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

AUGUST DEKKER, et al.,

Plaintiffs,

v.

Case No. 4:22-cv-00325-RH-MAF

JASON WEIDA, et al.,

Defendants.

## EXPERT DECLARATION OF PATRICK W. LAPPERT, M.D.

I, Patrick Lappert, M.D., pursuant to 28 USC 1746, declare as follows:

1. I am over the age of eighteen and submit this expert declaration based on my personal knowledge.

2. I have been retained by counsel for the defendants in the above captioned lawsuit to provide an expert opinion concerning the nature of gender surgery. That opinion will be based primarily in my own experience as a physician and surgeon. It will also be based in an evaluation of the scientific publications that Plaintiffs have provided to the court in support of their complaint. It will additionally include an examination the world literature on the subject, as well as an examination of the massive public controversies that have led to near complete reversal of public health policy in multiple European states who have turned away from the social, medical, and surgical transitioning of minors.

3. I am a retired plastic surgeon, as well as a retired senior medical officer in the United States Navy. I have been a physician for 40 years. I completed my undergraduate education at the University of California, Santa Barbara. While there I had significant experience in university level research having been invited to be an undergraduate research assistant, working in the laboratory of Dr. Philip C. Laris. It gave me experience in the evaluation of research publications. We were involved in the collaborative work of elucidating the electrodynamic and stoichiometric quantification of the sodium and potassium pump, located in every living cell. I completed my undergraduate degree in four years, and went directly to medical school.

4. I completed my preliminary medical training while on active duty in the US Navy. I attended the Uniformed Services University of the Health Sciences,F. Edward Hebert School of Medicine, graduating as Doctor of Medicine in 1983.

5. I completed a surgical internship at the Oakland Naval Hospital, followed by Aerospace Medicine/ Flight Surgeon Training at the Naval Aerospace Medical Institute, Naval Air Station Pensacola.

6. I then served for 2 1/2 years with a deploying, front-line Marine Corps fighter squadron, serving in the dual functions of medical department head, and squadron Radar Intercept Officer flying in the F-4 Phantom. I was deployed to Asia and the Western Pacific. I provided medical care to squadron personnel while deployed in Japan, Korea, and the Philippines.

7. I completed my General Surgery residency at the Oakland Naval Hospital- University of California, Davis/ East Bay Consortium. Following residency, I was retained there as a staff surgeon, and was responsible for the training of surgical residents. I was awarded the inaugural "Resident's Choice" award given to the attending surgeon deemed most effective by the residents in training, and presented by Claude Organ, MD, past President, American College of Surgeons.

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8. I trained in Plastic and Reconstructive Surgery at the University of Tennessee, Memphis, graduating in 1994. During that training I traveled to Peru and provided craniofacial surgical care for indigent Peruvian children. This included the publication of a case report of surgical management of a very late post traumatic ectopic frontal sinus mucocele.

9. I received Board Certification in General Surgery from the American Board of Surgery in 1992. I received Board Certification in Plastic and Reconstructive Surgery in 1997 from the American Board of Plastic Surgery. I recertified in Plastic and Reconstructive Surgery in 2008.

10. I served as a staff plastic surgeon at Naval Hospital Portsmouth, Virginia. 1994-2002. I became Department Chairman in 1998, and served in that office until my retirement. We had 5 staff plastic surgeons, and 10 Enlisted and civilian members. I established the Wound Care Center, providing specialized wound care services to a global catchment area. For example, our department was responsible for the limb and pelvic reconstruction of some of the sailors wounded when the USS Cole was attacked while at anchor at Aden in Yemen. I also established and chaired the multi-disciplinary Cleft Palate, Craniofacial Board. We provided comprehensive services for congenital pediatric deformities to a global catchment area.

11. Following selection to the rank of Captain, USN, I was selected to serve as Specialty Leader, Plastic and Reconstructive Surgery for the office of the Surgeon General, USN. In addition to being responsible for the selection and training of surgical residents, I was also responsible for Navy Medical Department policy concerning coverage for services, and medical evaluation and evacuation policy. I was responsible for the resolution of issues concerning what conditions constitute a requirement for immediate care in military hospitals, what may be purchased from civilian medical organizations and provided to eligible members on a delayed (elective) basis, and what is to be considered cosmetic surgery and therefore not an obligation of the government. I served in that position until my retirement. While serving as Department Chairman, I co-authored a textbook chapter on the management of combat injuries with the Chairman of Plastic Surgery at Harvard University, Dr. Eloff Ericksson. During that time I also published the first case report in the world literature detailing the use of endoscopic technique for reduction and plate fixation of a fronto-facial fracture.

12. I retired from the Navy after 24 years of continuous active duty. I was invited to join a surgical group in Scottsbluff Nebraska, primarily to provide comprehensive reconstructive surgery for women suffering breast cancer. I also provided reconstructive services to a very large regional catchment served by the Level II trauma center at Regional West Medical Center (RWMC). I established and chaired the Cleft Palate/ Craniofacial multi-specialty clinic at RWMC. I also established comprehensive wound care services for the many rural community hospitals in the western prairie including Nebraska, Eastern Wyoming, southwest South Dakota and northeast Colorado.

13. For reasons pertaining to the education of our six children, I moved my practice to Northern Alabama in 2005. I have been a solo practitioner here for the last 17 years. I was brought here by a local hospital that wanted to offer comprehensive breast reconstruction to women affected by breast cancer. I also started a comprehensive wound care center. I have also had a very active practice in aesthetic/ cosmetic surgery. I maintained my own surgical suite for in-office facial rejuvenation procedures as well as minimally invasive body contouring procedures. I was an early adopter of advanced techniques in autologous fat grafting for facial re-contouring as well as for the resolution of radiation burn wounds of the skin. I continued to serve in the training of medical students in my office practice.

14. Although I maintain a practice in wound consultation, skin care, and laser services, I retired from my surgical practice in 2020, after having practiced as a plastic and reconstructive surgeon for 30 years. I was an Active Member in good standing of the American Society of Plastic Surgery for all but the last two years in practice. With only two years remaining in my practice, I elected to forgo a third certification by the American Board of Plastic Surgery. The certification was no

longer necessary for maintaining my hospital credentials, and I saw it as an unjustifiable expense for a solo practitioner planning retirement. When my board certification lapsed, my membership in the American Society of Plastic Surgery lapsed as a result.

15. As can be gleaned from this summary, I have a meaningful breadth of experience, not only in the advanced surgical care of trauma, cancer, head/ neck disease, as well as cranial and facial birth defects. Many of those procedures require the use of the most advanced sensate, microvascular flaps, including composite and pre-fabricated flaps. These are all the same techniques employed by today's gender surgeons. As regards surgery of the breast, I co-authored a ground-breaking article regarding pre-operative plastic surgical planning in the care of women suffering from breast cancer. It is among the most frequently cited papers in the field of breast reconstruction.<sup>1</sup>

16. Since 2014 I have made a concerted effort to examine the medical literature as it pertains to the care of self-identified transgender persons including children and adults. I have had an eight year long running discussion on these issues with Family Practitioners, Pediatricians, Pediatric and Adult Psychologists and

<sup>&</sup>lt;sup>1</sup> Toth, B.A. and Lappert, P. (1991) Modified Skin Incisions for Mastectomy: The Need for Plastic Surgical Input in Pre-Operative Planning. Plastic and Reconstructive Surgery, 87, 1048-1053. <u>http://dx.doi.org/10.1097/00006534-199106000-00006</u>

Psychiatrists, Pediatric Endocrinologists, as well as PhDs who specialize in the evaluation of the validity of scientific publications. During that time I have made many public presentations to teachers, counselors, pastors, and administrators on the subject of transgender, and the medical-scientific evidence that informs that care.

17. I have offered testimony, both written and in person on this issue to state legislators, state health benefits management agencies, as well as to State Attorneys General.

18. I have also had experience in making judgments concerning distinctions between reconstructive surgery and cosmetic surgery. I gained this experience while serving in senior leadership for a government medical care system in which I had no financial stake. I have no financial interests in the matter in question, and the professional opinion that I offer is not influenced by my sources of income nor by my position in any organization that financially benefits from medical services that are discussed in this opinion.

19. My peer-reviewed publications include: Lappert PW. Peritoneal Fluid in Human Acute Pancreatitis. Surgery. 1987 Sep; 102(3):553-4; Toth B, Lappert P. Modified Skin Incisions for Mastectomy: The Need for Plastic Surgical Input in Preoperative Planning. J Plastic and Reconstructive Surgery. 1991; 87 (6): 1048-53; Lappert P. Patch Esophagoplasty. J Plastic and Reconstructive Surgery. 1993; 91 (5): 967-8; Smoot E C III, Bowen D G, Lappert P, Ruiz J A. Delayed development of an ectopic frontal sinus mucocele after pediatric cranial trauma. J Craniofacial Surg. 1995;6(4):327–331; Lappert PW. Scarless Fetal Skin Repair: "Unborn Patients" and "Fetal Material". J Plastic and Reconstructive Surgery. 1996 Nov; 98(6): 1125; Lappert PW, Lee JW. Treatment of an isolated outer table frontal sinus fracture using endoscopic reduction and fixation. Plastic and Reconstructive Surgery 1998; 102(5): 1642-5. I have also published the following medical textbooks: Wound Management in the Military. Lappert PW, Weiss DD, Eriksson E. Plastic Surgery: Indications, Operations, and Outcomes, Vol. 1; 53-63. Mosby. St. Louis, MO 2000.

