IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF FLORIDA
Tallahassee Division

JANE DOE et al.,

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

Plaintiffs,

v.

JOSEPH A. LADAPO et al.,

Defendants.

SUPPLEMENTAL EXPERT DECLARATION OF KENNETH W. GOODMAN, PhD, FACMI, FACE.

I, KENNETH GOODMAN, PhD, FACMI, FACE, have been retained by counsel for the Plaintiffs in connection with the above captioned litigation.

1. This declaration provides the following expert opinions which are explained in further detail below:

2. The Florida Board of Medicine and Osteopathic Medicine Emergency Rules (64B8ER23-7; 64B8ER23-9, Fla. Admin. Code (effective July 7, 2023) and Senate Bill 254 ("SB 254" effective May 17, 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 informed consent. I understand a violation of the

Board Rules is a basis for disciplinary action by the Boards of Medicine, and a violation of SB 254 may subject a medical provider to criminal and civil liability.

3. 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.

BACKGROUND AND QUALIFICATIONS

4. 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.

5. A more extensive description of my qualifications is included in my previous declaration and a full list of my credentials, experience and publications authored appears in my curriculum vitae, attached as Exhibit A to my previous declaration. (ECF 158-1.)

6. I have actual knowledge of matters stated in this declaration. 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.

7. In preparing this declaration, I reviewed the Board Rules and Mandatory Informed Consent Forms.

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

9. 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 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).

THE BOARDS' INFORMED CONSENT REQUIREMENTS DEPART FROM WELL-ESTABLISHED PRINCIPLES OF MEDICAL ETHICS

10. 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.

11. "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.

12. 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.

13. 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.[1] There are two critical reasons why the Informed Consent Requirements run afoul of these standards.

14. 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-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

[1] *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.

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.

15. 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.

16. 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."

17. 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.

18. 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" does not improve 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.

19. 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.

20. 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.

21. 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.

22. 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.

23. 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.

24. 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 July 24, 2023, in Miami, Florida.

Kenneth W. Goodman, PhD