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

AUGUST DEKKER, et al., *Plaintiffs*, v. SIMONE MARSTILLER, et al., *Defendants*.	Case No. 4:22-cv-00325-RH-MAF

EXPERT REBUTTAL DECLARATION OF
ARMAND H. MATHENY ANTOMMARIA, MD, PhD, FAAP, HEC-C

1. I have been retained by counsel for Plaintiffs as an expert in connection with the above-captioned litigation.

2. My background and credentials are detailed in my previous declaration submitted September 11, 2022 (ECF 11-5). My CV is attached as Exhibit A of that declaration.

3. I submit this rebuttal declaration to address aspects of Dr. Andre Van Mol's declaration submitted by Defendants in support of their opposition to Plaintiffs' Motion for Preliminary Injunction (ECF 49, Appendix Attachment 6).[1] Because there are many issues with Dr. Van Mol's declaration, I do not address

[1] I will refer to Dr. Van Mol's declaration with parenthetical citations in the text to page numbers in the appendix filed by Defendants at ECF 49-1.

every point he makes or every study or article that he cites. Instead, I focus on his declaration's major shortcomings: Dr. Van Mol's lack of experience in gender-affirming medical care or bioethics, his persistent mischaracterization of the evidence for gender-affirming medical care, and his erroneous statements regarding the ethics of clinical research and informed consent. I reserve the right to supplement my opinions as the case proceeds.

4. To begin, Dr. Van Mol is not an expert on the topics involved in this litigation, specifically gender-affirming medical care and the treatment of gender dysphoria in adolescents and adults. He does not report any formal training in bioethics beyond what he would have received as a medical student and resident, nor does he report any employment as a bioethicist. He is a board-certified family physician in full-time practice. This makes Dr. Van Mol one of over 100,000 board-certified family physicians in the United States.[2] Dr. Van Mol does not indicate that he previously provided or currently provides medical care to individuals with gender dysphoria in his clinical practice. He does not have any academic appointments and reports only "six peer-reviewed commentaries and letters." He is, in fact, the author of only a single peer reviewed article whose topic, health-care reform, [3] is not

[2] About the American Board of Family Medicine. American Board of Family Medicine. Accessed October 5, 2022. Available at https://www.theabfm.org/about.
[3] Van Mol A. Health-care reform's great expectations and physician reality. *Ann Pharmacother*. 2010;44(9):1492-5.

germane to gender-affirming medical care or the treatment of gender dysphoria. His other five publications are letters to the editor.[4] While major medical journals perform peer-review of submitted manuscripts, they do not generally peer review letters to the editor. Dr. Van Mol does not offer any evidence to that his letters were "peer-reviewed" in the common meaning of this term. His characterization of these letters is, therefore, misleading. Finally, rather than stating his own opinions in his declaration, Dr. Van Mol quotes extensively from others, including another expert witness retained by the Defendants, Dr. James Cantor.

5. Many of Dr. Van Mol's responses to my initial declaration fail to address the issues that I raised, and instead attempt to misdirect the reader. For example, instead of responding directly to my pointing out that there are other common medical diagnoses that do not require confirmatory laboratory or radiographic studies, Dr. Van Mol instead asserts alleged risks of gender-affirming

[4] Van Mol A. Premature termination of life is not palliative care. *Chest*. 2013;143(1):279; Laidlaw MK, Van Meter QL, Hruz PW, Van Mol A, Malone WJ. Letter to the Editor: "Endocrine treatment of gender-dysphoric/gender-incongruent persons: An Endocrine Society clinical practice guideline". *J Clin Endocrinol Metab*. 2019;104(3):686-687; Van Mol A, Laidlaw MK, Grossman M, McHugh PR. Gender-affirmation surgery conclusion lacks evidence. *Am J Psychiatry*. 2020;177(8):765-766; Rosik CH, Sullins DP, Schumm WR, Van Mol A. Sexual orientation change efforts, adverse childhood experiences, and suicidality. *Am J Public Health*. 2021;111(4):e19-e20; Laidlaw MK, Van Mol A, Van Meter Q, Hansen JE. Letter to the Editor From Laidlaw et al: "Erythrocytosis in a large cohort of transgender men using testosterone: A long-term follow-up study on prevalence, determinants, and exposure years." *J Clin Endocrinol Metab*. 2021;106(12):e5275-e5276.

