IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF FLORIDA
TALLAHASSEE DIVISION

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

REBUTTAL EXPERT REPORT OF PATRICK W. LAPPERT, M.D.

I, Patrick W. Lappert, M.D., declare that the facts contained herein are true and correct to the best of my knowledge and belief, and that the opinions expressed herein represent my own.

1. I have been asked by counsel for the Defendants to respond to the expert reports of Loren S. Schechter, M.D., and Johanna Olson-Kennedy, M.D., M.S. My qualifications, publications, prior expert testimony, and compensation are discussed in my prior expert declaration served on February 17, 2023.

2. I have been a physician for 40 years. For 30 of those years, I practiced as a plastic and reconstructive surgeon. Details of my multiple board certifications in plastic surgery and general surgery are contained in the narrative of my earlier declaration, as are my surgical experience in all forms of reconstructive surgery including pediatric, congenital, cancer, and trauma reconstruction, most of it gained during my 24 years of service in the United States Navy. I served in teaching positions for plastic surgery training programs, ran multidisciplinary teams for the management of congenital deformities in children, was a department head in a tertiary referral center, and specialty leader to the Office of the Surgeon General (USN).

3. The opinions I offer here are based in that body of experience, my knowledge of the medical and scientific literature that is offered by Drs. Schechter and Olson-Kennedy and those cited in the footnotes of this report, as well as on the

clear methods used to evaluate the quality of that same evidence in making clinical decisions.

4. In order to simplify my rebuttal to declarations of Drs. Schechter and Olson-Kennedy, it is useful to define and clarify the following terms frequently used by experts that often lead to misunderstanding about the value of scientific evidence.

Peer reviewed publications: When scientific papers are presented as having been published in peer reviewed journals, this is merely a statement about the process by which a paper is examined for possible publication. It says absolutely nothing about the evidentiary value of the paper. A paper may be published that shows high-quality, irrefutable evidence that a treatment method is curative in virtually all cases. Another paper may offer a single case report of a surprising cure that resulted serendipitously under unusual circumstances. The first paper has very high value evidence that is powerful in establishing a standard of care. The other paper is interesting, well reported, and documented, but is useful only in formulating a research project, and utterly useless in guiding the prudent care of patients. Both were published in the same "peer reviewed" journal, but only one is helpful in clinical decision making. The difference is based in how we grade evidence, and this distinction is crucial in evaluating the claims of plaintiffs' experts.

The Standard of Care: This is a phrase that must be used with the greatest caution because it suggests that any deviation from the 'standard' is likely to result in significant objective harms to the patient. It is a phrase that assures the reader that there exists a considerable body of research and high-quality outcomes data to support the particular treatment. It declares that a particular

treatment is so superior to any other known treatment that to choose otherwise is to risk significant harm to the patient. It is not based in professional opinion, no matter how esteemed the doctor may be. It is based in the reliable observation of objective facts. This understanding of the phrase "standard of care" is crucial in evaluating the claims made by Drs. Schechter and Olson-Kennedy in their respective declarations, particularly since their most frequent citation is the WPATH Standards of Care v.8, a document that in its first pages cautions that it is not a "standard of care" (see citation in my original declaration).

Treatment Guidelines: These are formulated by select experts from a medical specialty and compares treatment options, using those comparisons to help practitioners make clinical decisions in particular cases. These guidelines, if properly developed, typically include distinctions about particular patient characteristics that may influence treatment decisions. For example it may exclude certain patients from a particular treatment plan because of other health conditions. Such guidelines should offer a careful examination of the risks and benefits of all treatment options so that these can be discussed with the patient in the process of obtaining informed consent. Treatment guidelines are not promulgated to bind a physician to a particular course of treatment. They are there to assist the doctor and protect the patient from imprudent decision making.

This is particularly important when examining this case because new forms of care, when first introduced, must be compared to existing modalities which have known benefits and risks. The process of developing treatment guidelines is never a sudden, radical course change informed by a novel and unproven treatment method. It is a careful comparison, and thus the quality

of care advances while it protects the patient from incautious physicians. The complete absence of such comparison between the "affirmation care" model offered by plaintiffs' experts, and any other treatment model is startling, and bears consideration when evaluating their claims of efficacy, safety, and long-term outcome. It also greatly bears upon the processes of informed consent used by physicians and surgeons who practice gender affirmation.

