Supplemental Expert Report of
Dr. Farr Curlin, M.D.

Boe v. Marshall

United States District Court
Middle District of Alabama
Northern Division

Table of Contents

I. CREDENTIALS

1. I am the Josiah C. Trent Professor of Medical Humanities in the Trent Center for Bioethics, Humanities, and History of Medicine, and Professor in the Department of Medicine, at Duke University. I am also Co-Director of the Theology, Medicine, and Culture Initiative at Duke Divinity School and Senior Fellow in Duke University's Kenan Institute for Ethics. Prior to joining the Duke University faculty in January 2014, I served on the faculty of the University of Chicago.

2. I am licensed to practice medicine and maintain medical licensure in the State of North Carolina. I am an internist with board certification in Internal Medicine, as well as subspecialty board certification in Hospice and Palliative Medicine. From 2001 to 2013, I practiced general internal medicine, maintaining an outpatient primary care clinic from 2001 to 2008, and attending on the inpatient wards at the University of Chicago Hospitals from 2003 until I moved to Duke University at the end of 2013. Since January 2014, I have served as a palliative medicine consultant and hospice physician at Duke University.

3. I completed a fellowship in clinical medical ethics at the University of Chicago, and I have served on the medical ethics faculties of the University of Chicago and Duke University for 19 years, providing clinical ethics consultations (at the University of Chicago), attending regular ethics case conferences, teaching medical ethics, and completing research studies and other scholarly work regarding medical ethics. In addition, I was named to the Greenwall Foundation Faculty Scholars Program in Bioethics, through which, over the subsequent decade, I met numerous times with a community of leading scholars in bioethics.

4. My work on medical ethics has included peer-reviewed publications, invitations to lecture at universities nationwide and internationally, and being asked to speak as an expert before national advisory bodies. I have received awards in bioethics. My training, research, and experience give me familiarity with professional ethical norms regarding clinical medicine—their content, history, and application to clinical contexts, including the context of "gender affirmation." As reflected in my CV, I have published an academic book that addresses, and have given invited talks at a major medical school concerning, ethical issues surrounding transgender medicine.

5. In addition, I completed a two-year postdoctoral fellowship in health services research at the University of Chicago, and I have spent a substantial portion of my time since then conducting and publishing empirical research, including research on physicians' attitudes and practices regarding controversial practices. This training and experience give me added expertise in interpreting and applying scientific data to clinical contexts. My credentials and experience are

documented in further detail in my curriculum vitae, which I attach as Appendix B to this Report.

6. This report presents my independent, expert opinions based on my study, training, and experience as a physician, biomedical ethicist, and health services researcher; my review of relevant scholarly literature; and my discussions over the years with colleagues in medicine and bioethics. I do not speak herein for Duke University, nor is the affidavit intended to represent the opinions or policies of Duke University. I am being compensated for my time spent on this matter at a rate of $500 per hour, and $250 per hour for time spent on travel required to give testimony.

7. My most recent curriculum vitae, which lists my publications and my testimony provided within the last four years, is provided as Appendix B to this Report.

II. MATERIALS REVIEWED

8. As part of my preparation of this report, I have reviewed the materials listed in Appendix A to this Report.

III. QUESTIONS ADDRESSED

9. Dr. McNamara has asserted that "no institutional review board would approve a research protocol on a randomized control trial in essential medical treatment for gender dysphoria because of the established science which demonstrates the efficacy of treatment with transitioning medications." (McNamara Report 20-21.) Similarly, Dr. Antommaria states that "For randomized trials to be ethical, clinical equipoise must exist; that is, there must be uncertainty about whether the efficacy of the intervention or the control is greater." He asserts that a randomized trial in which the control group does not receive puberty blockers or cross-sex hormones would be unethical. (Antommaria Report 15-16.)

10. More recently, the Intervenor United States, through its agency the FDA, has issued a letter stating that it would be "reasonable" to include males down to age 13 in a clinical trial of cross-sex administration of estradiol as a medicalized gender transition ("MGT") treatment,[1] while suggesting that such a trial need not include a placebo control.[2] Meanwhile, the American Academy of Pediatrics (AAP), which has submitted an amicus brief in this case and which issued the 2018 "Policy Statement" which Plaintiffs and their experts have cited to this Court, recently

---

[1] In this report I use the term "medicalized gender affirmation" to refer to the use of puberty blockers and cross-sex hormones in patients experiencing gender dysphoria.

[2] https://www.statnews.com/2023/11/28/fda-gender-affirming-care-estrogen-approval/.

submitted a brief in another litigation addressing restrictions on MGT for minors in which the AAP asserted:

> '[I]n transgender clinical research individual randomized controlled trials (RCTs) may not always be feasible or ethically acceptable.' Sari L. Reisner et al., Advancing Methods for U.S. Transgender Health Research, 23(2) Curr. Opin. Endocrinal Diabetes Obes. 198, 199 (2016). With preexisting guidelines that recommend gender-affirming care for those with gender dysphoria, randomized controlled trials would violate the principle of equipoise, which safeguards the rights of individual trial participants. Richard J. Lilford & Jennifer Jackson, Equipoise and the Ethics of Randomization, 88 J. R. Soc. Med. 552, 552 (1995).[3]

11. Plaintiffs will likely claim that this letter from the FDA and this statement from the AAP support their experts' contention that it is unethical to withhold medical transition from minors.

12. I have been asked to give my expert opinion regarding whether withholding medicalized "gender affirmation" or "gender transition" treatments (MGT) from minors, whether to provide a control arm in a clinical experiment, or out of concern for potential harm to the patients, is consistent with the principle of equipoise in clinical research and other well-established principles of medical ethics.

IV. SUMMARY OF OPINIONS

13. While I set out my opinions throughout this report, I summarize here key aspects of those opinions.

14. I take as a premise, based on the science reviewed and the opinions offered by Drs. Cantor and Laidlaw, that the mental health benefits that are claimed to justify the administration of medicalized gender affirmation treatments to minors are currently unproven and disputed among informed observers. Position statements from professional associations cannot substitute for scientific evidence.

15. I also take it as a premise, based on the science reviewed and the opinions offered by Drs. Cantor and Laidlaw, that the known or reasonably anticipated harms to children and adolescents from MGT treatments are substantial and serious, threatening sterilization, failure to develop healthy sexual

---

[3] Brief of Amicus Curiae American Academy of Pediatrics submitted to the Supreme Court in *Williams et al. v. Skrmetti* (No. 23-466) on Petition for a Writ of Certiorari, dated December 4, 2023, at 22 n. 72.

response, impaired neurological (brain) development, and multiple other harms to bodily health.

16. There is not a consensus among medical professionals that MGT is beneficial or suitable for minors. This is amply supported by the published literature and the evaluations and position statements of a number of national health authorities of respected jurisdictions. Further, I know from my own experience and that of professional peers that both what is said and what is published in this field is severely distorted by what is sometimes referred to as a "cancel culture," with professionals fearing for their reputations and even their employment and livelihoods if they criticize or raise concerns about administration of MGT to minors, whether in scientific publications or in public discussion.

17. It is not possible to conclude that it is known beyond "equipoise" that MGT is on the whole beneficial for minors who suffer from gender dysphoria. Therefore, the ethical principle of equipoise does not prohibit including control groups that receive only psychological counseling but not MGT in studies to evaluate the benefits and harms of MGT. Nor is there a basis to assert that it is unethical to withhold MGT from minors in a clinical setting *outside* the context of formal clinical experimentation.