20. Over the past four years, I have testified at trial and/or deposition in the following cases: *Brandt v. Rutlege*, Case No. 4:21-CV-00450-JM (E.D. Ark.) and *Kadel v. Folwell*, Case No. 1:19CV272 (M.D.N.C.). I have also submitted an expert report in *Siefert v. Hamilton County Job and Family Services*, Case No. 1:17-CV-511 (S.D.Ohio).

21. For my services as an expert witness, I am being compensated at an hourly rate of \$400 for preparation of my written testimony as well for deposition and hearing. Additionally my travel expenses will be reimbursed. My compensation is not dependent upon the substance of my opinion nor upon the outcome of the litigation.

22. If called to testify in this matter I will do so truthfully, and to the best of my ability.

23. The Plaintiffs make the claim that "gender affirmation care" including "gender affirming (or confirming) surgery" should be paid for by the State of Florida because such care has scientifically proven efficacy, and safety. Furthermore they claim that there is such an abundance of scientific support for these treatments that they must be understood to be the standard of care, and that there is no controversy in the matter. As shall be seen in this report, the claims made by the plaintiffs are not supported in the science. This will be seen in the examination of those scientific documents which they cite in support of what will be seen to be experimental treatments on children.

24. In recent years professional medical societies have been making a concerted effort to strengthen the scientific basis upon which their particular specialties stand. This effort is commonly given the name "evidence based medicine". It is a systematic effort to categorize the quality of prognostic and therapeutic studies so that physicians reading these publications can distinguish what is vague and speculative from what is a matter of high likelihood, or grave certainty. Tools for making such distinctions have been developed that categorize clinical or experimental findings on the basis of how that data was obtained, the reliability of the test instruments used, the variability of the results, the sample size, and the

likelihood of bias among other factors. For the purposes of this response, I will use the tool developed by the American Society of Plastic Surgery<sup>2</sup>. For prognostic studies, the categorization of evidence is divided into Levels I- V, with Level I being the most rigorous and having the highest likelihood of scientific certainty, and Level V having the least rigor, and having very little certainty. Here are the definitions of those levels according to the American Society of Plastic Surgery:

<u>Level I</u>: High quality prospective cohorts study with adequate power or systematic review of these studies.

<u>Level II</u>: 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

<u>Level V</u>: Expert opinion; case report or clinical example; or evidence based on physiology, bench research or "first principles".

25. For therapeutic studies, the ASPS categorization is similar, but with a few helpful distinctions:

<sup>2</sup> The Levels of Evidence and their role in Evidence-Based Medicine <u>Patricia B. Burns</u>, MPH,1 <u>Rod J. Rohrich</u>, MD,2 and <u>Kevin C. Chung</u>, MD, MS3 <u>Plast Reconstr Surg. 2011 Jul; 128(1): 305–310.</u>

http://www.plasticsurgery.org/Medical\_Professionals/Health\_Policy\_and\_Advocac y/Health\_Policy\_Resources/Evidence-

<u>based\_GuidelinesPractice\_Parameters/Description\_and\_Development\_of\_Evidenc</u> <u>e-based\_Practice\_Guidelines/ASPS\_Evidence\_Rating\_Scales.html</u>.

Level	Type of Evidence
1A	Systematic review (with homogeneity) of RCTs
1B	Individual RCT (with narrow confidence intervals)
1C	All or none study
2A	Systematic review (with homogeneity) of cohort studies
2B	Individual Cohort study (including low quality RCT, e.g. <80% follow- up)
2C	"Outcomes" research; Ecological studies
3A	Systematic review (with homogeneity) of case-control studies
3B	Individual Case-control study
4	Case series (and poor quality cohort and case-control study
5	Expert opinion without explicit critical appraisal or based on physiology bench research or "first principles"

26. These distinctions are very important to physicians who seek to understand the weight of the evidence presented in support of a change in therapeutic care. Sometimes such scientific findings can be so compelling regarding an issue, that professional societies will publish clinical guidelines that strongly suggest conformity to a new treatment plan based in that evidence. Occasionally the evidence will be of such certainty, on a matter that is so grave, that professional societies and even public law will assert that there exists a standard of care based in this evidence that if ignored has a high probability of injury or harm to the patient. That is what is implied when the phrase "standard of care" is used.

27. To that end, the 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.

28. To summarize, it can be said that Level-V evidence is anecdotal, and in the world of surgery it is typified by the phrase "expert opinion". Such evidence is not to be dismissed since it is the known starting point for much meaningful research and discovery. A surgeon with great experience and unassailable credentials will observe something peculiar. He will form a hypothesis about its cause or treatment. Hopefully he will publish his single case report, and share his thoughts with the wider surgical community. Perhaps one of his residents will start a hunt for other cases. Perhaps surgeons who read his paper will report similar cases. Eventually it might lead the surgeon to apply his new principal to a series of cases, that would constitute an improvement to Level-IV evidence. Even then, it would be considered "poor" evidence because it suffers from the fact that it is a small collection of cases, from a single surgeon, and perhaps no one has yet replicated his observations. Additionally it may suffer from "selection bias" (as when the patient decides if he will receive long term follow up), lack of proper controls (which help us to separate out what is the result of our treatment, and what is within the range of normal variation in the population), inadequate study duration (if you claim a long term improvement in survival, you have to follow the patients long-term).

29. An example from the history of surgery will serve to illustrate how Level-IV and V evidence, when widely encouraged and applied through expert opinion, can result in grave missteps. For over 100 years, ulcer disease of the stomach was considered a surgical problem. This very debilitating disease did not appear to be manageable through medical means. Laboratory study of the stomach had already demonstrated that acid production in the stomach is regulated by particular nerves. That finding suggested that if those nerves are cut, acid production will decline, and the ulcer will heal. It was also determined that the surgery must include some form of "drainage procedure" because cutting the nerves would also impair the muscular contracture of the stomach. Through the course of the decades many of the greatest surgeons gave their names to the elegant techniques for selectively cutting the nerves, or draining the stomach in ways that hopefully would

not result in a "gastric cripple" (an all too common outcome). Long hospitalizations, and many months spent accommodating to the reordering of their digestive tract was expected. There is a syndrome of bad effects from these surgeries that most people adapt to but some never do. Nonetheless, untreated peptic ulcer disease was often deadly, either from peritoneal sepsis, or bleeding to death. Because of the gravity of ulcer disease, it was ethically sound to risk "post gastrectomy syndrome" if it meant saving a life.<sup>3</sup> By the 1980s, level II and I studies had demonstrated that peptic ulcer disease is actually a bacterial infection that can be treated with antibiotics and an acid-reducing medication. This had been very seriously suspected for at least 30 years. However, poorly designed studies published by the greatest academic surgeons of the day had utterly suppressed the bacterial explanation in favor of the surgical solution. A very well-reasoned 2014 paper by Seselja and Strasser<sup>4</sup> shows the heuristic pitfalls that can result in unintended harms to patients when surgical decision making is driven by expert opinions that aren't well supported by quality scientific evidence.

30. Generations of surgeons will follow what is taught to them by the academic surgeons. These are esteemed mentors who are responsible for training the

<sup>&</sup>lt;sup>3</sup> History and evolution of peptic ulcer surgery; John B.BlalockJr.MD1; <u>The</u> <u>American Journal of Surgery</u> Volume 141, Issue 3, March 1981, Pages 317-322 <sup>4</sup> Dunja Šešelja 1, <u>Christian Straßer</u>; Heuristic reevaluation of the bacterial hypothesis of peptic ulcer disease in the 1950s; Acta Biotheor 2014 Dec;62(4):429-54.

next generation of surgeons. That is how it has always been. However today, medical science has advanced in crucial ways through the application of the "science of science". We understand better now how to examine the evidence. We are less likely to make needless errors of judgement because we are better able to analyze the data particularly with regard to its reliability. This is indispensable when studying biological systems that, in every measurable trait, demonstrate great variability. It is particularly essential when examining and caring for the human person, because you have the added dimension of their subjective interior life.

31. In the professional literature that supports gender-affirmation care, the word "transgender" is defined on the basis of a subjective conflict within the patient's internal sense of themselves. It affirms this interior subjective division on the basis of an idea that sex is somehow "assigned" at birth, rather than scientifically discovered through tissue sampling, in utero ultrasound, or simple inspection at birth. In 99.98% of cases, simple inspection correctly detects the sex of the subject. Furthermore, this test can be administered by untrained personnel. His use of the term "assigned" implies that there can be errors of "assignment". Such an assertion demands not only that we examine the result, but we must also look at the consistency of the data. It is well understood that consistency of the data is one of the hallmarks of good evidence. Any test that can be correct 99.98% of the time regardless of who administers the test is perhaps unequaled in scientific medicine.