Reconstructive Surgery: This term describes those surgeries that aim at the restoration of form and function that may have been lost due to trauma, cancer care, or congenital abnormalities. Such surgeries begin with the objective definition of the defect including its composition and functional loss. The success of such surgeries can be objectively measured, typically including the restoration of function. For example, if I reconstruct the thumb of a farmer, I can measure his grip strength and dexterity with objects like keys both before and after surgery. Sometimes the result may only be cosmetic such as with breast reconstruction, but there is still a defined diagnosable objective loss that precedes surgery, and seeks remedy in surgery. Virtually all reconstructive operations have aesthetic (subjective) consequences, but the subjective improvement is not the first aim of the surgery, only one of the happy results.

Cosmetic Surgery: These are surgeries that are performed only to improve the subjective life of the patient. They begin in the subjective life of the patient when the patient identifies a personal physical attribute (such as shape of nose) as a source of annoyance, insecurity, emotional discomfort, or even profound fear and grief. The goal of the surgery is resolution of the subjective disturbance. There is no antecedent functional defect. There is no

objectively discoverable defect, only common variations in form seen in the general population. Likewise, the results of surgery are measured in the subjective life of the patient, using such instruments as Quality of Life tests. It is crucial to understand these clear distinctions between cosmetic and reconstructive surgery in order to evaluate the claims made by plaintiffs' experts.

Measures of Scientific Evidence: Beginning in paragraph 22 of my prior report, I presented the test instruments used by the American Society of Plastic Surgery (ASPS) when evaluating the quality of scientific studies, and how to apply that evidence in patient care. I will here offer the simple table that can be referred to when considering the publications offered by plaintiffs' experts:

- Level I: High quality prospective cohorts study with adequate power or systematic review of these studies.
- Level II: Lesser quality prospective cohort, retrospective cohort study, untreated controls from an RCT (randomized control study), or systematic review of these studies.
- Level III: Case-control study or systematic review of these studies.
- Level IV: Case series
- Level V: Expert opinion; case report or clinical example; or evidence based on physiology, bench research or "first principles".[1]

[1] The Levels of Evidence and their role in Evidence-Based Medicine Patricia B. Burns, MPH,1 Rod J. Rohrich, MD,2 and Kevin C. Chung, MD, MS3 Plast Reconstr Surg. 2011 Jul; 128(1): 305–310.
http://www.plasticsurgery.org/Medical_Professionals/Health_Policy_and_Advocacy/Health_Policy_Resources/Evidence-

The same ASPS document provides a grading system for Practice Recommendations that helps in the decision making. It is a synthesis of the breadth of scientific data that addresses the issue in question. In the case of Grade A there is an accompanying "Strong recommendation", versus Grade D where the evidence is so lacking in empirical value that the proposed treatment can only be offered as an option if at all, depending upon the strength of existing or alternative treatments, and the particular issues of a particular patient.

"Prevailing consensus of the medical community": This is a phrase without scientific merit. It is an allegation of broad agreement among doctors, but does not explain how that consensus was obtained. They do not describe to what extent that opinion prevails nor who was asked to agree or disagree with the opinion. This is discussed in greater detail in my original report, and is a misrepresentation. As we will see, there are many physicians, and even national healthcare systems that disagree with the therapeutic model of "gender affirmation" as is evidenced in the world literature, where whole nations are retreating from the affirmation model in the care of minors based upon a large body of high quality, long-term data. A claim of consensus demands an examination of the scientific data used to develop the opinion. Expert consensus has been shown to be a flawed methodology and is precisely the reason that modern medicine abandoned it in favor of "evidence-based medicine" (see my discussion in paragraph 27 of my earlier report). The failures of expert consensus methodology is why the American Society of Plastic Surgery, among other professional organizations,

based_GuidelinesPractice_Parameters/Description_and_Development_of_Evidence-based_Practice_Guidelines/ASPS_Evidence_Rating_Scales.html.

developed the orderly means for evaluating scientific information, such as the method described above, which we will use here.

