

**UNITED STATES DISTRICT COURT  
MIDDLE DISTRICT OF ALABAMA  
NORTHERN DIVISION**

BRIANNA BOE <i>et al.</i> ,	)	
	)	
<i>Plaintiffs</i> ,	)	
	)	
and	)	
	)	
UNITED STATES OF AMERICA,	)	
	)	
<i>Plaintiff-Intervenor</i> ,	)	
	)	
v.	)	No. 2:22-cv-00184-LCB-CWB
	)	Hon. Liles C. Burke
STEVE MARSHALL, in his official	)	
capacity as Attorney General of the	)	<b>SUBMITTED UNDER SEAL</b>
State of Alabama, <i>et al.</i> ,	)	
	)	
<i>Defendants.</i>	)	

**DEFENDANTS' MOTION TO EXCLUDE  
SELECTED TESTIMONY OF DR. JENIFER LIGHTDALE**

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## INTRODUCTION

Dr. Jennifer Lightdale proffers opinion testimony that the methodology employed by World Professional Association of Transgender Health (WPATH) to develop Version 8 of its “Standards of Care” (SOC-8) was “transparent, rigorous, and methodologically sound.” *Daubert*.DX9:¶19 (Lightdale Reb. Decl.).<sup>1</sup> She also proffers an opinion that even care providers who derive substantial income from procedures that would be affected by a set of clinical practice guidelines have no conflict of interest in participating in that guideline development process. *Id.* ¶31.

At her deposition, however, Dr. Lightdale revealed and admitted that she is not an expert in either methodologies for development of clinical practice guidelines or medical ethics. More, she proffers these opinions without having made any investigation at all into how WPATH actually developed the SOC-8 guidelines. Undisputed testimony of those who actually participated in that development process—and in particular SOC-8 Chair Dr. Eli Coleman—reveals that Dr. Lightdale’s *assumptions* about how WPATH created the SOC-8 guidelines were simply wrong in critical respects.

Opinions that Dr. Lightdale proffers that are outside her expertise, based on no factual investigation whatsoever, and instead based on factually false premises, trip over every threshold requirement of *Daubert*. They must be excluded.

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<sup>1</sup> Defendants use two main citations form in their *Daubert* briefing. The first—*Daubert*.DX#:#—refers to exhibits Defendants submit in support of their *Daubert* motions, where the first “#” refers to the exhibit number and the second “##” refers to the page numbers within that exhibit. The second citation form—SJ.DX#:#—refers to the exhibits Defendants submitted in support of their motion for summary judgment. *See* Docs. 557-60 (public exhibits) & 564 (sealed exhibits).

## LEGAL STANDARD

To avoid duplication, Defendants respectfully refer the Court to the statement of governing legal principles contained in Defendants' Motion to Exclude Testimony of Dr. Morissa Ladinsky. *See* [Doc. 593 at 2-8](#).

## ARGUMENT

### **I. Dr. Lightdale's Proffered Testimony And Opinions Concerning The Development Of WPATH SOC-8 Should Be Excluded For Lack Of Relevant Expertise And Reliable Basis.**

Dr. Lightdale proposes to testify that WPATH's method of developing SOC-8 was "transparent, rigorous, and methodologically sound" and "comparable or superior to the methodology that has been used by many other medical societies to develop clinical practice guidelines for the treatment of many other medical conditions, both pediatric and adult, and ... in line with best clinical practice guideline practices as outlined by the National Academy of Sciences." Lightdale Reb. Decl. ¶19. Moving into specifics, she proposes to testify that WPATH employed an "Evidence Team" "to present 'an evidence table,'" *id.* ¶20; that "chapter members graded each [proposed] statement [in the SOC]" using an evidence-evaluation system known as "GRADE," *id.*; and that all of the recommendations in SOC-8 "were approved by at least 75 percent of the SOC-8 members" using the "anonymous" "Delphi" process, *id.* ¶¶20, 24..

