UNITED STATES DISTRICT COURT MIDDLE DISTRICT OF ALABAMA NORTHERN DIVISION

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

DEFENDANTS' MOTION TO EXCLUDE SELECTED TESTIMONY OF DR. KENNETH GOODMAN

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INTRODUCTION

Dr. Goodman is not a medical doctor, having received his PhD in Philosophy (and his lower-level degrees in journalism and linguistics), but he has worked in the field of bioethics for many years. Defendants do not challenge his qualifications to speak to questions of medical ethics generally. However, at a few important points Dr. Goodman's short Expert Rebuttal Report wanders away from his expertise into topics to which he is not qualified to speak and about which it is evident that he has not applied any reliable methodology to inform himself. Specifically, Dr. Goodman's proffered testimony on the following three topics does not meet the minimum requirements of Daubert, so should be excluded:

- Substantive assertions about transgender medicine;
- The actual procedures followed by WPATH or any organization in the course of developing WPATH's "Standards of Care Version 8" (SOC-8) or any set of guidelines relating to treatment of gender dysphoria; and
- Conflict-of-interest principles applicable to the development of clinical practice guidelines.

GOVERNING LEGAL PRINCIPLES

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

Dr. Goodman Has Neither The Expertise Nor A Reliable Basis To Opine I. On Any Aspect Of The Medical Treatment Of Gender Dysphoria.

Dr. Goodman asserts that "[t]ransition medications for gender dysphoria are medically necessary for a particular patient being treated" and that "failure to treat gender dysphoria predictably causes serious and lasting harm, and ... the impact of such harm can similarly affect the rest of a minor's life." Daubert.DX10:8, 14 (Goodman Reb. Rep.).¹

As to expertise, Dr. Goodman is not a medical doctor, and he has never even been consulted about issues of transgender medicine in his capacity as an ethicist. SJ.DX74:12:5-22 (Goodman Dep.). Dr. Goodman is not qualified by either training or experience to offer opinions about what is or is not "medically necessary" in treatment of gender dysphoria, nor as to what the results of withholding any particular treatment might be.

Dr. Goodman makes no effort at all to show that his opinions on substantive medical questions are based on "reliab[le] ... sources and methods." Chapman v. Proctor & Gamble Distributing, 766 F.3d 1296, 1306 (11th Cir. 2014); see id. at 1312-1313 (burden on proponent of expert testimony). He cites nothing to support these opinions and does not claim to have taken any steps to research the relevant literature to inform himself—much less steps that could constitute a reliable

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 Defendant; submitted in support of their motion for summary jurgment. See Docs. 557-60 (public exhibits) & 564 (sealed exhibits).

methodology. Indeed, Dr. Goodman repeatedly admitted that "I am not competent to assess the scientific evidence" relating to the efficacy and safety of medicalized treatments of gender dysphoria. Goodman Dep. 16:11-18; see also id. at 17:18-24 ("I don't know that I'm competent to actually agree or disagree."), 19:18-25 (noting that "it would be inappropriate for me to have an opinion on" whether "medical interventions to treat gender dysphoria in minors pose a substantial risk of harmful effects"). Dr. Goodman should not be permitted to testify concerning the safety, efficacy, outcomes, or "medical necessity" of any treatment for gender dysphoria.

II. Dr. Goodman Has Neither The Expertise Nor A Reliable Basis To Opine About What Procedures Any Organization Followed In Developing Any Clinical Practice Guidelines.

Dr. Goodman proffers testimony that any organization (such as WPATH or the Endocrine Society) that undertakes to develop a set of clinical practice guidelines "would have a policy in place to identify and manage conflicts of interest for the drafting process." Goodman Reb. Rep. 6. He likewise opines that the organization would have in place procedures "to require recusal by [a conflicted] participant from guideline development activities." Id. And he asserts that a "treatment's medical necessity was established antecedent to the [WPATH SOC-8] guideline." *Id.* at 8.