18. On the contrary, for multiple reasons there is a serious question whether it is allowable, under accepted principles of medical ethics, to administer MGT to minors. Based on the descriptions of the available science provided by Dr. Cantor, Dr. Laidlaw, and position statements from national health authorities, it appears that animal studies that could give meaningful information about potential harms of MGT (including sterilization, brain development, bone development, and cardiovascular health) have not yet been done; that well-designed studies to evaluate both harms and efficacy have not been conducted; and that plans for careful long-term monitoring and management of reasonably anticipated risks of such disruptions of natural hormone levels and bodily maturation and function have not been identified and followed.

19. Further, it is not at all clear that meaningful informed consent for administration of MGT to minors can be obtained. There are strong reasons to doubt that minors can adequately appreciate and appropriately weigh the lifetime implications of sterilization, loss of sexual response, impaired neural development, and the other potential health and relational impacts identified in the literature, nor is it apparent that doctors possess (much less consistently disclose) adequate scientific information about these risks to enable anyone to make meaningfully informed decisions. Nor do ethical principles give parents unfettered power to provide effective consent on behalf of their children for medical interventions that pose such severe risks of irreversible harm to the bodily health of the child (including sterilization) in the absence of a countervailing and imminent threat of

bodily harm from a medical condition to be treated. No such imminent threat exists in the case of minors who experience gender dysphoria.

V. THE SCIENTIFIC CONTEXT RELEVANT TO ETHICAL ANALYSIS.

A. The hoped-for benefits from MGT are unproven.

20. I have read the descriptions of the state of knowledge provided in the expert reports submitted by Drs. Cantor and Laidlaw. I have been asked to and do assume that the descriptions of the articles and studies that they provide are accurate for purposes of forming my opinions provided in this case. On that basis, it is evident that multiple respected health authorities and sources have recently opined that the safety and efficacy of hormonal interventions to treat gender dysphoria in minors remain uncertain and unproven. While I rely on Dr. Cantor's and Dr. Laidlaw's descriptions of the scientific literature, I have myself also reviewed the illustrative examples that I summarize below.

21. An extensive review commissioned by England's National Health Service and chaired by eminent pediatrician Dr. Hilary Cass concluded that there has been "very limited research on the sexual, cognitive, or broader developmental outcomes" from the use of puberty blockers for gender dysphoria (Cass 2022 at 19), that it is an unanswered question "whether the evidence for the use and safety of [puberty blockers] is strong enough as judged by reasonable clinical standards" (Cass 2022 at 37), and that "the available evidence was not strong enough to form the basis of a policy position" with regard to use of both puberty blockers and cross-sex hormones in minors (Cass 2022 at 35).

22. Systematic reviews of the safety and efficacy of puberty blockers and cross-sex hormones as treatment for gender dysphoria in minors have been conducted by the England National Institute for Health & Care Excellence (NICE). These reviews concluded that available clinical evidence of efficacy and safety in the relevant population is uniformly of "very low quality." (Cantor ¶¶ 79-84.) "Very low quality" within the GRADE system of evaluation of medical information means: "We have very little confidence in the effect estimate: The true effect is likely to be substantially different from the estimate of effect." (GRADE Handbook at 13 (Section 5).)

23. In 2022, the Swedish National Board of Health commissioned its own systematic review and concluded that "the evidence on treatment efficacy and safety is still insufficient and inconclusive for all reported outcomes," and that "[f]or adolescents with gender incongruence, the . . . risks of puberty suppressing treatment with GnRH-analogues and gender-affirming hormonal treatment currently outweigh the possible benefits." (Cantor ¶¶ 28, 86; Swedish Socialstyrelsen Support 2022 at 10-12.)

24. In 2022, Norway's Healthcare Investigation Board (Ukom) concluded that "The knowledge base, especially research-based knowledge for gender-affirming treatment (hormonal and surgical), is insufficient and the long-term effects are little known" and that "This applies particularly to the teenage population." (Cantor ¶ 30-31; Ukom 2023, Summary and Section 7.)

25. In 2020, the Finnish Council for Choices in Health Care in Finland concluded that medical transition of minors "is an experimental practice." (Cantor ¶ 169, quoting COHERE Recommendation (2020) translation.) Dr. Riittakerttu Kaltiala, Chief Psychiatrist in the Department of Adolescent Psychiatry at Finland's Tampere University Hospital, has recently stated that young people who received MGT were "deteriorating" rather than "thriving," that her clinic has observed gender dysphoria spreading like a "social contagion" among teenage girls, and that increasing numbers of patients have begun returning to their clinic saying that they now regret their transition. (Kaltiala 2023b [Free Press Interview].)

26. Even the WPATH organization, which strongly advocates for medical transition of minors, repeatedly acknowledges the absence of vital science in its recently released and self-designated "Standard of Care" version 8 (SOC 8). The SOC 8 notes that a 2014 Dutch study "is the only study that followed youth from early adolescence... through young adulthood" (SOC 8 at S46) and "It is not clear if deviations from [the age and mental and social health screening requirements of the Dutch study approach] would lead to the same or different outcomes" (at S65). It also acknowledges that, "Despite the slowly growing body of evidence supporting the effectiveness of early medical intervention, the number of studies is still low, and there are few outcome studies that follow youth into adulthood." It adds, "A key challenge in adolescent transgender care is the quality of evidence evaluating the effectiveness of medically necessary gender-affirming medical and surgical treatments." (at S45-46.)

27. Studies summarized by Drs. Cantor and Laidlaw likewise document serious uncertainty about the efficacy and safety of MGT as a treatment for gender dysphoria. (Cantor ¶¶ 148-154, 178-201; Laidlaw ¶¶ 90-175.)

28. For example, a study from the Tavistock and Portman clinic in the UK found, "Relative to the time point before beginning puberty suppression, there were no significant changes in any psychological measure, from either the patients' or their parents' perspective." (Cantor ¶ 186.)

29. Multiple other studies have found persistently high suicide rates after MGT. (Cantor ¶ 149.) A cohort study of minors by Kuper et al. found that suicidal ideation, suicidal attempts, and non-suicidal self-injury all went up after starting MGT (Cantor ¶ 1521), and, "No studies have documented any reduction in suicide rates in minors (or any population) as a result of medical transition" (Cantor ¶ 148), a fact acknowledged by WPATH (Cantor ¶ 150).

30. I also reviewed two large and very recent studies discussed in Dr. Cantor's supplemental report dated February 2, 2024. The first (Glintborg 2023) examined the medical records of all individuals in Denmark diagnosed with gender dysphoria or gender incongruence from 2000 through 2021 (3812 patients, among whom 2089 underwent MGT). That study found that prescriptions of psychoactive medications increased rather than decreased after the start of MGT and remained elevated across multiple years. (Glintborg 2023 at. 341.) It also found that measures of negative mental health, compared against controls, "were stable after initiation of gender-affirming hormone treatment, without sign of decrease after date for first prescription of gender-affirming hormone." (at 342:2.) That is, the mental health of the patients who received MGT did not improve on average.

31. The second study (Kaltiala 2023) examined the medical records of persons who had contacted the national gender identity service of Finland between 1996 and 2019 (3665 persons) and compared them to age and sex-matched controls. That study found that the need for psychiatric treatment did not go down after MGT interventions. (Kaltiala 2023 at 2:1.) The authors referenced similar findings from an earlier study and noted, "Their findings and ours do not suggest that medical GR interventions resolve psychiatric morbidity among people experiencing gender distress." (at 6:1.)

32. Finally, I have reviewed the expert reports of Drs. McNamara, Antommaria, and Ladinsky and note that none of those reports cite any study that has found that medical transition reduced suicides in any population.

33. All of this contradicts the plaintiffs' claim that MGT is medically necessary, since an intervention cannot be said to be medically necessary if the benefits of the intervention are unproven, or indeed are cast into serious doubt by the most recent large-scale studies.

