IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF FLORIDA
TALLAHASSEE DIVISION

JANE DOE, et al.,

Plaintiffs,

Civil No. 4:23-cv-00114-RH-MAF

v.

JOSEPH A. LADAPO, et al.,

Defendants.
_____/

THE STATE'S MOTION TO PARTIALLY EXCLUDE EXPERT TESTIMONY OF PLAINTIFFS' WITNESS KENNETH W. GOODMAN, PhD, FACMI, FACE

Defendants Surgeon General Ladapo, the Florida Board of Medicine and its members, the Florida Board of Osteopathic Medicine and its members, and State Attorney Gladson move to partially exclude the expert testimony of Plaintiffs' witness Kenneth W. Goodman, PhD, FACMI, and FACE. As discussed in the attached memorandum, Dr. Goodman, a bioethicist, is not qualified to express opinions regarding the evidence base for the treatment of gender dysphoria.

Dated: September 25, 2023

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Respectfully submitted by:

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Counsel for the Surgeon General, the Department of Health, the Boards of Medicine, and the individual Board Members

CERTIFICATE OF SERVICE

I hereby certify that on September 25, 2023, I electronically filed the foregoing with the Clerk of Court by using CM/ECF, which automatically serves all counsel of record for the parties who have appeared.

/s/ Mohammad O. Jazil
Mohammad O. Jazil

MEMORANDUM OF LAW

As discussed below, Dr. Goodman is a bioethicist; not a physician or scientist. He does not consult with gender dysphoric patients. He does not rely on clinical guidelines. Yet Dr. Goodman proposes to give an expert opinion about the GAPMS report's evaluation of the evidence supporting treatments for gender dysphoria. He is not qualified to give such an opinion. Accordingly, he should be precluded from testifying about the evidence base for gender dysphoria treatments.

LEGAL STANDARD

Federal Rule of Evidence 702 governs the admissibility of expert testimony. In *Daubert v. Merrell Dow Pharmaceuticals, Inc.,* 509 U.S. 579, 597 (1993), the Supreme Court held that under Rule 702, the district courts are to perform the critical "gatekeeping" function concerning the admissibility of expert scientific evidence. *See also United States v. Frazier*, 387 F.3d 1244, 1260 (11th Cir. 2004) (en banc) ("The importance of Daubert's gatekeeping requirement cannot be overstated.").

In determining the admissibility of expert testimony under Rule 702, courts engage in a "rigorous" three-part inquiry to determine whether: (1) the expert is qualified to testify competently regarding the matters he intends to address; (2) the methodology by which the expert reaches his conclusions is sufficiently reliable as determined by the sort of inquiry mandated in *Daubert*; and (3) the testimony assists the trier of fact, through the application of scientific, technical, or specialized expertise, to understand the evidence or to determine a fact in issue. *Frazier*, 387 F.3d at 1260; *see also*

City of Tuscaloosa v. Harcros Chems., Inc., 158 F.3d 548, 562 (11th Cir. 1998). The Eleventh Circuit refers to these three considerations separately as "qualification," "reliability," and "helpfulness," and has emphasized that they are "distinct concepts that courts and litigants must take care not to conflate." *Quiet Tech. DC-8, Inc. v. Hurel-Dubois UK Ltd.*, 326 F.3d 1333, 1341 (11th Cir. 2003). The party offering the expert testimony has the "burden of establishing qualification, reliability, and helpfulness." *Frazier*, 387 F.3d at 1260. Plaintiffs cannot satisfy the qualification prong for the *Daubert* inquiry with respect to Dr. Goodman's proposed testimony regarding the evidence base for the treatment of gender dysphoria.

ARGUMENT

Dr. Goodman proposes to testify that "**the GAPMS Report Erroneously Concludes That There is Little or No Evidence For The Benefits of Medical Care for Gender Dysphoria.**" Expert Report (Exhibit 1), p.5 (emphasis in original). He bases that opinion primarily on his review of the Endocrine Society's clinical guidelines which were developed using the Grading of Recommendations Assessment, Development, and Evaluations (GRADE) guidelines. In his expert report, Dr. Goodman talks extensively about the GRADE guidelines, *id.* at 5-8, and ultimately opines that "[t]he GAPMS report mysteriously departs from the GRADE guidelines framework by excluding available as of 'low quality,'" *id.* at 7.

As to the first prong of the *Daubert* test, an expert may be qualified "by knowledge, skill, training, or education." *Griffin v. Coffee Cnty.*, 608 F. Supp. 3d 1363,

1368 (S.D. Ga. 2022) (quoting *Hendrix ex rel. G.P. v. Evenflo Co., Inc.*, 609 F.3d 1183, 1193 (11th Cir. 2010)). Dr. Goodman is not qualified.

Dr. Goodman is a bioethicist; not a physician or scientist. Depo. Tr. (Exhibit 2), at 39:14-17, and 51:16. He has a B.S. degree from the University of Florida Department of Journalism and Communication, *id.* at 8:21-9:8; an M.A. degree in theoretical linguistics, *id.* at 9:9-10:1; and a Ph.D. in philosophy, *id.* at 10:8-10:11 — nothing that qualifies him to render an opinion about the evidence base for gender dysphoria treatments.

Nor does Dr. Goodman have any experience, skill, or training that qualifies him to render an opinion about the evidence base for gender dysphoria treatments. He is a professor of medicine, but he does not teach medicine. He "teach[es] ethics, professional ethics, biomedical ethics, and related topics." *Id.* at 17:18-23. He does not make clinical recommendations for patients. *Id.* at 39:14-17. He does not consult with gender dysphoric patients. *Id.* at 27:4-7 and 73:17-19. And he himself said that he "is not in a position to rely on any kind of clinical guidelines, given what [he does]. *Id.* at 56:8-9. Perhaps most importantly, he does not use the GRADE guidelines, *id.* at 27:19, and he has never performed a systematic review of evidence using the GRADE guidelines. *Id.* at 28:5-7.

Stated simply, as a bioethicist with no relevant education, clinical experience, or training, Dr. Goodman is not competent to provide any expert testimony regarding the evidence base for gender dysphoria treatments. That testimony must be excluded.

CONCLUSION

For the reasons set forth above, this Court should grant the State's motion and preclude Dr. Goodman from testifying about the evidence base for treatments of gender dysphoria.

Dated: September 25, 2023

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Respectfully submitted by:

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Counsel for the Surgeon General, the Department of Health, the Boards of Medicine, and the individual Board Members

ATTORNEY CONFERRAL CERTIFICATION

I certify that pursuant to Rule 7.1(B), the State conferred with counsel for Plaintiffs on September 25, 2023. Plaintiffs oppose this motion.

/s/ Mohammad O. Jazil
Mohammad O. Jazil

CERTIFICATE OF COMPLIANCE

I certify under Local Rule 7.1(F) that this memorandum contains 774 words, excluding the parts that may be excluded, and I certify that this response complies with the requirements in Local Rule 5.1(C).

/s/ Mohammad O. Jazil
Mohammad O. Jazil

CERTIFICATE OF SERVICE

I hereby certify that on September 25, 2023, I electronically filed the foregoing with the Clerk of Court by using CM/ECF, which automatically serves all counsel of record for the parties who have appeared.

/s/ Mohammad O. Jazil
Mohammad O. Jazil

IN THE UNITED STATES DISTRICT COURT
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JANE DOE et al.,

Plaintiffs,

Civil No. 4:23-cv-00114-RH-MAF

v.

JOSEPH A. LADAPO et al.,

Defendants.

EXPERT REPORT OF KENNETH W. GOODMAN, PhD, FACMI, FACE ON BEHALF OF PLAINTIFFS

August 16, 2023

Prepared by
Kenneth W. Goodman, PhD, FACMI, FACE

CONFIDENTIAL

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I. INTRODUCTION AND SUMMARY OF OPINIONS

1. I have been retained by counsel for Plaintiffs as an expert in connection with the above-captioned litigation. I have actual knowledge of the matters stated herein. If called to testify in this matter, I would testify truthfully and based on my expert opinion.

2. The Florida Board of Medicine and Osteopathic Medicine Rules (64B8-9.019, Fla. Admin. Code (effective March 16, 2023) and 64B15-14.014, Fla. Admin. Code (effective March 28, 2023)) and Senate Bill 254 ("SB 254" effective May 17, 2023) (collectively the "Bans") prohibit doctors in Florida from providing transition medications to minors. Further, SB 254 and the Boards' Emergency Rules (64B8ER23-7; 64B8ER23-9, Fla. Admin Code (effective July 7, 2023) (collectively, the "Informed Consent Requirements")) limit access to gender transition care for minors and adults in Florida by, among other things, establishing rigid mandatory prerequisites for physicians to obtain lawful consent. I understand a violation of the Boards' rules is a basis for disciplinary action, and a violation of SB 254 may subject a medical provider to criminal and civil liability.

3. There is no valid basis for the State to disregard the robust clinical research studies demonstrating the safety and efficacy of gender transition medication, and, in the absence of dispositive evidence demonstrating that such treatments pose significant safety risks and/or lack of efficacy, it is unprecedented

for the Boards to intrude in the doctor-patient relationship to override the professional judgment of clinicians who adhere to established professional guidelines and standards of care. When parents consent to care for their transgender adolescents, they are consenting to established care supported by the same level and quality of evidence as many other widely accepted treatments for adolescents.

4. Also, there is no ethical or public-interest justification for legislative and/or regulatory stipulations regarding the exact setting or content for valid consent, such as the Requirements' rigid mandate that the consent be obtained in person (as opposed to, for example, via telemedicine or telephone), by the attending physician (as opposed to another qualified healthcare professional), in the presence of a witness, and on a form prescribed by the Boards.

A. ***Background and Qualifications***

5. I am the founder and director of the University of Miami Miller School of Medicine's Institute for Bioethics and Health Policy and the co-founder and director of the University's Ethics Programs. I also direct the Florida Bioethics Network and chair the UHealth/University of Miami Hospital Ethics Committee as well as the Adult Ethics Committee for Jackson Memorial Health System.

6. I am a full Professor of Medicine with tenure at the University of Miami, with additional appointments in the Department of Philosophy, the Department of Public Health Sciences, and the School of Nursing and Health

Studies. My responsibilities include teaching ethics to medical students and trainees and providing continuing education in medical ethics to health professionals at the University of Miami and elsewhere.

7. I received my PhD in Philosophy in 1991 from the University of Miami. I submit this report as an expert in the field of bioethics and the issue of informed consent. A full list of my credentials, experience and publications authored appears in my *curriculum vitae*, which is attached to my declaration (ECF 158-1). All institutional affiliations and positions listed here and in my *curriculum vitae* are purely and exclusively for the sake of identification and to demonstrate expertise. The views expressed herein are mine alone.

8. I have extensive experience as a bioethicist. Bioethicists examine the ethical issues that arise in medicine and life sciences. In addition to my research and publication as outlined in my *curriculum vitae*, I am responsible for providing clinical consultative services to providers across the Jackson and UHealth Systems and on a consulting basis to other institutions. The purpose of these consultations is to help clinicians make decisions concerning patient care in cases that presents unique or challenging ethical issues.

B. *Bases For Opinions*

9. I have actual knowledge of matters stated in this report. My expert opinions are based upon my education, training, research, and years of experience

as a teacher and medical ethicist, as well as my attendance at and participation in conferences relating to bioethics, and my ongoing review of the relevant professional literature on the subject.

10. In preparing this report, I reviewed the Florida Medicaid: Generally Accepted Professional Medical Standards on the Treatment of Gender Dysphoria ("GAPMS Report"),[1] the Endocrine Society Clinical Practice Guidelines,[2] the World Professional Association for Transgender Health Standards of Care,[3] the Boards' Rules, and Mandatory Consent forms. I also relied on my years of research and publication in the field of medical ethics, as set forth in my *curriculum vitae*, and the materials therein.

C. *Compensation*

11. I am not being compensated for offering these opinions, except for the reimbursement of expenses incurred in connection with the submission of this report.