5. In their respective declarations, Dr. Schechter and Dr. Olson-Kennedy have offered no scientific evidence that can be used to support any clinical decision making in the care of self-identified transgender minors. We will examine the papers cited in their declarations, evaluating the objective level of evidence, using the test instrument developed by the American Society of Plastic Surgery.

6. Dr. Schechter begins his report with a discussion of the WPATH Standards of Care, citing it as the primary reference document for decision making in the care of self-identified transgender minors. As discussed previously, the WPATH document is not a standard of care. It makes no scientific comparisons between the "affirmation care" model and any other established method for treating the condition. Within the document itself, under the discussion of the methodology which produced the document, it clearly states that the product of its consensus deliberations is either "recommend" or "suggest" (S247). As discussed above, the phrase "standard of care" is reserved for methods of care that must be followed because failing to do so has a high likelihood of harm to the patient. "Recommendations" and "suggestions" are what is found in treatment guidelines, and always include a discussion of alternative treatment modalities, and a comparison of objectively measured results.

7. Even if we accept the WPATH document as a treatment guideline, rather than a standard of care, such guidelines must stand or fall based upon the quality of scientific evidence presented in those papers cited by the authors. Given that Drs. Schechter and Olson-Kennedy are among the authors of the WPATH document, it may be expected that the scientific papers that they cite in support of their expert opinions will be of the highest evidentiary value. That, however, is not the case.

8. In support of his opinion that gender confirmation surgeries are "medically necessary", the only citation Dr. Schechter offers is a series of page references from the WPATH document. In paragraph 32 of his report, he states that "the medical community generally considers those surgeries to be medically necessary". He offers no evidence in support of that statement. He does not discuss how this consensus was obtained, who was asked, how they were asked, or how consistent the data has been over time. It is a statement without scientific merit, and is characteristic of historically flawed consensus methodology that has been replaced by evidence-based medicine. We will see below that a careful examination of the evidence cited in support of the WPATH Standard reveals a lack of evidence even to support a weak recommendation in a treatment guideline.

9. Also in paragraph 32 of his declaration, Dr. Schechter declares that "Gender confirming surgeries are not cosmetic". To support this opinion, he again

quotes the Standard of Care, and makes a claim of efficacy without citing the scientific evidence that one would expect to see when proposing radical and irreversible surgery in minors. His declaration rests upon his own opinion which also informed his writing of the Standard of Care.

10. In paragraph 33, Dr. Schechter contradicts the well-established principles that distinguish cosmetic surgery from reconstructive surgery by claiming that breast surgery in self-identified transgender minors "may be medically indicated for the treatment of gender dysphoria". Here he has confessed the fact that breast surgery conversely "might not" be indicated for treating minors who self-identify as transgender. This is exactly the problem which he fails to address. Dr. Schechter, and WPATH have no method for determining which minor "may benefit" and which minor "likely might not benefit" from irreversible breast amputation. Dr. Schechter offers no pre-operative test, with any degree of repeatable, verifiable accuracy that can be used to establish risk vs. benefit, and that can be presented to the parents of the minor to help them with the consent process. There is no such test. This startling shortcoming in the "gender affirmation" model of care is among the reasons why laws and professional sanctions are being used to stop these treatments in minors.

11. In paragraph 34, another claim of medical efficacy is made, and the additional claims of safety is added, both supported by Dr. Schechter's opinion and his own anecdotal reporting of his experience with certain patients and their post-

surgical subjective reporting. He cites the 2018 article by Agarwal et al. This article is a prospective case series by a single provider. The selection period extended over a period of 14 months. For each patient only two time points are examined: pre-operatively, and 6 months post operatively. There were 87 patients treated by the single surgeon who performed "chest masculinization" surgery on natal males seeking to present as female. Of those 87 patients, only 42 patients were present for the evaluation of results at the 6-month time point. The test instrument used at both time points was a quality-of-life measure, which gathers only subjective data.

12. Using the American Society of Plastic Surgery tool for the evaluation of the scientific basis of any opinion based upon the methodology (presented above), we see that this is a **Level IV** study which suffers from several critical problems. The first is that it is a single provider study. The second is that 52% of the patients fell out of the study, and no explanation is offered for their absence. Are they already disappointed with the result and chose not to come back? Are they hospitalized for an attempt at self-harm? Third, there is no comparison to established treatment methods, or comparison to no treatment at all. Fourth, all of the measures of outcome are in the area of subjective patient reporting (characteristic of cosmetic surgery). Lastly, the post operative follow-up interval is unsupportably brief. Since this study is at best barely **Level IV evidence**, it cannot be used to inform surgical decision-

making. Nor can it be used to inform parents or other legal custodians of minors concerning surgical risk or benefit.