B. The risks of harm from MGT are substantial and serious.

34. While the benefits of MGT for minors are at best unproven, the evidence summarized by Drs. Cantor and Laidlaw also indicates that MGT in minors poses risk of objective, often irreversible, harms to health, while also requiring life-long dependence on medical interventions.[4]

---

[4] McNamara writes, "The overwhelming majority of adolescents who receive transitioning medications continue to do so as adults." (McNamara at 23.)

35. Risks of harm recognized in the literature include:

a. Sterilization (Cantor ¶¶ 206-207; Laidlaw ¶¶ 90-98, 157-159);

b. Lifetime lack of orgasm and sexual function (Cantor ¶ 208)—an adverse effect acknowledged by Marci Bowers, current president of WPATH (Cantor ¶ 209; Laidlaw ¶¶ 99-100);

c. Potential adverse effects on neurological and cognitive development (Cass Review Letter 2022 at 6; Cantor ¶¶ 210-214);

d. Reduced bone development, especially in male to female transition (Cantor ¶¶ 217 – 220; Laidlaw ¶¶ 101-112), the long-term effects of which have not been studied;

e. Harm to psychosocial development (Laidlaw ¶¶ 114-117); and

f. "Increased cardiovascular risk, osteoporosis, and hormone dependent cancers." (Cass 2022 at 36; Cantor ¶ 224; Laidlaw ¶¶ 126-129.)

36. The leading Swedish pediatric gender clinic, following a systematic review of the available scientific evidence commissioned by Sweden's National Board of Health, concluded that hormonal interventions in minors are "fraught with extensive and irreversible adverse consequences such as cardiovascular disease, osteoporosis, infertility, increased cancer risk, and thrombosis," and that "In light of the above, and based on the precautionary principle, which should always be applied, it has been decided that hormonal treatments (i.e., puberty blocking and cross-sex hormones) will not be initiated in gender dysphoric patients under the age of 16." (Karolinska 2021, cited in Cantor ¶ 27.)

C. The fact that a particular intervention is medically indicated for one condition in one population does not imply that it is medically or ethically defensible for a different condition in a different population.

37. The plaintiffs' experts have suggested that because the drugs used in MGT have been used to treat conditions such as precocious puberty and complete androgen insensitivity syndrome, it is unjust to prevent their use in minors with GD. But the plaintiffs' experts are comparing apples and oranges.

38. While treatments for precocious puberty and complete androgen insensitivity syndrome aim to preserve and restore healthy development of secondary sex characteristics, MGT intentionally blocks healthy development of those characteristics. As Dr. Cantor notes, the former aim "to bring the patient within healthy norms", while the latter "is applied precisely to take the patient outside of healthy norms." (Cantor ¶ 276.) Similarly, while the Court noted that

"Doctors have also long used hormone therapies for patients whose natural hormone levels are below normal" (Opinion and Order dated 05/13/22, at 18), MGT contradicts this medical pattern; rather than correcting hormone levels that are abnormal, it induces hormone levels that are abnormal.

39. Dr. McNamara asserts that MGT in minors is safe, because puberty blockers have long been prescribed "in adolescents with cancer who need menstrual suppression as they undergo marrow-ablative chemotherapy." (McNamara at 13.) But as Dr. McNamara concedes, "puberty blockers are used in these patients to protect their gonads from toxicity induced by chemotherapy as a means of fertility preservation", whereas, by contrast, MGT directly hinders and suppresses healthy gonadal development and function, harming fertility. In one case, the drugs have medicinal effects; in the case of MGT, the drugs have toxic effects. As a result, the ethical analysis is entirely different and opposite.

D. The fact that GD is listed as a disorder in the Diagnostic and Statistical Manual of Mental Disorders (DSM 5) does not imply that GD marks a disorder of the body that warrants MGT in minors.

40. McNamara notes that the DSM 5 identifies GD as a disorder. (McNamara at 15.) But the DSM is a manual specifically of what it terms "*mental* disorders" created by the American Psychiatric Association; it does not identify or provide diagnostic criteria for medical illnesses. The Plaintiffs have not identified any other "mental disorder" for which the indicated treatment is to block or damage the development of healthy organs and functions. On the contrary, MGT in minors contradicts ordinary medical standards with respect to disorders of perception. The person suffering GD perceives their objectively healthy secondary sex characteristics as not compatible with their mental self-perception and therefore needing to be suppressed. MGT problematically takes the minor's mental perception as sufficient reason to treat healthy anatomy and physiology as if it were diseased, thereby contradicting medicine's ordinary regard for the healthy body as its standard. To my knowledge, in no other case do we treat a disordered perception by treating normal physiology and anatomy as diseased. We do not, for example, prescribe hand soap to children who, because of obsessive compulsive disorder, misperceive their hands as needing to be washed repeatedly. We do not lock children indoors who, because of agoraphobia, fear going outside. We do not encourage fasting in patients with anorexia nervosa.

41. Indeed, there is one historical precedent where doctors have removed or damaged healthy tissue attempting to treat mental disorders—that is, performing lobotomies on patients who suffered from mental illnesses, including schizophrenia, depression, melancholy, and obsessive-compulsive disorder. As with MGT, "The treatment was introduced … despite the fact that little research had been carried out on its effects." (Torkildsen 2022.) As with MGT, in the absence of adequate scientific data, many people "were convinced that lobotomy reduced

suffering." As with MGT, "those who promoted the method, were driven by idealism and a strongly held belief that their treatment alleviated suffering," and they "gave overwhelmingly positive reviews of the efficacy of the treatment, while grossly under-communicating its adverse effects." Lobotomy has come to be seen "as one of the greatest mistakes in modern medicine" (Torkildsen 2022)—a prominent example of a collective scientific and ethical misstep by the medical profession that harmed many patients. In my opinion, MGT is likely to be judged the same, not least because it treats a disorder of perception as if it were a disorder of the body, harming the healthy body in efforts to reduce mental suffering.

E. Statements by U.S. medical and advocacy organizations do not establish that MGT is medically necessary.

42. As already summarized above, ample objective evidence demonstrates dissensus regarding MGT across the community of experts and clinicians. Indeed, the health authorities and independent bodies that have systematically reviewed the scientific evidence regarding MGT in minors have concluded that evidence is insufficient to justify the conclusion that MGT improves even mental health outcomes. Indeed, the recent large studies from Denmark and Finland have found that mental and behavioral disorders do not decrease after MGT. (Glintborg 2023 at 341, Kaltiala 2023 at 1.)

43. In contrast to these reviews of evidence, "The Endocrine Society guidelines do not rely on any systematic review of evidence of efficacy of any form of treatment for gender dysphoria." (Cantor ¶ 256.) The AAP's 2018 policy statement, "unique among the major medical associations in being the only one to endorse an affirmation-on-demand policy" (Cantor ¶ 257), was authored by one physician and likewise was not based on a systematic review of available evidence. The policy statement cited no new evidence to justify offering MGT rather than therapy and watchful waiting, and the statement is contradicted by the very reports it cited. (Cantor ¶ 257.) Meanwhile, "the systematic review on which WPATH based its standards for minors included exactly one study on puberty blockers and three studies on cross-sex hormones. All other references represent cherry-picked citations of studies rejected by its own systematic process. Moreover, even among the four studies in WPATH's review, three were rejected by the Swedish review, due to the low quality of the science they contained." (Cantor ¶ 250.) WPATH likewise cited no reference or rationale to justify removing minimum age restrictions for MGT.

F. If WPATH allowed the SOC 8 development process to be influenced by financial and other non-medical considerations, then WPATH's Standards of Care report is unreliable not only because it is contradicted by the evidentiary base, but also because it is the product of ethical misconduct.

