IN THE UNITED STATES DISTRICT COURT FOR THE MIDDLE DISTRICT OF TENNESSEE Nashville Division

L.W., by and through her parents and next friends, Samantha Williams and Brian Williams, *et al.*,

Plaintiffs,

Civil No. 3:23-cv-00376

and

Judge Richardson

UNITED STATES OF AMERICA,

Judge Newbern

Plaintiff-Intervenor,

ν.

JONATHAN SKRMETTI, in his official capacity as the Tennessee Attorney General and Reporter, *et al.*,

Defendants.

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

- I, Armand H. Matheny Antommaria, hereby declare and state as follows:
- 1. I have been retained by counsel for Plaintiffs as an expert in connection with the above-captioned litigation.
 - 2. I have actual knowledge of the matters stated herein.
- 3. In preparing this declaration, I reviewed the expert declarations of James Cantor, PhD, Paul W. Hruz, MD, PhD, Stephen B. Levine, MD, Dr. Sven Román, Michael K. Laidlaw, MD, and Geeta Nangia, MD, filed by the Defendants in this case in opposition to Plaintiffs' Motion for Preliminary Injunction.

4. In this reply declaration, I explain how these experts inaccurately characterize the role of patients' symptoms in diagnosis, mischaracterize gender-affirming medical care as experimental, inaccurately represent European policies on this topic, inaccurately portray the informed consent process, and underestimate parents' and adolescents' medical decision-making capacity. Further, my review of the Defendants' experts' declarations has not provided me reason to change my opinion that there is no sound medical or ethical basis to prohibit healthcare professionals from providing gender-affirming medical care to minors.

Diagnosis of Gender Dysphoria and Other Medical Conditions

- 5. Medical care is greatly informed by patients' reports of their symptoms. As a pediatrician, when a patient's reports are unavailable, for example, a toddler with a limp or an adolescent with static encephalopathy (permanent brain damage) who is crying, diagnosis can be substantially more difficult.
- Contrary to the Defendants' experts' claims, the fact that the diagnosis of gender 6. dysphoria relies on patients' reports of their symptoms and is not confirmed by laboratory or radiographic testing does not undermine its validity as a medical condition. In addition to the fact that most mental health conditions have this characteristic, the diagnosis of some non-mental health conditions also relies on patients' reports of their symptoms and are unable to be confirmed by laboratory or radiographic testing. The diagnosis of migraine headaches, for example, depends on individuals' report of the number, duration, and characteristics of their headaches. These characteristics include the headaches' location, quality, intensity, and aggravating factors as well as the presence of nausea and/or vomiting, and light and sound

¹ Cantor 38, 283, Hruz 56, 95, Levine 218, 236, and Laidlaw 16-21, 49, 78. All references are to paragraphs in the Defendants' experts' reports unless specifically noted, e.g, Page or Footnote.

sensitivity.² Like gender dysphoria, there are no confirmatory laboratory or radiographic studies for the diagnosis of migraine headaches. Radiographic studies and electroencephalograms (EEG) are only used if the history and physical examination suggest that the headache is caused by another condition, e.g., meningitis or subarachnoid hemorrhage.³ Clinical trials of migraine treatments, including randomized, double-bind, placebo-controlled trails, rely on participants' daily headache diaries.⁴

Gender-Affirming Medical Care Including Clinical Practice Guidelines

7. The Defendants' experts characterize gender-affirming medical care as experimental. To the extent that they provide definitions of experimental, these definitions are erroneous. Dr. Cantor, for example, contends, "A treatment would continue to be experimental until the demonstration of (1) reliable, clinically meaningful improvement and (2) the reliable estimation of safety risks in randomized, controlled trials (RCTs) or research of equivalent evidence (165)."6 Dr. Cantor does not provide any references to support his claim. If this definition were correct, which it is not, many widely accepted medical treatments would be classified as experimental, including ones that the Defendants' experts accept are not experimental. The use of gonadotropin-releasing hormone (GnRH) analogs to treat central precocious puberty, for example, was approved by the U.S. Food and Drug Administration

² Headache Classification Committee of the International Headache Society (IHS). The international classification of headache disorders, 3rd edition. Cephalalgia. 2018;38(1):1-211.

