l J. Offender Therapy & Comparative Criminology 1 (2015), https://www.antoniocasella.eu/archica/Routh_2015.pdf (cited at S108).

Professor Ulrich has first-hand experience navigating these basic principles at the National Institutes of Health, and through scholarship analyzing how these principles should apply in medical settings. The relevant bioethics principles include respect for autonomy, beneficence (the duty to act in the patient’s best interest), and nonmaleficence (the duty to avoid harm, whether through acts of commission or omission).⁶⁸ While prison-specific factors may inform clinical judgment, they do not justify disregarding an inmate’s medical needs. The premise of Defendant-Appellant’s argument—that incarceration alters what constitutes medically necessary care—is flatly inconsistent with the ethical obligations clinicians owe to all patients, regardless of their institutionalized status.⁶⁹

Consistent with these principles, the National Commission on Correctional Healthcare has counseled that “the clinical decision making to initiate . . . [gender-affirming] surgical interventions while incarcerated . . . needs to be based on

⁶⁸ See Thomas R. McCormick et al., *Principles of Bioethics*, UW Med. Dep’t Bioethics & Humanities, <https://depts.washington.edu/bhdept/ethics-medicine/bioethics-topics/articles/principles-bioethics> (last visited June 15, 2026).

⁶⁹ See, e.g., Amber R. Comer, *Care of Patients Who Are Incarcerated*, 27 AMA Journal of Ethics 277, 280 (2025), <https://journalofethics.ama-assn.org/sites/joedb/files/2025-03/code1-peer-2504.pdf> (“[P]atients who are incarcerated should ethically be treated the same as other patients.”); AMA PolicyFinder, *Health Care While Incarcerated H-430.986* (2024), <https://policysearch.ama-assn.org/policyfinder/detail/h-430?uri=%2FAMADoc%2FHOD-430.986.xml> (advocating for “readily accessible gender-affirming care to meet the distinct healthcare needs of transgender and gender diverse people in the carceral system, including but not limited to gender-affirming surgical procedures”).

individual medical need, risks and benefits, analysis of alternatives, ruling out contraindications, accepted standards of care, and a thorough informed-consent process.”⁷⁰ Likewise, WPATH adheres to its bioethical obligations in recommending that, whether in prison settings or otherwise, “the entire list of recommendation[s] of the SOC-8[] [should] apply equally to [transgender] people living in institutions.”⁷¹

In sum, WPATH’s guidelines on institutionalized settings are not merely applicable to incarcerated individuals—they are in significant part derived from literature that focuses on carceral settings. These guidelines provide a framework for individualized clinical assessments of medical necessity that is consistent with recognized bioethics principles and standards for clinical guidelines. Defendant-Appellant’s attempts to carve out an exception to the definition of medical necessity for incarcerated persons, in contravention of the professional consensus on transgender healthcare, are without merit.

⁷⁰ Nat’l Comm’n on Correctional Healthcare, *Transgender and Gender Diverse Health Care in Correctional Settings* 3 (2020), <https://ncchc.org/wp-content/uploads/Transgender-and-Gender-Diverse-Health-Care-in-Correctional-Settings-2020.pdf>.

⁷¹ SOC8 at S105.

CONCLUSION

In light of the foregoing, Dr. Baker and Professor Ulrich respectfully request that this Court affirm the District Court's judgment.

Dated: June 24, 2026

Respectfully submitted,

/s/ Luke A. Barefoot

Luke A. Barefoot

Thomas S. Kessler

Jack Massey

Noopur Sen

Ariel Sheffey

Saifeldeen Zihiri

CLEARY GOTTlieb STEEN & HAMILTON LLP

One Liberty Plaza

New York, NY 10006

T: (212) 225-2000

F: (212) 225-3999

lbarefoot@cgsh.com

tkessler@cgsh.com

jamasse@cgsh.com

nsen@cgsh.com

asheffey@cgsh.com

szihiri@cgsh.com

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