IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF NORTH CAROLINA
CHARLOTTE DIVISION
No. 3:22-cv-191

KANAUTICA ZAYRE-BROWN, Plaintiff, v. NORTH CAROLINA DEPARTMENT OF ADULT CORRECTION, et al., Defendants.	**DEFENDANTS' RESPONSE TO PLAINTIFF'S MOTION TO EXCLUDE THE TESTIMONY OF FAN LI, PHD**

INTRODUCTION

Fan Li, Ph.D., a leading national expert in statistics and comparative effectiveness research, concludes that the studies cited by Plaintiff's expert, Randi C. Ettner, Ph.D., and the World Professional Association for Transgender Health (WPATH) do not support the assertions for which they are relied upon because the studies fail to provide rigorous and consistent statistical evidence of the effects of gender affirming surgery ("GAS") on quality of life and well-being. This narrow, yet important opinion is based on Dr. Li's education, training, and specialized knowledge, is specifically directed at rebutting the arguments of Plaintiff concerning the conclusiveness of the research, and is the result of a comprehensive, systematic, and consistent review and analysis of more than 80 studies. Thus, Dr. Li's opinion is based on her specialized experience and knowledge, is helpful to the trier of fact, and is reliable. Therefore, her opinions are admissible under Rule 702. In an effort to exclude Dr. Li, Plaintiff attacks opinions that she does not offer, ignores relevant case law, and otherwise overlooks the primary thrust and import of Dr. Li's opinion.

I. Factual Background Regarding Dr. Li

A. Summary of Dr. Li's Professional Education, Experience, and Expertise

Dr. Li is "a nationally leading expert on statistical methods for causal inference and comparative effectiveness research." (DE-65-15 at 1) She earned a Bachelor of Science in Mathematics from Peking University (one of the top universities in China) in 2001. (*Id*. at 27) In 2006, Dr. Li earned a Doctor of Philosophy in Biostatistics from Johns Hopkins University. (*Id*.) In 2008, Dr. Li completed a Postdoctoral Fellowship in Statictics with the Department of Health Care Policy at Harvard Medical School. (*Id*.)

Dr. Li is currently a statistician and a tenured Full Professor in the Department of Statistical Science, with a secondary appointment at the Department of Biostatistics and Bioinformatics at Duke University, where she has been a professor since 2008. (DE-65-15 at 1, 27) In addition to her appointment as a Full Professor at Duke, Dr. Li is also the "co-director of the Comparative Effectiveness Methodology at the Duke Clinical Research Institute, which is the largest clinical research organization in the world." (*Id*. at 1)

Dr. Li has published extensively on statistical methods and applications in causal inference in leading professional peer-reviewed journals in medicine, statistics, epidemiology, including Journal of the American Medical Association (JAMA), Proceedings of the National Academy of Sciences, and more. (DE-65-15 at 2) In 2022, Dr. Li served as the editor for Social Science, Biostatistics and Policy for the premier statistics journal "The Annals of Applied Statistics", and as an associate editor for a second premier statistics journal. (*Id*.) She also "served as a reviewer for a large number of academic journals, including JAMA," and others. (*Id*.)

Dr. Li has also been awarded multiple research grants from government agencies and research organizations, including the U.S. National Institutes of Health, and the National Science

Foundation, among others. (DE-65-15 at 2) Additionally, she was elected Fellow of the American Statistical Association in 2022 "for [her] contribution to statistics research and service." (*Id*.) Dr. Li's research work in statistics focuses on causal inference, biostatistics, missing data, Bayesian analysis, and applications to health, policy, and social sciences. (*Id*.) In addition to this research work, she has presented numerous seminars at national and international conferences and taught classes on causal inference at Duke. (*Id*.)

B. Background on Comparative Effectiveness Research and Causal Inference

Dr. Li explains that comparative effectiveness research is "the type of research used to evaluate the effects and safety of an intervention." (DE-65-15 at 5) "The statistical methodology for quality of life [research] belongs to the general statistical field of causal inference." (*Id*.) Dr. Li notes that a "first lesson in elementary statistics is that association does not imply causation[,]" because of the "presence of factors that are associated with both the treatment and the outcome[,] [t]hese factors are commonly referred to as confounders or confounding variables or confounding factors." (*Id*.) As an example, Dr. Li notes that in a study examining the benefits of a medical treatment, "comparing the outcomes of the treated and control patients, without adjusting for the difference in their baseline health conditions, would bias the causal comparisons." (*Id*.) This is referred to as "confounding bias." (*Id*.) When "confounders are observed and measured, analysts can use statistical methods for causal inference, . . . to control for the bias[,]" but when "confounders are unobserved or unmeasured, statistical analysis" cannot remove the confounding bias. (*Id*. at 6) Dr. Li's report details multiple other types of biases. (*See id*. at 6-7)

Dr. Li then discusses and ranks various study designs based on objective factors that can impact the quality of the study. (DE-65-15 at 7) Dr. Li opines that "the consensus gold standard for evaluating the efficacy, effectiveness, and safety of an intervention or treatment is the

randomized controlled trial[.]" (*Id*.) She further concludes that randomized controlled trials ("RCT") is "the gold standard for causal inference because [RCT] eliminates all confounding bias due to both measured and unmeasured confounders." (*Id*.)

"When randomized controlled trials are not available, researchers resort to observational studies for comparative effective research." (DE-65-15 at 7) Observational studies can vary in their design, which in turn can impact the quality of the study. (*See id*. at 7-8) Second to RCT, the "next preferred design is a prospective observational study with outcomes measured both before and after the intervention, which, in combination with proper statistical methods, can eliminate confounding bias due to measured confounders, but cannot eliminate confounding bias due to unmeasured confounders." (*Id*. at 8) Lastly, the "design of the lowest quality is a retrospective observational study, which is prone to confounding bias from both measured and unmeasured confounders, particularly when the baseline outcomes are not recorded." (*Id*.)

C. Dr. Li's Process and Methodology

Dr. Li was retained to review specific studies referenced in the Standards of Care for the Health of Transgender and Gender Diverse People, Version 8 ("WPATH 8"), the report and declarations of Plaintiff's expert, Randi Ettner, Ph.D., in support of various assertions, and then assess their quality, review their research design, analyze their outcomes, and determine whether the studies support the assertions for which they are cited. (DE-65-15 at 1, 3) To complete this work, Dr. Li reviewed "more than 80 studies relied upon by WPATH or Dr. Ettner, which are listed in Appendix B to [her] report." (*Id*. at 3)

Dr. Li's "investigation largely focuse[d] on the specific assertions that relate to the efficacy of [GAS] and that purport to be supported by research." (*Id*. at 11) In Appendix B, Dr. Li provides the verbatim text of the assertion that she analyzes and the source of that assertion (*e.g.*, WPATH

or Dr. Ettner). (*Id*. 24-25, 44-75) Her chart then contains information about the sources cited. (*Id*. at 24) In the body of her report, Dr. Li provides detailed analysis of key assertions and the studies referenced therein. (*Id*. at 11)

D. Summary of Dr. Li's Opinions

Dr. Li's primary and overall opinion is that the "evidence cited by Dr. Ettner and WPATH does not provide reasonable support for" the assertions made in reliance on this evidence. (DE-65-15 at 4) This opinion is supported by Dr. Li's additional conclusions, including that none of the studies relied upon by Dr. Ettner and WPATH are RCT, that the "few prospective studies that are cited point to mixed conclusions[,]" and that the vast majority of the cited "studies are based on observational retrospective designs, which are prone to severe confounding bias." (*Id*.) Among the "[a]dditional methodological shortcomings[,]" Dr. Li observes "small sample size, nonresponse bias, non-representative population (i.e., selection bias), [and] self-reported outcomes." (*Id*.) Dr. Li also notes that "most of the studies do not have before-after comparison of the same patients, and thus do not provide direct evidence on the effects of the treatment of interest." (*Id*.) Additionally, Dr. Li identifies that "the vast majority of these studies do not compare the results of [GAS] with alternative treatments, and thus do not provide evidence on the necessity or advantage of [GAS] over available alternative treatments." (*Id*.) Therefore, Dr. Li "concludes to a reasonable degree of statistical certainty, that these studies fail to provide rigorous and consistent statistical evidence" on the effects of gender affirming surgery ("GAS"). (*Id*. at 4-5)

II. Argument

A. Applicable Legal Standard

Rule 702 provides that "[a] witness who is qualified as an expert by knowledge, skill, experience, training, or education" can offer expert opinions if four factors are present:

> (a) that expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue; (b) the testimony is based on sufficient facts or data; (c) the testimony is the product of reliable principles and methods; and (d) the expert has reliably applied the principles and methods to the facts of the case.

A leading treatise on evidence condenses Rule 702 into three broad prerequisites: (1) the "testimony offered must be helpful to the trier of fact," (2) "the witness must be qualified to offer opinions on that topic," and (3) "the opinion testimony must be reliable from an evidentiary standpoint and must fit the facts of the case." 4 WEINSTEIN'S FEDERAL EVIDENCE § 702.syn (2023).

1. Rule 702 is Broadly Interpreted in Favor of Admission.

"[T]he Federal Rules of Evidence eliminated many formalistic barriers imposed by the common law on the introduction of opinion and expert testimony." *Kopf v. Skyrm*, 993 F.2d 374, 377 (4th Cir. 1993). "Rule 702 is broadly interpreted, and helpfulness to the trier of fact is its 'touchstone.'" *Id*. quoting *Friendship Heights Associates v. Koubek*, 785 F.2d 1154, 1159 (4th Cir. 1986). *See also*, *United States v. Offill*, 666 F.3d 168, 175 (4th Cir. 2011) (noting that the "touchstone of [Rule 702] is whether the testimony will assist the jury.")

"The presumption under the Rules is that expert testimony is admissible." 4 WEINSTEIN'S FEDERAL EVIDENCE § 702.02 (2023). The trial court has broad discretion in its "gatekeeper" function regarding these three requirements. *See General Elec. Co. v. Joiner*, 522 U.S. 136, 142 (1997) (admissibility of expert testimony reviewed on abuse of discretion standard). Moreover, the trial court has "broad discretion in choosing which *Daubert* factors to apply and how to consider them." *Belville v. Ford Motor Co*., 919 F.3d 224, 233-234 (4th Cir. 2019) (cleaned up)

Regarding the helpfulness requirement, "[t]estimony from an expert is presumed to be helpful unless it concerns matters within the everyday knowledge and experience of a lay juror." *Kopf*, 993 F.2d. at 377. With respect to the qualification requirement, as Plaintiff acknowledges,

"a person may qualify to render expert testimony in any one of the five ways listed" by Rule 702: "knowledge, skill, experience, training, or education." (DE 76 at 5 citing *Kopf*, 993 F.2d at 377) The expert simply must be qualified "on the issue for which the opinion is proffered." *Kopf*, 993 F.2d at 377. And, when an expert's qualifications are challenged, "the test for exclusion is a strict one . . ." *Id*.