medical care (App. 527) and instead of responding to my point that observational studies may be sufficient evidence upon which to base recommendations, Dr. Van Mol asserts that gender dysphoria is not a disease (App. 542). Furthermore, rather than attempt to refute my opinion that it is health care providers who make the diagnosis of gender dysphoria, Dr. Van Mol asserts, "The problem is that proper, extensive psychological evaluation and support of the gender dysphoric patient and family both is not assured or even consistent (App. 524)."

6. Contrary to Dr. Van Mol's unsupported assertion, clinical practice guidelines for the treatment of gender dysphoria are clear regarding the evaluation which should be performed prior to initiating gender-affirming medical care. The Endocrine Society's criteria for gender-affirming hormone therapy for adolescents include "A qualified [mental health professional] has confirmed that: the adolescent has demonstrated a long-lasting and intense pattern of gender nonconformity or gender dysphoria" and "any coexisting psychological, medical, or social problems that could interfere with treatment (e.g., that may compromise treatment adherence) have been addressed, such that the adolescent's situation and functioning are stable enough to start treatment."[5] It is not new or surprising that medical providers feel pressure from themselves, patients, families, and society to alleviate patients' pain

[5] Hembree WC, Cohen-Kettenis PT, Gooren L, et al. Endocrine treatment of gender-dysphoric/gender-incongruent persons: An Endocrine Society clinical practice guideline. *J Clin Endocrinol Metab*. 2017;102(11):3869-3903.

and suffering whether it is caused by gender dysphoria or another medical condition. It is, however, providers' responsibility, as professionals, to make sound treatment recommendations.

7. Dr. Van Mol's sole empirical evidence for his claims that evaluation and support of patients diagnosed with gender dysphoria is not "assured or consistent" comes from only two clinics, one in London, England and the other in New South Wales, Australia (App. n. 3, 6). Without conceding that there is significant nonadherence to clinical practice guidelines in these two clinics, there are other, more appropriate ways to address such alleged concerns, rather than withdrawing funding for gender-affirming medical care. Dr. Van Mol does not point to evidence of nonadherence in Florida or provide arguments that withdrawing funding is the appropriate response to alleged nonadherence.

8. With respect to my opinion that "off-label" uses of medications to treat gender dysphoria, like gonadotropin releasing hormone (GnRH) analogs, estrogen, and testosterone, does not mean they are experimental, untested, or unsafe, Dr. Van Mol again misrepresents my opinion by responding that "Safe and effective for a given approved indication should not be assumed to mean safe and effective for any other (App. 532)." The Defendants maintain that because these medications are being used off label, they are experimental and not safe and effective, which is false. GAPMS Memo at 8, 14, 16, 19, 21; Attachment G at 4. In my declaration, I cite

independent evidence of the safety and efficacy of the use of medications "off-label" to treat gender dysphoria (ECF 11-5, at ¶¶ 22, 33-34).

9. Dr. Van Mol claims that, because additional research is purportedly needed regarding gender-affirming medical care, such care should be denied to Florida Medicaid beneficiaries. It is not possible for clinicians to tell their patients with gender dysphoria, or any other clinical condition whose treatment is currently based on a similar level of evidence, to come back later when more evidence is available. Clinicians must make treatment recommendations based on the best, currently available evidence. For example, clinical trials frequently have restrictive inclusion and exclusion criteria to improve their methodological rigor. Clinicians must subsequently determine whether to recommend the intervention to a patient with the same condition who would not have been eligible for the clinical trial. An example is fetal surgery for spina bifida in a pregnant person with a body mass index greater than 35 kg/m^2. Additional research would be beneficial for most medical conditions.