44. My own review of SOC 8 indicates WPATH has problematically minimized the doctor's responsibility to exercise independent judgment and fiduciary responsibility to guide patient care for minors. In addition, Cantor and Laidlaw conclude that the WPATH committee members who participated in creating SOC 8 were subject to direct financial conflicts of interest as the guidelines would likely impact their own income (more procedures permitted, and increased insurance coverage, and their liability risk. (Laidlaw ¶ 187; Cantor Supp. ¶ 102-115, 119.) Insofar as these descriptions are accurate, then WPATH ignored significant conflicts of interest and violated accepted principles of medical ethics.

45. Beauchamp and Childress note:

> A conflict of interest exists when an impartial observer would determine that a professional's judgments, decisions, or actions are at risk of being unduly influenced by his or her personal interests, such as financial interests … The risk is that the professional's personal interests will create temptations, biases, and the like that will lead to a breach of role responsibilities through judgments, decisions, and actions other than those reasonably expected in the role. The reasonable expectation is that clinicians will seek the patient's welfare and respect his or her rights, that researchers will pursue objective and valid results, and so forth. A conflict of interest poses a risk that the professional in question will compromise these expectations and thereby damage patients' interests and rights, distort research, or teach trainees in a biased way. (Beauchamp and Childress at 328.)

46. As this explanation makes plain, it is beyond dispute that clinicians who practice (and are paid for) MGT have a conflict of interest in assessing whether MGT is supported by the evidence. It is problematic that this conflict of interest was neither mentioned in the SOC 8 report nor managed by including outside experts and perspectives in the standard-writing process. Insofar as changes in the recommendations were motivated not by dispassionate assessment of the data but by concern to protect clinicians' financial interests or professional reputations, or to further political or litigation agendas, that clearly "damage[s] patients' interests and rights, distort[s] research" and promulgates standards "in a biased way." All of this contradicts professional ethical norms and undermines trust in the medical profession. As Beauchamp and Childress also write, "Health care professions specify and enforce obligations for their members, thereby seeking to ensure that persons

who enter into relationships with these professionals will find them competent and trustworthy." (Beauchamp and Childress at 7.) If WPATH permitted its standard-development process to be dominated by individuals with a direct financial interest in providing the services covered by that document, without disclosing those conflicts of interest, then WPATH is neither competent nor trustworthy regarding its evaluations or advocacy of MGT.

G. The problematic influence of fear and intimidation on the scientific discourse relating to responses to gender dysphoria.

47. When confronted with claims of "medical consensus," the Court needs to be aware that social pressure and fear of censure within the United States medical and academic communities is affecting both what is published about MGT and the willingness of doctors to voice concerns about MGT.

48. Reuters recently published an investigative report documenting both growing concerns among physicians about MGT as well as intense backlash that clinicians, experts, and patients themselves have received when they voice such concerns. (Respaut 2022.)

49. I know from personal conversations with many medical ethicists and practitioners that doctors are afraid to speak up for fear of both social and employment repercussions, a problem also described by colleagues in Europe (Cass 28, Kaltiala 2023b).[5] I recently participated in a meeting of the Greenwall Faculty Scholars Program in Bioethics, which brings together a community of leading bioethicists nationwide. The meeting included a closed-door session titled, "Hot Topic: Bioethics Dilemmas in the Care of Transgender Minors." In that session, several colleagues voiced concerns, including a number of the ethical concerns I have raised in this report. Colleagues also expressed reservations about raising these concerns in public, for fear of being treated as a bigot or someone who is insensitive to the needs of people experiencing GD. This pattern reflects what the Cass report also reported in the UK, that clinicians there "are afraid of the consequences of ['taking a mental health approach to formulating a differential diagnosis'] in relation to gender distress because of the pressure to take a purely affirmative approach." (Cass 48.)

50. In December 2023 I participated in a meeting of the faculty of Duke University's Trent Center for Bioethics, Humanities & History of Medicine focused on this topic. In that meeting several faculty members voiced similar concerns about MGT and similar fears about speaking up. In November 2023 I gave an invited

---

[5] Kaltiala writes: "… health providers were failing to speak up. I understood this silence. Anyone, including physicians, researchers, academics, and writers, who raised concerns about the growing power of gender activists, and about the effects of medically transitioning young people, were subjected to organized campaigns of vilification and threats to their careers." (Kaltiala 2023b.)

lecture on this topic at the University of Chicago's MacLean Center for Clinical Medical Ethics, and there more than one colleague told me that they feared speaking up about their concerns regarding MGT, and that they had observed that other colleagues at the University, when they learned of the topic, had sought to have me disinvited prior to the lecture. After the lecture an undergraduate student waited until everyone who wanted to talk to me had left, and then came up and quietly thanked me for speaking up about the ethical problems with MGT for minors. She said that she had been on the pathway to MGT a few years before, but as she had gone through puberty she slowly had come to grips with being a woman and now calls herself a desister.

51. Both medical students and faculty at Duke University, where I am employed, have told me that they fear voicing concerns about MGT, and I probably would not have felt able to voice my own concerns were I not tenured. Having voiced my concerns, I was cancelled from giving a talk on an unrelated topic at Michigan State University spring of 2022, because students alleged that they would not feel safe listening to me lecture on that topic due to the concerns I had expressed elsewhere about MGT. I have found resistance to hosting public dialogue and debate about the topic even among colleagues that agree that MGT is ethically problematic. All of this makes evident that fear is muzzling open expression of widespread and growing dissent within the medical community regarding MGT.

VI. APPLICATION OF PRINCIPLES OF MEDICAL ETHICS TO THE STATE OF SCIENTIFIC KNOWLEDGE CONCERNING THE BENEFITS, HARMS, AND RISKS OF MGT.

A. The state of evidence does not support the conclusion that the ethical principle of equipoise forbids withholding MGT from minors, including in studies in which a control group does not receive MGT.

52. Benjamin Freedman, the bioethicist who first promoted the concept of equipoise in clinical research, has written, “The ethics of clinical research requires equipoise — a state of genuine uncertainty on the part of the clinical investigator regarding the comparative therapeutic merits of each arm in a trial.” (Freedman 1987.) In their respected textbook, *Principles of Biomedical Ethics*, Beauchamp and Childress note that “[t]he community of reasonable physicians is … in a state of ‘clinical equipoise’” when “No one knows, prior to conducting the research, whether it is more advantageous to be in the control group or in the experimental group … No patient, then, will receive something known to be less effective or to have a higher risk than an available alternative.” (Beauchamp and Childress 2012 at 335.) Notably, clinical equipoise depends on both foreseen benefits and foreseen harms.

53. To conclude that the principle of equipoise forbids an “untreated” “active control” arm in a clinical study of MGT, one would have to conclude that it is known as a matter of medical science that MGT brings about benefits that outweigh known or foreseeable but unstudied harms, and that those benefits cannot be

achieved by some other "established effective intervention" which could be included in the "active control." (Beauchamp and Childress at 336.) In the case of GD, such an active control (also called the "active comparator" (Cantor ¶ 265)) could include any customary psychotherapeutic interventions. Since large studies find that MGT does not lead to improved mental health outcomes, it is incorrect to assert that *not* offering MGT is contradicted by the principle of equipoise.