Regarding the reliability requirement, the factors are flexible and will depend on the unique circumstances of the expert testimony. *Westberry v. Gislaved Gummi AB*, 178 F.3d 257, 261 (4th Cir. 1999). This flexibility is particularly applicable when expert testimony is based on experience, "as there exist meaningful differences in how reliability must be examined with respect to expert testimony that is primarily experiential in nature as opposed to scientific." *United States v. Wilson*, 484 F.3d 267, 274 (4th Cir. 2007). While scientific expert testimony is "objectively verifiable, and subject to the expectations of falsifiability, peer review, and publication," experiential expert testimony "does not rely on anything like a scientific method." *Id*. (cleaned up). Even so, "this does not lead to a conclusion that experience alone—or experience in conjunction with other knowledge, skill, training or education—may not provide a sufficient foundation for expert testimony." *Id*.

2. The Rules are Even More Relaxed for Rebuttal Expert Opinions.

Furthermore, Federal Rule of Civil Procedure 26 permits parties to submit expert testimony that is "intended solely to contradict or rebut evidence on the same subject matter identified by another party." Fed. R. Civ. P. 26(a)(2)(D)(ii). "Rebuttal evidence is properly admissible when it will explain, repel, counteract or disprove the evidence of the adverse party." *Earthkind v. Lebermuth Co.,* No. 5:19-CV-00051, 2021 U.S. Dist. LEXIS 103080, *10 (W.D.N.C. June 1, 2021) (cleaned up). When offering rebuttal expert testimony, the expert has "no burden to produce

models or methods of their own; they need only attack those of the opposing party's experts." *Id.* (cleaned up) Rebuttal experts still "must meet *Daubert*'s threshold standards regarding" qualifications, sufficiency of the data, reliability of the methodology, and relevance of the testimony. *Id*.

3. Exclusion is Rare and Disfavored.

Not surprisingly, in light of the foregoing principles, "rejection of expert testimony is the exception, rather than the rule." *Lipitor (Atorvastatin Calcium) Mktg. v. Pfizer, Inc.*, 892 F.3d 624, 631 (4th Cir. 2018); *United States v. Smith*, 919 F.3d 825, 835 (4th Cir. 2019) (same). Notably, to the extent this case proceeds with a bench trial,[1] exclusion is particularly inappropriate, as "[t]he main purpose of [the] *Daubert* exclusion is to protect juries from being swayed by dubious scientific testimony." *Nease v. Ford Motor Co.*, 848 F.3d 219, 231 (4th Cir. 2017). Moreover, whether the case is tried by judge or jury, many of Plaintiff's concerns about Defendants' experts "can be handled on a rigorous cross-examination." *Earthkind*, 2021 U.S. Dist. LEXIS 103080, at *11.

B. Dr. Li's Opinions Provide Key Rebuttals.

As noted in Section (I)(D), Dr. Li's overall opinion is that the "evidence cited by Dr. Ettner and WPATH does not provide reasonable support for" the assertions that rely on this evidence. (DE-65-15 at 4) Thus, her opinion is expressly responsive to assertions by Dr. Ettner and WPATH, that Plaintiff uses to support her deliberate indifference claim.

Dr. Ettner offers numerous assertions about the efficacy of GAS in treating GD and cites dozens of studies and research as support, including WPATH, which itself sets forth many similar

[1] Although the Court has discretion to exclude expert testimony at the summary judgment stage, even if Plaintiff were to prevail on this motion, expert testimony is not necessary for Defendants to be awarded summary judgment based on the reasonable disagreement between the members of the Division TARC and Plaintiff regarding the proper course of her medical care.

assertions. (*See* DE-13-1 ¶¶ 45-62, 71-74; DE-61-2 at ¶¶ 50-61; Ex. A at 5-8) For example, Dr. Ettner asserts that "research shows that the risk of suicide can be significantly diminished with prompt and effective treatment." (DE-65-15 at 22, DE-61-2 ¶ 77) Dr. Li "carefully reviewed the part of the paper that is relevant to the assertion[,]" including reviewing the "[e]xact numbers [which] are reported" in the study[.] (*Id*.) Dr. Li concludes that these numbers indicate that the "relative risk of suicidal attempt" . . . "is ***not*** statistically significant. So, [Dr. Ettner's] claim of 'significantly diminished' is not supported by the statistical analysis in this reference." (*Id*. emphasis in original)

And WPATH asserts that "[g]ender-affirming interventions are based on decades of clinical experience and research; therefore, they are not considered experimental, cosmetic, or for the mere convenience of a patient. They are safe and effective at reducing gender incongruence and gender dysphoria." (*Id*. at 15) Dr. Li observes that among the 25 studies cited by WPATH to support the assertion none "directly measures gender incongruence and gender dysphoria as the main outcome variable but instead used derivative measures, for example, satisfaction with surgery or quality of life in general." (*Id*. at 16)

She further notes that among the 25 studies, there "are only four prospective studies with before-after comparison of the same patients[,]" which are the second best study design. (DE-65-15 at 8, 16) However, Dr. Li further notes that two of the four prospective studies "reported mixed results in whether [the intervention] improves various measurements of mental health" and the other two prospective studies "do not provide data on outcomes related to mental health or [quality of life]." (*Id*. at 16) Additionally, Dr. Li notes that "seven of [the 25] papers focus on describing the surgical techniques . . . and do not discuss mental health or [quality of life]." (*Id*.) Moreover, Dr. Li observes that the remaining studies referenced by WPATH to support this assertion are

retrospective studies that are subject to confounding bias, and most are subject to additional types of bias (*e.g.*, selection bias, nonresponse bias and recall bias). (*Id*. at 17) Thus, Dr. Li's conclusion as to this specific assertion is that the studies cited by WPATH "fail to provide rigorous statistical evidence to support the assertion that 'gender-affirming interventions are … effective at reducing gender incongruence and gender dysphoria.'" (*Id*.)

The body of Dr. Li's report, and the appendix thereto, continues in a similar fashion, highlighting specific assertions, analyzing the studies cited to support those assertions, and articulating precisely why those studies do not support the assertions. Dr. Li's ultimate conclusion is that, "to a reasonable degree of statistical certainty, [] these studies fail to provide rigorous and consistent statistical evidence" of the effects of gender affirming surgery ("GAS") on "quality of life and well-being." (DE-65-15 at 4-5) Given that Plaintiff relies so extensively on Dr. Ettner and WPATH to assert that the research is conclusive, and to claim that there can be no reasonable debate regarding the efficacy of GAS, this testimony counters a primary assertion in the case and is devastating to Dr. Ettner's credibility and the validity of her opinions. As such, it is proper rebuttal.

C. Each of Dr. Li's Opinions are Admissible Under Rule 702.

Dr. Li's conclusions and opinions would assist the trier of fact in understanding the fundamentals of study design, research methods, comparative effectiveness research, and in turn how to interpret assertions by Plaintiff, her expert, and WPATH. Moreover, Dr. Li's education and training as a biostatistician and her extensive specialized knowledge and experience as a leading national expert in statistics and comparative effectiveness research certainly qualify her to offer the opinions stated in her report and detailed above. Lastly, because Dr. Li's conclusions and opinions are based on her systematic and comprehensive review of specific studies and the

application of basic elements of research analysis, those conclusions and opinions are reliable from an evidentiary standpoint and fit the facts of the case. Thus, Dr. Li's opinions are admissible under Rule 702.

1. Dr. Li's Opinions Are Based on Her Specialized Education, Training, Knowledge and Experience and Are Useful to the Trier of Fact.

The first Rule 702 factor has two parts: (a) the evidence must be based on some specialized scientific, technical or other specialized knowledge; and (b) the evidence would be useful to the trier of fact. *Kopf,* 993 F.2d at 377. All of Dr. Li's opinions meet both requirements. Indeed, Plaintiff does not appear to challenge the first part of this factor, that the evidence is based on some technical or other specialized knowledge. This is for good reason. Dr. Li's entire report is firmly rooted in her knowledge of and experience in statistics and comparative effectiveness research. All of Dr. Li's conclusions and opinions are limited to and based on that specific specialized knowledge and experience. Indeed, Dr. Li's report is limited to discussions regarding the hierarchy of research design, the various factors that can impact the quality of studies, and conclusions regarding the various assertions based on her assessment of the relevant studies. Thus, Dr. Li's conclusions and opinions are undoubtedly based on her education, training, and experience.

Moreover, Plaintiff does not contend that the matters about which Dr. Li testifies (*i.e.*, the basics and hierarchy of research design, the various factors that impact the quality of studies, and the assessment of whether the relevant studies support various assertions) are matters within the everyday knowledge and experience of a lay juror. *See Kopf*, 993 F.2d. at 377) That is obviously not the case. Thus, Dr. Li's conclusions and opinions on these topics are "presumed to be helpful." *See id*.

2. Dr. Li is Qualified to Offer the Opinions Presented in Her Report.

When an expert's qualifications are challenged, the test for exclusion is strict. *See Kopf,* 993 F.2d at 377. Under Rule 702, one can qualify to offer an expert opinion by knowledge, skill, experience, training, or education. *See id*. Dr. Li qualifies under all these metrics. Given Dr. Li's education, training in statistics, causal inference, and comparative effective research, and extensive research experience in these areas, she is indeed qualified to offer opinions regarding the basics and hierarchy of research design, the various factors that impact the quality of studies, and the assessment of whether the relevant studies support the assertions for which they are cited. Plaintiff cannot credibly contend that Dr. Li is not qualified to opine on these topics.

3. Dr. Li's Opinions Are Reliable and Trustworthy.

The test of reliability is flexible and will ultimately depend on the unique circumstances of the expert testimony involved. *Westberry*, 178 F.3d at 261. "Expert testimony is admissible only if: (1) it is based on sufficient facts or data; (2) it is the product of reliable principles and methods; and (3) the witness has reliably applied the principles and methods to the facts of the case[.]" 4 WEINSTEIN'S FEDERAL EVIDENCE § 702.05 (2023).

In light of these flexible factors, Dr. Li's opinions are indeed reliable. Dr. Li's ultimate opinion, and all her underlying opinions, are supported by her comprehensive and systematic review of more than 80 studies. In her report, Dr. Li specifically identifies each assertion that she investigated, which is followed by a detailed and consistent analysis of each of the studies cited in support of that assertion. In short, Dr. Li's opinions are based on dozens of studies and the assertions of Dr. Ettner and WPATH (*i.e.*, sufficient data), that Dr. Li systematically reviewed (*i.e.*, the product of reliable methods), and consistently and comprehensively analyzed (*i.e.*, reliably applied methods). Accordingly, Dr. Li's opinions are reliable.

D. Responses to Matters Specifically Raised in Plaintiff's Challenge.

Plaintiff makes three arguments to exclude *all* of Dr. Li's opinions and conclusions. Plaintiff's first argument is that Dr. Li's conclusion regard the "low quality" studies is not relevant. (*See* DE-74 at 3) This argument lacks merit because it rests on an overly narrow view of the pertinent issues in this case and overlooks the broader implications of Dr. Li's testimony. Plaintiff's second argument is that Dr. Li is not qualified to opine on what constitutes reasonable support for assertions about gender-affirming medical treatments. (*Id*. at 9) This is a strawman argument that fails because Dr. Li does not offer any opinions about the level of research necessary to support a treatment recommendation. Lastly, Plaintiff argues that Dr. Li's opinions are not the product of reliable methods because, as she contends, Dr. Li "could not define what does or does not constitute reasonable support, and to the extent she is able to articulate a standard, it is an inappropriate one." (*Id*. at 11) This argument fails because it ignores relevant case law and the primary thrust of Dr. Li's work in this case.