10. As I detailed in my declaration, clinical practice guidelines for medical conditions other than gender dysphoria are also frequently based on similar, "low-quality" evidence. Other clinical practice guidelines also include qualifications, e.g., the guideline does not establish a standard of care. This simply indicates that clinicians must use their best clinical judgment in applying the guideline to

individual patients. Defendants are not, however, withdrawing coverage from all conditions whose clinical practice guidelines are based on a similar level of evidence or that make similar qualifications.

11. There are prospective observational trials that support the safety and efficacy of gender-affirming medical care. Immediately after the publication of these studies, providers and potential participants could still have had the clinical equipoise necessary to ethically conduct a randomized, placebo-controlled trail, e.g, they may have had genuine uncertainty about whether or not to use puberty blockers in adolescents. The reason why a randomized, placebo-controlled trial was not performed at that time is multifactorial including the lack of government or industry funding. With additional clinical experience, many potential investigators and participants no longer have equipoise. Other types of randomized, controlled trials may nonetheless be beneficial, such as trials comparing different dosing regimens.[6] Prospective observational studies, e.g., studies of the incidence of side-effects, may also contribute to patient care.

12. It is important to reiterate that even if a randomized, placebo-controlled trial of puberty blockers had been performed, it would not have provided "high quality" evidence in the way that Dr. Van Mol inaccurately suggests. Although

[6] Burinkul S, Panyakhamlerd K, Suwan A, Tuntiviriyapun P, Wainipitapong S. Anti-androgenic effects comparison between cyproterone acetate and spironolactone in transgender women: A randomized controlled trial. *J Sex Med*. 2021;18(7):1299-1307.

randomized trials are initially assigned the grade "high," this initial grade is decreased to "moderate" if there are serious limitations in the study's quality, and to "low" if there are very serious limitations. Criteria for quality include the adequacy of allocation, concealment, blinding, and follow up.[7] In the case of placebo-controlled trials of gender-affirming medical care, it is not possible to prevent the investigators or the participants from knowing whether a participant has been assigned to the intervention or the control group. Participants and investigators would know based on whether the participant develops secondary sexual characteristics or what type of characteristics the participant develops. Dr. Van Mol insists on a type of evidence that is neither ethically nor methodologically possible.

13. It is surprising that while Dr. Van Mol asserts additional research is necessary, he is critical of the ongoing, prospective observational study of gender-affirming medical care of adolescents in the United States (U.S.). Funding for The Impact of Early Medical Treatment in Transgender Youth study was approved on a competitive basis by the Eunice Kennedy Shriver National Institute of Child Health & Human Development and the study protocol was approved by the Institutional Review Boards at the four participating hospitals.[8]

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[7] Atkins D, Best D, Briss PA, et al. Grading quality of evidence and strength of recommendations. *BMJ*. Jun 19 2004;328(7454):1490.

[8] Olson-Kennedy J, Chan YM, Garofalo R, et al. Impact of early medical treatment for transgender youth: Protocol for the Longitudinal, Observational Trans Youth Care study. *JMIR Res Protoc.* 2019;8(7):e14434.

14. With respect to informed consent, Dr. Van Mol quotes European authors incorrectly implying that minors, rather than their parents or legal guardians, provide informed consent for gender-affirming medical care in the U.S. (App. 549-550). Dr. Van Mol also mischaracterizes a legal case from the United Kingdom (U.K.), Bell vs. The Tavistock and Portman NHS Foundation Trust, in support of his claims regarding informed consent (App. 550). In England and Wales, individuals 16- years-old and older are presumed to have the capacity to consent to medical treatment and those under 16 can consent if they possess sufficient understanding and intelligence to understand fully what is proposed. Although the court questioned the capacity of adolescents under age 16 to consent for gender-affirming medical care and suggested a role for the court in authorizing care for older adolescents, this ruling was later overturned by the Court of Appeal, [9] a fact that Dr. Van Mol conveniently fails to mention.