Broadly, Dr. Goodman does not claim either experience or training in creating clinical practice guidelines. He has never been involved in the development of any set of clinical practice guidelines. Goodman Dep. 25:4-6. More specifically, Dr. Goodman does not claim to have talked to any participants, reviewed any documents, or taken any other steps to inform himself as to what WPATH or the Endocrine Society did or did not do in the course of preparing their guidelines. E.g., id. at 44:16–457 ("I'm not competent or able – maybe I am competent, but I'm certainly unable in the circumstances" to be able to assess the Cass Review's conclusion that WPATH SOC-8 lacked methodological rigor); id. at 776:23–77:18. And he cites no source of information about the actual development process of either set of guidelines.

To the extent Dr. Goodman is assuming that these organizations did do what they should have done, such assumptions are not fact nor science nor reliable methodology. Dr. Goodman should not be permitted to offer any testimony about what WPATH or the Endocrine Society did or did not do. He has no information on that topic.

III. Dr. Goodman Has Neither The Expertise Nor A Reliable Basis To Opine About Conflict Of Interest Principles Applicable To The Development Of Clinical Practice Guidelines.

Dr. Goodman proposes to testify that the problem of "associational conflict" explained in Dr. Cantor's expert report "is apparently not recognized in the professional literature, [or] in standards for guideline development." Goodman Reb. Rep. 7. He similarly asserts that "[t]he idea of an 'intellectual conflict' is not established in the literature." Id. at 9. And he implies—without quite stating—that a doctor who derives even substantial revenues from doing procedures that would be affected by a set of guidelines does not have a financial conflict of interest relevant to his participation in developing those guidelines. Id.

While Dr. Goodman has expertise in bioethics, drafting a set of clinical practice guidelines presents different issues than designing an experimental protocol or making treatment decisions for a specific patient. Dr. Goodman has not participated in the development of any guidelines, nor in the development of a conflict-of-interest policy for any guideline development project, nor in the review of any such conflictof-interest policy. Goodman Dep. 25:4-9. Defendants do not doubt that—given his actual expertise—Dr. Goodman could have meaningfully informed himself about the recognized authorities and principles governing development of guidelines. But he chose not to do so.

Dr. Cantor has carefully set out the conflict-of-interest provisions of the two respected sets of "guidelines for guideline development" that WPATH expressly claims to have followed in creating Standards of Care 8. See SJ.DX116:S247(SOC-8); see also SJ.DX2:¶¶96-120 (Cantor Rep.). The two guidelines WPATH lists are (1) "Clinical Practice Guidelines We Can Trust," published by the Institute of Medicine ("IoM") (since renamed the National Academy of Medicine), and (2) the World Health Organization ("WHO") Handbook for Guideline Development.²

Bizarrely, while purporting to offer opinions in rebuttal to Dr. Cantor, and while declaring that whole categories of conflicts of interest spelled out in the IoM and WHO are "not recognized" or "not established" in "the professional literature," Goodman Reb. Rep. 7, 9, Dr. Goodman nowhere cites the extensive and detailed IoM conflict-of-interest guidelines for preparing guidelines that WPATH invoked, Dr. Cantor extensively quoted and explained, and Plaintiffs' guideline development expert Dr. Lightdale recognized as "widely respected" and "an important text in the

² While WPATH's citations to these two sets of guidelines in its Methodology Appendix were somewhat garbled (see SJ.DX2:¶¶98-101 (Cantor Rep.), these are in fact the guidelines for guideline development issued by the Institute of Medicine and World Health Organization. SOC-8 Chair Dr. Eli Coleman confirmed that these were the two documents that the WPATH Methodology Appendix intended to refer to. SJ.DX21:203-04 (Coleman Dep.)

field." SJ.DX69:141 (Lightdale Dep.). Nor does he cite or mention the equally lengthy WHO conflict-of-interest guidelines also invoked by WPATH and reviewed in detail by Dr. Cantor. See SJ.DX2:¶96-120 (Cantor Rep.). Indeed, Dr. Goodman testified that he hadn't even looked at the IoM conflict-of-interest guidelines for more than a decade and didn't review either document "for the purpose of" preparing his proffered opinions. Goodman Dep. 30:17–31:4 (did not review IoM guideline "since it was produced" in 2011—"Well, perhaps 2012"); id. at 29:25–30:2.