1. Plaintiff Cannot Show that Dr. Li's Opinions are Irrelevant.

Plaintiff's first argument rests on a series of unfounded contentions. Plaintiff contends that Dr. Li's conclusion that the studies cited by Dr. Ettner and WPATH do no provide support for the assertions made is "based on her conclusion that none of the studies are randomized controlled trials and they are 'low quality in terms of study design and statistical methodology.'" (DE-74 at 4) This contention is simply incorrect and premised on a grossly deficient and incomplete reference to Dr. Li's report. Contrary to Plaintiff's assertion, the basis for Dr. Li's opinion is not that there are no RCT among the more than 80 studies—this is simply an undisputable and salient fact that Dr. Li points out. Instead, Dr. Li's conclusion that the cited studies do not support the assertions is based on her review of each of those studies and her observation that all but a handful were

retrospective observational studies, which suffer from many methodological shortcomings, and the fact that the few prospective studies cited point to mixed results. Accordingly, Plaintiff's contention overlooks the actual basis for Dr. Li's opinions and conclusions.

Plaintiff also contends that "Dr. Li's opinion of the quality of the studies and the lack of 'rigorous and consistent statistical evidence' is not helpful to the trier of fact because" Dr. Li acknowledges that she "is not providing an opinion on what degree of statistical methodology is needed for a treatment to be included in a clinical practice guideline, nor . . . on whether the quality of the evidence impacts whether treatment can be provided." (DE-74 at 5) Thus, Plaintiff argues "Dr. Li's opinion has no bearing on clinical practice guidelines, treatment decisions, the practice of medicine, or—ultimately—the determinative issue of whether Defendants were deliberately indifferent to Plaintiff's need for gender-affirming surgery." (*Id*.)

Plaintiff is correct that Dr. Li is not opining as to the types of studies necessary to support clinical practice guidelines or treatment recommendations, as she is not a medical provider and thus is not offering opinions on medical necessity. However, Plaintiff is certainly incorrect about whether Dr. Li's opinions have any bearing on pertinent issues in this case. In contending otherwise, Plaintiff overlooks the fact that her case relies extensively on the assertions of her expert and WPATH regarding the conclusiveness of the scientific literature. Therefore, Dr. Li's opinion, which is a direct rebuttal to those assertions, is most certainly relevant to a fundamental issue in this case. Plaintiff cannot have it both ways. She cannot rely on assertions of her expert and WPATH to argue that the research is so conclusive that denying her surgery is not subject to reasonable debate and thus indicates deliberate indifference, and then argue that any evidence challenging those assertions regarding the research is not relevant.

Plaintiff also attempts to exclude Dr. Li's opinion by arguing that since clinical practice guidelines and treatment decisions are often based on "low quality" studies, her opinion regarding such studies is not relevant. (DE-74 at 7-8) This argument misses the mark. Again, Dr. Li is not offering opinions about clinical practice guidelines or treatment decisions. Instead, Dr. Li offers direct and specific criticisms of particular assertions by Dr. Ettner and WPATH. Thus, it is wholly beside the point that, as Plaintiff notes, the Endocrine Society and WPATH published guidelines based on "low" or "very low" evidence. (*See id*. at 8)

Defendants' point in offering this testimony is not to suggest that WPATH did something improper by issuing clinical guidelines based on low-quality evidence. Rather, these opinions demonstrate that Dr. Ettner lacks reasonable support for her conclusion that the literature conclusively establishes the efficacy of GAS. They also demonstrate that, despite Dr. Ettner's opinion and WPATH guidelines, there is reasonable room for debate, based on the state of the literature, about the efficacy of the intervention. These are central issues in the case.

Plaintiff is free to explore the limitations of Dr. Li's opinions on cross examination, but this argument provides no basis for excluding the opinions. *See Earthkind*, 2021 U.S. Dist. LEXIS 103080, at *10-11.

2. Plaintiff Cannot Show that Dr. Li is Not Qualified to Offer Her Opinions.

Plaintiff's second argument is premised on attacking Dr. Li's qualifications to provide an opinion that she does not actually offer. Plaintiff argues that "Dr. Li's experience as a statistician does not make her qualified to opine on the level of evidence sufficient to support clinical practice guidelines (like WPATH SOC) or medical treatment recommendations for the treatment of gender dysphoria." (DE-74 at 9) As with Plaintiff's first argument, this assertion misses the mark. Dr. Li does not offer any opinions about what evidence is needed to support practice guidelines or

treatment recommendations. Rather, Dr. Li's opinion is focused specifically and solely on rebutting the assertions that Dr. Ettner and WPATH based on an objective and systematic review of the studies cited. Instead of recognizing Dr. Li's conclusions for what they actually are, Plaintiff manufactures an opinion in an effort to attack it. For example, Plaintiff argues "[i]n other words, [Dr. Li] does not know what 'reasonable support' is in the context of the practice of medicine." (*Id*.) Plaintiff's attempt to attack an opinion that Dr. Li does not in fact provide fails. Dr. Li is not a medical provider and thus does not offer any opinion related to the practice of medicine. It is worth pointing out that, Dr. Ettner, just like Dr. Li, is not a physician, medical doctor, or the like. Thus, Plaintiff is yet again attacking Defendants' experts while overlooking similarities in her own.

Plaintiff also attempts to argue that Dr. Li is not qualified to offer her opinions by contending that Dr. Li seems to apply "a standard that is not the standard for medical treatment." (DE-74 at 9-10) Specifically, Plaintiff contends that Dr. Li "stated that her standard was whether there was enough evidence for acceptance into a medical journal; she would expect to see a randomized controlled trial *or* a well-designed observational study, but a retrospective study would not be enough." (*Id*.) (emphasis added)

Plaintiff's argument that this "standard" somehow implicates Dr. Li's qualifications is puzzling. Regardless, Dr. Li did not set forth a standard as Plaintiff misleadingly suggests. Dr. Li actually testified, in response to Plaintiff's questions, that the standard for acceptance into a medical journal would be a "[RCT or well-designed observational study," but that a retrospective study would not be enough. (*See* DE-73-1 at 26-28) This supports Dr. Li's contentions regarding the quality levels of various studies and how much support they provide for various interventions and assertions. Although Dr. Li has not opined that this is a requirement in order to be cited in a

treatment guideline, her concerns about the studies in this area are undoubtedly relevant to the strength of the evidence supporting the same.

Moreover, Plaintiff's reliance on the report of her second expert, Armand Antommaria, MD, Ph.D., here, is misplaced. (*See* DE-74 at 9-10) Dr. Antommaria's report opines that low quality evidence is used to support many medical interventions. (DE-71-2, ¶ 18) But this does not render irrelevant Dr. Li's opinion that the studies being used here are in fact low quality. Nor does this counter Dr. Li's conclusion that the studies cited by Dr. Ettner and WPATH do not support the assertions made by them.

While the evaluation of Dr. Li and Dr. Antommaria's respective opinions will be a matter for trial, it is worth noting that Dr. Antommaria's opinions do not directly rebut Dr. Li's in any event. Significantly, with the exception of three studies, Dr. Antommaria did not review the vast majority of the more than 80 studies analyzed by Dr. Li. (Ex. B at 6-7, 50-52, 57-68) Moreover, he does not maintain that high quality studies are available to support Dr. Ettner and WPATH. Instead, he opines that observational studies are available, but, unlike Dr. Li, he does not discuss the *types* of observational studies, (*e.g.*, retrospective vs. prospective study). (*See generally* DE-71-2) Nor does he acknowledge that the types at issue here are low-quality even among observational studies. (*See generally id.*)

Lastly, Plaintiff attempts to exclude Dr. Li by pointing out her lack of experience with gender-affirming medical care before being retained in this case. (DE-74 at 10) This is beside the point. Dr. Li's expertise is in statistics and comparative effectiveness research and her opinions are well within the bounds of those lanes. Familiarity with the subject matter of the underlying research that she is analyzing, is not necessary to allow Dr. Li to effectively analyze objective matters such as the basics and hierarchy of research design, the various factors that impact the quality of studies,

and the assessment of whether the relevant studies lend support to various assertions. In fact, Dr. Li and those in her field are generally called upon to study the effectiveness of various interventions in a number of different fields outside their own. (Ex. C at 2-6) Dr. Li has explained that her lack of previous work in this field "affords [her] the opportunity to [review and analyze the studies] based solely on [her] education, training, and experience and without any preconceived notions of what the evidence may or may not show. (DE-65-15 at 3)

3. Plaintiff Cannot show that Dr. Li's Opinions are Based on Unreliable Principles and Methods.

Plaintiff contends that Dr. Li cannot provide her opinion that "the studies on gender dysphoria and gender-affirming surgery do not constitute a rigorous and consistent body of evidence and do not provide reasonable support for the assertions by Dr. Ettner and WPATH[,]" because "she could not define what does or does not constitute reasonable support, and to the extent she is able to articulate a standard, it is an inappropriate one." (DE-74 at 11) Moreover, Plaintiff argues that Dr. Li is applying the "I'll know it when I see it" test. (*Id*. at 12)

This is a gross oversimplification of Dr. Li's opinions. While Dr. Li responded in questioning that she was not offering a specific standard for what would constitute "enough" support, she clearly determined in her report and explained in her testimony, that, based on her expertise in statistics and comparative effectiveness research, the cited studies were insufficient and did not provide reasonable support for the assertions made by Dr. Ettner and WPATH. She also provided detailed testimony regarding the types of studies she was looking for and why the studies at issue fell short. (DE-73-1 at 29-31, 64-70) The fact that she could or would not say exactly what the standard would be is reasonable, because the studies are nuanced and vary on numerous dimensions that impact their quality—including size of population studied, duration, design, and more. (*See id*. at 64-70) Presumably, various iterations of studies could combine in

different ways to support particular assertions. That is why Dr. Li conducted a detailed multi-page analysis of the studies to assess the level of support for the particular assertions at issue. It is unreasonable for Plaintiff to expect a meaningful answer to this hypothetical and even more unreasonable to suggest the lack thereof disqualifies Dr. Li from testifying.

Furthermore, rebuttal experts do not have a burden of producing models or methods of their own, but rather only have to attack those of the opposing party. *See Earthkind,* No. 5:19-CV-00051, 2021 U.S. Dist. LEXIS 103080, at *10. Thus, any inability to specifically articulate a recommended standard does not provide a basis to exclude Dr. Li.

Plaintiff summarily assumes, without any factual or legal basis, that whatever standard Dr. Li applies, was "an inappropriate one," and thus contends her opinions are based on unreliable methods. (DE-74 at 12) Dr. Li's conclusions are based on her systematic and comprehensive review of the same studies relied upon by Dr. Ettner and WPATH, and are grounded in her training and work as a leading statistician and comparative effectiveness expert. Plaintiff does not identify any basis to contend that Dr. Li's standards or methods here are not acceptable in the field of statistics or comparative effectiveness research. Plaintiff's bald pronouncement that Dr. Li's standard is somehow inappropriate does not make it so.

CONCLUSION

For the reasons stated herein, Defendants respectfully request that this Court deny Plaintiff's motion to exclude the testimony of Dr. Li, DE-73.

This the 11th day of December 2023.