54. Importantly—and contrary to what Dr. Antommaria suggests (Antommaria at 10)—whether clinical equipoise exists is not determined by what any one clinician or group of clinicians or investigators believes. Nor, contrary to the American Academy of Pediatrics, can the physician's ethical obligation to determine the existence (or absence) of clinical equipoise based on the available science be obviated by "preexisting guidelines that recommend gender-affirming care." (AAP amicus brief, *Williams v. Skrmetti*, supra n. 3.) Rather, clinical equipoise exists when, "[o]n the basis of the available evidence" (Beauchamp and Childress at 335), "there is genuine uncertainty within the expert medical community—not necessarily on the part of the individual investigator—about the preferred treatment" (Freedman 1987). As the above summaries make clear, the community of reasonable clinicians, as well as the international community of relevant experts, is at best genuinely uncertain about whether MGT is to be preferred to standard psychotherapeutic treatment without MGT. This is confirmed by the fact that multiple international bodies of experts have described MGT as "experimental." (Cantor ¶ 168-172.)[6]

55. Plaintiffs' assertions that it would be unethical to do clinical research with an arm that does not receive MGT are thus unsupported. I see assertions but no science cited by Plaintiffs' experts that should cause an Institutional Review Board (IRB) to reject a clinical trial in which the active control does not include MGT. IRBs do not defer to clinicians' judgment about equipoise, much less to those who are most enthusiastic about some intervention. When IRBs are fulfilling their role, they require clinicians and researchers to show sufficient evidence to justify their beliefs.

56. Moreover, that such studies can be ethical is evidenced by the fact that multiple countries, including the United Kingdom, have now announced policy changes to provide MGT only as part of formal research protocols. (Cantor ¶¶ 168, 170, 266.) Even pioneers of MGT have called for such research, with Dr. de Vries writing recently that "rigorous longitudinal outcomes studies that provide evidence about whether this approach [MGT in minors] is effective and safe are needed" and

---

[6] See also a 2023 article published in one of the world's most prestigious medical journals, the *British Journal of Medicine*, that was entitled, "Gender dysphoria in young people is rising and so is professional disagreement." (Block 2023.)

that "Future studies that *compare outcomes with different care models are needed*." (de Vries 2023 at 276; cited Cantor ¶ 283 (italics added).)

57. Thus, even if a trial cannot be randomized or blinded as a practical matter, the principles of medical ethics do not preclude a carefully constructed trial that includes an arm comprised of patients with GD who undergo psychotherapeutic care but do not undergo hormonal intervention.

B. An Institutional Review Board that approved the expanded clinical trial apparently advocated by the FDA would likely be violating its ethical obligations.

58. As I have summarized above, multiple international reviews of the available evidence have concluded that MGT has not been shown to improve mental health outcomes. Without reliable evidence of better mental health outcomes than achieved by psychotherapy alone, the known or reasonably foreseeable harms of MGT cannot be reasonably accepted. That is to say, the condition of equipoise not only does not forbid *withholding* MGT, it likely forbids *offering* MGT until and unless appropriately conducted research generates evidence that MGT is likely to generate health benefits that are at least proportionate to its known harms. Based on the reviews of the published evidence provided by Drs. Cantor and Laidlaw, such reliable evidence is lacking at present.

59. A clinical trial of MGT on minors would likely violate other accepted principles of medical ethics as well.

60. The Nuremberg Code, adopted after World War II in response to the human experimentation performed by medical doctors under the Nazi regime, is one of the foundational and internationally accepted statements of key principles of medical ethics pertaining to experimentation on humans. Paragraph 3 of the Nuremberg Code states:

> "The experiment should be so designed and <u>based on the results of animal experimentation</u> and a knowledge of the natural history of the disease or other problem under study, that the anticipated results will justify the performance of the experiment."

61. One point of this principle is that if a proposed treatment poses potential risks that could be explored through experiments on animals, then those animal experiments should be done before the treatment is tested on humans.

62. Animal experiments would be possible with respect to many widely recognized risks of puberty blockers and cross-sex hormones. For example, Chen (2020) validates the ability to do useful animal studies of effects of hormones on brain development, writing, "studies in rodents show ovarian hormones, acting during puberty, program cognitive flexibility by exerting long-lasting effects on

excitatory-inhibitory balance in the pre-frontal cortex . . . [and] testosterone, acting during puberty, programs the ability to adapt behavior as a function of social experience." (Chen 2020 at 253:2a.) Animal studies might also help to clarify whether and under what conditions MGT-induced sterilization is reversible; whether suppressed bone development leads to later fractures or other complications; and how MGT impacts cardiovascular health over time. To my knowledge, such studies have not been undertaken. A responsible IRB recalling the Nuremberg Code would want to know what animal studies were feasible, which had been done, and (if true) why feasible studies had not been done, before approving clinical trials of MGT on humans.

63. Another universally respected statement of principles of medical ethics is the Declaration of Helsinki, first adopted by the World Medical Association in 1964, and periodically updated since then. Paragraphs 17 and 18 of the Helsinki Declaration state that it is unethical to undertake any human experiments without first conducting a "careful assessment of predictable risks" and reaching a well-grounded conclusion that all of those risks "can be satisfactorily managed." (Helsinki Declaration ¶¶ 17, 18.)

64. A trial that subjects adolescents to MGT does not meet these standards insofar as the available science does not enable a conclusion that “predictable risks” of MGT in adolescents—including sterilization, negative impact on neurodevelopment, and negative impact on bone and cardiovascular strength—can be “satisfactorily managed.”

65. A third respected statement of principles of medical ethics is the Belmont Report, published in 1979 by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, authorized by the National Research Act of 1974. The Belmont Report states that prior to administration of experimental treatments to humans:

> “there should first be a determination of the validity of the presuppositions of the research; then the nature, probability and magnitude of risk should be distinguished with as much clarity as possible. … It should also be determined whether an investigator's estimates of the probability of harm or benefits are reasonable, as judged by known facts or other available studies.”
>
> “When research involves significant risk of serious impairment, review committees should be extraordinarily insistent on the justification of the risk (looking usually to the likelihood of benefit to the subject . . . .)” (Belmont Report § C.2.)

66. There can be no doubt that the known or potential harms of MGT discussed in the literature by knowledgeable observers—including sterilization, impairment of brain development, permanent deprivation of sexual response, and impaired bone development—constitute "risk of serious impairment." Further, the known facts and available studies as reviewed by Drs. Cantor and Laidlaw indicate that assertions that the benefits of MGT outweigh the potential harms are not empirically justified given the existing scientific record.

67. In my opinion, the plaintiffs have not met the bar of justifying the risk associated with MGT insofar as: the evidence to date does not support the claim that MGT brings mental health benefits; animal studies relevant to safety that can be done have not been done; there has not been "careful assessment of predictable risks," and no plan for how all the known risks "can be satisfactorily managed" has been identified.

C. Large and well-resourced medical systems have violated ethical principles by engaging in large-scale prescription of unproven therapies without undertaking well-designed research to evaluate safety and efficacy.

68. As the Helsinki Declaration states, a physician, in certain circumstances, may reasonably use an unproven intervention in the treatment of an individual patient, but "This intervention should subsequently be made the object of research, designed to evaluate its safety and efficacy. In all cases, new information must be recorded and, where appropriate, made publicly available." (Helsinki Declaration ¶ 37.) The Belmont Report likewise states, "in order to determine whether ['radically new procedures'] are safe and effective it is the responsibility of medical practices committees . . . to insist that a major innovation be incorporated into a formal research project at an early stage." (Belmont Report Part A.)

69. It follows that well-resourced academic medical centers with affiliated clinics where unproven MGT interventions are being clinically deployed bear a responsibility under these respected codes of medical ethics to sponsor research capable of investigating the harms and benefits of those interventions. Of course, such research must itself satisfy ethical principles. For example, thorough animal experimentation might be the only ethically justified experimentation given the present state of knowledge. (See above.) At the very least, academic medical centers are obligated to undertake long-term follow-up—into adulthood—of minors undergoing these unproven and "radically new" interventions. This they have not done (or at least, have not yet published), as evidenced by numerous systematic reviews concluding that there is very little evidence regarding the long-term effects of these interventions, and the evidence that exists is of very low quality.