D. *Prior Testimony*

12. I previously testified as an expert at trial or by deposition in the following cases: *Adams & Boyle, P.C., et. al. v. Herbert H. Slattery, III, et. al.*, Case

[1] Florida Medicaid: Generally Accepted Professional Medical Standards Determination on the Treatment of Gender Dysphoria, Florida Agency for Health Care Administration, https://ahca.myflorida.com/let-kids-be-kids.

[2] Endocrine Society, Endocrine Treatment of Gender Dysphoric/Gender-Incongruent Persons: An Endocrine Society Clinical Practice Guideline (September 2017), available at https://www.endocrine.org/clinical-practice-guidelines/gender-dysphoria-gender-incongruence.

[3] World Prof'l Ass'n for Transgender Health, Standards of Care for the Health of Transsexual, Transgender, and Gender- Nonconforming People (8th ver. 2023), https://www.wpath.org/publications/soc.

No. 3:15-cv-00705 (Middle Dist. TN), *Gainesville Woman Care, LLC, et. al. v. State of Florida, et. al.*, Case No. 37 2105 CA 001323 (Circuit Court, Leon County).

II. EXPERT OPINIONS

A. *The GAPMS Report Erroneously Concludes That There is Little or No Evidence For The Benefits of Medical Care for Gender Dysphoria*

13. The clinical practice guidelines established by the Endocrine Society were developed using the Grading of Recommendations Assessment, Development, and Evaluations (GRADE) guidelines. In this process, guidelines and recommendations are subjected to rigorous internal and external review, including public comment, and undergo peer review prior to publication. Guidelines are reviewed periodically and may be revised and republished based on new evidence.

14. GRADE is a widely accepted framework for developing and presenting summaries of medical evidence and establishing clinical recommendations and guidelines based thereon.[4] The framework considers the population in question – here, transgender adolescents experiencing gender dysphoria, and the outcomes desired from clinical intervention – and the alleviation of clinically significant distress associated with such dysphoria. The framework is then used to rank the quality of evidence as applied to the desired outcome to assess the strength of the correlation between the intervention and the desired outcome. The GRADE

[4] GRADE: Welcome to the GRADE working group. Accessed May 17, 2023. Available at https://www.gradeworkinggroup.org/#pub.

approach uses four categories to rate the quality of evidence: "high," "moderate," "low," and "very low." These rankings reflect the extent of confidence that the estimates of an effect are adequate to support a particular clinical decision or recommendation.[5]

15. In the rating of evidence, randomized control trials are initially rated as "high quality" and observational studies as "low quality." A randomized controlled trial ("RCT") is a study that divides patients randomly into a control group (no treatment) and a treatment group. In contrast, an observational study records information about patients in a real-world setting, *e.g.*, a cohort of patients seen at a clinic. The term "low quality" in this context does not reflect a condemnation of evidence but rather reflects that the body of peer-reviewed literature in this area is composed primarily of observational studies.

16. The determination of evidence as low quality does not imply the strength of a particular clinical recommendation. In fact, low quality studies regularly guide important aspects of clinical practice, and the GRADE framework specifically notes that GRADE should not be used to dismiss observational studies or to give absolute priority to RCTs, as it appears the Boards have done here.[6] Put another way, technically "low quality" evidence can, and often does, support strong

[5] Balshem H, Helfand M, Schunemann HJ, et al. GRADE guidelines: 3. Rating the quality of evidence. *J Clin Epidemiol*. 2011;64(4):403.

[6] Balshem et al., *supra* note 5, at 402.

clinical recommendations. Further, it is incoherent to suggest that, in the absence of "best-grade" evidence, clinicians should provide no clinical intervention or treatment at all, especially where there is solid evidence that all points in the same direction with respect to showing efficacy of treatment. From a practical perspective, if the standard were that clinical practice guidelines could only issue when there was evidence characterized under the GRADE system as "high quality," many well-established and effective medical treatments would be barred from use. Indeed, under current ethical standards, doing so would likely constitute medical malpractice.

17. The WPATH SOC and Endocrine Society Guidelines are parallel to countless other practice guidelines and, indeed, enjoy reliance on a robust and evolving literature. The GAPMS report mysteriously departs from the GRADE framework by excluding available evidence as of "low quality." This appears a calumny more than a reasoned critique. It is, moreover, noteworthy that though the GAPMS document purports to rely on standards for evidence-based medicine, it neglects to recognize a key aspect of its foundations: "Evidence-based medicine … is the integration of best research evidence with clinical expertise and patient values."[7] Leading scholars of evidence-based medicine have long and consistently

[7] Sackett, D.L., Straus, S.E., Richardson, W.S., Rosenberg, W., Haynes, R.B. *Evidence-Based Medicine: How to Practice and Teach EBM*. (2d ed. 2000).

made clear the essential role of patient values and clinical judgment in evidence-based medical practice. The role of legislatures in regulating that judgment and practice was, until recently, unthinkable. It is and remains, however, scientifically and ethically illicit. In normal circumstances, the measure in question would seem to compel physicians to commit medical neglect or abandonment and, sadly, do so based on ideology and not evidence.

18. In the context of medical treatment for gender dysphoria in adolescents, the use of an RCT would present serious ethical concerns. The medical care at issue here has been demonstrated, by reliable scientific methods, to be effective in alleviating the distress associated with gender dysphoria and improve mental health outcomes in adolescents. Given that there is broad medical consensus, based on solid, peer-reviewed research that these medical treatments are safe and effective, it would likely be unethical to conduct a randomized, placebo-controlled trial, which would entail the withholding of standard-of-care treatment from a control group of adolescents experiencing gender dysphoria.

19. The clinical practice guidelines for treatment of gender dysphoria in adolescents are consistent with guidelines developed in other areas of pediatric care where many interventions are supported solely or primarily by evidence regarded as less than high quality. Much pediatric practice would be utterly undone and out of bounds if the stance revealed in the GAPMS Report were applied to many conditions

afflicting adolescents. In pediatric oncology, for instance, numerous interventions are both the only options available and are, as such, embraced by the medical community. The same is true in many other specialties; indeed, the lack of RCT evidence has long been a challenge to the pediatrics community (where one analysis found that "43% [of pediatric practice guidelines] were based on experimental studies, 30% on observational studies, and 27% on expert opinion or no reference)."[8] The GAPMS report would, similarly, enjoin the use of most if not all off-label medication prescriptions. To be sure, observational and case-control studies "may be the only available or practical information in support of a therapeutic strategy."[9] Indeed, this is the case with all rare diseases, for which observational and real-world data are all that is available.[10] It would be medically and ethically impermissible to deny or delay treatment for millions of pediatric patients with a wide range of maladies because state legislatures found fault with the evidentiary bases of available treatments. Similarly, in Florida, minors frequently receive cosmetic procedures, including breast augmentation, ear surgery, liposuction, and rhinoplasty

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[8] Isaac, Andre et. al., Quality of Reporting and Evidence in American Academy of Pediatrics Guidelines. *Pediatrics*. April 2013;131(4):732–738. Available at https://publications.aap.org/pediatrics/article-abstract/131/4/732/31887/Quality-of-Reporting-and-Evidence-in-American?redirectedFrom=fulltext.

[9] PDQ Adult Treatment Editorial Board. Levels of Evidence for Adult and Pediatric Cancer Treatment Studies: Health Professional Version. *PDQ Cancer Summaries [Internet]*. October 2022. Available at https://www.ncbi.nlm.nih.gov/books/NBK65748/.

[10] *Liu, Jing et. al.*, Natural History and Real-World Data in Rare Diseases: Applications, Limitations, and Future Perspectives. *J Clin Pharmocology*. December 2022;62(S2):S38-S55. Available at https://accp1.onlinelibrary.wiley.com/doi/10.1002/jcph.2134.

– with a less-than-optimal evidence base. These procedures are intended to treat no malady and cure no disease.

20. It is worthy of note that an effort to establish a registry that would have improved gender dysphoria evidence was rejected by Florida's Boards of Medicine and Osteopathic Medicine. It is difficult to understand how and why those who are newly concerned about the evidence for gender dysphoria treatment would disdain existing evidence *and* impede efforts to acquire more and better evidence.

21. To my knowledge, the actions of the Florida Boards of Medicine and Osteopathic Medicine in prohibiting health care providers from following clinical practice guidelines or standards of care for the treatment of a particular patient population are unprecedented. No other pediatric clinical guidelines or standards of care have been rejected by the Florida Boards of Medicine and Osteopathic Medicine because the quality of the evidence supporting them is determined to be less than "high quality." Permitting these Boards to bar health care providers from following clinical practice guidelines or standards of care that are based on less than high quality evidence would subject many pediatric patients to serious harm.

22. To be clear, there are no other recommended pediatric clinical guidelines or standards of care subjected to the same degree of scrutiny as the Boards have applied here in an attempt to justify the prohibition on medical treatment for gender dysphoria.

B. *The Board's Informed Consent Requirements Depart from Well-Established Principles of Medical Ethics*

23. The Restrictions reflect a critical misunderstanding of the role of informed consent (more appropriately called "valid consent") for medical procedures. Rather than serving an interest in protecting the health and well-being of an individual seeking necessary gender transition care, the Restrictions subvert that interest.

24. "Informed consent" names the ethical and legal obligation of health care professionals to ensure that certain fundamental conditions are met before patients undergo medical procedures. Those conditions may be straightforwardly itemized as follows:

- The patient must receive adequate information about the procedure, including its risks, likely benefits and accepted alternatives;
- The patient must have the mental capacity to understand and appreciate the information as provided; and
- The patient's agreement to receive the treatment must be voluntary—that is, free of coercion or undue influence.

25. All three components apply, meaning that the term "valid consent" is more accurate than "informed consent" because, for instance, a patient might be adequately informed but lack the mental capacity to consent. Although there is disagreement and controversy on some subjects within the field of bioethics, these

standards for valid consent are not subject to dispute: they are universally accepted as core components of medical practice and research. The fundamental idea is that every mature person who is capable of making decisions should have the right to decide what should be done to her or his body.

26. This is at the foundation of uncontested national and international recognition of rights to self-determination and personal autonomy. The medical ethics literature is unequivocal about this.[11] There are two critical reasons why the Informed Consent Requirements run afoul of these standards.

27. First, valid consent is context-specific: physicians, allied health professionals, patients, and the precise medical services under consideration will all vary greatly and, together, for each patient, form an individualized pattern—a kind of "clinical fingerprint." There is wide variety in, for instance, physicians' and their allied health professionals' communication styles; patients' health histories, medical needs, previous experience in medical settings, and ability to travel to a health clinic; and the nature and risks of the procedures themselves. Thus, it is impractical and inappropriate to impose a blanket requirement that legal consent be obtained: (1) in-

[11] *See, e.g.*, Gert, B., Culver, C.M., and Clouser, K.D. 2006. *Bioethics: A Systematic Approach.* New York: Oxford University Press, esp. Ch. 9, pp. 213 ff.; Beauchamp, T.L, Faden, R.R. Informed Consent, I. History of informed consent, and II. Meaning and elements, in Jennings, B., ed., *Bioethics*, 4th Edition. Farmington Hills, MI: Macmillan Reference USA, 2014, Vol. 3, pp.
1673-1687; Berg, Jessica W., Paul S. Appelbaum, Charles W. Lidz, and Alan Meisel. 2001. *Informed Consent: Legal Theory and Clinical Practice.* 2nd ed. New York: Oxford University Press; Dworkin, Gerald. 1988. *The Theory and Practice of Autonomy.* Cambridge: Cambridge University Press. Faden, Ruth R., and Tom L. Beauchamp. 1986. *A History and Theory of Informed Consent.* New York: Oxford University Press; Goodman KW. *Ethics and Evidence-Based Medicine: Fallibility and Responsibility in Clinical Science*, Cambridge: Cambridge University Press, 2003.

person as opposed to other equally effective modes of communication), (2) by the physician prescribing the medication or performing the procedure as opposed to a competent allied health professional, (3) in the presence of a third-party witness, and (4) on a form prescribed by a regulatory agency. The context-specific nature of consent applies to every medical procedure— appendectomy, breast reduction or augmentation, tooth extraction, brain surgery, and so on; there is nothing medically unique about gender transition care in this regard.