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IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF NORTH CAROLINA
CHARLOTTE DIVISION
No. 3:22-cv-191

KANAUTICA ZAYRE-BROWN, Plaintiff, v. NORTH CAROLINA DEPARTMENT OF ADULT CORRECTION, et al., Defendants.	**APPENDIX TO DEFENDANTS' RESPONSE TO PLAINTIFF'S MOTION TO EXCLUDE THE TESTIMONY OF FAN LI, PHD**

Exhibit A	*Standards of Care for the Health of Transgender and Gender Diverse People, Version 8*
Exhibit B	Excerpts of the deposition of Armand H. Antommaria, M.D., Ph.D., taken on September 7, 2023.
Exhibit C	CV of Fan Li, Ph.D.

This the 11th day of December 2023.

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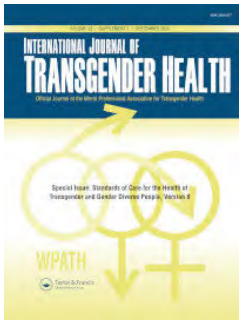

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Standards of Care for the Health of Transgender and Gender Diverse People, Version 8

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ABSTRACT

Background: Transgender healthcare is a rapidly evolving interdisciplinary field. In the last decade, there has been an unprecedented increase in the number and visibility of transgender and gender diverse (TGD) people seeking support and gender-affirming medical treatment in parallel with a significant rise in the scientific literature in this area. The World Professional Association for Transgender Health (WPATH) is an international, multidisciplinary, professional association whose mission is to promote evidence-based care, education, research, public policy, and respect in transgender health. One of the main functions of WPATH is to promote the highest standards of health care for TGD people through the Standards of Care (SOC). The SOC was initially developed in 1979 and the last version (SOC-7) was published in 2012. In view of the increasing scientific evidence, WPATH commissioned a new version of the Standards of Care, the SOC-8.

Aim: The overall goal of SOC-8 is to provide health care professionals (HCPs) with clinical guidance to assist TGD people in accessing safe and effective pathways to achieving lasting personal comfort with their gendered selves with the aim of optimizing their overall physical health, psychological well-being, and self-fulfillment.

Methods: The SOC-8 is based on the best available science and expert professional consensus in transgender health. International professionals and stakeholders were selected to serve on the SOC-8 committee. Recommendation statements were developed based on data derived from independent systematic literature reviews, where available, background reviews and expert opinions. Grading of recommendations was based on the available evidence supporting interventions, a discussion of risks and harms, as well as the feasibility and acceptability within different contexts and country settings.

Results: A total of 18 chapters were developed as part of the SOC-8. They contain recommendations for health care professionals who provide care and treatment for TGD people. Each of the recommendations is followed by explanatory text with relevant references. General areas related to transgender health are covered in the chapters Terminology, Global Applicability, Population Estimates, and Education. The chapters developed for the diverse population of TGD people include Assessment of Adults, Adolescents, Children, Nonbinary, Eunuchs, and Intersex Individuals, and people living in Institutional Environments. Finally, the chapters related to gender-affirming treatment are Hormone Therapy, Surgery and Postoperative Care, Voice and Communication, Primary Care, Reproductive Health, Sexual Health, and Mental Health.

Conclusions: The SOC-8 guidelines are intended to be flexible to meet the diverse health care needs of TGD people globally. While adaptable, they offer standards for promoting optimal health care and guidance for the treatment of people experiencing gender incongruence. As in all previous versions of the SOC, the criteria set forth in this document for gender-affirming medical interventions are clinical guidelines; individual health care professionals and programs may modify these in consultation with the TGD person.

KEYWORDS

adolescents; assessment; children; communication; education; endocrinology; eunuch; gender diverse; health care professional; institutional settings; intersex; mental health; nonbinary; population; postoperative care; primary care; reproductive health; sexual health; SOC8; Standards of Care; surgery; terminology; transgender; voice

interventions. In many countries, medically necessary gender-affirming care is documented by the treating health professional as treatment for Gender Incongruence (HA60 in ICD-11; WHO, 2019b) and/or as treatment for Gender Dysphoria (F64.0 in DSM-5-TR; APA, 2022).

There is strong evidence demonstrating the benefits in quality of life and well-being of gender-affirming treatments, including endocrine and surgical procedures, properly indicated and performed as outlined by the Standards of Care (Version 8), in TGD people in need of these treatments (e.g., Ainsworth & Spiegel, 2010; Aires et al., 2020; Aldridge et al., 2020; Almazan & Keuroghlian, 2021; Al-Tamimi et al., 2019; Balakrishnan et al., 2020; Baker et al., 2021; Buncamper et al., 2016; Cardoso da Silva et al., 2016; Eftekhar Ardebili, 2020; Javier et al., 2022; Lindqvist et al., 2017; Mullins et al., 2021; Nobili et al., 2018; Owen-Smith et al., 2018; Özkan et al., 2018; T'Sjoen et al., 2019; van de Grift, Elaut et al., 2018; White Hughto & Reisner, Poteat et al., 2016; Wierckx, van Caenegem et al., 2014; Yang, Zhao et al., 2016). Gender-affirming interventions may also include hair removal/transplant procedures, voice therapy/surgery, counseling, and other medical procedures required to effectively affirm an individual's gender identity and reduce gender incongruence and dysphoria. Additionally, legal name and sex or gender change on identity documents can also be beneficial and, in some jurisdictions, are contingent on medical documentation that patients may call on practitioners to produce.

Gender-affirming interventions are based on decades of clinical experience and research; therefore, they are not considered experimental, cosmetic, or for the mere convenience of a patient. They are safe and effective at reducing gender incongruence and gender dysphoria (e.g., Aires et al., 2020; Aldridge et al., 2020; Al-Tamimi et al., 2019; Balakrishnan et al., 2020; Baker et al., 2021; Bertrand et al., 2017; Buncamper et al., 2016; Claes et al., 2018; Eftekhar Ardebili, 2020; Esmonde et al., 2019; Javier et al., 2022; Lindqvist et al., 2017; Lo Russo et al., 2017; Marinkovic & Newfield, 2017; Mullins et al., 2021; Nobili et al., 2018; Olson-Kennedy, Rosenthal et al., 2018; Özkan et al., 2018; Poudrier et al., 2019; T'Sjoen et al., 2019; van de Grift, Elaut et al., 2018; White Hughto & Reisner, Poteat et al., 2016; Wierckx, van Caenegem et al., 2014; Wolter et al., 2015; Wolter et al., 2018).

Consequently, WPATH urges health care systems to provide these medically necessary treatments and eliminate any exclusions from their policy documents and medical guidelines that preclude coverage for any medically necessary procedures or treatments for the health and well-being of TGD individuals. In other words, governments should ensure health care services for TGD people are established, extended or enhanced (as appropriate) as elements in any Universal Health Care, public health, government-subsidized systems, or government-regulated private systems that may exist. Health care systems should ensure ongoing health care, both routine and specialized, is readily accessible and affordable to all citizens on an equitable basis.

Medically necessary gender-affirming interventions are discussed in SOC-8. These include but are not limited to hysterectomy +/- bilateral salpingo-oophorectomy; bilateral mastectomy, chest reconstruction or feminizing mammoplasty, nipple resizing or placement of breast prostheses; genital reconstruction, for example, phalloplasty and metoidioplasty, scrotoplasty, and penile and testicular prostheses, penectomy, orchiectomy, vaginoplasty, and vulvoplasty; hair removal from the face, body, and genital areas for gender affirmation or as part of a preoperative preparation process; gender-affirming facial surgery and body contouring; voice therapy and/or surgery; as well as puberty blocking medication and gender-affirming hormones; counseling or psychotherapeutic treatment as appropriate for the patient and based on a review of the patient's individual circumstances and needs.

Statement 2.2

We recommend health care professionals and other users of the Standards of Care, Version 8 (SOC-8) apply the recommendations in ways that meet the needs of local transgender and gender diverse communities, by providing culturally sensitive care that recognizes the realities of the countries they are practicing in.

TGD people identify in many different ways worldwide, and those identities exist within a cultural context. In English speaking countries, TGD people variously identify as *transsexual,*

CHAPTER 13 Surgery and Postoperative Care

Medically necessary gender-affirmation surgery (GAS) refers to a constellation of procedures designed to align a person's body with their gender identity (see Chapter 2—Global Applicability for medical necessity, Statement 2.1). This chapter describes surgery and postoperative care recommendations for TGD adults and adolescents. Please refer to Chapter 5—Assessment of Adults and Chapter 6—Adolescents for the assessment criteria related to surgery for adults and adolescents, respectively. A summary of the recommendations and assessment criteria can be found in Appendix D.

Recognizing the diverse and heterogeneous community of individuals who identify as transgender and gender diverse (TGD), gender-affirming surgical interventions may be categorized along a spectrum of procedures for individuals assigned male at birth (AMAB) and assigned female at birth (AFAB).

In appropriately selected TGD individuals, the current literature supports the benefits of GAS. While complications following GAS occur, many are either minor or can be treated with local care on an outpatient basis (Canner et al., 2018; Gaither et al., 2018; Morrison et al., 2016). In addition, complication rates are consistent with those of similar procedures performed for different diagnoses (i.e., non-gender-affirming procedures).

In individuals AFAB, gender-affirming chest surgery or "top surgery" (i.e. "subcutaneous mastectomy") has been studied in prospective (Agarwal et al., 2018; Frederick et al., 2017; Top & Balta, 2017; van de Grift, Elaut et al., 2017; van de Grift et al., 2016), retrospective (Bertrand et al., 2017; Claes et al., 2018; Esmonde et al., 2019; Lo Russo et al., 2017; Marinkovic & Newfield, 2017; Poudrier et al., 2019; Wolter et al., 2015; Wolter et al., 2018), and cross-sectional cohort studies (Olson-Kennedy, Warus et al., 2018; Owen-Smith et al., 2018; van de Grift, Elaut et al., 2018; van de Grift, Elfering et al., 2018). The efficacy of top surgery has been demonstrated in multiple domains, including a consistent and direct increase in health-related quality of life, a significant decrease in gender dysphoria, and a consistent increase in satisfaction with body and appearance. Additionally, rates of regret remain very low, varying from 0 to 4%. While the effect of top surgery on additional outcome measures such as depression, anxiety, and sexual function also demonstrated a benefit, the studies were of insufficient strength to draw definitive conclusions. Although further investigation is needed to draw more robust conclusions, the evidence demonstrates top surgery to be a safe and effective intervention.

In individuals AMAB, fewer studies have been published regarding gender-affirming breast surgery ("breast augmentation") and include 2 prospective (Weigert et al., 2013; Zavlin et al., 2018), 1 retrospective cohort (Fakin et al., 2019), and 3 cross-sectional cohort studies (Kanhai et al., 2000; Owen-Smith et al., 2018; van de Grift, Elaut et al., 2018). All the studies reported a consistent and direct improvement in patient satisfaction, including general satisfaction, body image satisfaction, and body image following surgery. Owen-Smith et al. (2018) demonstrated a positive trend toward improvement in both depression and anxiety scores with increasing levels of gender-affirming interventions. However, there was no statistical comparison between individuals who underwent top surgery and any other group.