13. In paragraph 35 of his report, Dr. Schechter proposes that there is no difference between the loss of function (breast feeding), and the loss of sensitivity in a woman undergoing mastectomy for breast cancer, versus a minor female undergoing mastectomy for gender dysphoria. He seems to suggest that the two are ethically equivalent because they are technically the same operation. Clearly the surgical management of a potentially lethal cancer often results in considerable wound and a functional loss to the patient. It is in the objective nature of the disease, and the objective limits of our therapeutic skills that brings about the loss. On the other hand, the dysphoric young woman has no objectively determined disease, only subjective complaints of anxiety, sorrow, and self-loathing. The surgical wound that she sustains is caused by the scientifically unsupported claim that the child is suffering due to the mere presence of her breasts. The surgeon has no means of measuring the likelihood of benefit pre-operatively, and no long-term follow-up data to prove that such surgery can prevent self-harm including suicide.

14. When I performed mastectomies for breast cancer, I was able to show the patient long-term evidence of benefit for mastectomy when applied to her particular cancer, based on the extent of spread, tumor type etc. She could understand the direct relationship between the disfiguring effects of the surgery, and the

likelihood that she would be cured of her cancer. With these objective truths she is then better able to make her choice. To expect that by irreversibly sacrificing a human function and producing two grievous wounds you will cure the emotional despair of an anxious minor is highly problematic. In no way can the two operations be equated from an ethical perspective. It would be exactly like comparing a leg amputation in a diabetic with gangrene, to the amputation of a leg from a healthy patient who is suffering from body dysmorphic disorder. It is morally unsupportable precisely because it is not supported by good science.

15. Dr. Schechter's discussion of safety in paragraph 37 does not offer any response to the issues of safety raised in my report. Surgical safety discussions must include all of the losses, including functional losses. Before the gender affirmation cosmetic operation called "chest masculinization" occurs, the patient is perfectly healthy, and has no physical or functional losses. Before the reconstructive operation called "breast reconstruction" begins, the patient has cancer, and the breast is missing due to cancer care. Before the breast removal in that case, the patient had a potentially lethal disease. Safety of mastectomy is considered (among other reasons) in light of the safety risk of not adequately treating breast cancer. Dr. Schechter claims that gender affirmation surgery is life-saving. He has yet to prove that point.

16. The first scientific article offered to support efficacy of affirmation surgery in self-identified transgender minors (Weigert et al. 2013) is a 10-year-old

article that declares in the abstract itself that it only offers **Level-IV evidence**. Such evidence is insufficient to inform clinical decision making. The treatment group was not minors, and the study duration was variable in length, but not more than 4 years. This is typical of the literature cited in support of affirmation surgery in minors. The fact that one of the leading surgeons in this field cites a 10-year-old, **Level-IV evidence** paper shows the utter poverty of quality scientific evidence in this area.

17. The next paper cited (Miller 2019) is a retrospective review of a single surgeon's experience with adult patients undergoing breast enhancement with implants over a 2 1/2 year study period. Average follow up interval was about 16 months. Efficacy of surgery was measured using a subjective test instrument that had 19 questions (typical of cosmetic surgery evaluations). The study does not involve any test of efficacy on self-identified transgender minors. Taken together this is **Level-V evidence** (single physician, small case collection, short follow-up, lack of comparison cohort, self-selection bias). Level-V evidence is not sufficient to inform clinical decision making, nor is it sufficient for consideration in obtaining consent for surgical care. Between the paper cited in paragraph 13, and this paper, ten years of affirmation surgery had elapsed, and the specialty could not yet produce scientific evidence to inform therapeutic decision making. The fact that a further 3 years of affirmation surgery has since passed, and papers such as this are cited as decisive by experts in the field of gender surgery, is alarming. This is not "standard

of care". It isn't even helpful for inclusion in a treatment guideline. This level of evidence is only useful for suggesting areas of future experimental research.