VII. THE POSSIBILITY OF MEANINGFUL INFORMED CONSENT TO MGT FOR MINORS IS DOUBTFUL.

70. The Belmont Report further states that respect for persons requires that research can only be conducted ethically if the subjects have given *informed consent*. In 1982, soon after the Belmont Report was published, the principle of informed consent was applied to clinical medicine in another landmark government report, *Making Health Care Decisions*. Since then, the principle and practice of informed consent has been uniformly established across the domains both of clinical research and clinical medicine. Beauchamp and Childress write, "Virtually all prominent medical and research codes and institutional rules of ethics now hold that physicians and investigators must obtain the informed consent of patients and subjects prior to a substantial intervention." (Health Care Decisions at 121.) The Belmont Report notes "widespread agreement" that informed consent requires the presence of sufficient "information, comprehension and voluntariness." (Belmont Report § C:1.) In my opinion, minors cannot give duly informed consent to MGT, because it is doubtful that any of these three conditions of informed consent can be met.

A. Doctors do not possess and are not providing information sufficient to enable children or parents to make "informed" decisions.

71. The absence of well-designed and controlled studies makes it impossible to give minors and their parents information sufficient to consider their consent duly informed, and the plaintiffs' experts by their own admission are misinforming patients regarding that fact. "*Caveat emptor*" does not meet the bar required for consent to be duly informed within clinical medicine and clinical research. It is not enough to say "we don't know" without doing the careful, incremental research to generate information needed for a consent to be duly informed. Moreover, by their own admission the plaintiffs' experts do not disclose to minor patients and their parents that the evidence base does not support their claims of benefit from MGT. As such, by their own admission, they are misinforming minors and their parents who are considering MGT, and therefore contradicting the first condition on which informed consent depends.

B. It has not been shown that minors are able to comprehend and reasonably evaluate the risks and lifelong implications of MGT.

72. It is doubtful that minors have the intellectual maturity to sufficiently *comprehend* the decision to undergo MGT and the potentially life-long consequences that decision will bring.

73. It is well recognized that the ability to evaluate and balance risk and reward, to consider long-term as well as short-term implications, and to make prudent and well-considered decisions is not well developed in children and

adolescents. WPATH's recently published SOC 8 acknowledges problems with minors' immature capacity for judgment, noting, "adolescence is . . . often associated with increased risk-taking behaviors" (SOC 8 at S44), and "Adolescents often experience a sense of urgency that stems from hypersensitivity to reward, and their sense of timing has been shown to be different from that of older individuals" (SOC 8 at S44). Beauchamp and Childress likewise note that immaturity hinders adequate understanding. (Beauchamp and Childress 2012 at 131.) For this reason among others, with few exceptions minors are *not* considered capable of granting informed consent to medical interventions. (Katz 2016 at e1, e9.)

74. Minors seem particularly incapable of comprehending the long-term implications of MGT, insofar as those implications involve relationships and experiences that come only with adulthood. As I have noted above, MGT brings lifetime physical and social implications including risks of impaired brain development, sterilization, and loss of sexual response. These risks cannot be adequately comprehended by children insofar as these risks relate specifically to aspects of human life that go with being an adult and are outside the life experience of children.

75. Moreover, one form of MGT—puberty blockers—*by design* blocks the mental, physical, and emotional maturation of puberty which may be essential for a child to come in time to comprehend decisions of this magnitude. (Cantor ¶ 214.) Dr. Cantor notes that "Blocking puberty blocks the awareness of sexuality and sexual orientation that can play an important role in the individual's understanding of gender identity" (Cantor ¶ 234), and "for all children, blocking puberty necessarily blocks the onset of adult sexual interest, sexual arousal, and sexual response which are part of 'the usual process of sexual orientation and gender identity development'" (Cantor ¶ 235, quoting Cass 2022 at 38).

76. In connection with the comprehensive review commissioned by the English National Health Service, Dr. Cass wrote, "We do not fully understand the role of adolescent sex hormones in driving the development of both sexuality and gender identity through the early teen years, so by extension we cannot be sure about the impact of stopping these hormone surges on psychosexual and gender maturation. We therefore have no way of knowing whether, rather than buying time to make a decision, puberty blockers may disrupt that decision-making process." (Cass Review Letter 2022 at 5.)

77. It is ethically problematic when the treatment in question—puberty blockers—not only cannot be comprehended adequately by minors, but also prevents the otherwise healthy development of their capacity to comprehend such decisions. This is all the more true for younger children, "[g]iven the highly reliable, repeatedly replicated finding that childhood-onset gender dysphoria resolves with puberty for the large majority of children," and that "the evidence indicates that

blocking a child's puberty blocks the child's natural maturation that itself would resolve the dysphoria." (Cantor ¶ 159.)

78. With respect to adolescents, WPATH's SOC 8 states that "decision-making regarding gender affirming medical treatments that have life-long consequences requires thoughtful, future-oriented thinking by the adolescent." (SOC 8 at S63.) However, neither WPATH nor any other source referenced by plaintiffs' experts establishes that minors, whether pre-pubertal or adolescent, are *able* to meaningfully comprehend and reasonably evaluate the risks and lifelong implications of MGT.

C. There is evidence that many minors who are subjected to MGT cannot meet the informed consent requirement of "voluntariness."

79. The opening statement of the Nuremberg Code declares,

> The voluntary consent of the human subject is absolutely essential. This means that the person involved should have legal capacity to give consent; should be so situated as to be able to exercise free power of choice, without the intervention of any element of force, fraud, deceit, duress, over-reaching, or other ulterior form of constraint or coercion; and should have sufficient knowledge and comprehension of the elements of the subject matter involved, as to enable him to make an understanding and enlightened decision.

80. As the Nuremberg Code indicates, voluntariness depends on adequate information and comprehension ("*sufficient knowledge and comprehension of the elements of the subject matter involved"*), both of which, as already noted, are doubtful in the case of minors considering MGT. But voluntariness also depends on freedom from controlling influences, both external and internal.

81. With respect to external influences, minors obviously are commonly under the controlling influence of parents, which I will address below. In addition, a number of international experts have indicated concern that the rapid increase in prevalence of GD, especially among adolescent females, reflects undue influence of social pressure. WPATH's recently published SOC 8 itself acknowledges, "For a select subgroup of young people, susceptibility to social influence impacting gender may be an important differential to consider." (SOC 8 at S45.)

82. Beauchamp and Childress note that in addition to external controlling influences, "no less important to autonomy are internal influences on the person, such as those caused by mental illness. All of these conditions can limit voluntariness." (Beauchamp and Childress 2012 at 105; see also id. at 138.) Dr. Cantor documents ample evidence that a high proportion of minors experiencing GD suffer from mental illnesses. (Cantor ¶ 160-162.) These mental illnesses constitute

an internal controlling influence that can prevent genuine voluntariness. As WPATH itself recognizes, "A young person's mental health challenges may impact their conceptualization of their gender development history and gender identity-related needs, the adolescent's capacity to consent, and the ability of the young person to engage in or receive medical treatment," and "The adolescent's mental health concerns . . . may interfere with diagnostic clarity [and] capacity to consent . . .". (SOC 8 at S62.) WPATH also recently admitted that "autistic/neurodivergent transgender youth represent a substantial minority subpopulation" of those seeking medical transition. (SOC 8 at S50.)