All of this is admittedly outside Dr. Lightdale's expertise and personal knowledge. Undisputed evidence shows that it is objectively false. In fact, at her deposition Dr. Lightdale essentially retracted all of these opinions, clarifying that her opinions did not extend beyond saying that "I thought *the process that they*

*describe on their website* looks like what you would want a process to look like.” SJ.DX69:216:20-22 (Lightdale Dep.). She agreed that she did not “have the information you would need to form an opinion as to whether they actually followed the process described in the methodology.” *Id.* at 217:21–218:1.

**A. Dr. Lightdale Lacks Expertise in Reliable Methodologies For Development of Clinical Practice Guidelines.**

Dr. Lightdale has herself participated in guideline development projects relating to endoscopy. However, she expressly disclaimed expertise in methodologies for developing reliable clinical practice guidelines, stating “I’m not a methodologist.” *Id.* at 26:16. Confirming this disclaimer, she testified that when she herself has participated in guideline development projects, those teams would enlist someone who *was* a methodologist, competent to evaluate and give guidance as to what would constitute a “rigorous, and methodologically sound” process. *See id.* at 26:12-13 (“I’ve followed a methodologist”); *id.* at 27:18-19 (she would “talk to a methodologist”); *id.* at 82:22-23 (“We made a decision ... working with methodologists”). Consistent with this, she also testified that her assertion in her report (at ¶26) that GRADE “is the most commonly used system for classifying [the strength of scientific] evidence” was based on nothing more than “[j]ust gut instinct, like what you’re hearing everyone talking about.” Lightdale Dep. 52:19-23.

Plaintiffs have brought the wrong person to court. Dr. Lightdale denies being an expert in reliable methodologies for developing clinical practice guidelines, and she herself consults an expert in methodology when *she* needs expertise on that topic. She fails the threshold requirement of being “qualified to testify competently

regarding the matters [she] intends to address.” *City of Tuscaloosa v. Harcross Chems., Inc.*, 158 F.3d 548, 562 (11th Cir. 1998).

**B. Dr. Lightdale Has No Knowledge Of, and Made No Investigation Into, the Methodology Actually Employed by WPATH to Develop SOC-8.**

**1. Dr. Lightdale has no factual knowledge concerning the SOC-8 development process.**

Dr. Lightdale proposes to testify that WPATH’s process for developing SOC-8 was “rigorous, and methodologically sound” despite the fact that she:

- Never read the WPATH SOC-8 guidelines. *See* Lightdale Dep. 217:6-7 (“I have no opinion on the guidelines themselves, because I didn’t look at them, and I frankly wouldn’t understand them.”).
- Never read the Appendix A to those guidelines in which WPATH represented to the public in some detail the methodology it *claimed* to use to develop those guidelines. *See id.* at 55:4-5, 15-18 (“I have not looked at it before” and did not even “know that SOC-8 had a methodology appendix”).
- Never talked to anyone who participated in the process in order to verify what process WPATH *actually* followed. *See id.* at 9:12–10:5.

Instead, Dr. Lightdale’s sole basis for all of her opinions about the WPATH guidelines was “probably an hour maximum” that she spent reading a page on the WPATH website that purported to give a high-level overview of the methodology employed to develop SOC-8. *Id.* at 38:13-17. She denies having any personal knowledge of that process, and took no steps to verify what she read on the webpage. *Id.* at 10:1-5 (“Q. Do you have any knowledge of the process that was used to develop the WPATH SOC-8 other than the methodology web page you refer to in your expert report? A. No. Just the web page.”).

In basing her opinions on a hasty review of an informal WPATH webpage, without taking any steps to verify what the WPATH SOC-8 authors actually did, Dr. Lightdale failed to exercise one of the most basic of all scientific principles: testing her subject matter. Her approach was the antithesis to the rigorous scientific method that a prudent scientist would undertake in examining an issue. Consequently, Dr. Lightdale’s methodology is unreliable and cannot withstand the “exacting analysis” that the Eleventh Circuit demands. *McCorvey v. Baxter Healthcare Corp.*, 298 F.3d 1253, 1257 (11th Cir. 2002).