18. The next paper offered is a 2015 paper by Horbach et al. It is a retrospective review of the gender affirmation surgical literature published over a 20-year period, looking specifically at male-to-female genital surgery. It examined technical surgical outcomes and complications. It did not examine issues of self-harm or suicide. In the introduction the authors describe that quality of life was one of the surgical outcomes examined. Within the paper, however, we see that out of the 26 papers, published over a 20-year period, only one paper examined quality of life. All of the papers were retrospective case collections without a comparison cohort. None of the papers examined outcomes in minors. Taken in summary, this paper is an examination of papers that present **Level-IV (or lower)** evidence. Such evidence is not sufficient for informing therapeutic decision making, particularly where irreversible harms are certain to occur. What is particularly startling here is that the authors conclude by saying, "The available literature is heterogeneous in patient groups, surgical procedure, outcome measurement tools, and follow-up. Standardized protocols and prospective study designs are mandatory for correct interpretation and comparability of data." So the very paper cited by Dr. Schechter to demonstrate a "standard of care" that he would have us apply to the care of minors actually points out the fact that the specialty hasn't even developed a standard

language for describing either the condition or its care over the course of the 20 years examined by the paper.

19. The next paper offered is by Hess et al. from 2014. It is single center, retrospective review of outcomes in 254 consecutive patients that had undergone male-to-female genital surgery. Patients were asked to fill out a questionnaire that asked questions about subjective satisfaction. There is no comparison cohort. The average post operative follow-up interval was 5 years. The authors report that less than half of the patients completed the survey. Such a single-center retrospective case collection, with such a massive drop-out rate (>50%), places this paper in the 'very low quality' category, **Level-V evidence**, which cannot be used to inform clinical decision making.

20. The next paper is by Hadj-Moussa published in 2018. This is actually the publication which formed part of the WPATH Standard of Care. Its title is "Feminizing Genital Gender-Confirmation Surgery," and its aim is **"To summarize the World Professional Association for Transgender Health's (WPATH) surgical eligibility criteria and describe how patients with gender dysphoria benefit from GCS, provide an overview of genital and non-genital feminizing gender-confirmation procedures, and review vaginoplasty techniques, preoperative considerations, complications, and outcomes."** Examination of this document is critical because it gives us insight into the working process that

produced the WPATH standard. That standard is cited as a being definitive and sufficient for making clinical/therapeutic decisions for irreversible surgical interventions in minors. If this paper is not sufficient, then it is safe to say that sufficient evidence to support gender affirmation surgery in minors does not yet exist.

21. Hadj-Moussa et al. cite a list of scientific publications all of which are either retrospective literature reviews, single surgeon retrospective reviews, or simple reviews of techniques and their complications. There is even one actual experimental study examining post operative sensation that was unable to reach any conclusions because no measurement standard had yet been established. This is experimental work of the most rudimentary kind, and taken in sum only constitutes **Level-IV evidence**. Even within the substance of the WPATH Standard itself, which is understood and promoted as the best summary of gender affirmation surgical care, there is no scientific evidence sufficient to guide clinical decision making. It cannot even be called a clinical guideline because it does not compare affirmation care with any other treatment strategies, and it offers no consistent measurable benefits.

22. If Level-IV evidence is all that informs the WPATH Standard, then any claims of necessity, efficacy, or safety can declared as unsupported, and cannot be understood to represent evidence-based medicine. The entirety of the document rests upon “expert opinion” which medical history has repeatedly shown to be unreliable

(as I discussed at length in paragraph 27 of my original report). Such evidence therefore is at best sufficient to support experimental work. At present any such treatment of minors would require strenuous oversight. Such oversight would require a consistent descriptive language, reliable and repeatable methods of measurement including long-term value in preventing suicide among other adverse outcomes, a comprehensive and shared database, and a centralized and monitored reporting system. None of those requirements have yet been met by gender affirmation surgeons in the US.

23. The remaining discussions of evidence by Drs. Schechter and Olson-Kennedy present the same poor level of evidence which I reviewed in my original report. None of the evidence is sufficient to inform clinical decision making, or to assist in pre-operative consent consultation with parents of minor children.