28. To be sure, many specialized procedures and surgeries do employ procedure-specific consent forms, but these are crafted by experts in the procedure or surgery who are not trying to discourage their patients; such forms are based on the specific and likely risks of the procedure, and not compelled by law or regulation. With the exception of gender transition care and abortion, no such form or process has, to my knowledge, ever been compulsory or required under threat of prosecution.

29. It is also unprecedented for a consent document to contain falsehoods such as those in the Boards' consent forms: "Medical treatment of people with gender dysphoria is based on very limited, poor-quality research with only subtle improvements seen in some patient's psychological functioning in some, but not all, research studies. This practice is purely speculative, and the possible psychological benefits may not outweigh the substantial risks of medical treatments and, in many cases, the need for lifelong medical treatments."

30. The consent forms approved by the Boards are utterly unlike any others in standard use. They require that each putative risk be initialed by the patient and parent; one such form requires 38 placements of initials. Many of the risks, cast as "statements," include material that has nothing to do with the standard consent process, e.g., "Compliance with the requirements explained above is a prerequisite for you to receive treatment with feminizing medications." It is highly unusual for a consent document to feature content clearly intended to discourage the treatment. (The "requirements" alluded to in that form comprise a list of 13 stipulations related to the practice of medicine or psychology, not to the valid consent process.) Moreover, demands for such things as ongoing medical monitoring and a specified number of follow-up visits and their periodicity are with few exceptions wholly outside the scope of the valid consent process.

31. It is particularly unusual to list risks of procedures a patient will not receive. Doing so undermines any suggestion that the forms are customized, which is a direct impediment to the valid consent process. Including these "statements" impairs the consent process and erodes the patient-doctor relationship. It is inconsistent with goals of valid consent to include mention of treatments a patient will not receive.

32. Such an unusual and highly granular list of warnings, threats, and risks, in conjunction with the requirement that patients initial all of them, has resulted in

documents that read like legal contracts. It is also well established that no promise or guarantee should ever be made in conjunction with a medical procedure, and it is extremely peculiar for a clinical consent document actively to discourage a particular intervention or imply its likely failure. The Boards of Medicine forms compel a departure from longstanding best practice in medicine.

33. Stated differently, a one-size-fits-all mandate for legal consent – particularly one that disregards the importance of patient-desired outcomes, originates outside the clinical relationship, and applies to all cases inflexibly – cannot, by definition, be adequate for every consent process. Rather, after the patient and health care provider have discussed the patient's preferences and unique medical history, as well as the specifics of the contemplated prescription or procedure, they are best equipped to determine together—without legislative interference—whether the patient is ready to provide valid consent.

34. The second reason the Informed Consent Requirements run afoul of consent standards is the common and widespread agreement that the doctor-patient relationship is of fundamental importance and therefore should be free from legislative or regulatory interference that does not serve a medical justification. A law such as the Informed Consent Requirements—which specifies the manner, form, and setting in which information must be delivered and the particular health

professional who must deliver the information—undermines the physician's judgment about how to serve a patient's best interests.

35. In order to advance the goals of valid consent, forms that list items for doctors to review with their patients should be accurate and clear. Having multiple statements that are not guided by evidence-based medicine and practice or that address procedures that a patient will not receive undermines patients' ability to make for themselves medical decisions that accurately take risks and benefits into account.

36. These principles apply as a matter of professional ethics notwithstanding any individual's personal viewpoint on gender identity or whether gender transition care should be legally accessible. A practitioner's duty is to provide the patient with the necessary information to allow the patient to make the most appropriate personal health decision, and then to respect the patients' autonomy. There is no medical or ethical justification for the Requirements as a tool of valid consent.

37. The mandates contained in the Informed Consent Requirements constitute an intrusion into universally accepted medical and ethical standards. These state-mandated Requirements override the clinical team's professional judgment to the potential detriment of the patient's health, undermine the physician-

patient relationship, and subvert fundamental tenets of medical ethics and universal standards for valid consent.

Executed on this 16th of August, 2023.

Kenneth W. Goodman, PhD

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF FLORIDA
TALLAHASSEE DIVISION

CASE NO. 4:23-cv-00114-RH-MAF

JANE DOE, individually and on behalf of her minor daughter, SUSAN DOE, et al.,

Plaintiffs,

vs.

JOSEPH A. LADAPO, in his official capacity as Florida's Surgeon General of the Florida Department of Health, et al.,

Defendants.

REMOTE DEPOSITION OF

KENNETH W. GOODMAN, Ph.D., FACMI, FACE

Friday, September 15, 2023

8:30 a.m. - 10:43 a.m.

LOCATION OF WITNESS:

Via Zoom

Miami, Florida

STENOGRAPHICALLY REPORTED BY:

SANDRA L. NARGIZ
RPR, CM, CRR, CRC, CCR-GA

APPEARANCES: (All appearing via Zoom.)

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ALSO PRESENT:

Sharon Minter, Observer

I N D E X

(STENOGRAPHER'S NOTE: All documents were sent to Stenographer electronically. A digital exhibit sticker was placed on the documents which were marked during the proceeding.)

INDEX OF EXHIBITS

The following Zoom proceedings began at 8:30 a.m.

THE STENOGRAPHER: Do you swear or affirm that the testimony you are about to give will be the truth, the whole truth, and nothing but the truth?

THE WITNESS: I do.

THE STENOGRAPHER: Thank you.

Thereupon,

KENNETH W. GOODMAN, Ph.D., FACMI, FACE

having been first remotely duly sworn or affirmed, as hereinafter certified, testified as follows:

DIRECT EXAMINATION

BY MR. PERKO:

Q Can you please state your full name for the record.

A Kenneth Wayne Goodman.

Q Dr. Goodman, my name is Gary Perko. I represent the medical defendants in this case.

Have you ever been deposed before?

A Yes, sir, I have.

Q Okay. How many times?

A Fewer than half a dozen, three or four.

Q Okay. So you know the drill. I'll be asking you questions about -- primarily about your expert report, but possibly other knowledge you

might have that's relevant to this lawsuit.

If you don't understand my questions at any time, please let me know and I will try to rephrase it. Otherwise, if you do go ahead and answer, we'll assume that you understood the question. Is that fair?

A It is.

Q I don't expect this deposition to be too long, but if you ever need a break to get some water, go to the restroom, just let me know, we'll accommodate you.

A Okay.

Q Dr. Goodman, let's just start off with a document on the screen here.

MR. PERKO: Excuse me, I'm not technically proficient here.

There we go.

BY MR. PERKO:

Q And do you see a document on the screen, at the top, it's in blue writing, it says "Case 4:23-cv-00114-RH-MAF, document 58-1."

Do you see that?

A Yes, sir.

Q This is entitled "Expert Declaration of Kenneth W. Goodman, Ph.D, FACMI, and FACE."

And I'll scroll down to the bottom, show you your signature here. Do you see your signature?

There we go.

A Yes, I do.

Q And does this appear to be a true and correct copy of the expert declaration that you submitted in this case?

A It appears to be.

Q Okay. In paragraph 12 you state that you previously testified as an expert or at trial or by deposition in several cases. The first one is Adams & Boyle, P.C., et al. versus Herbert H. Slatery.

When did that case occur; was it 2015?

A It's been 8, 7 to 10 years, yes.

Q Can you tell me what that case was about?

A That was a case involving termination of pregnancies, and if I'm not mistaken, involving mandatory waiting periods between -- for abortion, unless I am conflating with another similar one.

Q Did you testify as an expert?

A I did.

Q Do you recall what subject matter you testified about?

A Consent and the process for the termination of pregnancies.

Q Then the other case that you list here is Gainesville Woman Care, LLC, et al. versus State of Florida, et al. Circuit Court, Leon County.

Do you recall when that case occurred?

A It's more recent, and so it's not -- it's not styled -- more recent than that and on the same issue.

Q I'm sorry?

A I say it's more recent than that.

Q Okay. And what was that case about?

A The same issue, although a different waiting period, but a requirement that patients be required to go away and return to receive medical intervention.

Q And what did you testify about, what were your expert opinions?

A With the role of informed consent in that process and to the point that it was unusual that such a requirement would be made or imposed in that kind of case and not many other medical cases.

Q Are there other medical cases where that type of informed consent is required?

A To the best of my knowledge, no.

Q Now, Dr. Goodman, we're going to talk a little bit about your background, your professional

background and education. Do you recall submitting an expert declaration back in May, May 18th in this case?

A I do.

Q Okay. And you have a CV attached to that document. Would you have any additions or corrections to the CV that you submitted at that time?

A I've had some publications since then.

Q Okay. Can you tell me what those publications were about?

A One of them -- for example, one of them has to do with ethical challenges surrounding wastewater sampling to detect COVID.

Another one has to do -- CVs in academia are rather dynamic, but that's an example of two recent papers. One of them is -- several of them, rather, have to do with scientific projects surrounding the detection of COVID and other diseases in wastewater.

Q And I see from the CV that you received a BS degree with high honors from the University of Florida from the Department of Journalism and Communication. Can you tell me a little bit more about that degree, what it entailed?

A Are you asking for the content of the curriculum or --

Q Yeah.

A So journalism and communication, well-established at the University of Florida, was what I sought a degree in. We learned about theory and practice of the news media, with internships with actual newspapers, for example.

Q Okay. And it says here that you received an MA in 1982 from the University of Essex, Colchester, United Kingdom, from the Department of Language and Linguistics, and your program was in theoretical linguistics.

What is theoretical linguistics?

A In brief, it's the study of the structure of human language and similarities between and among different languages, having to do with their evolution, their origin, and what it is that makes utterance -- what -- the reason we're able to understand each other now is actually quite interesting when one comes to think of it.

And that has to do with the syntax that we understand, the semantic force of our utterances, what makes an utterance well formed or grammatical, if you will, and how it is the human brain is able

to do that.

Q And have you ever practiced in the area of theoretical linguistics?

A No, but some in the area of applied or practical linguistics. This was a theory-based program that does not -- is not associated with any form of practice.

Q Okay. And then you received a doctor -- a Ph.D. from the University of Miami from the Department of Philosophy in 1991; is that correct?

A Yes.

Q It says here that your dissertation was entitled, *Progress and Truth in Science*.

Can you tell me a little bit more about that?

A About the dissertation and its contents, you mean?

Q Yes, sir.

A There has been a debate probably for several thousand years now about what it is we do when we do science, and whether, for example, we learn truths about the world or, for example, to the contrary, whether we solve -- merely solve problems.

This is a great question in epistemology of the study of knowledge. Are we learning truths

about the world, is there a uniquely true description of the world and the way the world works, or do scientists solve problems such that, come a scientific revolution, everything that we believed before needs to be challenged.

A good example of that, for instance, is the Copernican revolution. For most of the history of the world people believed the world -- the earth was at the center of it. After Copernicus, we realized that the earth was no longer the center. That undermined quite literally ancient beliefs about what was up or down.

Newtonian revolution was another revolution in relativity theory and quantum theory. Science is revising itself on a regular basis, and that produces very interesting challenges about what we know, how we come to find it out, and how we can make assertions about the way the world works.

Q When you were getting your Ph.D., did you take any classes in the sciences?

A No.

Q On your list of publications you have a publication with Birnbach, D.J., entitled, "Ethics and Plastic Surgery" -- I'm sorry, "Plastic -- "and Plastic Surgery Practice," that's in, I guess, a

book entitled *The Unfavorable Result in Plastic Surgery: Avoidance and Management*. Can you tell me a little bit more about that? I guess it's a book chapter?

A It is. It's a survey of ethical issues in plastic surgery, so --

Q What -- go ahead.

A And there are many such issues, ranging from patient accommodations to the consent process to what happens when something goes wrong.

Q Can you give me some examples of the ethical issues you're talking about?

A In many areas of medical practice, one can arrange ethical issues under different headings. One of them is going to be privacy. And I think we're all familiar with that: Are you adequately protecting your patient's privacy while you're busy doing other things that require the sharing of information? Is your consent process adequate?