83. Despite the serious obstacle posed by mental health conditions to genuine voluntariness in decision-making by a minor, WPATH's SOC 8 is problematically unclear as to how these conditions will be addressed prerequisite to any MGT. Instead, it refers to an undefined "biopsychosocial assessment" (SOC 8 at S50), and only calls for known mental health concerns to be "addressed" rather than resolved before accepting consent (or assent) as voluntary (SOC 8 at S62). SOC 8 provides no guidance grounded on empirical evidence as to how or when consent/assent given by a minor who suffers from a mental health condition could be determined to be voluntary.

D. The fact that MGT is *wanted* by minors and their parents is not sufficient to justify MGT, medically or ethically.

84. WPATH's revisions of guidelines to eliminate or minimize the doctor's responsibility regarding decision-making with respect to MGT violate accepted principles of medical ethics. In its Standards of Care, version 8, WPATH suggests that gaps in evidence demonstrating the safety and efficacy of MGT should not prevent the use of MGT in adolescents "given the ethics of self-determination in care." (SOC 8 at S45.) The new guidelines also emphasize a "right to bodily and mental integrity, autonomy, and self-determination,"[7] and a putative need for healthcare practitioners to "[m]atch the treatment approach to the specific needs of patients, particularly their goals for gender identity and expression." (SOC 8 at S21.) This language ignores the potential conflict with MGT between "bodily integrity" and "self-determination," as well the conflict between the "needs of patients" and "their goals."

85. Much has been made of the importance of autonomy, but the ethical standard for medical decision-making with respect to minors is decidedly not "self-determination." Rather, as noted in the AAP Committee on Bioethics Report, "Informed Consent in Decision- Making in Pediatric Practice" (Katz 2016), the

---

[7] Among the "General Principles" asserted by WPATH are: "Respect universal human rights including the right to bodily and mental integrity, autonomy and self-determination; freedom from discrimination, and the right to the highest attainable standard of health." (SOC 8 at S21.)

physician acts in a fiduciary relationship with the child, governed by "the duties to protect and promote health-related interests of the child and adolescent … [, and] these duties may conflict with the parent's or patient's wishes." (Katz 2016 at e2.) Parents likewise have "an ethically parallel fiduciary obligation" (e2) to promote the child's best interests, whether or not that corresponds with what the child wants. "Historically and legally," the AAP report continues, "medical decision-making in children has centered on the best-interest standard, which directs the surrogate to maximize benefits and minimize harms to the minor." (e6) "A reliance on individual liberties and autonomy in the pediatric patient", the AAP report notes, "is not realistic or legally accepted." (e2)

86. By appealing to self-determination to justify MGT for minors, WPATH is putting the onus on children to make clinical decisions that they haven't information, comprehension, or authority to make, and thereby retreating from physicians' ethical obligations to protect children—a class of vulnerable subjects—from interventions that subject children to risks and harms without clear evidence of proportionate medical benefit.

87. For all of these reasons, it is doubtful that minors experiencing GD have sufficient information, comprehension, or voluntariness to make possible informed consent to MGT. If any minors do possess the level of comprehension and voluntariness required by ethical principles for a choice as momentous as undergoing MGT, I am aware of no evidence-based criteria for identifying those specific minors, and plaintiffs' experts cite none.

E. Parental consent cannot satisfy the doctor's ethical obligation to obtain informed, comprehending, voluntary consent.

88. In many medical contexts, medical ethicists speak of obtaining "assent" from minors, while obtaining "consent" from the child's parents. (Katz 2016, e8) This combination of adolescent assent and parental consent, however, cannot cure the problems with informed consent to MGT.

89. Children have long been considered a category of vulnerable subjects and therefore as deserving more protections. (Beauchamp and Childress at 63.)[8] For example, the Declaration of Helsinki requires that where a clinical trial or experiment involves "vulnerable groups and individuals", those patients must "receive specifically considered protection." (Helsinki Declaration ¶ 19.)

90. In the clinical domain, the vulnerability of children is addressed in part by requiring both parents and physicians to act in ways that are reasonably consistent with the child's medical best interest. (Katz 2016 at e2, e12.) That is to

---

[8] See also HHS policy statement, "Vulnerable and Other Populations Requiring Additional Protections," available at https://grants.nih.gov/policy/humansubjects/policies-and-regulations/vulnerable-populations.htm.

say that whereas adults are given greater latitude to refuse even medically indicated and life-saving treatments, children and their parents generally are not.[9] In parallel, parents have much more latitude to accept experimental interventions and even interventions that contradict bodily health (e.g. cosmetic procedures, physician-assisted suicide) for themselves than they have latitude to accept such interventions for their children. (Katz 2016 at e5.)

91. Because of the vulnerability of children, it is widely accepted that both physicians and the state are obligated to act as fiduciaries of children's best interests with respect to health, and if necessary to act *en loco parentis*. Just as parents are ethically obligated to prioritize the child's good over their own wishes, medical professionals are obligated to prioritize the child's best interest (where that involves the child's health) over the wishes of the parents. Beauchamp and Childress (at 221) describe such "paternalistic" actions as justified by the ethical principle of beneficence—the obligation to do good and promote the health of individuals, while protecting them from harm. The AAP report on informed consent comments:

> This parental responsibility for medical decision-making in caring for their child or young adult is not an absolute right, however, because the state also has a societal interest in protecting the child or young adult from harm and can challenge parental authority in situations in which the child or young adult is put at risk (the doctrine of *parens patriae*). Pediatric health care providers have legal and ethical duties to provide a standard of care that meets the pediatric patient's needs and not necessarily what the parents desire or request. (Katz 2016 at e5.)

92. By definition, minors experiencing GD are vulnerable subjects, and all the more so in light of the already noted high prevalence of mental illness and other comorbidities among this population. As such, minors experiencing GD are owed protection from interventions that contradict their medical best interest—their health. Because MGT disrupts and contradicts bodily health in several ways, it is doubtful that physicians have ethical warrant to offer, or that parents have ethical authority to consent to, MGT in minors.

---

[9] Beauchamp and Childress note, "Courts have often allowed adult Jehovah's Witnesses, for example, to reject blood transfusions for themselves, while disallowing parental rejections of medically necessary blood transfusions for their children. Parents are also sometimes appropriately charged with child neglect when they fail to seek or permit potentially beneficial medical treatment recommended by physicians." (at 325)

93. In addition, for the same reasons I have reviewed above, it is not possible to say that parents are receiving information about the implications of MGT sufficient to make any consent they might provide "informed."

94. If persons suffering GD faced imminent bodily harm from their condition, and if there were no other way to respond but to deploy MGT, and if evidence from animal studies and carefully controlled human trials gave reason to anticipate benefits from MGT proportionate to known harms, then an adult could potentially give valid consent to MGT in knowledge of the absence of otherwise necessary information. But none of these conditions in fact have been met, and that makes it doubtful that the principle of informed consent within clinical medicine and clinical research can be met at all with respect to MGT, much less with MGT for minors.

95. The fact that MGT creates a material risk (or even expectation) of sterilization and failure to develop healthy sexual response raises special ethical problems with accepting parental "consent" on behalf of the child. With respect to loss of healthy sexual response, I note that our society strongly disapproves of clitoral mutilation of girls (denying them sexual response in their future adult lives) despite parental consent. Indeed, such "medical" procedures have been prohibited by law as a felony subject to imprisonment.[10]

96. Sterilization has likewise long been recognized to raise special ethical issues. One systematic review found that a significant percentage of women who consent to sterilization at relatively young ages (under 30, in that study) later deeply regret that decision. (Curtis 2006; see also Burgart 2017; Hillis 1999.) Given the possibility of regret and deprivation of what is considered a basic human right in other contexts, it is generally accepted that sterilizing procedures should only be performed on a minor when necessary to save his or her life. And even then, "The validity of parental consent to a sterilizing procedure can be challenged when the procedure could be safely postponed until the child can consent [i.e., when the child reaches adulthood], or where less-invasive alternatives are available." (Burgart 2017; Tamar-Mattis 2009.)