32. Gender, on the other hand, as it relates to sex, is a very different matter. While there are some aspects of gender that are more fixedly related to the sex, there are large areas of gender that are learned within the milieu of the local culture, and find their origins in family life. There is no objective, repeatable test, with known error rates, that can be used to detect "gender". Gender, as the term is used in the world of medicine and surgery is not objectively measurable. Such traits as hair length, occupation, preference for violent sport, clothing selection, among others, may have vague gender associations, but are so variable from culture to culture as to be useless for our purposes. This is because "gender" is one of the many expressions of the interior life of the person. It is a mercurial thing because it is not entirely fixed to that part of the patient that is a reliable object for examination and treatment. That difficulty with diagnosis and prognosis is further complicated by the fact that variability in gender presentation doesn't just occur within any particular human grouping, it is also known to vary within the span of the life of a single patient.((Zucker, K. J. (2018). The myth of persistence: response to "A critical commentary on follow-up studies and 'desistance 'theories about transgender and gender nonconforming children" by Temple Newhook et al. International Journal of 19(2). 29. 2018. Transgenderism, 231 - 245.Published online Mav http://doi.org/10.1080/15532739.2018.1468293)

The claim is made that hormone therapy and gender confirmation 33. surgeries can help alleviate gender dysphoria, and that these treatments have been shown to be an effective treatment for gender dysphoria. In support of this claim, a further claim will be made that there is a prevailing consensus of the medical community that these treatments are medically necessary, and are safe and effective treatments for gender dysphoria. We will examine the efficacy, and safety by examining the papers offered in support of these claims. We will examine the world literature more broadly in order to evaluate the claim of a "prevailing consensus". The claim of consensus insists on an absence of important controversy surrounding the use of social, medical, and surgical gender affirmation, particularly with regard to the young. That examination will show that there are startling and permanent differences in outcomes between "affirmation-care" as proposed by the plaintiffs, and the historically proven approach that begins in proven psychological care, and results in resolution nearly 90% of the time.

34. In virtually every instant when the claim of the efficacy and safety of gender-affirmation is made, the WPATH "Standards of Care" will be cited in support. This document is the product of the World Professional Association of Transgender Health. It has had 8 iterations. This document has been, and continues to be produced through a process of consensus-seeking within working committees of experts. As we have seen in our discussion about the grading of scientific

evidence, expert opinion is the most rudimentary level of evidence. It is the starting point of scientific investigation, not the end. As any medical subject is investigated over time, the expert opinion becomes better supported by well developed and monitored scientific processes. In short, expert consensus is only as valuable as the scientific evidence that can be reviewed and evaluated which supports the opinion. If the evidence hasn't progressed very far beyond the category of expert opinion, then we are speaking about evidence that is neither sufficiently developed so as to drive either clinical decision making, nor fiduciary decision making when public or invested resources are involved.

35. It will be recalled that the use of the words "standards of care" imply that a particular treatment or clinical principle, if not employed, would have an unacceptable probability of harm to the patient. The term "standard of care" addresses issues of duty, negligence, harm, and causation. It is a legal term that is applied when evaluating the malpractice of medicine. In its Introduction to the WPATH standards, the authors acknowledge that their document is meant to be a guideline only, and subject to individual and local adaptation, and that it is not binding in any way. On page 2 of v.7 in bold face it states "The Standards of Care are flexible clinical guidelines". This calls into question the motivation for the use of the phrase "standards of care" in all of its publications and statements.

36. If the WPATH document is actually a collection of clinical guidelines, then we must examine how such guidelines are developed. In the International Journal of Quality in Healthcare (2016) Kredo et al.<sup>5</sup> offer a helpful examination of that process. They point out that in the past they were just consensus statements offered by experts in the field. They were "systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances." With the push toward evidence based medicine, it was realized that guidelines required more scientific rigor, so in 2011 the definition was changed to, "statements that include recommendations intended to optimize patient care that are informed by a systematic review of evidence and an assessment of the benefits and harms of alternative care options". In order to have real value, clinical practice guidelines must therefore do two things: Use high quality scientific data to evaluate risks, and beneficial results while presenting alternative approaches for the practitioner and patient to consider.

37. With respect to the particular questions at issue in this case, "high quality scientific data to evaluate risks, and results while presenting alternative approaches for the practitioner and patient to consider", should be evidenced in the complaint, and its supporting documents.

<sup>&</sup>lt;sup>5</sup> Guide to clinical practice guidelines: the current state of play; Kredo et al. <u>Int J</u> <u>Qual Health Care.</u> 2016 Feb; 28(1): 122–128.Published online 2016 Jan 21. doi: <u>10.1093/intqhc/mzv115</u>

Among the scientific publications frequently cited in support of the 38. efficacy and safety of hormonal treatment of transgender persons is a paper by Hembree et al.<sup>6</sup> which is itself a clinical practice guideline promulgated by the Endocrine Society (hereafter ES). Since this paper is a product of the Endocrine Society, it must be understood by reconstructive surgeons given that the referral path of children into the surgical treatment arm is universally through the prior evaluation by an endocrinologist. This guideline was produced in order to update an earlier guideline from 2009. It was produced using GRADE consensus methodology, and is the product of 9 experts who formed the committee. The GRADE methodology cautions its users that "inconsistency of result across multiple studies", "indirectness of evidence", "imprecision in measurement", and "publication bias" are to be watched for in its application; essentially that doctors must watch out for sloppy measurement, and bias in the working group. The scientific evidence used to support the Endocrine Society's special treatment guidelines for gender dysphoric/ gender incongruent persons appears to be of low to very low quality, since the clinical recommendations were so equivocal. It was published in 2017 and includes the statement:

<sup>&</sup>lt;sup>6</sup> Wylie C Hembree, et al. Endocrine Treatment of Gender-Dysphoric/Gender-Incongruent Persons: An Endocrine Society Clinical Practice Guideline, *The Journal of Clinical Endocrinology & Metabolism*, Volume 102, Issue 11, 1 November 2017, Pages 3869–3903, <u>https://doi.org/10.1210/jc.2017-01658</u>

"guidelines cannot guarantee any specific outcome, nor do they establish a standard of care": "The guidelines should not be considered inclusive of all proper approaches or methods, or exclusive of others. The guidelines cannot guarantee any specific outcome, nor do they establish a standard of care. The guidelines are not intended to dictate the treatment of a particular patient." P. 3895.

39. As was discussed earlier, this language of uncertainty when included in a clinical practice guideline is what we would expect with low quality evidence. This is what the ASPS would call a Grade D result that rests on level IV-V evidence, and is therefore not useful in directing clinical decision making. This consensus process described by Hembree et al. would likely appear very similar to the decision making that drove peptic ulcer surgery in opposition to evidence that it is a bacterial disease. Academic physicians of the highest calibre were making recommendations to their fellow practitioners, as they are now, based upon anecdotal experience and low level evidence.

40. Just 2 years later, in 2019, the ES, along with an international panel of endocrinology societies, concluded "the only evidence-based indication for testosterone therapy for women is for the treatment of HSDD [Hypoactive sexual desire disorder]," and that "There are insufficient data to support the use of testosterone for the treatment of any other symptom or clinical condition, or for disease prevention." Also, "The safety of long-term testosterone therapy has not been established."<sup>7</sup>

41. It is somewhat alarming to note that these findings are entirely consistent with a consensus statement from 5 years earlier in 2014 (8). In the span of just 5 years, the Endocrine Society consensus has swung from "no other indication for androgen in women" to something akin to, "it is crucial that androgens be given to women who are gender dysphoric", and then back to "no other indication for androgen". This kind of consensus oscillation is what you would expect when there is such scant scientific basis for the decision making.

42. Leading experts in the nascent field of "gender-affirmation surgery" will cite the ES guidelines as the "criteria for initiation of surgical treatment", and that such surgery is "often necessary and effective". Additional citation of other specialty consensus statements, developed by similar methodology, includes the American Pediatric Society, and the American Psychiatric Association. These

<sup>&</sup>lt;sup>7</sup> Endocrine SocietySusan R Davis, et al, Global Consensus Position Statement on the Use of Testosterone Therapy for Women, *The Journal of Clinical Endocrinology & Metabolism*, Volume 104, Issue 10, October 2019, Pages 4660– 4666, <u>https://doi.org/10.1210/jc.2019-01603</u>.

<sup>(8)-</sup> Margaret E. Wierman, et al. Androgen Therapy in Women: A Reappraisal: An Endocrine Society Clinical Practice Guideline, *The Journal of Clinical Endocrinology & Metabolism*, Volume 99, Issue 10, 1 October 2014, Pages 3489– 3510, <u>https://doi.org/10.1210/jc.2014-2260</u>

consensus statements are also important for reconstructive surgeons to be familiar with since it is in these areas of practice that the initial diagnosis of gender dysphoria is made, a diagnosis which constitutes the foundation for referral to surgery. The surgeon must understand the strength of the scientific support of the diagnosis given that in some instances breast surgery, and in all instances genital surgery is an irreversible mutilation of the child resulting in permanent losses to essential human functions.

43. Surgeries that are used in gender-affirmation care are described by plaintiffs experts as being "reconstructive". They include surgeries of the face, the chest, and the genitals. It is crucial to understand the meaning of the term reconstructive surgery, and contrast it with the term "aesthetic surgery". It is precisely this distinction that distinguishes medical necessity, which in turn is the basis for evaluating claims of obligation on the part of the State or any other 3rd party payor, to pay for these procedures. This is an area where I have some experience, having served the office of the Surgeon General, USN as specialty leader for reconstructive surgery. Making determinations of coverage for any agency is essentially about rightly answering this as the first question: "Is this reconstructive, or is this cosmetic?"