Gender-affirming vaginoplasty is one of the most frequently reported gender-affirming surgical interventions; 8 prospective (Buncamper et al., 2017; Cardoso da Silva et al., 2016; Kanhai, 2016; Manero Vazquez et al., 2018; Papadopulos, Zavlin et al., 2017; Tavakkoli Tabassi et al., 2015; Wei et al., 2018; Zavlin et al., 2018), 15 retrospective cohort (Bouman, van der Sluis et al., 2016; Buncamper et al., 2015; Hess et al., 2016; Jiang et al., 2018; LeBreton et al., 2017; Manrique et al., 2018; Massie et al., 2018; Morrison et al., 2015; Papadopulos, Lelle et al., 2017; Raigosa et al., 2015; Salgado et al., 2018; Seyed-Forootan et al., 2018; Sigurjonsson et al., 2017; Simonsen et al., 2016; Thalaivirithan et al., 2018), and 3 cross-sectional cohort studies have recently been reported (Castellano et al., 2015; Owen-Smith et al., 2018; van de Grift, Elaut et al., 2018).

Although different assessment measurements were used, the results from all studies consistently reported both a high level of patient satisfaction (78–100%) as well as satisfaction with sexual function (75–100%). This was especially evident

Statements of Recommendations

13.1- We recommend surgeons who perform gender-affirming surgical procedures have the following credentials:
13.1.a- Training and documented supervision in gender-affirming procedures;
13.1.b- Maintenance of an active practice in gender-affirming surgical procedures;
13.1.c- Knowledge about gender diverse identities and expressions;
13.1.d- Continuing education in the field of gender-affirmation surgery
13.1.e- Tracking of surgical outcomes.
13.2- We recommend surgeons assess transgender and gender diverse people for risk factors associated with breast cancer prior to breast augmentation or mastectomy.
13.3- We recommend surgeons inform transgender and gender diverse people undergoing gender-affirming surgical procedures about aftercare requirements, travel and accommodations, and the importance of postoperative follow-up during the preoperative process.
13.4- We recommend surgeons confirm reproductive options have been discussed prior to gonadectomy in transgender and gender diverse people.
13.5- We suggest surgeons consider offering gonadectomy to eligible* transgender and gender diverse adults when there is evidence they have tolerated a minimum of 6 months of hormone therapy (unless hormone replacement therapy or gonadal suppression is not clinically indicated or the procedure is inconsistent with the patient's desires, goals, or expressions of individual gender identity).
13.6- We suggest health care professionals consider gender-affirming genital procedures for eligible* transgender and gender diverse adults seeking these interventions when there is evidence the individual has been stable on their current treatment regime (which may include at least 6 months of hormone treatment or a longer period if required to achieve the desired surgical result, unless hormone therapy is either not desired or is medically contraindicated).
13.7- We recommend surgeons consider gender-affirming surgical interventions for eligible* transgender and gender diverse adolescents when there is evidence a multidisciplinary approach that includes mental health and medical professionals has been involved in the decision-making process.
13.8- We recommend surgeons consult a comprehensive, multidisciplinary team of professionals in the field of transgender health when eligible* transgender and gender diverse people request individually customized (previously termed "non-standard") surgeries as part of a gender-affirming surgical intervention.
13.9- We suggest surgeons caring for transgender men and gender diverse people who have undergone metoidioplasty/phalloplasty encourage lifelong urological follow-up.
13.10- We recommend surgeons caring for transgender women and gender diverse people who have undergone vaginoplasty encourage follow-up with their primary surgeon, primary care physician, or gynecologist.
13.11- We recommend patients who regret their gender-related surgical intervention be managed by an expert multidisciplinary team.

** For eligibility criteria for adolescents and adults, please refer to the Assessment for Adults and Adolescents chapters and Appendix D.*

when using more recent surgical techniques. Gender-affirming vaginoplasty was also associated with a low rate of complications and a low incidence of regret (0–8%).

Recent literature reflects the increased clinical interest in metoidioplasty and phalloplasty as reflected by 3 prospective cohort (Garaffa et al., 2010; Stojanovic et al., 2017; Vukadinovic et al., 2014), 6 retrospective cohort (Cohanzad, 2016; Garcia et al., 2014; Simonsen et al., 2016; van de Grift, Pigot et al., 2017; van der Sluis et al., 2017; Zhang et al., 2015), and 4 cross-sectional studies (Castellano et al., 2015; Owen-Smith et al., 2018; van de Grift, Elaut et al., 2018; Wierckx, Van Caenegem et al., 2011), which reviewed the risks and benefits of these procedures.

In terms of urinary function, between 75 and 100% of study participants were able to void while standing. In terms of sexual function, between 77 and 95% of study participants reported satisfaction with their sexual function. Most of these studies report high overall levels of postoperative satisfaction (range 83–100%), with higher rates of satisfaction in studies involving newer surgical techniques. Two prospective and two retrospective cohort studies specifically assessed regret following surgery and found no transgender men experienced regret. While study limitations were identified, the reported results were consistent and direct.

In recent years, facial GAS (FGAS) has received increased attention, and current literature supports its benefits. Eight recent publications include 1 prospective cohort (Morrison et al., 2020), 5 retrospective cohort (Bellinga et al., 2017; Capitán et al., 2014; Noureai et al., 2007; Raffaini et al., 2016; Simon et al., 2022), and 2 cross-sectional studies (Ainsworth & Spiegel, 2010; van de Grift, Elaut

include an assessment of the impact on the patients' mental health delays may cause in addressing gender dysphoria (Byne et al., 2018).

Statement 18.3

We recommend when significant mental health symptoms or substance abuse exists, mental health professionals assess the potential negative impact mental health symptoms may have on outcomes based on the nature of the specific gender-affirming surgical procedure.

Gender-affirming surgical procedures vary in terms of their impact on the patient. Some procedures require a greater ability to follow preoperative planning as well as engage in peri- and postoperative care to achieve the best outcomes (Tollinche et al., 2018). Mental health symptoms can influence a patient's ability to participate in the planning and perioperative care necessary for any surgical procedure (Paredes et al., 2020). The mental health assessment can provide an opportunity to develop strategies to address the potential negative impact mental health symptoms may have on outcomes and to plan support for the patient's ability to participate in the planning and care. Gender-affirming surgical procedures have been shown to relieve symptoms of gender dysphoria and improve mental health (Owen-Smith et al., 2018; van de Grift, Elaut et al., 2017). These benefits are weighed against the risks of each procedure when the patient and provider are deciding whether to proceed with the treatment. HCPs can assist TGD people in reviewing preplanning and perioperative care instructions for each surgical procedure (Karasic, 2020). Provider and patient can collaboratively determine the necessary support or resources needed to assist with keeping appointments for perioperative care, obtaining necessary supplies, addressing financial issues, and handling other preoperative coordination and planning. In addition, issues surrounding appearance-related and functional expectations, including the impact of these various factors on gender dysphoria, can be explored.

Statement 18.4

We recommend health care professionals assess the need for psychosocial and practical support of transgender and gender diverse people in the perioperative period surrounding gender-affirmation surgery.

Regardless of specialty, all HCPs have a responsibility to support patients in accessing medically necessary care. When HCPs are working with TGD people as they prepare for gender-affirming surgical procedures, they should assess the levels of psychosocial and practical support required (Deutsch, 2016b). Assessment is the first step in recognizing where additional support may be needed and enhancing the ability to work collaboratively with the individual to successfully navigate the pre-, peri-, and postsurgical periods (Tollinche et al., 2018). In the perioperative period, it is important to help patients optimize functioning, secure stable housing, when possible, build social and family supports by assessing their unique situation, plan ways of responding to medical complications, navigate the potential impact on work/income, and overcome additional hurdles some patients may encounter, such as coping with electrolysis and tobacco cessation (Berli et al., 2017). In a complex medical system, not all patients will be able to independently navigate the procedures required to obtain care, and HCPs and peer navigators can support patients through this process (Deutsch, 2016a).

Statement 18.5

We recommend health care professionals counsel and assist transgender and gender diverse people in becoming abstinent from tobacco/nicotine prior to gender-affirmation surgery.

Transgender populations have higher rates of tobacco and nicotine use (Kidd et al., 2018). However, many are unaware of the well-documented smoking-associated health risks (Bryant et al., 2014). Tobacco consumption increases the risk of developing health problems (e.g., thrombosis) in individuals receiving gender-affirming hormone treatment, particularly estrogens (Chipkin & Kim, 2017).

Tobacco use has been associated with worse outcomes in plastic surgery, including overall complications, tissue necrosis, and the need for surgical revision (Coon et al., 2013). Smoking also increases the risk for postoperative infection (Kaoutzanis et al., 2019). Tobacco use has been shown to affect

IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF NORTH CAROLINA
CHARLOTTE DIVISION

* * *

KANAUTICA ZAYRE-BROWN,
Plaintiff,
vs. CASE NO. 3:22-cv-191
NORTH CAROLINA DEPARTMENT
OF PUBLIC SAFETY, et al.,
Defendants.

* * *

Videotaped deposition of ARMAND H. ANTOMMARIA, M.D., Ph.D., Expert Witness herein, called by the Defendants for cross-examination pursuant to the Rules of Civil Procedure, taken before me, Vicky L. Marcon, a Notary Public within and for the State of Ohio, at the offices of Regus, PNC Center, 201 E. 5th Street, Suite 1900, Cincinnati, Ohio, on Thursday, September 7, 2023, at 9:00 a.m. Eastern

* * *

been deposed?

A. I believe this will be my fourth time that I've been deposed.

Q. Fourth time. When was your first deposition, year? What year was your first deposition?

A. Approximately two years ago.

Q. Okay. So, four, and this will be your fourth in a couple of years?

A. Yes, sir.

Q. All right. So, I won't belabor the sort of what some people call ground rules or logistical issues. I'm going to ask you some questions, you give me some answers. If you need to take a break, that's fine. If there's a question pending, just answer the question before we break. Otherwise, it should be pretty straightforward.

So, I want to start by asking you what you did to prepare for your deposition today?

A. I reviewed the -- Dr. Li's report, my rebuttal report, and some relevant studies referenced in that material.

Q. In which material, your rebuttal

report or Dr. Li's report?
A. Dr. Li's report.
Q. Okay. Do you recall which studies you reviewed?
A. La Costa, the Scandinavian study, and Papadopulos.
Q. Aside from those three studies you just referenced, did you review any other studies in preparation of your deposition?
A. No, sir.
Q. And when did you conduct this review of these studies?
A. Over the last week, sir.
Q. Okay. Did you review any other materials in preparation for your deposition outside of your report, Dr. Li's report, and these three studies that you mentioned?
A. I also reviewed a discussion related to confounding in a textbook about study design.
Q. Do you recall the name of that textbook?
A. I believe it's referenced in my rebuttal report, but I don't recall the title off the top of my head.

sir.

MR. RODRIGUEZ: All right. This is a good natural stopping point for a break. If you guys are good with it, we'll just do a quick five.

THE VIDEOGRAPHER: We're off the record at 10:13 a.m.

(Break taken.)

THE VIDEOGRAPHER: We're back on the record at 10:21 a.m.