So many patients have expectations about plastic surgery that are sometimes shaped or reshaped by the consent process. Those, as I recall, are -- actually the second one was the major one that the article addressed -- as well as accommodating patient preferences. In the course of

preparing the article, I changed my mind about something.

Q I'm sorry, Doctor. You're breaking up.

MR. PERKO: Sandi, were you able to take that down?

THE STENOGRAPHER: Yes.

MR. PERKO: You were? Okay. Is he breaking up on you?

THE STENOGRAPHER: No.

MR. PERKO: Okay.

BY MR. PERKO:

Q Well, I have an understanding of what you said, Doctor, but you were breaking up there on my system for some reason.

A Should I -- should I try and repeat what I said?

MR. PERKO: Sandi -- if -- Sandi, you were able to get that down on the transcript?

THE STENOGRAPHER: Correct. Correct, yes.

BY MR. PERKO:

Q Then you don't need to repeat it, Doctor.

There is another book chapter attributed to you on your CV entitled, "Ethical and Legal Issues in Decision Support," and that was in a book entitled *Clinical Decision Support Systems: Theory*

and Practice.

Can you tell me a little bit more about that book chapter?

A That chapter addresses challenges that arise when clinicians use computers to help them make decisions. For example, diagnoses and prognoses is a whole issue, although it's very much of the moment. Some of us have been writing about it for quite some time.

If you are a physician, should you use a computer to help you render a diagnosis for me? And the literature on that is actually quite extensive.

One of the legal issues is obviously our colleagues in the practice of medicine are always concerned about liability, and it's been suggested that failure to use a new technology might itself be blameworthy.

Q Those were the legal issues you addressed in your chapter?

A Yes.

Q And so --

A And others.

Q What were the others?

A If, for example, you were my physician and you used a computer to diagnose my condition, or to

help you diagnose one, and it turns out it was a mistake, would that be your fault, would that be the manufacturer's fault, the software writer's fault? It's quite an interesting question, both in terms of moral responsibility and in liability.

On the other hand, these programs are improving to the point where if one failed to use one, and no reason to believe that it might have rendered an accurate diagnosis that you missed, then that also would be blameworthy.

Q Okay. This says that that chapter was fully revised from second edition in 2000. How was it revised?

A To the best of my memory, Counselor, it would have been about updating references and clarifying arguments as necessary. That's -- I'd have to -- I'd have to compare the two versions after 20 years.

Q Okay. Later down in your CV, under your list of publications, you had listed a paper that you did with Rosenfeld, P.J., entitled, "When is Off-label Drug Use in the Patient's Best Interest?"

Can you tell me a little bit more about that paper?

A It was a paper about drugs and

ophthalmology where -- where one in particular was found by ophthalmologists to be really quite useful and quite helpful and where, for a number of reasons, some of them, financial or legal, they were not able to do some of the studies they wanted to do and therefore this particular drug was really quite helpful in the management of the eye condition. And so it was essential that ophthalmologists be able to use that drug off label.

Q I'm sorry, Doctor, you broke up on my end. Could you -- could you repeat that?

A The article made clear that there are circumstances in which off-label use of drugs is sometimes essential for proper patient care.

Q Okay. Thank you. And how would you determine whether off-label use of a drug is essential for patient care?

A I would not, but people in the practice of ophthalmology who are familiar with the drug and its effects on their patients in communication with others would be able to do that.

Q Do you know how they would go about doing that?

A How physicians communicate with each other, is that what you're asking?

Q How they determine when off-label drug use is appropriate?

A When the -- well, there's several ways. It's appropriate, this is a function of its safety and efficacy and so people with extensive experience with it will be able to make a judgment based on that. When people who are familiar with each other's practice communicate, they will be able to communicate with each other the literature about off-label use. So you have publications, you have scientific conferences, and so forth.

Q Doctor, you are currently -- sorry.

What's your current position at the University of Miami?

A I'm a faculty member, I'm a professor of medicine, and I direct the Institute for Bioethics and Health Policy.

Q And what do you teach in the School of Medicine?

A I teach ethics, professional ethics, biomedical ethics, related topics. We're struggling now with the appropriate use of computers in medicine.

Q Can you describe for me some of the ethical issues that you address in your classes?

A The ethics curriculum for medical students tends to have -- I beg your pardon -- tends to have several key components.

One of them is privacy and how protecting and ensuring that the patients are able to trust their physicians who need to know sometimes very intimate things about their patients, privacy is crucially important.

Another component is valid consent, circumstances under which a patient can appropriately be treated or participate in a research project.

Third component, we spend some time on end-of-life care, which is related to valid consent in many ways.

Fourth component has to do with social medicine or access to care, where we teach physicians that once they've learned how to help people, they have an obligation to continue to do so.

It is, in some fields -- I'm sorry -- is uncontroversial to some of us that people have a right to healthcare and therefore up to physicians and nurses to help them enjoy that right.

Q Can you tell me a little bit more about

what you teach in the area of valid consent?

A I can.

MR. PERKO: I'm sorry, Doctor, you're breaking up. You might want to get closer to the microphone.

THE WITNESS: Or -- how's that? Seem to help?

MR. PERKO: Much better. Thank you.

THE WITNESS: Now you understand why professors need elbow patches for their --

A As a result of work by people in ethics, and for that matter also the law, we are clear now about the components of valid consent.

So if I'm going to be your patient -- I beg your pardon -- if I'm going to be a patient, then my physician or my nurse is going to be duty-bound to make sure that three things are the case.

One of them is that I'm adequately informed. That's where the phrase "informed consent" originates from; adequately informed about risks, benefits, and alternatives.

There may be other kinds of information and how that information is communicated and how it's made accessible based on everything from an

educational level to language, that's the informed part.

It's also important that if I'm going to be a patient, that I have capacity, namely that I can understand and appreciate all that information in coming to a decision; or that my guardian, surrogate, or proxy is thus informed and capacitated.

And then, thirdly, that my choice is a free one, that it is -- that I'm not coerced into agreeing to go forward with a treatment or a procedure or risk.

Q Is there a specific valid consent process for adolescents?

A In general, you mean?

Q Yes, sir. Is there a difference between obtaining informed or valid consent from adolescents as compared to adults?

A Well, if they're under the age of majority, then the consent process includes their parents or guardians. In other words, under -- under -- under -- under well-agreed standards, I guess, if you were 17 or younger, then you are officially regarded as unable to consent to your own medical treatment.

There are a number of debates about that, one might note, and in which case the valid consent process includes the legally authorized representative of the patient, and that would be a guardian or a parent.

Q Doctor, going back to your education, can you -- did you take any courses in scientific fields?

A In -- since when?

Q Well, let's just say when you were obtaining your Ph.D. at the University of Miami.

A So my duty at the University of Miami was -- it didn't involve science courses, although I have over the years attended a number of science courses. But as an undergraduate, linguistics is a science and so in some respects, some of those courses were science courses.

Q You mentioned that you had over the years taken other science courses. Was that in your undergraduate degree, or have you since -- since you obtained your Ph.D., have you taken scientific courses?

A Could I ask you to clarify, by a "course," are you -- well, what exactly are you referring to? Because many people are exposed to scientific

education without taking a course at a university.

Q Okay. Well, what type of scientific education have you obtained outside the university?

A Well, that would take a while to go through.

I attend a lot of scientific conferences, where either I'm asked to participate in one way or another; so in the practice of medicine, the practice of nursing, public policy; I've enjoyed collaborating with the Florida Bar over the years.

Q How have you collaborated with the Florida Bar?

A By giving presentations at Bar conferences and supporting projects related to trying to improve statute as it relates to end-of-life care, for instance.

Q How did you improve that statute? What was your work related to?

A Oh, I -- please do not infer that I have implied that I improved any statute.

Q Maybe I misunderstood you. What was your involvement with that statute?

A So that statute in Florida is Chapter 765, which addresses -- it's entitled "Advanced Directives," but it addresses many issues besides

advanced directives.

So many years ago there was a statewide initiative to update, and so we had to revise that statute to make it more apt, if you will. And in the process -- so, for example, in the process you are learning a great deal about the science of -- well, of biomedical science, including neurology, which sometimes bears on capacity, about pulmonology and cardiology, which are -- along with urology -- among the ways that we can die, and so forth.

The challenge in many jurisdictions is one between -- is about how best to protect people while at the same time not infringing on their rights.

And so, for instance, our discussion about valid consent has as its adverse valid refusal. Those are basically attributed to that, so a competent, informed adult can refuse any treatment she wants.

Q And how does the statute deal with valid consent?

A To the best of my recollection, it had -- it is implied throughout. I mean, it's -- the patient's rights to consent or refuse treatment, it's more valid refusal than consent.

I am not prepared to discuss 765 today.

This -- this work -- working group by the Florida legislature is much earlier in the century.

Q Fair enough. Have you had any other involvement with the Florida Bar?

A I've given a number of presentations at Bar programs over the years. The community of lawyers who deal in health law, sometimes elder law, overlaps in many ways. But people who do what I do is healthcare organizations, namely trying to manage the consent and refusal process for people who are dying.

Q You list your professional affiliations in your CV, but I was curious, are you a member of the World Professional Association for Transgender Health, or WPATH?

A I am not.

Q I'm sorry?

A No.

Q I'm going to go back to your expert report here, if I can bring it up.

Do you see your expert declaration on the screen, Doctor?

A Yes.

MR. PERKO: Sandi, can we mark this as Exhibit Number 1, please?

(Exhibit 1 was marked for identification.)
(Exhibit 2 was marked for identification.)
(Discussion off record.)
BY MR. PERKO:
Q And, Dr. Goodman, in paragraph 8 of your expert declaration, you state that in addition to your research and publication as outlined in your curriculum vitae, you are "responsible for providing clinical" consultive serv- -- "consultative services to providers across the Jackson and UH Health Systems and on a consulting basis to other institutions. The purpose of these consultations is to help clinicians make decisions concerning patient care in cases that present unique or challenging ethical issues."
Can you tell me, give me some examples of the consultations you have undertaken that you're referring to here?
A Sure. They're -- they're -- most of them are in the hospital, at least, and it will be similar to what my colleagues do elsewhere.
The most common source of consult requests will be from, for example, colleagues and institutions -- in a hospital where a patient has lost capacity, an elderly, sick patient lacks

capacity and spouses or children or siblings are insisting on a level of treatment that the team in its professional judgment believes is inappropriate.

It's a very common phenomenon in U.S. hospitals, the idea that it's a hospital and that's where you stop people from dying. Unfortunately, some people die no matter what, and the challenge then is to what extent should a physician and/or a nurse be compelled to render treatment against their clinical judgment or to withhold treatment based on their clinical judgment.

Q Have any of these consultations involved gender dysphoria?

A No.

Q Do you have any experience with patients or physicians regarding treatment of gender dysphoria?

A I am aware of cases and have communicated with my colleagues who used to do this, although those cases were largely shaped by the fact that their practice had been altered by -- by -- by regulation. Their concerns were continuity of care, for example.

Q In the context of gender dysphoria?

A Yes.

Q Approximately how many of those consultations involved gender dysphoria?

A How many --

Q I'm sorry, you answered that question. None of your consultations have involved --

A No formal consultations have been about gender dysphoria.

Q Thank you. And in paragraph, beginning in paragraph 13, you talked about "clinical practice guidelines established" --

Sorry, something's beeping in here.

You talk about "clinical practice guidelines established by the Endocrine Society that were developed using the Grading of Recommendations, Assessment, Development, and Evaluations or GRADE guidelines."

Tell me about your experience with use of those GRADE guidelines.

A I do not use the GRADE guidelines. The GRADE guidelines are intended obviously to try and support clinicians who are grappling with a great deal of evidence in biomedicine and the evidence-based medicine movement over the past half century has tried to support physicians and nurses and other clinicians in trying to capture, to

understand, to incorporate, to metabolize, if you will, evidence that -- that can be used to guide their practice. But I, for example, don't use them because I don't practice medicine or nursing.