44. Reconstructive surgery is the restoration of form and function for a person who has suffered a loss through genetic, in utero developmental accident,

trauma, infection, or surgery for infectious events or cancer. It begins with the most comprehensive knowledge available concerning the nature and function of the injured part, and seeks to optimize function as the primary goal, while seeking to restore the natural form. Both form and function are understood objectively, and both have subjective effects. Restoration of form and function in a combat injured leg has measurable effects on mobility, range of motion, strength, and capacity for work. Subjectively, the impact is profound as well, but it is not the central purpose of the operation.

45. In contrast, aesthetic surgery begins in the subjective life of the patient. The patient presents seeking an opinion concerning the aesthetics of a particular feature, such as the nose. They will express a dislike of the feature. Their hope is that by modifying its appearance, they will improve their interior subjective life. What the patient is seeking is a normal human objective: to improve the aesthetics of things, for ourselves and for the people around us. When the surgeon is planning and performing the operation on the nose, there is great objective precision; however, all of it is placed in the service of the subjective life of the patient. It is of no use for the surgeon to impress himself with a technically perfect result if the patient loathes it. The surgeon additionally has the grave duty of managing the risk for the patient and weighing it against the potential benefit. The patient must not be submitted for a surgery which entails a significant risk of loss if the surgery is being performed only to achieve an aesthetic outcome. If there is a certainty of loss, then there is a certainty of error. To give a young woman a perfect nose, and in the process destroy her ability to breath through it would be a terrible error of surgical decision making. It is axiomatic in plastic surgery that we are to avoid a predictable sacrificing of function in the pursuit of cosmetic improvement.

46. All of the world's literature in the area of gender affirmation medicine and surgery begins in the subjective life of the patient. In the past the associated diagnostic terms directed us to consider the subtle processes at work in the mind of the patient that cause obsessive thinking, and compulsive behaviors that center on how the world views their sexed appearance. More recently the condition has been "de-pathologised" and now the preferred term of "gender dysphoria" has come into use. This new language has hidden away virtually all of the issues of the interior emotional life of the patient, and left us only with the vaguest descriptions of the patient's condition: "dysphoria", "unhappy". Simple though the term is, it is still entirely in the subjective life of the patient. There is nothing found in the term "gender dysphoria" that points to a lost or otherwise damaged body structure in need of reconstruction. No functional or physical loss is described or even suggested by the term "gender dysphoria". It is a fundamental characteristic of a cosmetic surgery patient that the presenting complaints are only subjective, and in the course of the complete evaluation of the patient, no functional or structural defect is found.

47. A further reason for the crucial importance of clarity in separating what is reconstructive from what is cosmetic is the part that this distinction plays in surgical planning, and informed consent processes. Planning for a reconstructive operation includes an assessment of the size and severity of the wound, or the dimensions and tissue types of the missing part. This determination guides the selection of tissue from other body areas that can be employed in the reconstruction. At the same time the surgeon must understand the scope of the harm that will be caused by harvesting that tissue to complete the reconstruction. That harm is given the name "donor defect", and it forms an important part in the risk/ benefit calculation. For example if I were to reconstruct a man's jaw that was shot away in combat, one of my first options would be to use a portion of bone from the leg. I can transpose that bone to the face, attach the blood supply, then cut and form the bone segment to replace what was lost. One of the important considerations is to prevent loss of function of the leg (donor defect). The operation is in part designed around that consideration because we seek to limit (entirely if possible) the magnitude of the functional loss caused by the donor defect. The only reason that we accept any loss at all is because of the grave nature of the original wound. We accept some small degree of loss if by doing the operation we restore the functions lost in the wounding event. Furthermore, whatever function is lost because of the donor defect is considered a complication had there been any way to avoid it.

48. In contrast cosmetic surgeries, because they begin with an otherwise fully intact person, they do not begin with any assessment of any loss from any of the wounding processes described above. The only measurable findings in cosmetic surgery are those of aesthetic proportion, and which being aesthetic find their importance in the subjective life of the observer. In the case of the cosmetic operation, any functional loss caused by surgery is considered an avoidable complication since the surgery neither anticipates nor yields any functional improvement except in the subjective life of the patient. This is why measures of success in cosmetic surgery are always made using subjective "quality of life" questionnaires.

49. As we examine the particular surgeries used in gender affirmation we will see that there is a very troubling abandonment of these first principles of reconstructive surgery. The first troubling example is "chest masculinization" surgery in female to male presentation patients. This surgery actually begins with the known expectation that the surgery will produce a loss of two essential human functions, namely: sexual arousal, and breast feeding. Both functions are permanently and irretrievably lost, and that loss is one of the expected results or the surgery. This step is then followed by the cosmetic shaping of the chest through the use of liposuctioning in an effort to further masculinize the appearance of the chest. This surgery is now being routinely performed on minor girls, and version 8 of the

WPATH "standards of care", which is presented as authoritative by proponents of gender affirmation, actually recommends mastectomy in girls as young as 15 years of age. This surgery does not involve the restoration of form and function, and is therefore not reconstructive. It is an operation that begins in the subjective life of the patient and aims at a result that also resides entirely within the subjective life of the patient. It is thus by definition an aesthetic (cosmetic) surgery. Because it includes the 100% likelihood of a massive functional loss, it must be considered unsupportable as a matter of policy.

genital surgery procedures 50. Similarly. cannot be considered reconstructive because they do not meet the definition of reconstructive surgery. They begin with an obsessive concern or anxiety in the subjective life of an otherwise normal, healthy person. They involve the planned destruction of an essential human function, and they are not restoring a form that is missing due to trauma, genetic accident, in utero event, or disease. The surgery seeks to create counterfeit structures that never could have existed in the patient, except as an artifact of surgery. I have done many reconstructive surgeries involving the entire genital area in patients with military injuries and infectious illnesses. If the injury is so devastating as to require a counterfeit structure, and that is all that can be offered, then there is no question as to how the surgeon must proceed. In contrast, gender affirmation surgery only produces counterfeit structures that are created to serve the

subjective life of the patient. Because these surgeries are cosmetic, and because they are 100% certain to produce grave functional losses, they must not be supported as a matter of public policy, and never be paid for using public funds.

51. In spite of these clear distinctions between reconstructive and cosmetic surgery, proponents of gender affirmation surgery will claim that such procedures are medically necessary. This language of medical necessity is found in the WPATH "standards of care". It should be remembered that the WPATH standard of medical necessity is not supported in reliable scientific evidence, but only on rudimentary, low level, expert opinion/ consensus statement data, which is no support at all. The use of the term "medical necessity" is language that is used by medical insurance programs, both private and public to establish insurance coverage in the case of particular procedures. Benefits of insurance programs can vary from policy to policy, but when the term "medically necessary" is used, it implies that failure to cover the care is likely to cause harm to the beneficiary. For this reason, insurance programs, including state Medicaid programs routinely examine the efficacy of treatments in the management of medical conditions, and develop policies of coverage or exclusion if benefit has not been demonstrated, or if a less hazardous or less expensive process of care can be offered to the beneficiary.

52. There are circumstances in which the exact same surgery may be considered reconstructive in one patient, but cosmetic in another. It is important to

be familiar with this problem since advocates of gender affirmation surgery will use the similarity as the basis for claiming that it should be a covered benefit, and that failure to include surgery in the insurance coverage is evidence of legal prejudice against a particular class of patients. For example, the claim will be made that removal of breast tissue from a female seeking to present as a male is the same as removing breast tissue from a male who suffers from the condition of gynecomastia (female breast tissue on a male chest). Or they will offer the analogy that mastectomy (complete removal of the breast) in a healthy female who seeks to present as male is the same as prophylactic mastectomy in a female who has inherited a high lifetime risk of breast cancer. Both females are at present healthy, both females get mastectomy. Gender affirmation advocates will ask, why one is a covered benefit, and the other excluded?

53. One of the essential mechanisms that third-party payors (including state Medicaid agencies) have for distinguishing reconstructive surgery from cosmetic surgery is found in the laboratory examination of tissue removed during surgery. This tissue examination by the pathology department is required by insurance programs in order to confirm that the operation performed was reconstructive (covered benefit) and not cosmetic (excluded from coverage). Two operations may be outwardly identical even while one is reconstructive and the other cosmetic. An excellent example is breast reduction surgery. This surgery may be reconstructive

if it is performed on patients who suffer from chronic neck, back, and shoulder pain caused by the orthopedic effects of their heavy breasts. The same, technically identical operation, might be done for purely cosmetic reasons. In the case of reconstruction, the patient has an objectively diagnosable condition that causes lost time from work, frequent covered visits to physical therapy, or to pain clinics, chiropractors and radiologists. There is abundant actuarial data, based upon the highest levels of scientific support, that a breast reduction of sufficient weight (based upon the anthropometric measurement of the patient) has a very high probability of resolving the chronic pain. High quality medical literature that addresses this issue, and its importance to insurance plans, is typically very precise in its data gathering and actuarial interpretation.<sup>8</sup> However, pain cannot really be measured. Pain is reported by the patient. Nonetheless, health insurance plans are able to distinguish cosmetic breast lift from reconstructive breast reduction based upon the measured and reported weights of the breast tissue that is submitted to pathology during surgery. An objective, repeatable medical test, with known error rates is used to confirm the diagnosis, ensure correct care for the patient, and separate cosmetic

<sup>&</sup>lt;sup>8</sup> Accuracy of Predicted Resection Weights in Breast Reduction Surgery: Kung, Theodore A. MD;

Plastic and Reconstructive Surgery - Global Open: June 2018 - Volume 6 - Issue 6 - p e1830

surgery from reconstructive surgery in the interest of preserving medical resources and preventing fraud.