BY MR. RODRIGUEZ:

Q. Okay. As you were preparing your report, who did you speak with aside from any attorneys for the plaintiff?

A. I don't believe anyone else, sir.

Q. So, you didn't speak with Dr. Ettner?

A. No, sir.

Q. All right. And, as you were preparing your report, what materials did you review?

A. Um --

Q. You don't have a copy of it.

A. Oh, you haven't given me the report. If I -- as I stated in the report, I reviewed Dr. Ettner's report, Dr. Li's report,

the information attached to those reports, and other relevant background information, which is cited in the content of my report.

Q. Did you review any materials that are not listed in your report?

A. No, sir.

Q. So, then, you didn't review any medical records of the plaintiff?

A. No, sir, I did not.

Q. You didn't review any mental health records of the plaintiff?

A. No, sir, I did not.

Q. Did you -- you didn't review, then, the department's policy concerning the evaluation, management and treatment of transgender offenders?

A. So there were attachments to Dr. Ettner's report which included, to the best of my knowledge, some institutional policies, but I would need to refer to the report to refresh my memory about the specific titles of those policies or reports or --

Q. Okay. Did you review the expert report of Dr. Penn?

A. No, sir.

Q. Did you review the expert report of Dr. Boyd?
A. No, sir.
Q. Did you read the deposition transcript of Dr. Penn?
A. No, sir.
Q. Deposition transcript of Dr. Boyd?
A. No, sir.
Q. Did you review any deposition transcripts?
A. No, sir.
Q. When you sat down to begin working on your report, were you supplied any assumptions?
A. Can you clarify what you mean by supplied with assumptions, sir?
Q. Yeah. Were you -- when you were engaged in this case, were you given a set of assumptions to just assume were the case in preparation of your report?
A. No, sir, I was not.
Q. So, aside from reviewing the materials that you list in your report as reviewing, and speaking with counsel for the plaintiff, did you do anything else to prepare

A. Correct. It is a general issue.
Q. So, are you offering any opinions about the provision of mental healthcare to this particular patient?
A. No, sir.
Q. Are you offering any opinions about the state of the plaintiff's mental healthcare? Or excuse me. I'll ask a new question. Are you offering any opinions about the state of the plaintiff's mental health?
A. No, sir, I am not.
MR. RODRIGUEZ: All right. What are we on, six? For the witness.
THE WITNESS: Thank you.
(Thereupon, Exhibit 6, Expert Report of Fan Li, PhD, was marked for identification.)
BY MR. RODRIGUEZ:
Q. Do you recognize this document, Dr. Antommaria?
A. Yes, sir.
Q. What is it?
A. It appears to be Dr. Li's report, including the appendices.
Q. The -- if you turn to page 12, Dr. Li writes, in the second sentence there at the

top, this assertion cites 21 references. And I'll represent to you that this assertion that Dr. Li is referring to appears on the previous page as WPATH Assertion 1. Did you review any of those 21 references that are cited in support of WPATH Assertion 1?

A. So, minimally I reviewed da Silva and Lindqvist.

Q. And is da Silva one of the cases that you referenced reviewing, or one of the studies that you referenced reviewing earlier today in preparation for your deposition?

A. Yes, sir.

Q. It is?

A. Yes, sir.

Q. Is that the La Costa one, or is that the Papadopulos one, or the Scandinavian one?

A. Oh. So, I misspoke, sir. It would be what I erroneously referred to as La Costa.

Q. It was da Silva instead?

A. Yes.

Q. Okay.

A. And it's D-A S-I-L-V-A.

Q. All right. So, da Silva you said you reviewed it minimally. What does that mean?

A. I read the article, sir.

Q. All right. And then what was the second study, the other study you said you referenced, or you reviewed?

A. Lindqvist. L-I-N-D-Q-V-I-S-T.

Q. All right. Is that the Scandinavian study?

A. Yes, sir.

Q. Okay. And that third study that you referenced, Papadopulos, you mentioned earlier that you looked at that study in preparation of your deposition. Do you know if that was one of these 21 studies? And for ease of reference, the reason why I included the appendix to this one is because it lists all of the studies.

A. So, to the best of my knowledge, sir, or to the best of my recall, no, I believe that it's referenced later in Dr. Li's report.

Q. Okay. So, aside from da Silva and Lindqvist, have you reviewed any of the other 19 studies referenced by Dr. Li here?

A. So, I try to maintain my familiarity with the literature, sir, and may have read them in my work in this field but do not recall reviewing them in particular in preparation for my report.

Q. Okay. Page 15 of Dr. Li's report, the last sentence on that page, he says, this assertion -- which, again, I'll represent is WPATH Assertion 2, which appears on the same page. Quote, this assertion cited 25 studies, 15 of which were cited also in WPATH Assertion 1. Do you know if you reviewed any of the balance of those studies or any of the ten other studies that were not referenced in WPATH 1?

A. To the best of my knowledge, sir, I did not review any of the balance of the studies.

Q. All right.

A. And doing so was not necessary to the formation of my opinion in my report.

Q. Okay. We'll turn to page 17, middle of the page there beneath the paragraph WPATH Assertion 6. The next full paragraph starts, Brown and Jones. Did you review Brown

and Jones, 2015?

A. Not to the best of my knowledge, sir.

Q. Okay. Same page, WPATH Assertion 10, flip to page 18, first clause there, this assertion cites 26 references. Did you review any of those studies?

A. So, on page 18, Papadopulos, P-A-P-A-D-O-P-U-L-O-S, is listed.

(Zoom interruption.)

MR. RODRIGUEZ: John, you're not on mute anymore, bud. There you go.

THE WITNESS: As well as da Silva.

Q. All right. So, there's Papadopulos is referenced in there, and then da Silva is also referenced. Beyond da Silva and Papadopulos, did you review any of these studies, any of the other 26 studies, or 24 studies?

A. Not to the best of my knowledge, sir.

Q. All right. Page 19, with respect to WPATH Assertion 11, Dr. Li writes that, this assertion cites two references. Did you review either of those two?

A. No, sir.
Q. And then dropping down with respect to Ettner Assertion 1, Dr. Li writes, this assertion cited three references. Did you review any of those references?
A. So, I only see one of the three listed on page 19, and I did not review that. I don't immediately see what the other two were, sir.
Q. I can tell you in one second.
A. Thank you, sir.
Q. So, the first one is the Pfafflin and Junge, which I believe is the one that's stated there in the document, and then the other is Smith, et al., 2005. It appears on -- in the appendix. Unfortunately, it's not numbered.
MS. NOWLIN-SOHL: May I show him?
MR. RODRIGUEZ: Yes.
THE WITNESS: Sir, I believe I'm familiar with other studies in the same cohort that's reported by Smith, et al., and I did not review the third study listed.
Q. Okay. Page 20, Dr. Ettner's Assertion 2, she references Gijs and Brewayes.

Did you review that?

A. No, sir, I did not.

Q. That study apparently analyzed 18 other studies. Did you review any of the other studies referenced in Gijs and Brewayes?

A. So, Dr. Li's management of systematic reviews is complicated, because she discusses the reviews but not the individual studies reported in the reviews. And so, I don't know -- and I don't believe she actually lists the other 18 studies. So, no, sir, I don't -- I may have reviewed them in other contexts. So, I don't --

Q. Well, you didn't review Gijs and Brewayes in the context of preparing your report?

A. No, sir. And I didn't explicitly review the 18 studies that they listed, but I may be familiar with those studies through other work.

Q. Okay. Page 21, Ettner Assertions 5 through 9, the next paragraph below that Dr. Et -- or Dr. Li writes, quote, first among the 24 cited references. Did you review any of those studies for purposes of writing your

report?

A. No, sir, I did not.

Q. And page 22, Dr. Ettner Assertion 10 refers to a single paper, which is Bauer, G. and Scheim, 2015. Do you recall reviewing that in preparation of your report?

A. I'm sorry. You're on page 22, Ettner Assertion 10, sir?

Q. Yeah. And the actual study is not listed there. So, you have to use the appendix to --

A. No, sir, I did not.

Q. On page 23, Ettner Assertion 11, Dr. Li writes, this assertion cites Brown and McDuffie, 2009. Did you review that?

A. No, sir, I did not.

Q. Same page, Ettner Assertion 12, Dr. Li refers to the meta-analysis, which it said is Weinforth, et al., 2019. Did you review that?

A. I did not, sir.

Q. That meta-analysis was a literature review of 13 studies. Did you review any of those 13 studies that would have been referenced in Weinforth for purposes of

drafting your report?

A. So, my testimony would be the same, sir. I may be familiar with some of those 13 studies, but I did not review Weinforth at all and so did not explicitly look for those 13 studies and explicitly review them for the purposes of writing my report.

Q. So, are you offering any opinions about whether the studies that Dr. Li discusses in her report and that are contained in the appendix, whether any of those studies provide rigorous and consistent statistical evidence on the benefits of quality of life and well-being for gender-affirming surgery?

MS. NOWLIN-SOHL: Object to form.

THE WITNESS: I am offering opinions about what Dr. Li identifies as rigorous and consistent and reasonable evidence, and, in particular, as that applies to the -- so, in general, that is my primary opinion but do have opinions regarding how that applies to the three studies that we have mentioned previously.

Q. Okay. I'm going to have to ask the question, I guess, differently, because that wasn't quite what I was asking, or perhaps

it was and we're just talking past each other. So, you just testified that you didn't review the vast majority of the studies referenced in Dr. Li's report. Is that accurate?

A. Yes, sir.

Q. And you didn't review the vast majority of the -- you reviewed a handful of those studies. Correct? Right? You said you reviewed three of them?

A. Yes, sir.

Q. And you said that you reviewed -- you may be familiar with some of the other studies in other contexts. Correct?

A. Correct.

Q. But with the exception of those three, you just testified that you didn't review any of the other studies that are listed in here for purposes of writing your report. Right?

A. Correct, sir.

Q. So, my question is whether you're offering an opinion about whether those studies that are specifically referenced in this report by Dr. Li, whether those studies provide rigorous and consistent statistical evidence on

the benefit of quality of life and well-being for gender-affirming surgery?

MS. NOWLIN-SOHL: Object to form.

THE WITNESS: So, yes, I am, sir, because I'm offering an opinion as to what -- that Dr. Li mischaracterizes what constitutes rigorous and consistent, and because her broad category is inappropriately characterized in terms of making medical decisions, that opinion has implications for her characterization of the individual studies.

Q. So, you're making -- so, you are offering an opinion about whether these specific studies provide rigorous and consistent statistical evidence without having reviewed all of the studies, with the exception of three?

MS. NOWLIN-SOHL: Object to form. Mischaracterizes prior testimony.

THE WITNESS: So the predominant opinion that I am offering is that, again, that Dr. Li's criteria for rigorous and consistent is an inappropriate criteria.

Q. Let me ask this question. Are you offering any opinions about these studies and

whether these studies provide rigorous and statistical support for quality of life and well-being of gender-affirming surgery, these specific studies?

MS. NOWLIN-SOHL: Object to form. Asked and answered.

THE WITNESS: So, Dr. Li's report characterizes the methodology of the studies that she cites, including the studies being, some studies being prospective observational studies with before and after comparisons and other studies being cross-sectional studies. And I am offering an opinion that those types of study designs offer sufficient evidence for the safety and efficacy of medical treatments.

Q. So, is that a no, that you're not offering an opinion about whether these specific studies provide rigorous and consistent support for benefits of quality of life and well-being for gender-affirming surgery?