³ Steiner TJ, Jensen R, Katsarava Z, et al. Aids to management of headache disorders in primary care, 2nd edition. J Headache Pain. 2019;20(1):57.

⁴ Powers SW, Coffey CS, Chamberlin LA, et al. Trial of amitriptyline, topiramate, and placebo for pediatric migraine. N Engl J Med. 2017;376(2):115-124; Ailani J, Lipton RB, Goadsby PJ, et al. Atogepant for the preventive treatment of migraine. N Engl J Med. 2021;385(8):695-706.

⁵ Cantor 282, Hruz 115, 145, and Levine 14.

⁶ See also "GnRH analogue medications have not been FDA approved for this use. The use of GnRH analogue medication for this purpose in adolescents is experimental as there have been no randomized controlled trials for this specific use case (Levine 75)."

(FDA) and is accepted as the standard of care based on observational studies and not RCTs. 7 Dr. Cantor's definition of experimental appears to be based on the conclusion that gender-affirming medical care is experimental, rather than as serving as the independent basis for this conclusion.

- 8. Dr. Laidlaw's contention that "Dr. Antommaria fails to recognize that the purpose and use of hormones and surgeries in [gender-affirming treatment] is fundamentally different than cardiopulmonary resuscitation for life support (192)" entirely mises the point. I cited the American Heart Association's guideline for Pediatric Basic and Advanced Life Support in my expert report as an example of the limited high- and moderate-quality evidence available in pediatrics. The purpose of gender-affirming medical care and cardiopulmonary resuscitation is irrelevant to the level of evidence that supports these practices.
- 9. The Defendants' experts emphasize the results of systematic reviews of the literature.⁸ The Cochrane Collaboration defines systematic reviews as follows: "A systematic review attempts to collate all empirical evidence that fits pre-specified eligibility criteria in order to answer a specific research question. It uses explicit, systematic methods that are selected with a view to minimizing bias, thus providing more reliable findings from which conclusion can be drawn and decisions made." Key characteristics of systematic reviews include grading the quality of the evidence. Systematic reviews have many critical roles including identifying future

⁷ HIGHLIGHTS OF PRESCRIBING INFORMATION. May 2017. Accessed February 26, 2023. Available at https://www.accessdata.fda.gov/drugsatfda docs/label/2017/020263s042lbl.pdf; Mul D, Hughes IA. The use of GnRH agonists in precocious puberty. Eur J Endocrinol. 2008;159(Suppl 1):S3-8; Carel JC, Eugster EA, Rogol A, et al. Consensus statement on the use of gonadotropin-releasing hormone analogs in children. Pediatrics. 2009;123(4):e752-762.

⁸ Cantor 70-87, Hruz 120, 133, Levine 134-137, 176, 228-236, and Laidlaw 179.

⁹ The Cochrane Collaboration. "What is a systematic review?" in Cochrane Handbook for Systematic Reviews of Interventions. Version 5.1.0. ed. Higgins JPT, Green S. March 2011. Accessed May 26, 2023. Available at https://handbook-5-

research priorities. 10 In contrast to clinical practice guidelines, they do not, however, make treatment recommendations. 11 Dr. Laidlaw's statement that the conclusions of systematic reviews done by Sweden, Finland, the United Kingdom, and McMasters University "agree that the risks of puberty suppression and cross-sex hormones outweigh the possible benefits (176)" inappropriately confuses systematic reviews and clinical practice guidelines.

- 10. The quality of the evidence, as defined by a grading system, is only one factor considered in clinical practice guidelines when making recommendations and rating their strength. The other factors are the balance between the desirable and undesirable outcomes, the confidence in values and preferences and variability, and resource use. 12 Dr. Cantor's purported scientific expertise (9-15) is not sufficient for developing and rating treatment recommendations; clinical expertise is necessary to understand the potential benefits, risks, and patients' values and preferences, and to balance the potential benefits and risks from the patients' perspective.
- Dr. Cantor states that individuals who provide care to patients with gender 11. dysphoria have conflicts of interest (260, 292, 297). They do not have conflicts of interest in the relevant sense. If treatment were hypothetically to change, providers would continue to be compensated for providing this new treatment or treating patients with other conditions. It is unclear who Dr. Cantor expects to write clinical practice guidelines if not experts in the field. Professional organizations have mechanisms to screen potential authors of clinical practice guidelines for real conflicts of interest such as compensation from or equity interest in

¹⁰ Page MJ, McKenzie JE, Bossuyt PM, et al. The PRISMA 2020 statement: An updated guideline for reporting systematic reviews. BMJ. 2021;372:n71.