**2. Dr. Lightdale’s assumptions and assertions about the process employed by WPATH are false in important respects.**

In fact, precisely because she did no meaningful investigation, Dr. Lightdale repeatedly based her opinions and her assertions about WPATH’s process on assumptions rather than facts, and on assumptions that undisputed evidence now shows to be false.

Careful evaluation of the scientific evidence. Dr. Lightdale asserts as fact that chapter members “graded each statement [in SOC-8 guidance] using GRADE.” Lightdale Reb. Decl. ¶20. But that is false. Dr. Eli Coleman, former WPATH President and Chair of SOC-8 project, admitted to colleagues that WPATH “did not use GRADE explicitly.” SJ.DX190:8 (WPATH Ex. 17).

Use of an anonymous Delphi process to arrive at recommendations. Dr. Lightdale asserts as fact that “WPATH’s method for developing SOC-8 is exemplary and follows best practices for using a Delphi method to achieve consensus.” Lightdale Reb. Decl. ¶20. And she emphasizes that anonymity of input from the participants



is an integral aspect of those “best practices.” *Id.* at ¶24. At deposition, she elaborated that this anonymity is “important” to “mitigate bias” in the consensus-forming process and avoid undue influence from “peer pressure” among the participants. Lightdale Dep. 81:18–82:16. But again, she was mistaken in her assumptions. The undisputed testimony of Dr. Eli Coleman establishes that WPATH’s Delphi process was *not* anonymous, SJ.DX21:267:8–4 (Coleman Dep.), and was therefore vulnerable to precisely the distorting biases that Dr. Lightdale warned against.

Approval of all recommendations by membership vote. Critically, Dr. Lightdale asserts that all SOC-8 recommendations were approved through this Delphi process by a 75% vote. Lightdale Reb. Decl. ¶20. But while the prior version of WPATH’s guidelines restricted all surgical procedures to those who had reached the “Age of majority” in the relevant jurisdiction, SJ.DX19:25-27 (WPATH SOC-7)—as Alabama’s challenged law requires—the undisputed testimony of Dr. Coleman establishes the disconcerting fact that *all* minimum ages for surgeries were stripped out of the SOC-8 recommendations *after* the Delphi process had approved recommendations that *included* minimum ages, and *without* submission to the committee members for any vote of approval—in response to political pressures rather than any new science. SJ.DX21:292:11–295:16 (Coleman Dep.). There could hardly be a more important change to the guidelines.

Given that Dr. Lightdale did not investigate how WPATH actually developed its SOC-8, and was mistaken in some of the most important factual assumptions on which she based her opinions, it is evident that Dr. Lightdale’s opinions that WPATH’s methodology was “rigorous, and methodologically sound” do not come

close to resting on the “reliable foundation” necessary to establish admissibility under *Daubert*. See *Daubert v. Merrell Dow Pharms., Inc.*, [509 U.S. 579, 580](#) (1993).

**3. Dr. Lightdale did not investigate, and has no knowledge of, whether WPATH was transparent in the development of SOC-8.**

Dr. Lightdale’s repeated assertions that WPATH was “transparent” with respect to the development and evidence base of SOC-8, Lightdale Reb. Decl. ¶¶19, 29, are equally detached from knowledge and reality.

Dr. Lightdale is correct in stressing that “transparency has ... become really important” for guideline development. Lightdale Dep. 144:16-17. As to substance, she agreed that a core aspect of that transparency is disclosing enough information “to enable other members of the medical, scientific community to evaluate whether they agree or disagree with your treatment of the evidence” *Id.* at 46:6-11. As to process, Dr. Lightdale testified that “the most important transparent thing is to say ... what you were looking to do and how you did it,” *id.* at 143:16-20, and that “if you’re going to state something [about the guideline development process], then you followed it,” *id.* at 168:6-10.