---

[10] https://travel.state.gov/content/travel/en/us-visas/visa-information-resources/fact-sheet-on-female-genital-mutilation-or-cutting.html#:~:text=Violation%20of%20the%20law%20is,are%20prohibited%20under%20U.S.%20law.

97. While medical procedures that impose substantial risk of serious harm are ethical in some settings, plaintiffs' experts do not remotely establish that the necessary conditions justifying such procedures exist in the case of GD and MGT, especially for minors.

98. I declare under penalty of perjury that the foregoing is true and correct to the best of my knowledge.

This declaration was executed on February 2, 2024.

Farr A. Curlin, MD

Appendix A: Bibliography and Other Materials Considered

Beauchamp, T.L. and Childress, J.S., Principles of Biomedical Ethics, 7th edition (2013). Oxford University Press.

Block, J. (2023). Gender dysphoria in young people is rising and so is professional disagreement. *British Journal of Medicine,*2023: 380*,* 382.

Burgart, A.M., Strickland, J. et al. (2017). Ethical controversy about hysterectomy for a minor, *Pediatrics* 139:6, e20163992.

Cass, H. (2022, February). The Cass Review: Independent review of gender identity services for children and young people Interim report. National Health Service (NHS), UK.

Cass, H. (19 July 2022). Independent review of gender identity services for children and young people – further advice. Letter from H. Cass to J. Stewart, NHS England. *The Cass Review*.

Chen, D., Strang, J. F., Kulbuck, V. D., Rosenthal, S. M., Wallen, K., Waber, D. P., …Garofalo, R. (2020). Consensus parameter: Research methodologies to evaluate neurodevelopmental effects of pubertal suppression in transgender youth. *Transgender Health, 5,* 246–257.

COHERE Finland (Council for Choices in Health Care in Finland) (2020, June 16). Medical treatment methods for dysphoria associated with variations in gender identity in minors—Summary of a recommendation. [Translated] Retrieved from https://palveluvalikoima.fi/documents/1237350/22895008/Summary_minors_en+(1).pdf/fa2054c5-8c35-8492-59d6-b3de1c00de49/Summary_minors_en+(1).pdf?t=1631773838474

Coleman, E.,et al. (2022). WPATH standards of care for the health of transgender and gender diverse people, version 8 (“SOC 8”)*. International Journal of Transgender Health* 2022, Vol.. 23, No. S1.

Curtis, K.M., Mohllajee, A.P. et al. (2006). Regret following female sterilization at a young age: A Systematic Review, *Contraception* 73:205.

Freedman, B. (1987, July 16). Equipoise and the ethics of clinical research. *New England Journal of Medicine*, 317, 141–145.

Glintborg, D., Moller, J-J., Rubin, K. et al. (2023). Gender-affirming treatment and mental health diagnoses in Danish transgender persons: a nationwide register-based cohort study. *Eur. J. Endocrinology* 189:336-345.

GRADE Handbook, Quality of evidence definitions table. https://gdt.gradepro.org/app/handbook/handbook.html#h.wsfivfhuxv4r at Section 5.

Hillis, S.D., Marchbanks, P.A. et al. (1999). Poststerilization regret: findings from the United States Collaborative Review of Sterilization, 93:6 *Obstetrics. & Gyn*. 93(6):889.

Kaltiala, R., Holttinen, T., Tuisku, K. (2023). Have the psychiatric needs of people seeking gender reassignment changed as their numbers increase? A register study in Finland. European Psychiatry. doi.org/10.1192/j.eurpsy.2023.2471.

Kaltiala, R. (2023b). Gender-affirming care is dangerous. I know because I helped pioneer it. *The Free Press*. https://www.thefp.com/p/gender-affirming-care-dangerous-finland-doctor, Oct. 20, 2023.

Karolinska Institute (March 2021). Policy change regarding hormonal treatment of minors with gender dysphoria at Tema Barn – Astrid Lindgren Children's Hospital.

Katz A., Webb S. (2016) AAP Committee on Bioethics: Informed Consent in Decision-Making in Pediatric Practice. *Pediatrics*. 2016;138(2):e20161485.

Nuremberg Code (1947).

Respaut, R., Terhune, C., Conlin, M. (2022). Why transitioners are crucial to the science of gender care. Reuters. https://www.reuters.com/investigates/special-report/usa-transyouth-outcomes/Reuters.

Swedish Socialstyrelsen (2022, Feb. 22). Uppdaterade rekommendationer för hormonbehandling vid könsdysfori hos unga. [*Updated recommendations for hormone therapy for gender dysphoria in young people.*] Retrieved from https://www.socialstyrelsen.se/om-socialstyrelsen/pressrum/press/uppdaterade-rekommendationer-for-hormonbehandling-vid-konsdysfori-hos-unga/.

Swedish Socialstyrelsen (2020). The evolution of the diagnosis of gender dysphoria: prevalence, co-occurring psychiatric diagnoses and mortality from suicide. www.socialstyrelsen.se Article number 2020-2-6600.

Swedish Socialstyrelsen (2022, February). Stöd, utredning och hormonbehandling vid könsinkongruens hos barn och ungdomar Delvis uppdatering av kunskapsstöd. [*Support, investigation and hormone treatment at gender incongruity in children and young people.*] Available from https://www.socialstyrelsen.se/globalassets/sharepoint-dokument/artikelkatalog/kunskapsstod/2022-2-7774.pdf

Tamar-Mattis, A. (2009). Exploring gray areas in the law about DSD and sterilization, *Endocrine Today*, 2009 October ed., https://bit.ly/2YdAHNU).

Torkildsen, Ø. (2022). Lessons to be learnt from the history of lobotomy. Tidsskr Nor Legeforen. Available at: https://tidsskriftet.no/en/2022/12/essay/lessons-be-learnt-history-lobotomy

Ukom Norway (March 9, 2023). Patient safety for children and adolescents with gender incongruence. Unofficial translation.

U.S. Department of Health, Education, and Welfare (1979, Apr. 18). Belmont Report: ethical principles and guidelines for the protection of human subjects of research, 44 *Fed. Reg.* 76, 21392–97 (Apr. 18, 1979). ("Belmont Report")

U.S. President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research (1982). Making health care decisions: the ethical and legal implications of informed consent in the patient-practitioner relationship. U.S. Gov't Printing Office. ("Health Care Decisions")

World Medical Association (1964). Declaration of Helsinki: Ethical principles for medical research involving human subjects. ("Helsinki Declaration")

Other Materials Considered

1. Vulnerable Child Compassion and Protection Act (the "Act").

2. Opinion and order granting preliminary injunction dated May 13, 2022 ("Order granting PI")

3. Second Amended Complaint dated September 19, 2022.

4. Expert Report of Meredithe McNamara, dated Feb 8, 2023

5. Expert Report of Armand Antommaria, dated Feb 13, 2023

6. Expert report of James Cantor, dated May 19, 2023

7. Supplementary Expert Report of James Cantor, dated February 1, 2024 (Nonconfidential portions)

8. Expert Report of Michael Laidlaw, dated May 19, 2023

9. Supplementary Expert report of Michael Laidlaw, dated May 19, 2023

10. Eleventh Circuit Court Opinion dated August 21, 2023

11. Production documents HHS-0169973 to -0619991

Appendix B: Curriculum Vitae of Dr. Farr Curlin, MD