¹¹ National Heart, Lung, and Blood Institute. About systematic evidence reviews and clinical practice guidelines. Accessed May 26, 2023. Available at https://www.nhlbi.nih.gov/node/80397. ¹² Andrews JC, Schunemann HJ, Oxman AD, et al. GRADE guidelines: 15. Going from evidence to recommendation-determinants of a recommendation's direction and strength. J Clin *Epidemiol.* 2013;66(7):726-735.

pharmaceutical manufacturers.

- Several of the Defendants' experts cite comments made by Gordon Guyatt 12. regarding the Endocrine Society's and World Professional Association for Transgender Health's (WPATH's) clinical practice guidelines.¹³ These comments appear in a features article¹⁴ written by an independent journalist¹⁵ rather than in a peer reviewed article written by Dr. Guyatt himself. One of the potential criticisms is that the Endocrine Society's clinical practice guideline makes strong recommendations based on low- or very low-quality evidence. The Grading of Recommendations Assessment, Development and Evaluation (GRADE) approach does not, however, preclude this from being done and identifies 5 situations in which it is appropriate.¹⁶ The Defendants' experts have not shown that none of these criteria apply to the Endocrine Society's guideline. They instead seem to categorically dismiss this guideline based on allegations about its methods or results that also apply to clinical practice guidelines unrelated to gender dysphoria. Table 1 (Exhibit B) of my expert declaration shows that 26 of the American Heart Association's 130 recommendations (20%) in its Guideline for Pediatric Basic and Advanced Life Support are strong recommendations based on limited data.¹⁷
 - 13. Several of the Defendants' experts cite disclaimers that appear in the Endocrine

¹⁴ Block J. Gender dysphoria in young people is rising-and so is professional disagreement. *BMJ*. Feb 23 2023;380:382.

¹³ Hruz 98-99.

¹⁵ Jennifer Block. Bio. Accessed May 21, 2023. Available at http://jenniferblock.com/bio/.

¹⁶ Andrews JC, Schunemann HJ, Oxman AD, et al. GRADE guidelines: 15. Going from evidence to recommendation-determinants of a recommendation's direction and strength. J Clin Epidemiol. 2013;66(7):726-735.

¹⁷ Topjian AA, Raymond TT, Atkins D, et al. Part 4: Pediatric basic and advanced life support: 2020 American Heart Association guidelines for cardiopulmonary resuscitation and emergency cardiovascular care. Circulation. 2020;142(16 suppl 2):S469-S523. These clinical practice guidelines use different terminology than the GRADE approach for describing the quality of the evidence and the strength of recommendations.

Society's and WPATH's clinical practice guidelines and systematic reviews accompanying WPATH's clinical practice guideline. ¹⁸ The disclaimers in the guidelines emphasize that clinicians must use their judgment in applying the guideline's recommendations to individual patients. When Dr. Levine emphasizes that "The 2017 Endocrine Society Guidelines themselves expressly state that they are *not* 'standards of care (80, italics in original)," he inappropriately relies on the differences between the colloquial use of the term "standard of care" and its technical meaning in malpractice litigation. A provider who deviates from the guidelines does not inherently commit malpractice, i.e., violate the standard of care. The disclaimer on the systematic review reinforces the independence of the review from WPATH, the type of independent evaluation for which Dr. Cantor calls (4).

European Statements

- 14. The Defendants' experts reference the reports and decisions of European agencies. 19 Most importantly, no European country has banned gender-affirming medical care as has Tennessee. The experts' appeals to this material do not undermine the Endocrine Society's and WPATH's clinical practice guidelines for several reasons including (i) the sources are frequently not available in official English translation, (ii) the experts misrepresent or incompletely report this material, and (iii) they hold this material to a different standard.
- 15. No European country has banned gender affirming medical care as has Tennessee. The only categorical prohibition of a form of gender-affirming medical care appears to be the Finnish Council for Choices in Health Care's statement, "Surgical treatments are not part of the treatment methods for dysphoria caused by gender-related conflicts in minors." Pubertal

¹⁸ Cantor 92-93, 254, Levine 80, and Laidlaw 175.