But Dr. Lightdale made no effort to verify whether WPATH followed the process it claimed in its webpage (much less in the more detailed methodology appendix she never read), nor did she even look at the SOC-8 guidelines to see whether or to what extent WPATH disclosed enough information to enable other scientists to evaluate WPATH’s “treatment of the evidence.” *Id.* at 46:6-11.

Quite the contrary, Dr. Lightdale’s opinions again rest on assumptions that undisputed testimony by those with actual knowledge shows are false, or assumptions that Dr. Lightdale admits she has no knowledge of.

Disclosing methods used to search for scientific evidence. Dr. Lightdale rightly testified that an “important” aspect of transparency for a set of guidelines is to “explain how you searched for evidence,” *id.* at 32:12-14, including disclosing “search terms used [and] sources consulted,” *id.* at 31:20–33:6, sufficiently that “somebody can go and do the search and feel that you found the same evidence,” *id.* at 35:12-15. But Dr. Lightdale admitted she simply does not know whether WPATH has disclosed details of its own searches in the development of SOC-8 because “I didn’t look.” *Id.* at 34:6-12, 35:3-7.

Describing the strengths and limitations of the evidence. Dr. Lightdale further testified that it is “important” that guideline developers both assess and “clearly describe[]” the “strengths and limitations of the body of evidence,” *id.* at 40:10-13, disclosing for each source “what was the risk of bias in the study,” such as flaws in the experimental design that could result in “false positives” or “false negatives,” *id.* at 41:18–43:11. (The GRADE system—which SOC-8 Chair Dr. Coleman admitted WPATH failed to apply despite claiming to do so—is precisely a system for “rat[ing] the quality of evidence.” Lightdale Dep. 53:20–54:9.) But when asked “whether, in connection with any of the recommendations of SOC-8, WPATH disclosed or provided any description of risk of bias of studies that it relied on,” Dr. Lightdale didn’t know: “I didn’t look at the guideline, so I can’t answer that.” *Id.* at 43:17-22.

Presenting evidence tables. Finally, Dr. Lightdale explained at her deposition that publication of evidence tables that link specific evidence to specific guideline recommendations is an “important” aspect of transparency to show “that your recommendation is backed up by ... studies” and “enable other members of the medical, scientific community to evaluate” that evidence and those recommendations. *Id.* at 45:22–46:11. As a result, Dr. Lightdale’s own team did publish evidence tables for the clinical guidelines that they developed. *Id.* at 44:20–45:6. But when asked whether WPATH had published evidence tables for SOC-8, she admitted, “I don’t know. I don’t know.” *Id.* at 46:12-15. A cursory look at SOC-8 itself would have revealed that no evidence tables of any sort documenting the evidentiary basis of specific SOC-8 recommendations are provided. But of course, Dr. Lightdale didn’t look.

Opining on a document without even looking at it has nothing in common with any “reliable” or scientific methodology. Because—as she repeatedly emphasized—Dr. Lightdale never looked at the SOC-8, and so has no knowledge as to what the SOC-8 document does or does not disclose, her proffered opinions attributing “transparency” to WPATH rest on no reliable methodology, and are utterly unreliable. Her opinions do not rest on “good grounds, based on what is known,” *Daubert*, 509 U.S. at 590 (cleaned up), and should be excluded, *see City of Tuscaloosa*, 158 F.3d 548 at 562.

**II. Dr. Lightdale’s Proffered Opinions Concerning Conflict Of Interest In The Development Of WPATH SOC-8 Should Be Excluded For Lack Of Relevant Expertise And Reliable Basis.**

Dr. Lightdale proposes to opine that there is “no basis in medical ethics or science” for asserting that a provider who treats gender dysphoria in and of itself creates a conflict of interest with respect to participating in the development of guidelines on the topic. Lightdale Reb. Decl. ¶31. But asked: “do you consider yourself to be an expert in conflict-of-interest principles?”, Dr. Lightdale gave an absolute and unqualified answer: “No.” Lightdale Dep. 182:23–183:1.