15. Dr. Van Mol, again quoting others, asserts that there is no established standard for informed consent and that practice varies considerably (App. 549). There are, in fact, well established standards of informed consent. Although states differ in the standard they utilize to determine if the disclosure of potential benefits and risks is adequate (the professional practice or the rational person standard), the

[9] Thornton J. Court upholds Gillick competence in puberty blockers case. *Lancet*. 2021; 398(10307):1205-1206.

standard is well established within individual states.[10] Again, Dr. Van Mol provides no empirical evidence of practice variation in Florida and, even if he were to, there are preferable ways to address such variation, were it to exist, other than completely withdrawing coverage for one type of medical care.

16. With respect to Dr. Van Mol's assertion that the Florida Medicaid Rule is non-discriminatory, the references that he cites do not support his claim (App. 553-54). As stated in above, the U.K. High Court's opinion in Bell v. Tavistock was overturned on appeal and therefore cannot be used for support as Dr. Van Mol attempts to do. The National Institute of Health and Care Excellence (NICE) reviews of puberty blockers and cross-sex hormones are systematic reviews of the literature[11] and, while they grade the quality of the evidence, they do not make treatment recommendations. The Swedish Agency of Health Technology Assessment and Assessment of Social Services report is a scoping review (a review which identifies knowledge gaps or the scope of a body of literature, clarifies concepts, or investigates research conduct)[12] and again does not make treatment recommendations. Instead of banning or defunding gender-affirming medical care,

[10] Murray B. Informed consent: What must a physician disclose to a patient? *Virtual Mentor*. 2012;14(7):563-6.
[11] Cook DJ, Greengold NL, Ellrodt AG, Weingarten SR. The relation between systematic reviews and practice guidelines. *Ann Intern Med*. 1997;127(3):210-6.
[12] Munn Z, Peters MDJ, Stern C, Tufanaru C, McArthur A, Aromataris E. Systematic review or scoping review? Guidance for authors when choosing between a systematic or scoping review approach. *BMC Med Res Methodol*. 2018;18(1):143.

the U.K. and Sweden are reorganizing the delivery of gender-affirming medical care into regional interdisciplinary clinics and supporting research on gender-affirming medical care. For example, in her interim report, Dr. Hilary Cass recommends, "regional centres should be developed, as soon as feasibly possible, to become direct service providers, assessing and treating children and young people who may need specialist care, as part of a wider pathway."[13] To the best of my knowledge, neither the U.K., Sweden, Finland, nor France is banning or defunding gender-affirming medical care.

17. Dr. Van Mol fails to reference any evidence for his claim that "There are alternative treatments of mental health natures which are at least as effective. And without the harms of hormonal and surgical interventions (App. 555)." Such claims are based on case reports or anecdotes[14] which represent a lower level of evidence than prospective observational studies. Recall that Dr. Van Mol asserts

[13] Cass H. Independent review of gender identity services for children and young people: Interim report. February 2022. Accessed October 5, 2022. Available at https://cass.independent-review.uk/publications/interim-report/.

[14] D'Angelo R, Syrulnik E, Ayad S, Marchiano L, Kenny DT, Clarke P. One size does not fit all: In support of psychotherapy for gender dysphoria. *Arch Sex Behav*. 2021;50(1):12; Levine SB. Transitioning back to maleness. *Arch Sex Behav*. 2018;47(4):1295-1300; Schwartz D. Clinical and ethical considerations in the treatment of gender dysphoric children and adolescents: When doing less is helping more. *J Infant Child Adolesc Psychother.* 2021;20(4):439-449; Zucker KJ. The myth of persistence: Response to "A critical commentary on follow-up studies and 'desistance' theories about transgender and gender non-confirming children" by Temple Newhook et al. (2018). *Int J Transgenderism.* 2018;19(2):238-9.

prospective observational studies, let alone case reports or anecdotes, are an unacceptable level of evidence to support gender-affirming medical treatments.

18. Dr. Van Mol's declaration provides no substantive reasons for me to alter my conclusions that treatment for gender dysphoria is not experimental and is consistent with generally accepted professional medical standards including standards for informed consent. I remain of the opinion that there is not a sound medical or ethical basis for excluding such care from coverage by Florida Medicaid and so doing is inconsistent with the program's other medical coverage decisions.

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Executed on October 7, 2022

ARMAND H. MATHENY ANTOMMARIA, MD, PhD