¹⁹ Cantor 16-33, Hruz 131, Roman 7, 18, and Levine 77. Cf., Laidlaw 229.

suppression and gender affirming hormone treatment are nonetheless permitted for minors in Finland.²⁰ Furthermore, Tennessee appears to not only ban gender-affirming medical care but also the research on gender-affirming medical care for which the Defendants' experts and these European countries call.

Much of the material on which the Defendants' experts rely is not available in 16. official English translations. Dr. Cantor, for example, references two Finnish documents, Pasternack 2019 (22) and COHERE Recommendation 2020 (24), quoting from the latter. These documents are in Finnish and there are not official English translations, not even of a summary.²¹ Dr. Cantor's Curriculum Vita, Appendix 1, does not indicate that he has reading competency in Finnish. There are sound reasons to believe Google Translate is unreliable to translate medical documents.²² Drs. Hruz (Footnotes 306, 315, 316) and Román (Footnote 10) reference

²⁰ Palveluvalikoima. Summary: Medical treatment methods for dysphoria associated with variations in gender identity in minors – recommendations. June 16, 2020. Accessed May 21, 2023. Available at

https://palveluvalikoima.fi/documents/1237350/22895008/Summary minors en+(1).pdf/fa2054c 5-8c35-8492-59d6-b3de1c00de49/Summary minors en+(1).pdf?t=1631773838474.

²¹ Pasternack I, Söderström I, Saijonkari M, Mäkelä M. Lääketieteelliset menetelmät sukupuolivariaatioihin liittyvän dysforian hoidossa. Systemaattinen katsaus. May 15, 2019. Accessed May 21, 2023. Available at

https://palveluvalikoima.fi/documents/1237350/22895008/Valmistelumuistion+Liite+1.+Kirjallis uuskatsaus.pdf/5ad0f362-8735-35cd-3e53-

³d17a010f2b6/Valmistelumuistion+Liite+1.+Kirjallisuuskatsaus.pdf?t=1592317703000;

Palveluvalikoima. Palveluvalikoimaneuvoston suositis: Alaikäisten sukupuoli-identiteetin variaatioihin liittyvän dysforian lääketieteelliset hoitomenetelmät. Accessed May 21, 2023. Available at

https://palveluvalikoima.fi/documents/1237350/22895008/Alaik%C3%A4iset_suositus.pdf/c987 <u>a74c-dfac-d82f-2142-684f8ddead64/Alaik%C3%A4iset</u> suositus.pdf?t=1592317701000. See also Roman's (21) reference to Trysell K. De flesta har skärpt rutiner för ny hormonbehandling hos minderåriga. September 9, 2021. Accessed May 21, 2023. Available at https://lakartidningen.se/aktuellt/nyheter/2021/08/de-flesta-har-skarpt-rutiner-for-nyhormonbehandling-hos-minderariga/.

²² Cornelison BR, Al-Mohaish S, Sun Y, Edwards CJ. Accuracy of Google Translate in translating the directions and counseling points for top-selling drugs from English to Arabic, Chinese, and Spanish. Am J Health Syst Pharm. 2021;78(22):2053-2058.

documents posted on the Society for Evidence Based Gender Medicine's website and translated by the organization. This is an advocacy organization²³ and it does not provide documentation that the translations were performed by a certified translator.²⁴ Other documents have broken links²⁵ or original sources are not specified.²⁶ It, therefore, is difficult to evaluate the Defendants' experts' claims and one must question how they are able to make them in the first place.

With respect to the experts' characterization of these materials, they are 17. frequently inaccurate or incomplete. Dr. Cantor, for example, asserts "These range from medical advisories to outright bans on the medical transition of minor (16)." As described above, no European county has banned the medical transition of minors. Some experts reference the British High Court opinion in Bell v. Tasistock without acknowledging that this ruling was overturned

²³ Society for Evidence Based Gender Medicine. About Us. Accessed May 21, 2023. Available at https://segm.org/about us.