24. In paragraph 53, Dr. Schechter declares that higher quality evidence is unavailable because double-blinded placebo control studies are not ethically acceptable. This presumes that there is no level of evidence between Level-II and Level-IV. This is a misrepresentation of the world literature. An examination of the ASPS instrument we have been using here to evaluate scientific evidence shows us that Level-III evidence is defined as "Case-control study or systematic review of these studies." This kind of evidence has been in the world literature at least since 2011, and is the reason why European gender clinics are all abandoning the social,

medical, and surgical transitioning of minors. (See footnote below re: Dhejne, Cass Review, Karolinska Policy, etc.). The discussions of that literature which Dr. Schechter includes in his report only discuss the rewriting of a conclusion in a single paper. Nothing in that rewrite changed any of the comprehensive Level-III data, which shows that long-term risk of suicide is not improved, nor is substance abuse, incarceration for violence, or any other objective measure. The study clearly shows that the morbidity and mortality of fully transitioned transgender persons climbs precipitously after 8 to 10 years. Since the American publications never follow patients beyond 3 to 5 years, and only rely on evidence plagued by self-selection bias, it is easy to understand why American physicians and surgeons might have a high opinion of the treatment model. The Swedish database tracks patients lifelong, and can compare transitioned patients to the general population in many ways, over a long interval. That Level-III evidence (longitudinal, cohort study) tells us there is no long-term benefit from the gender affirmation care model.

25. It is impossible to accept the position that affirmation care is the only model of care, when England, Sweden, and Finland have abandoned this approach and are returning to the proven psychological approaches of family therapy,

cognitive-behavioral care, and the care of co-morbid conditions that may be at play in the distress that the minor is experiencing.[2] [3] [4]

26. In their expert reports, Drs. Schechter, and Olson-Kennedy have presented only low-quality scientific information, none of it above Level-IV. For this reason, none of it can be used to inform clinical decision making in the care of self-identified transgender minors. Their position in support of gender affirmation medicine and surgery is based in low quality, expert consensus-seeking methodologies which professional organizations have abandoned in favor of evidence-based methodologies, as illustrated by the ASPS tool which we have used

[2] The Tavistock-Portman Institute in London was the sole provider of gender affirmation services to minors in England. In the wake of a very public personal injury case against Tavistok, Dr. Hillary Cass, past president of the Royal College of Paediatrics undertook a comprehensive review of those affirmation services. The result was the immediate process of closure, and a return to the proven methods which are now elaborated in Public Consultation: Interim service specification for specialist gender dysphoria services for children and young people, dated 20 October 2022. That service specification details many substantive changes, and begins by emphasizing that there is very poor evidence in support of hormonal manipulation, that care must turn in the direction of psychology/ neurology, and account for the many co-morbid conditions including Autism. https://www.engage.england.nhs.uk/specialised-commissioning/gender-dysphoria-services/user_uploads/b1937-ii-interim-service-specification-for-specialist-gender-dysphoria-services-for-children-and-young-people-22.pdf

[3] In April 2021, the Karolinska Institute in Sweden formally, and publicly abandoned medical gender affirmation in minors below age 16, and allows it for 16-18yo minors, but only under highly supervised experimental protocols. This speaks clearly to the experimental nature of affirmation care in the treatment of minors.
https://segm.org/Sweden_ends_use_of_Dutch_protocol

[4] "The Finnish Health Authority (PALKO/COHERE) deviated from WPATH's 'Standards of Care 7,,' by issuing new guidelines that state that psychotherapy, rather than puberty blockers and cross-sex hormones, should be the first-line treatment for gender-dysphoric youth. This change occurred following a systematic evidence review, which found the body of evidence for pediatric transition inconclusive."
https:segm.orgFinland_deviates_from_WPATH_prioritizing_psychotherapy_no_surgery_for_minors

in this response. Given this absence of compelling evidence to support the efficacy of gender affirmation medicine and surgery, and given the known harms that such interventions cause to minors, it is reasonable that children should be protected from this form of care.

I declare under penalty of perjury, pursuant to 28 U.S.C. § 1746, that the foregoing is true and correct.

Executed this 10th day of March 2023.

/s/ Patrick W. Lappert
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Patrick W. Lappert, M.D.