54. No such process exists in the case of mastectomy for chest masculinization of self-identified transgender females seeking to present as males. There is no physical, biochemical, hormonal or tissue pathology, that can be demonstrated to localize the patient's condition in her healthy breasts. It is the young woman's subjective sense of revulsion when she looks at herself that has caused her to believe that mastectomy might make her feel better.

55. In spite of this glaring lack of objective, scientifically validated methodologies for making the diagnosis, or for proving benefit of care, advocates for gender affirmation care will cite many papers, published in peer reviewed professional journals, that claim sufficient improvement in the subjective life of the patient that lifelong morbidity and suicide are avoided. Close examination of this literature will show the very low quality of evidence that is offered, even after many years of affirmation care. Before reviewing the literature supporting gender affirmation, we must understand what it means when an article is reported as "peer reviewed".

56. Peer review is the very important process by which highly educated and trained experts review scientific medical papers for publication. They are examined in order to ensure that the corpus of medical literature is protected from imprecise,

substantively erroneous, or conceptually flawed publications. It is an essential part of the historic, magisterial process in medicine. In fact, it is so much a part of the life-long learning process of doctors that any reputable training program will have a robust "journal club" in which doctors at every level of training take turns at publicly "peer reviewing" an article and leading a lively discussion of its value. A good doctor is constantly peer reviewing. It is an essential element of good medical care because it keeps the doctor in contact with the finest practitioner in their particular field, and thus improving care.

57. Establishing that an article is peer-reviewed is a basic and essential practice. You might read a medical paper with level-III evidence of high quality, or a paper that is level-V evidence of low or questionable quality, both of which undergo peer review, and are published. The level-III will likely drive decision making, and possibly a recommendation as high as "standard of care", while the poor-evidence paper suggests research, or perhaps the consideration of an alternative approach, if that approach does not put the patient in any significant risk. Papers that have very low-quality evidence, such as single case reports, or case collections by a single practitioner, or collected from several practitioners at a single medical center, will be published by peer reviewed medical journals. These papers are not offered to guide clinical decision making. They are offered in the service of advancing the understand of complex problems, and suggesting areas of research

that might lead to higher quality evidence, and thus to future improvements in the quality of care. So, the label "peer reviewed" says absolutely nothing about the value of the evidence for either clinical decision making, or larger issues of practice guidelines, and policies of medical coverage or exclusion by healthcare agencies like state Medicaid programs.

A 2019 publication by Miller et al.<sup>9</sup> is typical of a single-surgeon, case 58. collection paper published in a peer reviewed medical journal. It reports a collection of cases that claims to show complete satisfaction on the part of the patients (that 100% would do it again). Upon examination of Dr. Miller's paper we see that it is a report of a single surgeon, and is a retrospective review of his cases. It begins with a chart review of only 34 patients, only 12 of whom responded to the quality-of-life questionnaire. This means 74% of the study patients dropped out (patient selfselection bias, with dropout rate greater than 20% being unacceptably high for publication in most journals). All of the data is based in subjective reporting by the patients, rather than objective findings such as substance abuse rates, psychiatric hospitalization rates, suicide attempt etc.. Published reports which use purely subjective evaluations such as satisfaction surveys, or quality of life surveys etc. are characteristic of the cosmetic surgery literature, not the reconstructive surgery

<sup>&</sup>lt;sup>9</sup> Miller, TJ, et al. Breast Augmentation in Male-to-Female Transgender Patients: Technical Considerations and Outcomes, 21 JPRAS Open 63-74 (2019)

literature. He reports that "every patient surveyed at 1 year" reported that "their life had changed for the better". This statement is again reporting only subjective data, this time following a meaninglessly short follow-up of a very small group that has been biased by self-selection. The overall study is little better from the standpoint of the duration of the study because the final follow-up was only 4 to 7 years. This paper presents level-IV and level-V (low to very low quality) evidence, and is possibly useful in suggesting further research, particularly since the author is a subject matter expert. It is not useful for clinical decision making. Neither can it be presented as evidence for anything more than a cautiously worded practice guideline (as in the ES guideline concerning the use of cross-sex hormones presented above), and certainly can never be used in support of a "standard of care".

59. A 2006 paper by Newfield et al.<sup>10</sup> is an example of a paper that was published in a peer reviewed journal, and perhaps ought not to have been. This paper asserts that mastectomy and chest masculinization in transgender biological females "increases self-esteem and improves body image" while providing the patient with "some security and safety for those who remove their shirts in public areas such as gyms or beaches". This assertion is made by the authors in the paper's preamble, and is an assertion frequently quoted when the paper is cited in evidence to support

<sup>&</sup>lt;sup>10</sup> Newfield, N, et al., Female to-Male Transgender Quality of Life, 15 Quality of Life Research 1447- 1457 (2006)

gender affirmation surgery. In reading the entirety of the paper one finds that it does not demonstrate this claim at all. The assertion is a personal editorial opinion expressed by the authors in support of transgender surgery. The assertion is never verified in the objective data on post-surgical patients.

60. The paper is a report of an anonymous survey. It claims to provide meaningful information about the effect of female to male transitioning medicine and surgery without even verifying that the subjects who responded to the survey have in fact undergone medical and surgical gender transition. Subjects were recruited "via online promotion and printed materials, including flyers and postcards that were distributed to San Francisco Bay Area community centers, cafes, stores, and health clinics that serve the transgender community." In terms of self-selection bias (patient determines who is followed by the study) it is hard to imagine a more problematic patient selection process. The researchers even admit that they were unable to determine how many surveys may have been submitted multiple times by the same study respondent. They write: "Although this procedure *helped* (italics mine) prevent duplicate submissions by the same participant, we could not employ more sophisticated computerized systems due to administrative and financial constraints".

61. All of the demographic information contained in the study was selfreported but not verified, including age, sex, health status, history of hormonal therapy, and history of gender surgery. The study uses a quality-of-life survey with 36 questions in 8 areas of interest, producing only self-reported subjective information. Even the claim of simple benefit is poorly support, as is reflected in the conclusion to the paper. The authors write, "The 376 US FTM transgender participants analyzed in this sample had diminished mental-health related QOL compared with the general US population, as measured by the SF36v2. These findings are consistent when compared against specific age and sex norms." This statement demonstrates the lack of value in the study. The study participants demonstrated a quality of life that is statistically significantly lower than the age/ sex comparison cohort, and the authors can only speculate as to the cause. There is no way to tell if treatment helped, had no effect, or harmed the patients because there was no information available about the anonymous subjects. This is because the anonymous test subjects hadn't received pre-treatment evaluation using the same or comparable test instrument. This study which is frequently offered in support of the claim of efficacy is of the lowest evidentiary value, may be useful for suggesting future research, but is of no value in directing clinical decision making, or meaningful allocation of public resources in the service of public health.

62. Another peer reviewed article, presently cited in filings by advocates in cases pending before federal courts, is from 2013 by Weigert et al.<sup>11</sup> which makes the claim that there is a statistically significant improvement in "psychosocial wellbeing" following cosmetic breast augmentation in biological males who are presenting as women. This paper is very simple to analyze and classify as not helpful in clinical-therapeutic decision making, or for establishing coverage/ exclusion criteria for public health agencies. At the bottom of the published article is written, "Clinical question/level of evidence: Therapeutic, IV." As was discussed above, this paper is at the same alarmingly low level, because it is a single-center sampling of a small cohort of patients, and relies on subjective, self-reporting through questionnaire, over a short study duration. Patient collection was made between 2008-2012. The paper was published in 2013. If the peer review process followed the usual timeline, it is likely that there are a significant number of patients in the study who were followed for less than a year. The authors, in the abstract are only able to report the pre-surgery, and the 4th month post-surgery as assured time points. This is remarkably short follow up even for a cosmetic breast augmentation study group. The article is perhaps useful in suggesting inquiry into why their cohort

<sup>&</sup>lt;sup>11</sup> Weiger, R, Frison,E., Sessiecq, Q., et al.; Patient Satisfaction with Breasts and Psychosocial, Sexual, and Physical Well-Being after Breast Augmentation in Male to Female Transexuals. Plastic and Reoncstructive Surgery, 132(6), 1421-1429. doi:10.1097/01.prs.0000434415.70711.49 (2013)

reported no improvement in physical well-being, given the known association between emotional health and physical health. There is nothing in the article to support even a guardedly worded clinical guideline suggestion.

63. Another citation in legal claims presently before federal courts and offered in support of gender surgery is another peer-reviewed study by Horbach et al. published in 2015.<sup>12</sup> This is a review of transgender surgical literature published between 1995 and encompassing nearly 20 years. It yielded 26 papers that satisfied the search criteria, and includes 1,461 patients. The paper claims that "transgender women (biological males presenting as women) who had vaginoplasty found that study participants' mean improvement in quality of life after surgery was 7.9 on a scale of one to ten". In the conclusion of the paper the authors write, "

## "Sexual function and patient satisfaction were overall acceptable, but many different outcome measures were used. QoL was only reported in one study. Comparison between techniques was difficult due to the lack of standardization."

64. Of the merely 26 studies out of a sampling that spanned 20 years, only one paper was found to have used a standardized metric, one that only measures subjective, patient reported information, and the rest could not even be compared to each other. The authors write,

<sup>&</sup>lt;sup>12</sup> Horbach, SER, Bouman, M, Smit, JM et al.Outcome of Vaginoplasty in Male-to-Female Transgenders: A Systematic Review of Surgical Techniques ; J Sex Med2015 Jun;12(6):1499-512. doi: 10.1111/jsm.12868.55.