²⁴ See, for example, Palveluvalioima. SEGM unofficial translation: Recommendation of the Council for Choices in Health Care in Finland (PALKO / COHERE Finland). Accessed May 21, 2023. Available at

https://segm.org/sites/default/files/Finnish Guidelines 2020 Minors Unofficial%20Translation

²⁵ The link to Swedish Socialstyrelsen Support 2022 (Cantor 25), https://www.socialstyrelsen.se/globalassets/sharepointdokument/artikelkatalog/kunskapsstod/202 2-2-7774.pdf, resulted in a 404 error when I attempted to access the page on May 21, 2023. ²⁶ Cantor quotes from "a new policy statement" from the Karolinska Institute, Karolisnka 2021, but does not provide a source for this statement in his references or clarify who translated it. See also Ukom 2023. While this document does appear to be available on the internet, it is only available in Norwegian. Ukom. Pasientsikkerhet for barn og unge med kjønnsinkongruens. March 9, 2023. Accessed May 21, 2023. Available at https://ukom.no/rapporter/pasientsikkerhetfor-barn-og-unge-med-kjonnsinkongruens/sammendrag.

on appeal²⁷ or incorrectly stating that it is still being appealed.²⁸ Finally, some experts emphasize that these countries constrain the provision of gender-affirming medical care to research protocols²⁹ without acknowledging that this research need not be randomized controlled trials. For example, the Swedish National Board of Health and Welfare (NBHW) states, "To ensure that new knowledge is gathered, the NBHW further deems that treatment with GnRH-analogues and sex hormones for young people should be provided within a research context, which does not necessarily imply the use of randomized controlled trials (RCTs)."30 This undermines Dr. Cantor's claim that randomized controlled trials are feasible (286).

None of these documents meet the standards to which the Defendants' experts 18. hold the Endocrine Society and WPATH. The Swedish National Board of Health and Welfare summary of its December 2022 National Guidelines for the care of children and adolescents with gender dysphoria, for example, does not clearly enumerate its recommendations. Some, but not all, of its recommendations are bulleted and bullets are also used to denote reasons for the recommendations. This makes it difficult to identify the recommendations. The quality of the

²⁷ Roman 7, 18. Cf., Cantor 18 and Laidlaw 229-30. See Bell v. The Tavistock and Portman NHS Foundation Trust [2021] EWCA Civ 1363 Appeal No. C1/2020/2142. September 17, 2021. Accessed May 22, 2023. Available at https://www.judiciary.uk/judgments/bell-and-another-v-thetavistock-and-portman-nhs-foundation-trust-and-others/. Also relevant and unmentioned is a separate case involving the Trust in which the High Court ruled that parents can consent to the use of GnRH analogues if their child does not dissent. See AC v. CD [2021] EWHC 741 (Fam) Case No. FD21P00063. March 26, 2021. Accessed May 22, 2023. Available at https://www.judiciary.uk/judgments/ac-v-cd-and-ors/.

²⁸ Levine 77. See The Supreme Court. Permission to appeal. Accessed May 22, 2023. Available at https://www.supremecourt.uk/news/permission-to-appeal-april-may-2022.html.

²⁹ Cantor 20, 21.

³⁰ Socialstyrelsen. Care of children and adolescents with gender dysphoria: Summary. Accessed May 21, 2023. Available at https://www.socialstyrelsen.se/globalassets/sharepointdokument/artikelkatalog/kunskapsstod/2022-3-7799.pdf. See also, The Cass Review. Independent review of gender identity services for children and young people: Interim report. February 2020. Recommendation 8, Page 22. Accessed May 21, 2023. Available at https://cass.independent-review.uk/publications/interim-report/.

evidence supporting each recommendation and the strength of the recommendation is not consistently specified. Finally, it does not appear from the summary that a systematic review of the literature was conducted in the formulation of each and every recommendation.³¹ The Defendants' experts appear to hold materials which they believe supports their position to a lower standard.

19. Finally, it should be noted that the Defendants' experts do not provide a systematic review of European policies; they selectively reference policies that they believe support their position.