MS. NOWLIN-SOHL: Object to form. Asked and answered. Argumentative.

THE WITNESS: Can you restate your question, sir?

May 24, 2023

CURRICULUM VITAE

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EDUCATION

2006	Ph.D., Biostatistics, Johns Hopkins University
2001	B.Sc., Mathematics, Peking University, China

POSTDOCTORAL TRAINING

2006-2008	Postdoctoral Fellow in Statistics Department of Health Care Policy, Harvard Medical School

PRIMARY ACADEMIC APPOINTMENT

(All in Department of Statistical Science, Duke University)

2021-present	Professor
2015-2021	Associate Professor
2008-2015	Assistant Professor

SECONDARY ACADEMIC APPOINTMENT

2021-present	Professor Department of Biostatistics and Bioinformatics, Duke University
2017-2021	Associate Professor Department of Biostatistics and Bioinformatics, Duke University
2018-present	Co-director Program for Comparative Effectiveness Methodology, Duke Clinical Research Institute
2017-present	Affiliated Faculty Duke Clinical Research Institute

HONORS AND AWARDS

2022 Fellow, American Statistical Association

PUBLICATIONS

Peer-reviewed Articles

(* student or postdoc supervised by FL)

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71. Chen J, Gan Z, et al., **Li F**, Carin L, Tao C*. (2021) Simpler, Faster, Stronger: Breaking The log-K Curse On Contrastive Learners With FlatNCE. arXiv:2107.01152.

72. Yang S*, Zhou R*, **Li F**, Thomas LE. (2023). Propensity Score Methods for Causal Subgroup Analysis with Time-to-Event Outcomes.

73. Liu B*, Wruck L, **Li F**. (2022). Principal stratification for noncompliance with time-to-event outcomes. arXiv:2301.07672

74. Chang* C-R, Song Y, **Li F**, Wang R. (2022). Covariate adjustment in randomized experiments with incomplete covariate and outcome data.

75. Cheng C, Guo G*, Liu B, Wruck L, **Li F**, F Li. (2023). Multiply robust estimation for causal survival analysis with treatment noncompliance. arXiv:2305.13443.

SOFTWARE PACKAGE

1. `PSweight` (2020): Propensity Score Weighting for Causal Inference. Tianhui Zhou, Guangyu Tong, Fan Li, Laine Thomas, Fan Li. `https://CRAN.R-project.org/package=PSweight`

2. `PStrata` (2022): Principal Stratification for Causal Inference. Bo Liu, Fan Li. `https://CRAN.R-project.org/package=PStrata`

GRANTS

1. Innovative Biostatistical Methods for Analysis and Assessment of Clinical Trials Augmented by Real World Data. Burroughs Wellcome Fund Innovation in Regulatory Sciences Award. 2021-2026. Role: Co-PI (PI: Laine Thomas). Total cost: $500,000.
2. COVID-19 Enhancement: Methods for the Design and Conduct of Subgroup Analysis in Observational Studies. PCORI ME-2018C2-13289, 2019-2023. Role: Co-I (PI: Laine Thomas). Total cost: $349,999.
3. New causal inference methods for cluster randomized trials with post-randomization selection-bias. PCORI ME-2019C1-16146, 2020-2023. Role: PI. Total cost: $946,222
4. Methods for the design and conduct of subgroup analysis in observational studies. PCORI ME-2018C2-13289, 2019-2022. Role: Co-I (PI: Laine Thomas). Total cost: $731,268
5. The biodemography of early adversity: social behavioral processes in a wild animal model. NIH 1R01 AG053308-01A1, 2018-2023. Role: Co-PI (PI: Susan Alberts). Direct cost: $1,542,592
6. A life course perspective on the effects of cumulative early adversity on health. NIH 1R01 AG053330-01A1, 2017-2022. Role: Co-PI (PI: Beth Archie). Total cost: $2,352,291
7. Religion, Spirituality and CVD Risks: A Focus on African Americans. NIH 5R01MD011606-02, 2017-2022. Role: Statistical Investigator (PI: Bentley-Edwards). Total cost: $2,831,644
8. Prospective Multicenter Observational Cohort Study of Comparative Effectiveness of Disease-Modifying Treatments for Myasthenia Gravis (MG). PCORI R-1609-35953, 2017-2020. Role: Statistical Investigator. (PI: Don Sanders). Total cost: $2,517,289
9. New weighting methods for causal inference. NSF-SES 1424688, 2014-2017. Role: PI. Total cost: $190,000.
10. Bayesian multivariate analysis for causal inference with intermediate variables. NSF-SES 1155697, 2012-2015. Role: PI. Total cost: $80,000.
11. Collaborative research: Statistical modeling and inference for high-dimensional multi-subject neuroimaging data. NSF-DMS 1208983, 2012-2015. Role: PI. Total cost: $71,100.
12. The Triangle Census Research Network. NSF-NCRN, 2011-2016. Role: Investigator (PI: Jerry Reiter).

MENTORING

Doctoral Advisees

Scott Schwartz	2010 Statistical Geneticist and Bioinformatics Scientist, Texas A&M University
Nghi Maggie Nguyen	2018 Research Scientist, Duke University Department of Neurology
Fan (Frank) Li	2019 (Biostatistics& Bioinformatics) Assistant Professor, Yale University Department of Biostatistics

Abbas Zaidi	2019 (co-advise with Sayan Mukerjee) AI researcher, Facebook
Elizabeth Lorenzi	2019 Statistical Scientist, Berry Consultants
Shuxi Zeng	2021 Research Scientist, Facebook
Siyun Yang	2022 (co-advise with Laine Thomas, B& B) Research Scientist, Facebook
Bo Liu	2021-
Yueqi Guo	2022-

Postdoctoral Mentees

Georgia Papadogeorgou	2018-2020 (co-advise with David Dunson) Assistant Professor, University of Florida Department of Statistics
Jason Poulos	2019-2021 Postdoctoral Fellow, Harvard Medical School Department of Health Care Policy
Chenyang Tao	2021 Applied Scientist, Amazon
Ruiwen Zhou	2021-2022 (co-advise with Laine Thomas)

Master Advisees

Ying Yang (Neurobiology, MS)	2011
Olanrewaju Akande (Statistical Science, MSEM)	2015
Eve Oh (Statistical Science MSEM)	2015
Shuo Wang (MSS), Joon Sup Park (MSS) Robert Wan (MIDS), Chengxin Yang (MSS)	2022

Undergraduate advisees

Colin Hwang	2011
Ekaterina Petrova	2012
Jack Fu	2013
Tracy Qi Dong	2014
Fiamma Li	2015
Anna Jiang	2016
Jerry Chia-Rui Chang	2019
Pei Yi Zhuo	2023

Doctoral thesis committee

2011 Hongxia Yang, Chiranjit Mukherjee
2012 Yajuan Si, Jochi Nakajima, Kai Cui
2013 Fangpo Wang, Jared Murray
2015 Monika Jincheng Hu, Tsuyoshi Kunihama
2016 Tracy Schifeling, Feifei Wang (Peking University)
2018 Victor Pena
2019 Olanrewaju Akande, Jodi Heck Wortman, Phil White
2020 Danni Lu (Virginia Tech)

Preliminary oral committee

2009 Hongxia Yang, Chiranjit Mukherjee, Minhui Shi
2010 Fangpo Wang, Yajuan Si, Jochi Nakajima
2011 Kai Cui
2012 Tsuyoshi Kunihama
2014 Michael Lindon
2015 Victor Pena
2016 Jody Heck Wortman, Elizabeth Lorenzi
2017 Kyle Burris, Abbas Zaidi, Olanrewaju Akande, Phil White
2019 Shuxi Zeng
2021 Serge Assaad

Master thesis committee

2010 Shouqiang Wang (Operational Research), Arturas Rozenas (Pol Sci)
2012 Yiting Deng (Computer Science)
2014 Yingjian Wang (ECE)
2019 Gauri Kamat, Yunji Zhou (B&B)
2020 Yangfan Ren
2021 Haoling Zheng, Marco Morucci (Pol Sci)
2022 Yi Liu (B&B)

Undergraduate thesis committee

2018 Andrew Cooper
2019 Vivek Sriram
2020 Daniel Spottiswood

TEACHING

(All in Department of Statistical Science, Duke University)

STA 130 Probability and Statistics in Engineering (2010F, 2012-14F, 2012S, 2015S)
STA 320 Design and Analysis of Causal Studies (2011F, 2014S, 2016S)
STA 440 Case Studies in the Practice of Statistics (2019F)

STA 610 Hierarchical models (2023F)
STA 611 Introduction to Mathematical Statistics (2008F)
STA 640 Causal Inference (2015F, 2017-18F, 2020F, 2021-2023S)
STA 723 Statistics Case Studies (2014-19S)
STA 732 Statistical Inference (2009-10S)
STA 790 Special Topics: Causal Inference (2009F), Bayesian Causal Inference (2022F)

PROFESSIONAL APPOINTMENTS AND SERVICE

Editorial Boards

2023-	Editor for Social Science, Biostatistics and Policy, *Annals of Applied Statistics*
2023-24	Guest Editor, Special Issue on "Causal Inference: past, present, and future" *The New England Journal of Statistics in Data Science (NEJSDS)*
2016-2023	Associate Editor, *Bayesian Analysis*
2019-	Associate Editor, *Observational Studies*
2020-	Associate Editor, *Journal of American Statistical Association - TM*
2016-2019	Associate Editor, *Journal of American Statistical Association - ACS*
2013-2017	Associate Editor, *Journal of Statistical Theory and Practice*
2018	Associate Editor, *The American Statistician* special issue on "Statistical inference in the 21th century"

Peer Review Activities

American Statistician, Annals of Applied Statistics, Annals of Internal Medicine, Bayesian Analysis, Biostatistics, Biometrics, Biometrika, BMC Research Methodology, BMJ, Canadian Journal of Statistics, Circulation, Computational Statistics and Data Analysis, Health Services and Outcomes Research Methodology, International Journal of Methods in Psychiatric Research, Journal of Causal Inference, Journal of Computational and Graphical Statistics, JAMA, JAMA Cardiology, JAMA Network Open, Journal of American Statistical Association, Journal of Applied Econometrics, Journal of Causal Inference, Journal of Royal Statistical Society (Series A, B, C), Journal of Statistical Planning and Inference, Neuroimage, Observational Studies, Psychometrika, Scandinavian Journal of Statistics, Statistical Methods in Medical Research, Statistica Sinica, Statistical Science, Statistics and Computing, Statistics in Medicine, Statistics and Probability Letters, Survey Methodology.