Q Okay. Have you ever undertaken a systematic review using the GRADE guidelines?

A No, but --

Q The next sentence -- I'm sorry.

A Strictly speaking, no. No, I have not.

Q In the next sentence, you talk about "In this process," and I believe you're talking about the Endocrine Society's development of clinical practice guidelines; is that correct?

A Yes.

Q You say, "The guidelines and recommendations are subjected to rigorous internal and external review, including public comment, and undergo peer review prior to publication."

Can you tell me about the "rigorous internal review" that the Endocrine Society conducts?

A I don't have -- I don't have direct acquaintance with what the Endocrine Society did, other than what I've read and what's available at public sources.

Q So you don't know what internal review the Endocrine Society undertook?

A I've read some of the reports that I see are admitted as documents in the case, but I don't have direct acquaintance of -- with -- I'm not a member of it and I wasn't involved in the guidelines, so I do not know with detail that would be adequate to the task how they -- how they did that.

Q So how --

A It's not my practice to try and do it that way, though.

Q How do you know that the Endocrine Society undertook -- or the internal review process was rigorous?

A Because it is suggested in the literature, and absent any -- I can't believe that they -- because it has been reported publicly as such.

Q Okay.

A As, for example, are many guidelines, the GRADE system itself, while it's an attempt to help physicians and nurses and others guide policy, itself, for example, has not been reviewed or externally evaluated. The debate about evidence-based practice basically is really quite

far reaching and it would be -- it would be inapt for anybody to say of any particular guideline -- parenthetically, there are now guidelines for guidelines -- or any particular requirements for reporting of clinical trials.

The GRADE is about trying to synthesize recommendations, but there now -- there are guidelines for how the trials that they use should have been reported in the first place.

So the idea that there is an easy or a straightforward mapping between GRADE guidelines and any professional organization's practice guidelines is going to be very, very difficult to draw. It's not that simple.

Q Well, getting back to my original question, what's your basis for saying that the Endocrine Society's internal review was rigorous?

A That it is reported trustworthily to be a bit rigorous.

One second, Counselor. May I read this?

Q Sure.

A (Examining document.)

I think -- I think one of us has misunderstood something. If -- what I intended to be communicating here is not the Endocrine Society

guidelines, although they are reported to be rigorous.

What I'm saying is in this process, guidelines and recommendations are subject to rigorous external -- that's the appropriate application of the GRADE guidelines for anybody who's coming up with practice guidelines, not the Endocrine Society.

Q But you said also including public comment is when the GRADE guidelines are implemented and recommendations are subject to it. Is there always rigorous internal review, external review, and public comment?

A For all the guidelines in the world? I would not know.

Q But here you were talking generally and not with regard to the Endocrine Society guidelines?

A I'm talking about the GRADE guidelines, describing the GRADE process whereby guidelines and recommendations are subject to -- the intent of GRADE is to provide that support. In fact -- I -- I -- because of the nature of our discussion, the Endocrine Society guidelines have been publicly reported to have been rigorous.

I'm not competent to judge whether that

was the case or not. My comments here are about how these guidelines are -- how it should be used by anybody seeking to develop practice guidelines.

Q In paragraph 14, you state that "the framework," and I believe you're talking about the GRADE guidelines, is that correct, when you refer to framework?

A Yes, the GRADE -- the GRADE framework for summarizing medical evidence.

Q Okay. You say "The GRADE framework considers the population in question, here transgender adolescents experiencing gender dysphoria and the outcomes of the desired" clinical -- "from clinical intervention and the alleviation of clinically significant distress associated with gender dysphoria."

I'd like to go to another document here, if you'll give me a --

I'll represent for the record that this was an exhibit that was submitted in the trial in the Dekker case. It was Exhibit DX24.

Doctor, if you could take a look at this. Are these the Endocrine Society guidelines that you referred to in your expert report?

A They appear to be.

Q On page 3872 of this paper, under the heading "Method of Development of Evidence: Clinical Practice Guidelines," it states that -- it states that "In terms of the strength of recommendations, strong recommendations use the phrase 'we recommend' in number 1, and weak recommendations use the phrase 'we suggest' in the number 2. Cross-filed circles indicate the quality of evidence, such that one out of four circles indicates" -- or "denotes very low-quality evidence; two out of four, low-quality; three out of four, moderate-quality; and four out of four, high-quality."

Do you see that?

A I do.

Q Now, going back up to the prior page, there are some recommendations and suggestions for the treatment of adolescents. Do you see that?

A Yes.

Q And it's Section 2.0. Now, there appears to be -- there are six recommendations and suggestions here in Section 2.0. And would you agree with me that three of them are suggestions based on low-quality evidence?

A I would need to read them. You're talking

about 2.1 through 2.6?

Q Yes, sir.

A Yes, apparently so.

Q Okay. And the recommendations here, 2.3, 2.4, are based on low-quality evidence as well; is that correct?

A Given those labels, apparently so.

Q And then there's 2.5. At the last sentence, it says, "As with the care of adolescents, greater or equal to 16 years of age, we recommend that an expert" admissible -- "multidisciplinary team of medical and MHPs manage this treatment."

And that's a recommendation, correct?

A Apparently, yes.

THE WITNESS: I beg your pardon.

MR. PERKO: No problem. Would you like to take a break, Doctor?

THE WITNESS: No, I'm good. I'm just getting over a cold, and so thank you all for your indulgence.

MR. PERKO: All right.

THE WITNESS: We're coming up on the hour, so maybe at 9:30 you'll let me refresh my tea.

MR. PERKO: Sure.

I'm sorry, Sandi, can we mark this as

Exhibit Number 2 (sic), please.

THE STENOGRAPHER: Yes.

(Exhibit 3 was marked for identification.)

BY MR. PERKO:

Q And, Doctor -- well, first of all, let me go back. I apologize, getting ahead of myself here.

Going back to your expert report, or expert declaration, there's a sentence here that these rankings -- and you're talking about quality of evidence: High, moderate, low, and very low -- "these rankings reflect the extent of confidence that the estimates of an effect are adequate to support a particular clinical decision or recommendation."

Then you have a footnote 5 after that sentence and you cite to a paper by Balshem, Helfand, Schunemann, et al., entitled, "GRADE Guidelines: 3. Rating the Quality of Evidence." It was in the *Journal of Clinical Epidemiology*.

Are you familiar -- and this is one of the series of papers discussing the GRADE guidelines; is that correct, this number 3?

A It's the ... there's many papers about the GRADE guidelines. This is among them, yes.

Q And they're developed by what's called the

"GRADE working group"; is that correct?

A To the best of my recollection, yes.

Q And you would consider these to be reputable and scientific papers that could be -- should be or can be relied upon?

A There's several questions there. Are they reputable? To the best of my ability to judge that, yes.

Whether any particular paper or scientific report can be relied on is actually another and a very large question, and I don't think -- in fact, it goes to the nature of our case here: What can be relied on to guide practice?

So -- but the idea that there's a particular publication and it alone is dispositive is -- is rarely the case in science, especially biomedical science.

Q Fair enough. I'm going to pull up another paper here. It's entitled, "GRADE Guidelines:" Number "15. Going from Evidence to Recommendation" slash, "Determinants of a Recommendation's Direction and Strength."

Are you familiar with this paper?

A Yes, I am.

Q Okay. Going down to page 731 of this

paper, under the heading 2.3.1, "Low Confidence in Effect Estimates May Rarely be Tied to Strong Recommendations."

Do you see that?

A I do.

Q And right after that, it states, "In general, we discourage guideline panels from making strong recommendations when their confidence in estimates of effect for critical outcomes is" very low -- "is low or very low."

Is that your understanding, that the GRADE working group discourages guideline panels from making strong recommendations when their confidence and estimates of effect for critical outcomes is low or very low?

A That seems to be the case.

Q Now, going back to your expert report, at the bottom of page 6, paragraph 16, you state, "Put another way, technically, low-quality evidence can and often does support strong clinical recommendations."

What's your basis for saying that low-quality evidence often does support strong clinical recommendations?

A In the case especially of pediatrics and

especially the case of rare diseases, there's not going to be a very easy mapping between the body of research that's available and a recommendation that a clinician is going to value to guide her practice.

And so the challenge is -- and it's not just with the interventions we're talking about here, but across the medical spectrum -- you'd need to be able to, if you will, play with the cards you're dealt.

And so sometimes it's not so much that we wish -- we wish we had better evidence for all medical interventions, but for those that for various reasons are not as extensive, not as large, or not as good as we want it, that's not a license to not proceed.

And so you -- sometimes you find yourself in a situation -- I beg your pardon -- in a situation where you'd need to act as a matter of your professional duty to take care of your patients with imperfect evidence. And so in circumstances like that, conceptually one could argue it would be irresponsible to say I'm not going to go something because the last randomized trial wasn't good enough or the cohort wasn't large enough.

The challenges here have to do with how to

make clinical decisions under some measure of uncertainty. And therefore you can get a strong guideline or strong practice guideline in other contexts, obviously, even though the GRADE system, which is not to say the only possible one, in itself is open to criticism, says would be low.

That's the basis of my -- of my statement that you can make a strong clinical recom- -- one could make a credible, strong recommendation even though under the GRADE scale, the evidence was regarded as moderate or low, because there was no alternative and you had patients who needed treatment.

Q Now, you don't make clinical recommendations for patients, correct? You're not a physician?

A Correct.

Q So when you're talking about "you," you're talking about physicians generally or the medical health professionals?

A Correct. I'm talking about people with prescribing authority who have patients, yes. That might include nurses in some jurisdictions.

Q Fair enough. My question really relates to your statement that low-quality evidence often

does support strong clinical recommendations.

Given that the GRADE working group discourages using low-quality evidence to support strong recommendations, what's your basis for saying that low-quality evidence often does support strong clinical recommendations?

MR. STARR: Objection.

BY MR. PERKO:

Q You can answer the question, Doctor.

A I'm trying -- I'm trying to -- if you look at the spectrum of rare diseases, in oncology, for example, or transplant science or neurology or cardiology, especially in pediatrics, you will see that there's -- there's either inadequate or low-quality evidence in a situation where physicians need to act, and that's what I'm trying to say there.

Strong clinical recommendations, by the way, is ambiguous about who's making them, right? The fact of the matter is, different professional organizations, including the American Academy of Pediatrics, have different ways of recommend- -- making recommendations. Some make strong recommendations, some make recommendations.

And that's the distinction that the

American Academy of Pediatrics uses. So we've got -- we need to, like, maybe -- so we'll have to be careful about whose recommendation, what recommendations are made, by whom, in what context, or what audience against what it would -- with what evidence.

So I'm speaking generally here, not about the GRADE guidelines, or -- but about -- about evidence that's regarded as low or weak being the best that's available, but which could still conceptually and without controversy -- otherwise we wouldn't be able to treat kids for cancer -- be able to guide a clinician in her practice.

Q But in this paragraph 16 you're talking in the context of the GRADE framework, are you not?

A I'm -- well, I'm not -- I'm talking about -- could you scroll to the next page, please?

Q Sure.

A The GRADE recommend- -- the GRADE estimation of evidence quality could be used by any number of professional organizations. So while, yes, I'm talking about the GRADE criteria, those GRADE criteria could be used in many different science -- in various specialties, rather, to guide clinical practice and to produce a recommendation

that -- that could be regarded as.

Strong. What you've shared and what I've tried to give examples of is how different professional organizations try and convey their -- the confidence that they have in their recommendation.

And so, for example, you have strong, not so strong, sort of strong, strongly recommend, or just recommend.

By the way, a physician will be forgiven for not knowing how to make that distinction when you have a patient in front of you who needs medical treatment.

So the point is I'm talking about the GRADE guidelines as they could be applied to any recommendation by any organization.

Q So are you saying that the GRADE guidelines are not uniformly applied in determining clinical guidelines?

A Oh, I think that they're not uni- -- that's a question I'm not sure if I know the answer to. I hypothesize they're not.

Q Why did you discuss the GRADE guidelines in your expert declaration?

A Because they were used. Because, for

example, the Endocrine Society used them, and it seemed to be salient.