Informed Consent for Gender-Affirming Medical Care

- 20. The Defendants' experts inappropriately focus on adolescents', rather than their parents', consent.³² Dr. Levine, for example, states "Given the considerable risk of harms, which include premature death and other less obvious problems discussed in this report, the question of whether minors may provide consent for medical and surgical treatments quickly arises (137, reference omitted)." Except in exceptional circumstances, for example, a minor has been emancipated by the court, the consent of parents or legal guardians is required for genderaffirming medical care for minors.
- 21. Dr. Nangia's claim "I don't believe that parents should be able to provide medical consent with minor assent for medical gender transition (135, see also 158)" highlights the ban's inconsistent treatment of different medical conditions. Dr. Nangia argues that "for a parent to provide consent to non-emergent treatment that stand to affect the rest of a minor's life in every

³¹ Socialstyrelsen: The National Board of Health and Welfare. Care of children and adolescents with gender dysphoria: Summary of national guidelines. December 2022. Accessed May 22, 2023. Available at https://www.socialstyrelsen.se/globalassets/sharepointdokument/artikelkatalog/kunskapsstod/2023-1-8330.pdf.

³² Levine 237 and Nangia 71.

area, and to do so without the minor's full ability to appreciate the above debate and potential long-term ramifications, violates the minor's future right to autonomy (135)."33 The ban however permits other medical treatments to which this statement would apply; the ban permits the performance or administration of medical procedures to treat a minor's congenital defect which includes differences of sex development (DSD) 68-33-103(b)(1)(A). Non-emergent medical procedures, to which parents can consent, to treat DSD which have similar long-term ramifications include feminizing genioplasty and gonadectomy. The ban treats different medical conditions inequitably and Defendants' experts' claims highlight the lack of justification for the differential treatment.³⁴

22. Claims that parents and legal guardians are inadequately informed or coerced lack empirical evidence. Dr. Levine, for example, asserts without supporting evidence that "Many affirmative care clinicians, because they don't understand the vital differences between suicidality and suicide, provide unethical coercive guidance commonly summarized as, 'Would you rather have a trans daughter than a dead son (205)?" Although he refers to minors, Dr. Hruz also makes an unsubstantiated empirical claim regarding informed consent: "Using 'affirming' treatment on minors violates this essential principle by using experimental treatments on vulnerable population without properly informing them of the actual risks and limitations of treatment (114)." He provides no evidence that parents or their adolescent children are not

³³ Dr. Nangia's claim is inapplicable to gender-affirming medical care because this medical care is not "non-emergent"; delaying gender-affirming medical care permits the development of secondary sexual characteristics inconsistent with an individual's gender identity that are irreversible.

³⁴ Dr. Nangia also provides cosmetic surgery in minors, specifically breast augmentation for patients under 18 years old, as an example of a procedure for which it is difficult to obtain meaningful informed consent (159-161). This procedure, however, also appears to be permitted under the ban if it is not performed as part of gender-affirming medical care.

properly informed. Even if these claims were true, and I am not conceding that they are, there are other less restrictive means to address inadequate informed consent than banning genderaffirming medical care. Such means include credentialing,³⁵ licensing,³⁶ and malpractice litigation.³⁷

23. Claims that parents cannot understand the relevant information is also without foundation. Dr. Levine, for example, claims, "[parents] cannot be expected to understand the limitations of the science pointed out by the Swedish systemic review (237)."38 Why not? Parents can understand that gender-affirming medical care might not have the benefits predicted and that it might have future risks that have not yet been proven such as effects on executive function. When parents enrolled their children in clinical trials of COVID-19 vaccines, for example, they understood that the vaccine might not be effective and that there were potentially unknown side-effects. This is in the context of an irreversible intervention; a vaccine cannot be removed once administered. Even after COVID-19 vaccines were authorized by the FDA for pediatric age groups, there remained uncertainty about side-effects both because the vaccines were tested on relatively small groups of children and because follow up had been for a limited time. The FDA issued an Emergency Use Authorization for the Pfizer-BioNTech vaccine for children 5 to 11 years of age based on studies of approximately 4,700 children and examined the

³⁵ Patel R, Sharma S. Credentialing. *StatPearls*. October 30, 2021. Accessed May 22, 2023. Available at https://www.ncbi.nlm.nih.gov/books/NBK519504/.