Instead, Dr. Goodman cited only three very short websites that address conflicts of interest in decisionmaking by National Institute of Health employees and grant applicants and by National Science Foundation employees. Goodman Reb. Rep. n.1. Dr. Goodman admitted that *none* of these "address conflicts of interest in the development of clinical practice guidelines," Goodman Dep. 37:12-21—the relevant topic which (as Dr. Goodman also admitted) *is* expressly addressed by the IoM and WHO guidelines. *Id.* at 36.

The result is that Dr. Goodman's proffered opinions regarding conflict of interest ignore the relevant literature and are thus uninformed and unreliable. While Dr. Goodman proposes to opine that "intellectual conflicts of interest" are "not established in the literature," Goodman Reb. Rep. 9, he admitted that he did no research before arriving at this conclusion, Goodman Dep. 106:9-21, and that he was not "aware that the Institute of Medicine had discussed intellectual conflicts when [he] wrote [his] report," *id.* at 108:7-10. But it does: the IoM conflict-of-interest guidelines discuss "intellectual conflicts" explicitly and extensively, and accord

them equal importance with financial conflicts of interest. SJ.DX76:102-08 (Goodman Dep. Exh. 5 – IoM Clinical Practice Guidelines We Can Trust).

Similarly, while Dr. Goodman proposes to testify that "associational conflict" is "apparently not recognized" in the literature, Goodman Reb. Rep. 7, the IoM guidelines address *precisely* the problem of conflicts of interest of sponsoring associations, cautioning that "CPG's funded by medical societies dependent on membership dues [such as WPATH and the Endocrine Society] may be cause for concern regarding conflict of interest if their recommendations would likely affect their members' incomes," SJ.DX76:72 (Goodman Dep. Exh. 5 – IoM Clinical Practice Guidelines We Can Trust); *see also* SJ.DX2:¶102 (Cantor Rep.). Dr. Goodman's opinion demonstrates that he simply doesn't know what is "recognized" in the literature.

Again, Dr. Goodman did no research to inform his proffered opinions about conflict-of-interest principles applicable to guideline development. He purports to rebut Dr. Cantor's opinions while ignoring the detailed, relevant, and respected sources invoked by WPATH and discussed by Dr. Cantor, instead citing a few short and irrelevant websites. This does not reflect a reliable basis or a reliable methodology for determining "what is known." *City of Tuscaloosa v. Harcros Chems., Inc.*, 158 F.3d 548, 562 (11th Cir. 1998). A "reliable expert would not ignore contrary data," "make sweeping statements without support," or "cite papers that do not provide the support asserted." *Abarca v. Franklin Cnty. Water Dist.*, 761 F. Supp. 2d 1007, 1066 n.60 (E.D. Cal. 2011) (citation omitted). Dr. Goodman's proffered

testimony about conflict-of-interest principles applicable to the development of clinical practice guidelines should be excluded.

CONCLUSION

"Expertise in one field does not qualify a witness to testify about others." Lebron v. Sec'y of Fla. Dep't of Child. & Fams., 772 F.3d 1352, 1368 (11th Cir. 2014). Defendants do not doubt Dr. Goodman's expertise in the areas of his actual work and knowledge. However, that expertise is at best tangential to disputed issues in this case. For the reasons set forth above, Dr. Goodman's proffered opinions with respect to the following topics do not satisfy the reliability requirements of Daubert, and so should be excluded:

- Substantive assertions about transgender medicine;
- The actual procedures followed by WPATH or any organization in the course of developing WPATH's "Standards of Care Version 8" (SOC-8) or any set of guidelines relating to treatment of gender dysphoria; and
- Conflict-of-interest principles applicable to the development of clinical practice guidelines.

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