Q Seemed to be what, I'm sorry?

A Salient.

Q Thank you. Now, at the beginning of paragraph 17, you talk about the GAPMS report. I believe that's referring to the Generally Accepted Professional Medical Standards report that was prepared by the Florida Agency for Health Care Manage- -- or Agency for Health Care Administration; is that correct?

A I believe so, yes.

Q You say that the report "mysteriously departs from the GRADE framework."

Are you familiar with an attachment to that report that's a review of the evidence prepared by Doctors Brignardello-Petersen and Wiercioch?

A I would ask you to help refresh my memory by showing it to me, if that's not impermissible.

Q I'll have to come back to that.

MR. PERKO: Did you want to take a break now, Doctor?

THE WITNESS: Yes, could we do that for just a hundred seconds or so?

MR. PERKO: We could do five minutes or

10 minutes, whatever is good for you.

THE WITNESS: Five minutes would be lovely, 9:35.

MR. PERKO: I'll see you in five minutes?

THE WITNESS: Yes, please.

MR. PERKO: Thank you.

THE WITNESS: Thank you.

(A recess took place from 9:30 a.m. to 9:35 a.m.)

BY MR. PERKO:

Q Dr. Goodman, I'm going to try to bring up that document that I was referring to. Do you see a document on the screen that's labeled Attachment C?

A I see a page, I see Attachment C, the document --

(Overlapping speech.)

BY MR. PERKO:

Q I'm sorry.

The next page starts a paper entitled, "Effects of Gender-affirming Therapies in People with Gender Dysphoria: Evaluation of the Best Available Evidence," by Romina Brignardello-Petersen, DDS, MSc, Ph.D., and Wojtek Wiercioch, MSc, Ph.D.

And I'll state for the record this is

Attachment C to the GAPMS report. My question is: Did you review this document as part of your analysis for this case?

A Yes.

Q Okay. And this presents review of the evidence using the GRADE guidelines; is that correct?

A Yes.

Q Did you take this into account when you prepared your expert report?

A Yes.

Q How so?

A In the context of the evolution of evidence-based practice, and -- and the -- and the -- and the -- how shall I say -- some of the controversies surrounding it.

There are precious few guidelines that are immune from criticism, so I -- and in fact, I think criticism of -- from the study design through practice guidelines based on concatenation of many different studies is itself a field in ferment. And so I took it into an account as an example of a review of a review of a review that comes to a different conclusion than the review did.

Q I'm trying to understand what you mean by

"a review of a review of a review." What are you saying there?

A So this is a document that is commenting on practice guidelines, that's one review.

The practice guidelines are a review of other reviews, namely the biomedical research that led to the practice guidelines. So it's three -- it's three levels out, if you will, from the actual studies, which themselves are open to criticism, if you will.

Q Can you tell me where this document refers to "guidelines" and is a review of guidelines?

A It in itself is an -- so for example, it says right there under Methods, "an overview of systematic reviews."

So basically what they're saying is that they used -- whether it's reproducible or not, I'm not able to assess -- "to serve, select, prioritize, appraise, and synthesize available evidence."

But a systematic review is itself a review of the evidence. And what we've learned is systematic reviews and meta-analyses sometimes contradict each other, which is why it is actually not incoherent to -- for some people who call for guidelines for guidelines. None of these documents

is dispositive, is what -- is -- is what I'm trying to say.

Q Fair enough.

MR. PERKO: Sandi, can mark that as the next exhibit, please?

THE STENOGRAPHER: That'll be number 3.

MR. PERKO: Okay. Did we get the paper that I referenced? Did we get that marked?

THE STENOGRAPHER: No, you didn't, the last one. So that -- you want to mark that one as 4 and this one as 5?

MR. PERKO: Yes, please.

THE STENOGRAPHER: Okay. Will do.

MR. PERKO: Thank you.

(Exhibit 4 was marked for identification.)

(Exhibit 5 was marked for identification.)

BY MR. PERKO:

Q Doctor, paragraph 17 of your expert declaration you say that "The GAPMS report mysteriously departs from the GRADE framework by excluding available evidence as of low quality. This appears to be a calumny more than a reason to critique."

What are you suggesting when you say "this appears to be a calumny"?

A In this and many other cases, especially those of high public interest and controversy, there is a great deal of -- of -- of effort to try and ensure that -- that the -- that a conclusion comports with a position independent of other considerations. We -- I suppose it's part of the human condition, Counselor, but what's happening, on would -- would make the observation that here and elsewhere, there are -- there are -- there are -- how shall we say it? -- conflicting advocates on different positions, and that sometimes what conclusions are drawn are drawn in part from the evidence or the available evidence as selected that supports a particular position.

As I say, this is not a criticism of any particular group. I think this is very common, unfortunately, in the sciences. We see it in many sciences. In fact, we see it -- we see it here, we see it -- sometimes see it in climate change. We sometimes see it in gun violence. We sometimes see it in other areas of great public controversy and interest that -- that -- that -- that reasoned critique is hard to come by, and that's why it appears to be an insult more than that; that we are -- that there is partisans trying to move

forward a position and that sometimes leaves science as -- as less -- as less -- on the side of a contentious debate. That's all.

Q Would you agree with me that there are partisans on both sides of the issue in this case?

MR. STARR: Objection.

A I think there are many sides to these issues and that there are partisans at all in this case is unusual in medicine.

Well, you sometimes will see quote/unquote partisans in cardiology or of hepatology.

What seems to be occurring here is somewhat different in kind. In cardiology, different scientists might have different approaches or theories or beliefs based on their work about what works and what doesn't work.

In this case, we have the evolving practice, which unusually has led to efforts to regulate it, which you do not see elsewhere in medicine.

(Exhibit 6 was marked for identification.)

BY MR. PERKO:

Q And here, Doctor, can you see a document entitled, "Can We Trust Strong Recommendations Based on Low Quality"?

A Yes.

Q And one of the authors is Gordon H. Guyatt. Are you familiar with Dr. Guyatt?

A I'm familiar with his work.

Q I'm sorry?

A Yes, I am.

Q Okay. If you could read the first two paragraphs, I'd like to ask you some questions about them.

A Yes.

Q And then the third paragraph states that "Basing treatment decisions or clinical guidelines on low-quality evidence means that the true effects of treatment or clinical decision might differ considerably from best estimates. This discrepancy could result in launching campaigns such as those designed to persuade women to use hormone replacement therapy, that are based on unjustified faith in net benefit instead of transparently sharing the uncertainties in the quality of evidence on which the recommendations were based."

Do you agree with that statement?

A I might point out that in key places, treatment or clinical decisions might differ considerably from best estimates, that and also they

might not. This represents it could result, which means that it could -- it also might not. It's framed as -- this is by a scientist who's made great contributions in the world of evidenced-based practice who is trying to -- who appears to be trying in this article -- I do not know more, I don't know anything about the background of this article other than it's a very brief article.

And what it's saying is that there's -- he's alleging that there's a gap between -- basing guidelines on low-quality evidence produces a tension. And as a general proposition, one could say, as is rough and ready advice, that would seem to be okay; that we have a history of biomedical science, we -- and this would be editorial and empirical "we" -- I'm not a scientist, but as a citizen who understands a fair bit of it, I'm keen that more and better science will lead to more and better healthcare.

And there are, as a matter of fact, especially in the context of rare diseases -- osteoporosis is not a rare disease, by the way, for which one might receive hormone replacement therapy -- that is really quite difficult to draw mapping rules between evidence which may be -- which

is not nearly as voluminous as in other fields, but for which there's a patient population that is expecting, requiring, hoping ardently for treatment.

So it's not so much that one would agree or disagree with this, as you need to frame it in the context of a much larger debate, a debate we've been having for a half a century about what evidence ought we to have and how ought it to guide clinical practice.

That is an extraordinary large, and complex problem, which I think is, as obviously in the page and a half here, not being comprehensively reviewed; not that it was the intent to do so, mind you. But this is basically making a garden-variety observation that the better the evidence, the better the recommendations, which I think is uncontroversial.

MR. PERKO: Sandi, were you able to get that down? It broke up for me at parts.

THE STENOGRAPHER: Yes.

MR. PERKO: Doctor, if I could get you to get closer to the microphone. You're breaking up on me.

BY MR. PERKO

Q Well, let's talk about the sentence that

says "This discrepancy." And I believe they're talking about basing clinical guidelines on low-quality evidence, right, when they refer to "this discrepancy"?

A Yes.

Q And it says that "This discrepancy could result in launching campaigns such as those designed to persuade women to use hormone replacement therapy that are based on an unjustified faith in net benefit instead of transparently sharing the uncertainties in the quality of evidence on which the recommendations were based."

Do you disagree with that statement?

A This discrepancy could also not result in launching campaigns. This discrepancy could result in launching campaigns that actually are transparently sharing uncertainties.

This is -- this is -- this is an -- this is well-argued advocacy, but I think that I would want to parse it with far finer granularity than we likely are going to be able to today.

The history, for example, of hormone replacement therapy and other -- or for that matter, it doesn't matter, there are many examples of people advocating for patients based on the best available

evidence. Whether or not, as it is implied here, they're being intellectually dishonest, which I'd be disappointed if that's what Professor Guyatt is doing -- is an entirely different question, when -- when you -- if you care about the health of patient populations, it is possible to be too -- too -- too quick to judge or too slow to judge. We just don't know until we've done it for a while.

And as I say, in the case where there are patients in front of you who have a malady that's been identified and they are demanding treatment for it, then the advocacy is not for any particular form of treatment necessarily, but simply that there needs to be some treatment in the best available, however imperfect it might be, is an opportunity for physicians and nurses to discharge their duty to their patients and provide it.

That we -- that any individual criticism of individual studies or practice guidelines are important for future fine-tuning of them and improvement of them. So I would need more research for all of this. But I -- but this is not a dispositive criticism of, for example, the Endocrine Society's guidelines, which I'm sure are open to criticism by people more competent to criticize them

than I am.

But in the absence of anything else with a patient population that one could argue deserves treatment, it puts clinicians in a tight spot if there are no guidelines. If the guidelines are imperfect, it's not a justification for them not treating their patient.

Q Do you see a document on the screen entitled "BMJ Investigation: Gender dysphoria in young people is rising, slash, and so is professional disagreement."

Do you see that?

A Yes.

Q I'm going to go down to the second page of this document at the very end, actually the third page -- yeah, second page.

At the very end it states that Guyatt -- and I believe they're talking about Dr. Gordon Guyatt -- Guyatt, who co-developed the GRADE, found, "serious problems with the Endocrine Society guidelines, noting that the systematic reviews didn't look at the effect of intervention on gender dysphoria itself, arguably the most important outcome. He also noted that the Endocrine Society had at times paired strong recommendations --

phrased as 'we recommend' -- 'we recommend' with weak evidence."

If you -- if Dr. Guyatt actually made those observations, would that give you pause for concern for relying on the Endocrine Society guidelines?

A On themselves -- on itself, I told you, I'm not in a position to rely on any kind of practice guidelines, given what I do. But I have been studying for many years the way in which the literature around this has evolved, and how controversies ebb and flow and go back and forth.

Such criticism I think is important as we get clearer about how best to take care of patients.

That a particular scholar has found fault with a particular document is good and it's something that we all need to scrutinize, but I don't know what the counterarguments by an expert who disagrees with them consist in, for example. And I -- and I can tell you this is also parallel to that -- disputes in areas that are not quite as contentious, where there's not a social or an advocacy component as much as there is a scientific one. And people -- scientists are famous for disagreeing.

The previous document used the word "reproducible." Reproducibility is one of the greatest challenges we face now in biomedical research. When one team does a study, the other team can't reproduce it for one reason or another. And yet at the end of the day, in all of these cases, there are doctors and nurses saying we've got patients in our waiting room and we need to take care of them.

And I'm not in a position, any individual clinician could say, to become a philosopher of evidence. I need my society to give me guidelines.

Are they going to be perfect? Of course not.