³⁶ Federation of State Medical Boards. About Physician Discipline. Accessed May 22, 2023. Available at https://www.fsmb.org/u.s.-medical-regulatory-trends-and-actions/guide-to-medicalregulation-in-the-united-states/about-physician-discipline/.

³⁷ Dobbs D, Hayden P, Bublick E. Liability of health care providers. *Hornbook on Torts*. 2nd ed. West Academic Publishing; 2016.

³⁸ See also Hruz 111.

risk of contracting COVID-19 7 days after the second dose.³⁹ Decisions parents make regarding gender-affirming medical care are comparable to other decisions that they make for their children, which the Defendants' experts do not appear to challenge.

- 24. Dr. Nangia asserts that the tasks necessary for a minor to provide informed consent for gender-affirming medical care are insurmountable (119, see also 132-134, 152-156, 168). 40 She, however, acknowledges that the MacArthur Competence Assessment Tool (MacCAT) has been shown to be valid and reliable in children (79). Lieke J.J.J. Vrouenraets and colleagues used the treatment version of this tool to assess the capacity of transgender adolescents, who had completed their diagnostic evaluation and were ready to start puberty suppression, to consent. (Individuals who were not yet Tanner Stage 2 or who had serious psychiatric conditions or psychopathology that would interfere with treatment were appropriately not included in this study.) Seventy-three adolescents participated. Their mean age was 14.71 years old, and their ages ranged from 10.63 to 18.34. Sixty-six (89.2%) of the participants were judged to have medical decision-making capacity using this tool.
- 25. Dr. Nangia does not discuss this study and the potential reasons for the significant discrepancy between her opinion and this evidence. One potential confounder is her belief in the efficacy of exploratory therapy (117) and her view that "impulse-prone" adolescents are more likely to choose gender-affirming medical care because they perceive it to be "quicker" (118). Dr. Nangia, however, does not present evidence for the efficacy of what she characterizes as exploratory therapy to treat gender dysphoria. Dr. Levine, one of the Defendants' other experts,

³⁹ U.S. Food & Drug Administration. FDA authorizes Pfizer-BioNTech COVID-19 vaccine for emergency use in children 5 through 11 years of age. October 29, 2021. Accesses May 21, 2023. Available at https://www.fda.gov/news-events/press-announcements/fda-authorizes-pfizerbiontech-covid-19-vaccine-emergency-use-children-5-through-11-years-age.

states, "To my knowledge, there is no evidence beyond anecdotal reports that psychotherapy can enable a return to male identification for genetically male boy, adolescents, and men, or return to female identification for genetically female girls, adolescents, and women (45)." Dr. Cantor would emphasize that this is one of the lowest, if not the lowest, levels on the Pyramid of Standards of Evidence (Figure 1, Page 18).

26. The logical conclusion of some of the experts' views is that the age of majority should be increased until individuals have completed their neurological development in their mid-20s. Dr. Román, in fact, claims, "It is my opinion that the irreversible measure of sterilization should not be carried out until the age of 25 [when the frontal lobe matures], and it is therefore appropriate to have the same age limit for gender reassignment treatment for gender dysphoria (39)." The ban does not however prohibit all sterilizing procedures on minors, demonstrating again the inequitable treatment of gender-affirming medical care and other forms of medical treatment. Although sterilization is not the intent of gender-affirming medical care and the potential infertility caused by pubertal suppression and gender-affirming hormones is not universal or always permanent, treatments permitted by the law, including gonadectomy in minors with DSD, cause permanent infertility.

Conclusion

27. My review of the Defendants' experts' reports has not provided me reason to change my opinion that "there is no sound medical or ethical basis to prohibit healthcare professionals from providing gender-affirming medical care to minors. Doing so puts clinicians in the untenable position of having to harm their patients and violate their integrity and ethical obligations due to the threat of losing their licenses and incurring economic penalties."

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

Executed on: May 29, 2023

ARMAND H. MATHENY ANTOMMARIA, MD, PhD

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CERTIFICATE OF SERVICE

I hereby certify that on June 1, 2023, the undersigned filed the foregoing document via this Court's electronic filing system, which sent notice of such filing to the following counsel of record:

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