"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."

65. This result is startlingly reminiscent of a paper offered by Tolstrup et al. published in 2020 (&&). It is a comprehensive literature review on the subject of breast surgery in transgender patients, including both male to female, and female to male presentation. It is a scoping review that yielded 849 papers of which 47 papers met the inclusion criteria based upon title, abstract, and full text. In the study results, the authors report that,

"The summary of outcome domains and classifications showed that there are large variations in outcome evaluation between studies. Although several studies reported on similar outcome categories, there was a high level of heterogeneity of domains and classifications of outcomes." The authors then conclude by explaining that "Evaluation of outcomes in gender-confirming chest surgery showed large variations in reporting, and further streamlining of reporting is therefore required to be able to compare surgical outcomes between studies."

66. Tolstrup's review of the literature<sup>13</sup> show us that the general level of evidence for the efficacy of gender affirmation breast surgery is in the category of "early experimental" evidence. None of the articles examined rates of psychiatric hospitalization, substance abuse, self-harm behaviors, or suicide. This tells us that the most compelling reason offered for performing these surgeries

<sup>&</sup>lt;sup>13</sup> Tolstrup A<sup>1</sup>, Zetner D<sup>1</sup>, Rosenberg J<sup>1</sup> Measures in Gender-Confirming Chest Surgery: A Systematic Scoping Review. **Aesthetic Plastic Surgery**, 29 Oct 2019, 44(1):219-228 DOI: 10.1007/s00266-019-01523-1

(psychological distress and suicide risk) isn't even evaluated by the researchers, and can support no claims of efficacy in the world transgender surgery literature.

67. Professionally speaking, these are very disappointing findings from the comprehensive examination of the transgender surgery literature. To have a surgical sub-specialty working diligently, and guided by professionals at the highest levels of academic expertise, that has only produced case-series reports, retrospective case collections, and fruitless 20 year literature reviews, and still only have level-IV and V evidence to show for its work is alarming. It shows that the sub-specialty has not developed uniform descriptive language, standardized reporting nor test instruments that might raise the value of expert opinion to a level that could make reliable recommendations that might help in surgical decision making, rightly inform the consent process, or guide decision making by officials entrusted with the care of public and private medical resources. It would cause me to make a sober review of the medical and surgical principles that are guiding this work.

### The Question of Consent in Gender-Affirmation

68. It is firmly established in high quality research<sup>14</sup> (that persons with gender dysphoria have a greater than 30% likelihood of being on the autism

<sup>&</sup>lt;sup>14</sup> Kaltiala-Heino R, Sumia M, Työläjärvi M, Lindberg N. Two Years of Gender identity service for Minors: overrepresentation of natal girls with severe problems in adolescent development.

spectrum, and a nearly 40% probability of a diagnosis of depression or major anxiety disorder. The proponents of gender surgery will rightly point to the high probability of self-harming behavior, including suicide attempts and completed suicide among self-identified transgender persons.

69. However, as is known by all surgeons, it is considered imprudent to obtain consent from patients suffering from psychological conditions that provoke the patient to acts of self-harm, or to suicidal ideation. These psychological disturbances are known to impair the patient's capacity for understanding the information they are hearing from the surgeon, interpreting that information, and reasoning from that information. If those capacities are impaired by psychological disturbances sufficient to consider suicide, then meaningful consent is not actually possible. Certainly in the case of conditions that constitute a threat to life and limb in a patient with decreased competence, consent may be obtained with the assistance of family, guardian, or in particularly urgent cases a group of professionals who agree on the grave necessity to proceed with surgery.

70. The problem however is that none of the surgeries, on the list of commonly performed gender affirmation surgeries, can be described as emergency operations performed to save the life of the patient. They are all elective because

Child and Adolescent Psychiatry and Mental Health (2015) 9:9.)

they are scheduled when convenient and after the patient is deemed fully ready. Furthermore, an ever-growing percentage of patients submitted for gender surgeries are minors who by definition are not competent to consent. The claim is made that these surgeries are in fact "lifesaving". This is a claim that is not supported in high quality scientific evidence. In fact, high quality evidence, which I will present below, shows that while self-harm and suicide rates are improved in the very short term for some sub-groupings of patients, in the long-term these problems remain if not worsen.

71. Documents like the WPATH v.8 speak of the need to have these psychological disturbances "well-controlled" prior to surgery. This must be taken to mean that self-harming or suicidal thoughts must be well controlled before one can proceed with surgery. If that is the case, then the main reason for the consenting the child for surgery has been successfully treated medically, and the patient no longer requires the surgery. That would be very felicitous news to the child's parents.

72. What is more troubling is that the co-morbid conditions of autism spectrum disorder, clinical depression, and major anxiety disorder are never examined as the possible causes of the gender identity disturbance. These are conditions that, if treated, might improve or even resolve the gender problem. To the contrary, these serious problems are viewed as mere impediments to gender surgery that must be "reasonably well-controlled" so that surgery may proceed. This is

consistent with the regnant WPATH model that there is a single explanation that the child's condition is caused by a disconnection between biological reality and subjective identity which has an as-yet undiscovered cause, and has only a single solution: the social, medical, and surgical affirmation of the child's gender discordance.

73. Such a single cause/ single solution assumption would seem to be unlikely, given the massive range and the recent complete reversal in the demographics of transgenderism. What used to be a condition that was nearly exclusively found in little boys, and resolved nearly 90% of the time<sup>15</sup>, is now predominantly a condition affecting young women, and at a rate that has risen between 4000 and 5000% in the course of the last decade.

74. The claim is often made that gender affirmation surgery is not cosmetic, because it is based in a "medical diagnosis" that can be found listed in the Diagnostic and Statistical Manual. This is a document produced by the American Psychiatric Association. It is essentially a dictionary of terminologies recommended in descriptions of psychiatric conditions. This publication used to include the terms "body dysmorphic disorder", and "gender identity disorder" among others used to describe self-identified transgender person. Changes to the language found in the

<sup>&</sup>lt;sup>15</sup> Irreversible Damage: The Transgender Craze Seducing Our Daughters; Abigail Shreier, (2020)

DSM are based upon expert consensus methodologies described above, which are the lowest form of scientific evidence. The consensus in not obtained by polling the membership of the Society, but within a small group of provider- advocates. Conditions that were once in the category of paraphillias are now considered normal and not listed. It is in this committee that the decision was made to "depathologize" gender discordance. The difficulty is that without a medical diagnosis, you cannot generate billing for medical services. This is why the term "gender dysphoria" was chosen. No high quality scientific evidence was presented and reviewed by the committee in making the changes.

75. This methodology by the DSM committee has made the document essentially useless in making either a diagnosis, establishing principles of care, or estimating likely resolution of psychiatric medical problems. This appears to be why the National Institute of Mental Health, which has been the original source of funding for the DSM publicly its support for the DSM project just weeks before the present iteration was published in 2013. The fact that gender affirmation physicians and surgeons cite the DSM as a source document for diagnostic criteria is further proof that the condition exists in the subjective life of the patient, and therefore surgery performed to address the subjective condition is by definition cosmetic surgery.

76. Diagnostic and pre-operative selection for of patients for surgery is through a process that begins in psychology, continues with psychological support, and concludes with certification by psychological services that the patient is ready for surgical modification. At no point is there described any medical diagnostic process of history-taking, physical examination, laboratory evaluation, or radiographic examination that is used to confirm a surgical diagnosis. The entire process is in psychological services which is operating on the premise that the anxious child has made a correct diagnosis. The indication for surgery begins in the subjective life of the patient. Surgery is offered to the patient with the assurance that it is likely to improve the subjective life of the patient, and is therefore by definition cosmetic surgery.

## **On the Safety of Gender Affirmation Surgery**

77. A discussion of surgical safety must include anticipated losses which are either expected, or even remotely possible. In order to examine the comparable issues in transgender versus reconstructive surgery our effort is simplified by comparing identical operations. I will describe two operations which use the identical techniques, and even the same tissue source so that we can better compare gender affirmation surgery, with actual reconstructive surgery.

78. On several occasions I have performed the reconstructive operation called "Sensate radial-forearm microvascular free flap hypopharyngeal

reconstruction". I performed this surgery in order to reconstruct the tongue and throat of patients who had suffered a grievous wound of the mouth and throat when he underwent removal of an aggressive cancer. The defects caused by that wounding needed to be replaced with thin, pliant, abrasion and fluid resistant tissue. It needed to provide the patient with sensation in the reconstructed area so that they can feel the food and liquids in their mouth, and manipulate the food so as to swallow it. We selected an area of skin on the inside of the forearm that has regular and robust blood flow, is thin and durable, and has an easily dissected sensory nerve that can be attached to the nerves in the wound. The forearm flap satisfied all the requirements. An operation of this complexity, duration, and technical requirements has many issues, big and small, that can diminish or destroy the result.