But are they going to be the best available evidence, given that my patients -- that there is treatment available and my patients are -- are asking for it, then I'm going to have to play with the cards that I've been dealt.

Dr. Guyatt is a well-established scientist and I take his criticisms to be important data, if you will, in the assessment of all of these guidelines. But no particular quote in what basically The BMJ publishes -- this is journalism, you'll notice, and The BMJ is not a scientific

article. And I don't know what someone might say to disagree with him.

Due diligence on all our parts would require that we seek that out.

Q Well, you disagree -- assuming Dr. Guyatt said that, do you disagree with him, with regard to the Endocrine Society guidelines?

A With regard to what -- you said several things here.

Q I'm sorry, assuming that Dr. Guyatt had these criticisms of the Endocrine Society guidelines, do you disagree with him?

A For example, bottom of page 2, found, quote, serious problems, quote.

Do I agree that there are serious problems? I don't think that I am competent to assess that as much as somebody who is Dr. Guyatt's counterpart.

Is it true that, that gender dysphoria itself, arguably the most important outcome? Well, it is arguable, right? And so I -- I -- I find myself saying: I would really like to learn a whole lot more about all of this before I would agree.

"Pairing strong recommendations -- phrased as 'we recommend' -- with weak evidence."

Well, that's what -- we've been discussing that for a while. Sometimes when -- when you have a patient population that has a malady that is identified, where a professional society has provided guidelines, however flawed they might be, then the option is not, well, we're going to not treat our patients and wait for the wheels to turn to produce more and better biomedical evidence.

Dr. Guyatt's reasoned criticism is not something that I'm prepared to agree with or disagree with. I don't -- I would have to spend a lot more time reviewing the literature and the foundational literature and all of that. And even then, it's possible that I'd be incompetent to agree or disagree with him.

The point is that agreeing with him or disagreeing with him is not something that I think any individual clinician needs to be prepared to do either.

Q Going back to your expert declaration, Dr. Goodman, on page 9, you state, carrying over to page 10, "Similarly in Florida, minors frequently receive cosmetic procedures, including breast augmentation, ear surgery, liposuction, and rhinoplasty with less than optimal evidence."

What's your basis for saying that minors frequently receive those treatments?

A That in my experience, and you may recall the article about plastic surgery, I have spent some time looking at cosmetic surgery in minors to be able to communicate with residents and others in my department. And it is according to my learned colleagues on whom I rely that, in fact, minors receive cosmetic surgery with some frequency, especially in Florida.

Q And these procedures are intended to treat no malady or they cure no disease; is that correct?

A Generally speaking, yes. It does raise the difficult question between trait and malady, which is a very large and important and difficult question in medical histomology that need not delay us. But if someone -- but somebody who's seeking, for example, breast augmentation, I think would not be regarded as having a malady or a disease, especially as a minor; it is a trait.

MR. PERKO: I apologize. I'm having technical difficulties here.

THE WITNESS: No worries.

BY MR. PERKO:

Q Do you see your expert report on the

screen?

A I see my report, yes.

Q Beginning on page 11, you talk about "The board's informed consent requirements depart from well-established principles of medical ethics."

What experience do you have with developing informed consent requirements?

A Over the years I have participated, for example, in the context of human subjects research on institutional review boards. And so I have been in a position of reviewing and approving consent documents. Otherwise, I -- that's my best experience.

Q When you say "consent documents," what are you referring to?

A It is very often important that not only do our colleagues in medicine and nursing need to obtain consent, they need to document that they have obtained consent. And that has led to the preparation of documents. And there are many -- for example, every study that's being conducted will have a distinctive consent document based on the goals and the risks of the study.

And so I've contributed to that process.

Q I guess I'm a little bit confused about

your answer. You say that there are consent documents for studies?

A My experience, which you asked about, with consent documents consists in serving on an institutional review board, which duties include, among other things, reviewing the adequacy of the consent documents.

Q Okay. So you're -- if you can get closer to the microphone, Doctor. I apologize.

So I understand it, you're talking about consent documents for patients who intend to participate in a study?

A Who are -- who are -- whether they intend to or not, who are -- these documents will be available, will be made available to people who are recruiting subjects in the study to participate in the study, or the research project, if you prefer.

Q Are you familiar with instances where, let's say, the UHealth, University of Miami Hospital or Jackson Memorial Health System use informed consent documents for specific -- for patients undergoing specific procedures?

A Well, any hospital, depending on the proced- -- so we're moving from research to clinical practice; is that your intent?

Q Yes, sir.

A So it's not unique to my institutions, from which I like to -- my -- my -- my service here is -- my identification with those institutions is for identification only, and nothing I say should be taken to bear on any process or practice at my institutions, which doesn't matter for our purposes because it's pretty standard across all hospitals; namely, that there's usually a standard consent form.

And then certain other procedures will sometimes have additional consent documents, which will describe sometimes in more detail as appropriate the risks that arise, given the procedures.

So, for example, the general consent form might be adequate for hospital admission, but if you're going to be getting a liver transplant, there's going to be a separate set of documents that will describe the liver transplant.

Q Have you been involved in developing those types of consent documents?

A Episodically. I mean, not so much to develop them as to review them, I think would be more appropriate.

Q What do you mean by "review them"?

A Well, so, for example, all forms in all hospitals are -- you don't simply write it and start giving it to patients. There's a process by which forms are vetted. And sometimes I find myself being asked: What's your opinion about this form or this document? And then I will share my opinion about it.

Q At the end of paragraph 21 of your report, or your expert declaration, you state, "Permitting these boards to bar healthcare providers from following clinical practice guidelines or standard of care that are based on less than high-quality evidence would subject many pediatric patients to serious harm."

Now, to be clear, you're not a physician, correct?

A No. I mean, correct. It is correct, I'm not a physician.

Q What's your basis for saying that the Florida boards' "bar of healthcare providers from following clinical practice guidelines or standards of care that are based on" high-quality -- "less than high-quality evidence"?

Is it your understanding that the Florida

boards have barred treatments based on less than high-quality evidence?

That's inartfully stated. Let's strike that.

What's your basis for saying that barring such treatments would subject many pediatric patients to serious harm?

A The point is made in a plenary way about the nature of pediatric evidence, which in many cases would not enjoy a high -- a high mark under the GRADE standards. That's because the patient populations are few, the studies are hard to design, the statistical significance is not as good as they would want it, as, for example, is the case in oncology or in neurology, or any other areas of pediatric practice.

The pediatricians have traditionally enjoyed both great responsibility and great privilege in being able to use their clinical judgment to take care of their patients even though they do not have perfect or dispositive evidence.

And so -- and because of their excellence and their knowledge of medicine, and responses to medicine and interventions, they have done a good job in taking care of children and preventing them

from harm.

The overarching remark is if the Board of Medicine were to basically say: In ophthalmology or in neurology or in cardiology or oncology, we are going to take the same stance with those that we have taken with managing gender dysphoria, then a lot of children would come to grief.

Q So are you saying that what the boards of medicine have done here would subject many pediatric patients to serious harm?

A I'm -- well, that's not clear yet. All I'm saying is in a broader sense, any -- any -- any legislatively imposed restriction of a physician's ability to use her clinical judgment to take care of her patients would, if broadly applied, undermine a great deal of pediatric practice; because the nature of the population, the nature of the research, the nature of the small number of subjects that you get in the studies are rarely going to lead to the kind of high-quality evidence that we would prefer.

But to say that because you don't have high-quality evidence, therefore you should not treat your cancer patient would, I think, strike most people as wholly inappropriate.

Q What other -- what pediatric clinical

guidelines have you reviewed in connection with this report?

A In one way or another I have looked at a number of them. I'm quite interested, for example, in otitis media, very, very common pediatric malady, and if -- the American Academy of Pediatrics, they list two kinds of recommendations.

This is basically -- sorry, that's a fancy word for ear infection. And when you have an ear infection, there are a number of things you can do.

One is you can do nothing. Another is you can treat it with an antibiotic. And another, if you can -- if you're familiar with the tubes they sometimes put in kids' ears, that's actually a source of great -- it's a really quite common pediatric malady, for which there is a lot more evidence, still does not have a standard treatment that you would impose on every patient.

And the American Academy of Pediatrics has -- the recommend- -- if I recall correctly, Counselor, I was -- but we could perhaps get that in front of us. If I'm not mistaken, they make both what they call a "strong recommendation" and a "recommendation."

I don't know the quality of the evidence;

I haven't reviewed it. I don't know how -- what I'm saying is there are a lot of practice guidelines in pediatrics and, so one is ear infections, obesity, forms of injury, I can't remember all of them. There are a fair number of them.

Q But you haven't evaluated the evidence in association with those clinical guidelines?

A Evaluate the evidence in association with --

Q Those clinical guidelines that you were talking about?

A No, I have not evaluated the evidence. You asked me if I was familiar with the guidelines. And I am familiar with the guidelines and the -- and the -- and the number -- and that there are many of them, and they are varied.

MR. PERKO: I'm sorry, Doctor, could you get closer to the microphone?

(Discussion off record.)

BY MR. PERKO:

A So in the context of this report, I have not reviewed the evidence basis for other pediatric guidelines.

Q And beginning on page 11 you talk about the boards' informed consent requirements and their

forms. The bottom of -- the last sentence in paragraph 26, you state, "There are critical reasons why the informed consent requirements run afoul of these standards."

And in 27 you say, "First, valid consent is context-specific."

Are the consent forms that you're familiar with, that patients sign before they can undergo certain treatments, are they individualized?

A The documentation of consent, recall there are two components to this. One of them is ethical; the other is medical legal.

In a physician or nurse's communication with her patient, it will be enough for me to answer questions, and one might or might not document that somebody asked a question and it was answered.

But consent process, properly speaking, is an ongoing -- well -- process.

The document is a way of making clear for a number of reasons, some of which are medical legal, that that process or at least a component of that process has occurred. And so you thereby have a signature on a consent form which documents that, in fact, some element of that process has been successfully completed.

And so rarely do you have hyper-granular consent forms because you have to change every one for every patient. And so, therefore, there's some reliance on communication between team members and patients to be sure that patients or their legally authorized representatives have had adequate time to ask questions and have them answered to their satisfaction.

There's no way a document can do that.

Q Are there standard consent forms for various treatments?

A There are in many cases standard consent forms where the risks are well-known and agreed to and -- standards is not the right word because obviously every institution is going to be responsible for its own consent process and its documentation. But there's a lot of overlap among institutions who tend to rely on each other to try to frame this in a way which is shaped at least -- is shaped at least as much by a desire to get it right and ensure a good consent process as to be -- as well as to be mindful of the fact that that documentation serves important medical legal goals.

So the context-specific component of the consent process is crucial. Whether that's in a

form or not may be immaterial. When it's in a form, and it's very fine-grained, then it might be there's something in the form that applies for one patient but not another. And so framing that carefully will be a great challenge.

Q In paragraph 28 you state, "To be sure, many specialized procedures and surgeries do employ procedure-specific consent forms, but these are crafted by experts in the procedure or surgery who are not trying to discourage their patients."

When you -- you're talking about "procedure-specific consent forms," are you talking about consent forms that are given -- the same consent forms are given to patients undergoing the specialized procedures and surgeries?

A I'm sorry, make sure I understand. Could you reframe that, please?

Q Sure.

When you talk about these procedure-specific consent forms in paragraph 28, I'm trying to understand whether those consent forms differ for each patient or are they the same for each patient?

A The forms are generally, to the best of my understanding, the same for each patient. But

that's why it's very important that the other components of the consent process be completed, namely that there be questions that can be answered.

Q Where you state there, "but these are crafted by experts in the procedure or surgery who are not trying to discourage their patients," do you know who develops the consent forms for the Boards of Medicine?

A The Board of Medicine and people who it turns to to develop the consent forms. I don't know who -- the authors are not --no, I -- just what I read in the lay media, they're the forms that were developed.

What you were asking about originally was so, for example, if someone's going to get a kidney transplant, then the forms are going to be crafted in part by people who are familiar with transplanting kidneys. And therefore they have great experience doing this, or more or less experience, depending on how early we are in the days of kidney transplantation.