Dr. Lightdale acknowledged that the document “Clinical Guidelines We Can Trust” published by the Institute of Medicine (“IoM”) is a “respected” and “important text in the field.” *Id.* at 141:16-19. Perhaps more importantly, it is one of the two “guidelines for guideline development” that WPATH tells the world it followed. *Id.* at 140:5-14. Dr. Lightdale agreed with the IoM definition of conflicts of interest as encompassing any situation in which “an independent observer might reasonably question whether the individual’s professional actions ... are motivated by personal gain, such as ... clinical revenue streams.” *Id.* at 170:12–171:7. And she recognized that the IoM conflict-of-interest guidelines go on to elaborate that “[d]irect financial commercial activities include clinical services from which a committee member derives a substantial portion of his or her income.” *Id.* at 172:18–173:3.

It is despite this plain and authoritative language that Dr. Lightdale proposes to tell the Court that there is “no basis in medical ethics” to contend that a provider who makes his or her livelihood from providing hormones or surgery to minors as treatments for gender dysphoria would have a conflict of interest in shaping

guidelines that might restrict such procedures. *See* Lightdale Reb. Decl. ¶31. Dr. Lightdale provides no citation in her report to any authority to support this opinion, and did not identify any in her deposition. Combining her disclaimer of expertise in conflict-of-interest principles with her failure to identify any supporting authority, this opinion must qualify as a classic example of mere *ipse dixit*, *Hendrix ex rel. G.P. v. Evenflo Co.*, [609 F.3d 1183, 1194](#) (11th Cir. 2010), or “unscientific speculation offered by a genuine scientist,” *Chapman v. Procter & Gamble Distrib., LLC*, [766 F.3d 1296, 1306](#) (11th Cir. 2014 ), both of which the Eleventh Circuit has warned against.

Finally, Dr. Lightdale admitted she has no knowledge of whether—or to what extent—WPATH followed the recommendations of the Institute of Medicine on managing conflicts of interest in developing SOC-8, nor whether any chair, co-chair, or chapter lead in the SOC-8 process had any financial or intellectual conflict of interest. Lightdale Dep. 183:2–184:17 (“Q. [Y]ou haven’t looked at the SOC-8 itself to see what conflicts they in fact disclosed? A. No.”), 185:24–186:20 (“Q. Do you have any knowledge, Dr. Lightdale, as to whether the chair of SOC-8 had either intellectual or financial conflicts of interest relevant – relating to treatment of gender dysphoria? A. I have no idea.”).

In sum, Dr. Lightdale has not made even the most cursory showing that could meet Plaintiffs’ burden of establishing qualification, reliability, and helpfulness with respect to opinions about any aspect of conflict of interest as it relates to the development of WPATH’s SOC-8. *See Boca Raton Cmty. Hosp., Inc. v. Tenet Health*

*Care Corp.*, 582 F.3d 1227, 1232 (11th Cir. 2009). She should not be permitted to offer opinion evidence on any such topics.

### CONCLUSION

*Daubert* tasks trial courts to act as gatekeepers to screen out “speculative” and “unreliable expert testimony.” *Kilpatrick v. Breg, Inc.*, 613 F.3d 1329, 1335 (11th Cir. 2010). Not only does Dr. Lightdale lack the relevant expertise to opine on the issues raised in her expert report, but for the reasons set forth above, her proffered opinions about WPATH’s methodology for developing its SOC-8, the “transparency” of those guidelines, and conflicts of interest which may have affected those who drafted and voted on those guidelines are categorically unreliable and speculative. Plaintiffs have fallen far short of their burden in establishing the three prongs of admission required by the Eleventh Circuit of qualification, reliability, and helpfulness. *United States v. Frazier*, 387 F.3d 1244, 1260 (11th Cir. 2004). As a result, Dr. Lightdale should not be permitted to offer expert testimony on these topics.

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