79. The throat reconstruction operation is in almost every way identical to the second most commonly performed female to male (FtM) gender affirmation surgery of the genital. It is called the "Sensate radial forearm microvascular free flap phalloplasty". In that operation, the identical flap is raised and transferred. It too must be resistant to abrasion, be water tight, pliant, sensate, and of correct volume. Through a process of incision, plication and suturing, a tubular phallus is constructed within which is a skin lined tube which will serve as the urethra. The suture closures in both flaps is where most things go wrong because the skin edges that define the suture line can lose their blood supply to varying degrees. In the phalloplasty, when this happens, the patient suffers from delayed healing, urine leakage, varying degrees tissue death, and scarring. All of those problems can happen with either the throat flap, or the phallus flap. When the phallus flap fails, the patient suffers due to varying degrees of tissue loss, chronic urinary leakage, or urinary obstruction due to scarring that can cause kidney injury if left un-treated. When the throat flap fails, bacteria laden saliva will leak into the neck where it can cause fulminant infections, or erode into a major artery and cause the patient to bleed to death in a matter of moments. A singularly terrible event.

80. In the case of the throat operation, if the removal of the cancer had not been performed, there was a known and significant probability that the cancer would have eroded into the tissues of the neck and caused a fulminant infection, or eroded into a large blood vessel, as described above. In contrast, if the phallus flap operation, had not been performed, the patient would have remained fully functional in every human capacity, though suffering from an inner subjective disturbance called gender dysphoria, which has not yet been adequately treated.

81. Both operations involve the use of a highly complex surgical techniques to remedy a wound. In the case of the cancer operation the wound was the result of a cancer that would have ended in a terrible death. In the case of the phallus operation the surgeon is creating multiple physical wounds in a healthy child (castration, loss of pelvic organs of reproduction, de-gloving injury of the forearm, skin graft donor site injury), with their associated risks of complications. The surgery is performed in attempt to remedy a subjective, patient-reported sense of their identity.

Clearly the pre-operative condition of the cancer patient is far more 82. grievous than the condition of the young person who is suffering from gender dysphoria. The cancer patient would likely be more than willing to endure significant loss, such as voice, or teeth, or the sense of smell. And yet, if I were discussing surgical risk pre-operatively with my patient who has the throat cancer, and told him that there was a certainty that in the course of the operation he would lose all of his reproductive organs, he would be justified in asking why he was being subjected to such an unsafe operation. The patient wouldn't be even slightly interested in any further discussion of operative risks. The question of safety addresses itself to the question of potential losses caused by surgery. Transgender surgery of the genital apparatus predictably causes grievous loss that dwarfs such complications as infection, local tissue loss, urinary leakage or scarring. Such surgery can justly be considered universally unsafe in all cases, and particularly grievous when visited upon the young.

83. One of the peer reviewed article presented in support of masculinizing chest surgery, and found in numerous expert opinions submitted in pending federal

cases. It is a 2017 paper, published in the peer reviewed journal JAMA Pediatrics<sup>16</sup>. it claims to support the conclusion that "surgical intervention (mastectomy, or chest masculinization) positively affected both minors and adults". This paper is perhaps the most alarming of all the citations presently offered and deserves a detailed examination.

84. The principle author, Dr. Olson-Kennedy is also an academic expert in her capacity as Associate Professor of Clinical Pediatrics, Keck School of Medicine of USC, and Medical Director of The Center for Transyouth Health and Development in Los Angeles. She holds professional membership in The Society for Pediatric Research, the World Professional Association for Transgender Health(WPATH), and the Society for Adolescent Health and Medicine. If any gender affirmation expert would be in a position to offer high quality, evidencebased publications, it would certainly be Dr. Olson -Kennedy.

85. In their summary of findings, the authors report that "chest dysphoria" is common among "trans males" (natal females seeking to present as males), and that the dysphoria is decreased by surgery. They claim that regret for surgery is "rare". It is a retrospective review of children treated at a single center. The article

<sup>&</sup>lt;sup>16</sup> Olson-Kennedy, J., Warus, . et al. Chest Reconstruction and Chest Dysphoria in Transmasculine Minors and Young Adults: Comparisons of Nonsurgical and Postsurgical Cohorts; JAMA Pediatr2018 May 1;172(5):431-436. doi: 10.1001/jamapediatrics.2017.5440.

reports breast removal surgery on at least one girl aged 13 years. The average age was 19. Children were entered into the study through recruitment from among patients visiting the clinic, and by telephone over a six-month period. The authors found that patients recruited from among visitors to the clinic (convenience sampling) yielded an abundance of non-operated patients, so they were forced to reach out to all the known post-surgical patients by phone. 26% of the clinic's postsurgical patients could not be reached for various reasons including no working phone, or failure to respond to multiple messages. A 26% drop-out rate is never questioned by the authors. Were they lost to follow up because of dissatisfaction, psychiatric hospitalization, or suicide? This problem is called "self-selection bias", and is evidence of careless study design. Of the remaining 74% of patients, only 72% of them (only 53% of the study patients) completed the survey. This is a second example of self-selection bias. Why would some post-surgical patients who had been successfully contacted, not complete the survey? The authors do not ask the question.

86. In the study, dysphoria was measured using "a novel measure" (an unproven test instrument) which was a series of subjective questions about happiness. Among the designers of this novel test instrument were some of the adolescent patients themselves. Their flawed methodology included the use of an entirely unvalidated test instrument, with no known error rates, or proven predictive power, **that was in part designed by the minors and young adults who were the subject of the study.** Furthermore, the post-surgical patients were given the survey at varying time intervals post-surgery. The longest interval between surgery and the satisfaction survey was 5 years, but children less than a year post surgery were included in their flawed sample, and yet the authors claim evidence of "negligible regret." This is a remarkable claim given that long term, longitudinal population studies show that there is a dramatic rise in post-surgical problems such as depression, hospitalization, substance abuse, and suicide beginning at around year 7 post surgery (Dhejne cited below). Surely Dr. Olson-Kennedy is familiar with the international literature on transgender outcomes?

87. Having promised in the introduction to her paper that "chest dysphoria" is reduced by surgery, at the conclusion they confess the fact that the study design and execution produced very low-quality data that is not useful for patient selection, or prediction of outcomes. They even confess that the study does not address the efficacy of surgery in improving outcomes regarding the single most compelling reason for performing the operation: mitigation of depression and suicide. The authors write:

"An additional limitation of the study was the small sample size. The nonsurgical cohort was a convenience sample, recruited from those with appointments during the data collection period. There could be unknown imbalances between the nonsurgical and postsurgical cohorts that could have confounded the study findings.

# Finally, the Chest Dysphoria Scale is not yet validated, and may not represent distress or correlate with validated measures of quality of life, depression, anxiety, or functioning."

88. This paper is a typical example of a publications which are used to support transgender medicine and surgery, written by board certified transgender expert physicians who practice in our nation's largest pediatric gender clinics, and was published in peer-reviewed medical journals. The article is essentially useless in making any clinical decisions regarding who should be offered surgery, what the likelihood is that they will benefit from it, or the likelihood that they will regret their decision. Most importantly, it cannot even vaguely estimate if the risk of hospitalization, incarceration, or suicide will be reduced. For the same reason that the paper is not useful in clinical decision making, it is likewise not meaningful in decision-making by persons responsible the just management of public and private medical resources.

## **On the Experimental Nature of Transgender Surgery**

89. One of the important usages of the term "experimental" in the world of medical care is in the domain of insurance services, both public and private. Leadership in these agencies is charged with the responsibility of managing medical resources in a way that both preserves resources, while at the same time applying those resources to the patient as correctly as medical science and their own actuarial information will allow. Whenever a novel therapy is proposed for a given condition,

insurance services will examine the medical and actuarial data to see if the proposed therapy is likely to yield a result that serves those two purposes (health of the patient, and financial soundness of the insurance process). Typically, in the early years of a new treatment there is resistance on the part of the payors because early on (as discussed in detail above) all that the proponents are able to present is low-level scientific papers that present anecdotal case collections without controls, or multiple studies that can not be compared due to methodological variation or are methodologically questionable due to unvalidated test instruments. History has shown, and the fact remains, that good surgery demands good evidence, particularly when permanent damage to the client is a possible result.

90. Nonetheless, if the insurance agency reviewer see evidence that a new approach may be helpful, they prudently insist that therapies of known value be tried to their reasonable limit first, and that they be found to have failed in solving the patient's condition. Only the will consideration be given to the new treatment.

91. This dynamic process between the patient, the physicians, and the insurance industry has many problems, but good, well validated scientific evidence is not one of those problems. In fact well validated science is typically the best remedy for those problems. Sometime the good science is from the doctors, and sometimes the good science comes from the actuaries. In both cases the patient benefits.

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92. From the perspective of the case in question, this sense of the term "experimental surgery" may be the most important. How did the affirmation care scientific model and its associated social, medical and surgical treatments enter into the mainstream of the medical community? Did it follow this same process of gradual acceptance in both the medical and insurance communities through a process of steadily improving evidence levels? Was it used on a careful trial basis after having exhausted treatment by established methods? The answer is that it did so, but only in part.

93. The historically validated treatment model for what is today called gender dysphoria is what is called "watchful waiting". On hearing the name one is tempted to think of this as a resignation to inaction. It is not. It is a psychotherapeutic process that is rooted first in an examination of the cognitive processes of the child, and seeing how the child has responded to the reality of their life. For this reason, in order to be effective, it must include family therapy. The goal is to keep the anxious and confused child in loving contact with reality, while seeking to understand and remedy the subjective dynamic that is provoking the condition of distress. It is essentially the same process used in helping persons who suffer other obsessive-compulsive issues, like eating disorders. Psychological research, having high level evidence, has shown that over the course of time this approach results in over 80%

resolution of the cross-sex self-identification during adolescence, and nearly 92% by young adulthood.(Zucker et al.).