I don't know the case here, but I hypothesize that the Board of Medicine forms were not written by people who provide gender-affirming therapy, rather those that oppose the very idea of

it.

Q So in order to develop an appropriate consent form, you say that the author must be someone who provides gender-affirming care?

A No, I wouldn't say that, Counselor. What -- the knowledge of a procedure, not -- basically how to frame risks, benefits, and alternatives, I think would -- the proper development of a consent form is really quite a diverse process, and a number of people with different kinds of expertise should be involved.

But I think it would be uncontroversial to observe that if you're going to have a consent form for a kidney transplant, that somebody who does kidney transplants is involved in that process somewhere along the line.

Q But you don't provide any consultations to patients with gender dysphoria; is that correct?

A Correct.

Q You say here, "these are crafted by experts in the procedure or surgery who are not trying to discourage their patients."

Are you suggesting here that the forms at issue in this case are intended to discourage patients?

A They struck me very much to be trying to do so. To somebody who is familiar with different kinds of consent forms, I know -- and I'd love to be corrected on this, but I know of no antecedent or precedent of regulatory consent forms in this granularity for something -- for any other malady or treatment.

And so I've inferred that the intent of the forms is to dissuade people from receiving therapy. There may be another explanation. I'd be -- I'd like to know what it is.

Q I'm sorry, you broke up at the end there, Doctor. Could you repeat that?

A If there's another explanation, I would be -- devoutly love to hear it. If you read the forms, it is clear that these are forms that are negative, that frame the procedures as -- in ways that are not agreed to by the people who provide this treatment.

Q Are you familiar with the consent forms required for medical marijuana in Florida?

A I'm not.

Q Have you done -- when you say that there are no other consent forms like these, what research have you done to see what consent forms are used in

the medical field?

A Actually, I -- I believe -- at least I hope I said to the best of my knowledge. And having spent more than 30 years working in academic medical centers, I and my colleagues tend not to see consent forms issued by regulatory agencies that are this numerous, this detailed, and framed in this way.

I have not conducted any research at all on the topic. These leap out as unusual.

Q You talked about "legislative interference with the consent process."

Are you suggesting that the legislature has no role in regulating the informed consent process at all?

A In fact, statute requires that patients provide valid consent for treatment. So no, one couldn't suggest that there's no legislative role. But it is not -- but the role is that -- follow -- you need to follow your professional standards in obtaining consent. This is the case for -- well, for most things that happen in the hospital.

So the legislature clearly has a role in requiring consent, but rarely does the legislature say what the consent process should contain for heart transplants or neurosurgery or hip

replacement, for instance. That -- it would be highly unusual for the legislature or any regulatory agency to specify with this granularity what the consent process ought to consist of.

Q Are you suggesting that the legislature prescribe what the consent forms should say in terms of granularity?

A No, on the contrary, I was suggesting that it shouldn't.

Q I'm asking in this case, are you saying that the legislature prescribed too much granularity in developing the consent forms?

A That it prescribes any granularity at all is -- is -- is putting physicians and nurses in a real tight spot, because they need to be able to manage, to titrate their communication to their patients based on their individual patients. And risks and benefits and alternatives are going to be quite diverse. And that applies to any particular drug.

If you take ear infections, for example, you can agree, okay, there are three things to do. Antibiotics are recommended; now the further question is which antibiotic. There are many antibiotics available, but -- I'm possibly mistaken

here, but the idea that the Florida -- or any legislature, Board of Medicine would say we want -- that the consent form for treating otitis media needs to include the variable risks of every antibiotic you might choose to use would be -- would be really quite peculiar.

There -- there'd be -- the idea that of all the drugs that are prescribed, that there needs to be a legislative or regulatory description of that drug and its risks in this population would -- would -- medicine would grind to a halt by noon.

Q I'm sorry, what was that last statement?

A Medicine -- the practice of medicine would grind to a halt; that there are thousands of drugs, thousands of interventions, and heretofore legislators and regulatory boards have not seen it necessary to compel physicians to in stat- -- in language they must use to describe drug risks, for example, in a certain way. I -- there may be some precedent. I don't know of it.

Q Okay. What if a procedure or treatment is experimental? Would that necessitate some degree of granularity in the consent forms?

A The word "experimental" is -- is relative in our context. So if you're referring to an

experiment in which someone is studying the comparative utility of two drugs, or of one drug against a placebo, then in that experiment, yes, you would -- you would -- that would be the consent form for the patients to sign.

And some of these are very high-risk studies, you understand. But I know of no case in which the government has required language for those forms. That's based on learned scholars and colleagues who basically are trying to do due diligence to make sure their patients understand risks, benefits, and alternatives.

If you were studying, for example a -- well, take a drug, an antibiotic that was being studied, you're comparing -- there's no antibiotic being compared to a previous one. It would be highly unusual for the Florida legislature or Boards of Medicine to say: Here in your experiment are the ways in which you must describe the risks of these two drugs.

Q Switching gears a little bit, Doctor. When did you become involved in this lawsuit?

A When I was approached by plaintiffs' counsel.

Q Do you know when that was?

A I beg your pardon?

I -- in the last year. I'd have to check my calendar. A year ago.

Q Okay. A year ago?

You submitted your -- I'm sorry.

A Go ahead. I don't recall exactly. I'd have to look.

Q Okay. You submitted your expert declaration in May of 2023. How much time did you spend in preparing that expert declaration?

A Several -- several hours. You know, when you're not billing, you don't keep track of it. I -- oh, you asked me the number of hours, number of days I worked on it. I worked on it for more than a week, at least.

Q So 40 --

A I did not keep track of the amount of time I spent on individual documents, I'm afraid.

MR. PERKO: So if we could just take a five-minute break, I'm close to being finished here. I just want to read my notes.

(A recess took place from 10:31 a.m. to 10:37 a.m.)

BY MR. PERKO:

Q Just a few more questions, Dr. Goodman.

In paragraph 8, at the bottom of paragraph 8 of your expert declaration, you talked about your consultations that you make with clinicians concerning patient care in cases that present unique or challenging ethical issues.

I may have asked you this previously, but those consultations that you're referring to there, have you done any that have involved gender dysphoria?

A No.

Q You talk a little in your expert report about the GAPMS report. In page 9 you state that "The GAPMS report would similarly enjoin the use of most, if not all off-label medical prescriptions."

What do you mean by that statement?

A That off-label use of medications is very common and has evolved as part of the standard of care for many maladies. And -- and -- if you were to require certain levels of evidence for use of a medication in a particular case, then you would say well, we're not allowed to use it for this because there's inadequate published evidence of this sort that you get from a randomized trial or a meta-analysis or a systematic review or a case-control study or an observational study because

they -- because it's been used off label. In other words, it's being used without FDA approval.

And yet, such approval is customary and permissible. We all wish we had more of that, but you would not want to constrain a physician and say you may not use this drug off label because it doesn't enjoy that high-quality evidence.

Q Would you agree that the appropriateness of using off-label medication prescriptions is an individualized consideration that should take into account the risks and benefits of the off-label use?

A All medications, all prescriptions, whether off label or not, ought to take that into account, yes.

Q Dr. Goodman, do you intend to provide any testimony or opinions beyond what you stated in your expert report, Exhibit Number 1?

A I don't know that I have any intentions as regards to my future contributions. If I'm asked to provide an opinion, I will be honored to do so.

Do I understand your question correctly?

Q Yes, sir. I was just wondering at this time -- or do you know if there are any opinions that you would provide beyond what's stated in your expert report?

A If I am asked and it's appropriate in the context, then I will. I don't -- I understand there may be additional components to this process where I might be asked to contribute and I will be -- I will be privileged to do so.

Q What additional -- sorry. What phrase did you use there: There may be some additional --

A Components to the process that we're -- taking place that we are engaged in now, that there may be other hearings or trial settings that might -- that might entail an opportunity for me to contribute again.

Q Outside of this case?

A In this or any case. If I were asked again in a future context to share and to answer more questions, I would be -- I would be willing to do so.

I'm not sure I understand really. I don't intend to, but I am prepared to.

Q Okay. At this time you don't intend to?

A I don't have any intentions beyond our -- our -- our session here this morning. I believe that there may be a need in the future for additional components to this process, and if that's realized, then I will participate if I am asked.

Q I'm still just trying to understand what you mean by "additional components of this process." Are you talking about this lawsuit or something outside of this lawsuit?

A No, this -- this -- no, this lawsuit. I'm talking about this lawsuit. If this lawsuit were to go to trial and I were asked to testify at the trial, then I would testify at the trial.

MR. PERKO: Okay. I have nothing further, Counsel.

MR. STARR: Nothing from my end.

MR. PERKO: Okay. Are you going to read, Jason?

MR. STARR: Yeah. Read and sign.

THE STENOGRAPHER: Okay.

MR. PERKO: And, Sandi, we'd like a copy -- a copy of the transcript.

THE STENOGRAPHER: Okay. And you need a copy, Mr. Starr?

MR. STARR: Yes.

THE STENOGRAPHER: Okay. Very good.

(Proceedings concluded at 10:43 a.m.)

CERTIFICATE OF OATH

STATE OF FLORIDA)
COUNTY OF LEON)

I, the undersigned authority, certify that KENNETH W. GOODMAN, Ph.D., FACMI, FACE remotely appeared before me on September 15, 2023, and was duly sworn.

SIGNED AND SEALED on September 19, 2023.

IDENTIFICATION: Driver's license.

SANDRA L. NARGIZ
RPR, RMR, CRR, CRC, CCR-GA
snargiz@comcast.net
Commission #HH239213
EXPIRES: APRIL 18TH, 2026

CERTIFICATE OF REPORTER

STATE OF FLORIDA)

COUNTY OF LEON)

I, SANDRA L. NARGIZ, Registered Professional Reporter, certify that I was authorized to and did stenographically report the remote deposition of KENNETH W. GOODMAN, Ph.D., FACMI, FACE; that a review of the transcript was requested, and that the foregoing transcript, pages 1 through 83, is a true record of my stenographic notes.

I further certify that I am not a relative, employee, attorney or counsel of any of the parties, nor am I a relative or employee of any of the parties' attorney or counsel connected with the action, nor am I financially interested in the action.

DATED on September 19, 2023.

SANDRA L. NARGIZ
RPR, RMR, CRR, CRC, CCR-GA
Notary Public in Florida
snargiz@comcast.net

September 19, 2023

JASON STARR, ESQUIRE
Jason.Starr@hrc.org

RE: Doe, et al. vs. Joseph A. Lapado, et al.
Case No. 4:23-cv-00114-RH-MAF
Deposition of KENNETH W. GOODMAN, PhD, FACMI,
on September 15, 2023

Dear Counsel:

The transcript of the above proceeding is now available and requires signature by the witness. Please have your witness read your copy of the transcript, noting any corrections/changes on the Errata sheet. Once completed, please print, sign, and return to the email address listed below for distribution to all parties.

If the witness does not read and sign the transcript within a reasonable amount of time (or 30 days if Federal), the original transcript may be filed with the Clerk of the court. If the witness wishes to waive his/her signature now, please have the witness sign in the blank at the bottom of this letter and return to the email address listed below.

Very truly yours,

Sandra L. Nargiz, RPR, RMR, CRR, CRC, CCR-GA
snargiz@comcast.net

I do hereby waive my signature.

_____
KENNETH W. GOODMAN, PhD, FACMI, FACE

ERRATA SHEET

DO NOT WRITE ON TRANSCRIPT - ENTER CHANGES HERE

In Re: Doe, et al. vs. Joseph A. Lapado, et al.
Case No.: 4:23-cv-00114-RH-MAF
KENNETH W. GOODMAN, PhD, FACMI, FACE
September 15, 2023

PAGE	LINE	CHANGE	REASON

Under penalties of perjury, I declare that I have read the foregoing transcript of the above proceeding and I hereby swear that my testimony therein was true at the time it was given and is now true and correct, including any corrections and/or amendments listed above.

Signature of Witness:_____
Dated this___day of _____, 2023.
email to: snargiz@comcast.net