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.

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