Grant Review Panel

National Science Foundation	2013, 2015, 2016, 2018
National Health Institute - BMRD	2016

Ad-hoc Review of Grant Proposals

Netherlands Organisation for Scientific Research (NWO)
Natural Sciences and Engineering Research Council of Canada (NSERC)
Canadian Statistical Sciences Institute (CANSSI)
Health Effects Institute

Conference and Workshop Organizing

2013-14 Group leader, Causal Inference working group, SAMSI CMSS program
2015 Organizer, the G70 Conference: A Celebration of Alan Gelfand's 70th Birthday, Durham
2017 Organizer, NISS workshop on causal inference and machine learning/high dimensional statistics at Atlantic Causal Inference Conference (ACIC), UNC-Chapel Hill
2018 IMS Program Chair, ENAR spring meeting, Atlanta
2019 Organizer, Bayesian causal inference workshop, MBI, Ohio State University
2019 Organizer, Opening workshop of SAMSI Causal Inference Program, Duke University
2020 Organizer, SAMSI Causal Inference Program
2021-22 Member, ISBA 2022 World Meeting Program Committee

Professional Societies

2018, 20 Member, Nominating Committee, International Society for Bayesian Analysis (ISBA)
2019 Member, Selecting Committee for the founding co-editors of the IMS Data Science Journal
2022 Member, Mitchell Prize Selection Committee, ISBA
2023-2024 Member, Committee on Nominations, Institute of Mathematical Statistics

Promotion and External Reviews

2019- Promotion review (Yale, Peking, U Wisconsin at Madison, U Michigan)
2022 Member of External Review Panel of Department of Statistics and Data Science, Wharton School of Business, University of Pennsylvania

ACADEMIC SERVICE

Department of Statistical Science

2009-10, 17 First Year PhD Exam Coordinator
2009-16, 19-20 PhD Admissions Committee
2010-12 Seminar Series Coordinator
2013, 16-17 Master's Program Admissions Committee
Master's Program Director
2017- Master's Program Advisory Committee
2018, 22 Tenure-Track Faculty Search Committee
2019 PhD Program Evaluation committee
2021 DST faculty search committee chair

Duke University

2014 Faculty compensation equity committee
2014-16 Academic Council
2017-22 Academic Program Committee (APC)
2018-19 Search Committee for Chair of Department of Biostatistics & Bioinformatics
2019-20 Search Committee for Executive Vice Chancellor at Duke Kunshan University
2020-21 Duke Strategy Team 2030 Faculty Group
2021 Duke 2030 Working Group on Research
2021-2023 Duke Kunshan University (DKU) Faculty Hearing Committee
2022 Review Committee of the Executive Vice Provost

PRESENTATIONS

Short Course and Tutorial

1. (2011) Short course on "Statistical Methods in Causal Inference". Finnish Society of Epidemiology. Helsinki, Finland.
2. (2017) Tutorial on propensity score methods in traffic safety research. Transportation Research Board Annual Meeting. Washington, DC.
3. (2017) Short course on "New weighting methods in comparative effectiveness research". Duke-Industry Statistics Symposium 2017. Durham, NC.
4. (2018) Tutorial on "Causal inference". Duke Plus Data Science, Durham, NC.
5. (2019) Short course on "Bayesian causal inference". Atlantic Causal Inference Conference, Montreal, Canada.
6. (2019) Tutorial on "Bayesian causal inference". Bayesian Causal Inference Workshop, Ohio State University, Columbus, OH.
7. (2020) Tutorial on "New weighting methods for comparative effectiveness research." International Conference on Health Policy Statistics 2020, San Diego, CA.
8. (2023) Tutorial on "Propensity score weighting for comparative effectiveness research: methods, new developments and software". International Conference on Health Policy Statistics 2023, Scottsdale, AZ.
9. (2023) Short course on "Bayesian causal inference". Applied Bayesian Summer School 2023, Florence, Italy.
10. (2023) Short course on "Causal inference". Columbia University, Department of Statistics.

Seminars

1. (2023) McGill University, Department of Epidemiology, Biostatistics and Occupational Health, Keynote speaker at Student Career Day
2. (2023) University of Cambridge, MRC Biostatistics Unit (virtual)
3. (2023) University of Michigan, Department of Statistics
4. (2022) Texas A&M University, Department of Statistics
5. (2022) Georgia Tech ISyE Statistics Seminars
6. (2022) DCRI Clinical Research Fellowship Program
7. (2022) Duke University Department of Philosophy Causation Group
8. (2022) Michigan State University Department of Statistics and Probability (virtual)
9. (2022) Online Causal Inference Seminar (OCIS) Series (virtual)
10. (2022) OHDSI Methods Working Group, UCLA
11. (2022) International Biometric Society Journal Club

12. (2022) Criteo AI lab (virtual)
13. (2021) Online interdisciplinary seminars on statistical methodology for social and behavioral research, University of Connecticut (virtual)
14. (2021) Duke University, Department of Population Health Sciences (virtual)
15. (2021) Harvard School of Public Health, Working Group on Causal Inference and Machine Learning (virtual)
16. (2021) University of Pennsylvania, Center for Causal Inference (virtual)
17. (2021) Carnegie Mellon University, Department of Statistics and Data Science (virtual)
18. (2021) Online Causal Inference Seminar (OCIS) Series (virtual)
19. (2020) Icahn School of Medicine at Mount Sinai, Institute for Translational Epidemiology (virtual)
20. (2020) University College London, Department of Statistical Science (virtual)
21. (2020) Duke University, Plus Data Science, COVID-19 Data Science Seminar (virtual)
22. (2020) University of Chicago, Department of Statistics
23. (2020) Vanderbilt University, Department of Biostatistics
24. (2019) University of Michigan, Department of Biostatistics
25. (2019) Brown University, Department of Biostatistics
26. (2019) University of Pennsylvania, Department of Statistics
27. (2018) University of Pennsylvania, Department of Biostatistics, Epidemiology and Informatics
28. (2018) Johns Hopkins Bloomberg School of Public Health, Department of Biostatistics
29. (2018) North Carolina State University, Department of Statistics
30. (2018) University of Texas School of Public Health, Department of Biostatistics and Data Science
31. (2018) SAS, Cary, NC
32. (2017) Virginia Tech, Department of Statistics
33. (2016) University of California, Berkeley, Department of Statistics, Neyman Seminar
34. (2016) Duke University, Comparative Effectiveness Research Program
35. (2016) Duke Clinical Research Institute, Duke University
36. (2016) University of Maryland at Baltimore, Department of Mathematics
37. (2015) Tsinghua University (China), Center for Statistical Science
38. (2015) University of Turku (Finland), Department of Mathematics
39. (2015) University of North Carolina at Chapel Hill, Causal inference research group
40. (2014) University of North Carolina at Chapel Hill, Department of Biostatistics
41. (2013) Durham Veterans Administration, Division of Health Services Research and Development

42. (2013) Cornell University, Weill Medical College, Department of Public Health, Division of Biostatistics and Epidemiology
43. (2013) Collegio Carlo Alberto, University of Turin, Italy
44. (2012) University of Florence, Department of Statistics, Italy
45. (2012) University of North Carolina at Chapel Hill, Center for Developmental Science
46. (2012) Ohio State University, Department of Statistics
47. (2012) IBM Watson Research Center
48. (2012) Columbia University, Department of Psychiatry, Division of Biostatistics
49. (2011) University of Pennsylvania, Department of Statistics
50. (2011) University of North Carolina at Chapel Hill, Causal inference research group
51. (2011) University of Virginia, Department of Statistics
52. (2011) Brown University, Center for Statistical Sciences
53. (2008) Duke University, Department of Statistical Science
54. (2008) University of Maryland at College Park, Department of Epidemiology and Biostatistics
55. (2008) University of North Carolina at Chapel Hill, Department of Biostatistics
56. (2007) Fox Chase Cancer Center, Biostatistics Facility
57. (2006) Harvard University, Department of Health Care Policy
58. (2006) Group Health Cooperative, Center of Health Studies
59. (2006) University of Chicago, Department of Health Studies
60. (2006) University of Pittsburgh, Department of Statistics
61. (2006) Ohio State University, Department of Statistics

Invited Conference Presentations

1. (2023) ENAR Spring Meeting, Nashville, TN
2. (2022) BAYES2022 - Bayesian Biostatistics Conference, Bethesda, MD
3. (2022) JSM 2022, Washington DC
4. (2022) ISBA World Meeting, 2022, Montreal, Canada
5. (2022) Workshop on Complex Data with Missingness, Measurement Errors, and High Dimensionality, Banff International Research Station (virtual)
6. (2021) Workshop on Computational Advertising, Banff International Research Station (virtual)
7. (2021) Pacific Causal Inference Conference (PCIC) 2021 (virtual)
8. (2021) JSM 2021 (virtual)
9. (2021) ISBA 2021 World Meeting (virtual)

10. (2021) SAMSI Opening Workshop on Data Science in the Social and Behavioral Sciences (virtual)
11. (2020) SAMSI Games, Decisions, Risk and Reliability (GDRR) Program Transportation Workshop, Durham, NC
12. (2019) Translating Duke Health Immunology & Transplant Initiative Symposium, Duke University, Durham.
13. (2019) JSM, Denver, CO
14. (2019) ICSA China Conference, Tianjin, China
15. (2019) Atlantic Causal Inference Conference 2019, Montreal, Canada
16. (2019) ENAR Spring Meeting, Philadelphia, PA
17. (2019) University of Florida, Gainsville. UF Winter Statistics Workshop.
18. (2018) JSM, Vancouver, Canada
19. (2018) Conference on Evidence and the Individual Patient: Understanding Heterogeneous Treatment Effects for Patient-Centered Care. National Academy of Medicine, Washington, DC
20. (2018) Webinar, Predictive Analytics and Comparative Effectiveness (PACE) Center, Tufts Medical Center.
21. (2018) ENAR Spring Meeting. Atlanta, GA
22. (2017) International Workshop on Objective Bayes Methodology (O-Bayes17). Austin, TX
23. (2017) SAMSI summer workshop on transportation statistics, Durham, NC
24. (2017) Joint Statistical Meeting, Baltimore, MA
25. (2017) European Meeting of Statisticians, Helsinki, Finland
26. (2017) Atlantic Causal Inference Conference 2017, UNC-Chapel Hill
27. (2016) University of Columbia, Department of Statistics, Causal Inference Conference
28. (2016) Fourth International Conference on the Interface between Statistics and Engineering, Palermo, Italy
29. (2016) ISBA 2016 World Meeting, Sardinia, Italy
30. (2016) Atlantic Causal Inference Conference, New York City
31. (2016) Technical Advisory Committee (TAC) annual meeting, Federal Highway Adminstration, McLean, Virginia
32. (2014) SAMSI Computational Methods in Social Sciences Program Transition Workshop, Durham, NC
33. (2014) ENAR spring meeting, Baltimore, MD
34. (2013) Technical experts meeting on statistical methodologies, Federal Highway Adminstration (FHWA), Durham, NC
35. (2013) International Workshop on Objective Bayes Methodology, Durham, NC
36. (2013) Joint Statistical Meeting, Montreal, Canada

37. (2013) ENAR spring meeting, Orlando, FL
38. (2013) SAMSI Computational Methods in Social Sciences Program Opening Workshop, Durham, NC
39. (2013) SAMSI Neuroimaging Data Analysis Summer Program, Durham, NC
40. (2012) ISBA 2012 World Meeting, Kyoto, Japan
41. (2012) ENAR spring meeting, Washington, DC
42. (2012) 5th Annual Bayesian Biostatistics Conference, Houston, TX
43. (2011) Joint Statistical Meeting, Miami, FL
44. (2011) IISA Conference on Probability, Statistics, and Data Analysis, Raleigh, NC
45. (2010) The Eighth ICSA International Conference, Guangzhou, China
46. (2007) Joint Statistical Meeting, Salt Lake City, UT