94. This watchful-waiting approach is likely the reason why gender discordance used to be a rare diagnosis. The vast majority of people with the condition resolved the issues, and went on to live their lives without the need for life-long medications, without destructive surgeries, without the loss of their sexual faculties, and without the loss of fertility. What has happened, however, is that the dynamic between patient, physician, and insurance services has been severely disrupted.

95. The science based medical and actuarial management of this condition has been separated from the evidence, and now rests entirely on the opinions of academic experts who have managed to influence the decision makers in their favor. In large part, they have accomplished this by never speaking about watchful waiting except to dismiss it as folly. This process of silence and dismissal is exactly what ulcer surgeons did to the proponents of the scientifically correct infection model of ulcer disease.

96. Silence and dismissal about watchful waiting is not the only reason for the 5,000% increase in the diagnosis of transgender over the past decade. Surgeons who were seeking to achieve the best results for their transgender patients came to realize that most of the difficulty with good cosmetic results was that young men seeking to present as women tend to appear too masculine, and young women seeking to present as men tend to appear too feminine. They reasoned that if their masculine or feminine development had been arrested early, they would achieve better results. It was reasonable, in light of their treatment model, to think that a better cosmetic result would mean a better resolution of the gender incongruence. Thus the idea was born that the earlier the child was transitioned, the better the cosmetic surgical result, and thus the better psychological result, which is the goal.

97. This theoretical improvement in outcomes for transgender persons through early transition was certainly an idea worth investigating. Because the lifelong effects of the approach might include some really bad outcomes for the children, and because the actual outcomes were unknown at the time, it would have been prudent, and scientifically consistent to categorize this from the above described insurance industry perspective, as experimental. It would have required that the patients exhaust the fully established and proven treatment model of watchful waiting. If that treatment failed to resolve the issue, then on a trial basis, and supervised under very strenuous human experimentation oversight, the affirmation model could be tried.

98. In order for any highly supervised experimental approach to pass ethical standards in human experimentation there would have to have been a previously established diagnostic and patient selection process of very high specificity. If the proven and established method of watchful waiting is yielding 92% resolution, then what the ethically minded surgeon is really supposed to be doing is trying to find that 8% of children who would have failed watchful waiting, and select them out for surgery earlier in their life. Then studying the result on a very long-term and comprehensive basis, he would have been able to provide high-value evidence that his hypothesis about the successful early management of transgenderism is a safe and valid option for his patient. This was not done. Instead, the routine social and medical transitioning of children began, which includes puberty blockade, and cross-sex hormones in children and youth.

99. Instead of seeking the historically small cohort of children who would have carried the condition into adulthood and treating them, physicians and surgeons are treating all of those children now. Instead of seeking the scientific methodology with which to make a correct diagnosis so as to increase the likelihood that you are operating on the right person, the transgender treatment model is essentially turning all affected children into "the right person". By the time the youth or young adult person arrives in the surgeon's office the process has been locked into place.

100. It would seem that the best course of action for those who serve the insurance industry, including state Medicaid, is to return this process to the time tested dynamic model of patient, physician, and insurance plan discussed above.

Because the affirmation model rests upon such low-quality evidence, it seems justifiable to suspend financial support until such time as testing and patient selection processes are improved to acceptable levels of reliability. Given the serious, lifelong consequences of mis-diagnosis, and the misapplication of surgery, levels of patient selection reliability would have to be quite high.

101. A review of the European literature on this topic is instructful. The American literature used in support of the claim of benefit is of low reliability. We make this assertion based on the fact that to date all scientific citations offered in support of gender affirmation medicine and surgery is that they report studies of short duration. Follow up durations of less than 3 years are common. Some, as we have seen are as short as 4 months. This fact helps us to understand why proponents of the affirmation model are enthusiastic. Medical services in a number of European countries utilize centralized medical databases which employ uniform language, and report care over the life of the citizen.

102. The Swedish medical establishment maintains an excellent and centralized data base of all episodes of care for beneficiaries. It uses uniform language, and captures treatment events at all levels, from school clinics, to psychiatric hospitals, to prison infirmaries, to public clinics. The database can be analyzed for such things as emergency room visits, drug addiction treatment, hospitalization for suicide, psychiatric admissions for self-harming event etc.

In 2011, Dhejne et al.<sup>17</sup> published a population based, longitudinal 103. cohort study of that database that sought to examine the lifetime hazard ratio of such things as substance abuse, incarceration for violent behavior, psychiatric hospitalization, and completed suicide. This is level-III evidence of high order given the methodology employed and the proven reliability of the database. It examined persons who have fully completed the gender affirmation process and compares them to age and sex matched controls in the Swedish population. It did not use anonymous surveys, or other faulty convenience sampling. It found the posttransition patients by finding the associated episodes of care, such as when hormone therapy prescriptions began, or admission for gender surgery occurred. The data set spans 30 years. What it shows is that fully transitioned subjects showed a relative risk of suicide roughly equal to the age/ sex matched controls, but the effect appears to last for just a few years. The trend line for death from any cause begins a sharp drop at approximately 10 years and continues to drop massively over the subsequent 15 years. When the researchers looked at the aggregate life-time relative risk of suicide, persons who fully transitioned were over 19 times more likely to have killed themselves when compared to age and sex matched controls. If you only look at the subgroup of biological females who transitioned to male-presentation, the risk of

<sup>&</sup>lt;sup>17</sup> Dhejne,C., Lichtenstein, P., et al. Long-term follow-up of transsexual persons undergoing sex reassignment surgery: cohort study in Sweden; PLoS One2011 Feb 22;6(2):e16885. doi: 10.1371/journal.pone.0016885.

suicide is 40 times higher than the control group. Results such as these, because they are obtained using tested and reliable methodology, are able to help meaningfully in clinical and administrative decision making, and in several European countries it has.

104. Over the past several years, the medical systems in Great Britain, Sweden, Finland, and France<sup>181920</sup> have stepped away from early medical and surgical transitioning of the young. The Tavistock-Portman Institute in London, which was the sole provider of these services to children in Great Britain was closed

<sup>18</sup> NHS Amendments to service specifications for Gender Identity Development Service (GIDS) for children and adolescents, effective 01 Dec 2020.

https://www.england.nhs.uk/wp-content/uploads/2020/12/Amendment-to-Gender-Identity-Development-Service-Specification-for-Children-and-Adolescents.pdf <sup>19</sup> Sweden's Karolinska Hospital (affectingAstrid Lindgren Children's Hospital's pediatric gender services) issues a policy change effective April 1, 2021:

- "These changes shall not affect the continued psychological and psychiatric care within BUP (*Public Child and Adolescent Psychiatry*) for patients under 18 years of age." "The patient must receive comprehensive information about potential risks of the treatment..."
- Cited UK High Court Decision, NHS policy change in light of it, and that in "2019, the SBU (*Swedish Agency for Health Technology Assessment and Assessment of Social Services*) published an overview of the knowledge base which showed a lack of evidence for both the long-term consequences of the treatments, and the reasons for the large influx of patients in recent years."<sup>19</sup>
- "These treatments are potentially fraught with extensive and irreversible adverse consequences such as cardiovascular disease, osteoporosis, infertility, increased cancer risk, and thrombosis."

Karolinska Policyförändring K2021-3343 March 2021 (Swedish).pdf Karolinska Policy Change K2021-3343 March 2021 (English, unofficial translation).pdf

<sup>20</sup> Finland rejects routine "affirmation" pathway for minors with GD. From Finnish Health Authority, *Council for Choices in Health Care in Finland (COHERE Finland)* 2020:

<sup>• &</sup>quot;...hormonal treatments (*i.e., puberty blocking and cross-sex hormones, see above*) will not be initiated in gender dysphoric patients under the age of 16."

<sup>• &</sup>quot;For patients between ages 16 and 18, it is hereby decided that treatment may only occur within the clinical trial settings approved by the EPM (*Ethical Review Agency/Swedish Institutional Review Board*)."

recently following the public declaration by a review committee that the Institute was "unsafe for children". Similarly, the Karolinska Institute in Stockholm reversed its policy by suspending the medical and surgical transitioning of the young in favor or psychological support and treatment. Similar changes in treatment guidelines for self-identified transgender youth have been published in Finland, and are currently being developed in Italy.

105. Based upon these developments in Europe, it is very troubling to read assessments or declarations by leaders in the field of transgender surgery which assert that these treatments are mainstream and beyond controversy, or that they are part of a core curriculum of surgical training, or that an oral board examiner might fail a candidate surgeon if their answers reveal a reticence to join the mainstream as defined by gender affirmation advocates. The world literature demonstrates emphatically that early medical and surgical transitioning is in fact so controversial that medical leadership in multiple countries has put a stop to it.

106. In summary, transgender surgery is based in a treatment model of affirmation that lacks scientific support based in quality evidence. The scientific support offered by the leaders in the field is entirely composed of small studies, single provider /single center studies that are lacking in control cohorts, and are often rendered uninterpretable due to haphazard case-collections such as the solicitation of study participants without methodology to confirm that the patient is a treatment

subject. All of the studies cited in expert filings by gender affirmation practitioners have short follow-up, and most studies suffer from massive self-selection bias and high drop-out rates. The studies often employ untested assessment methodologies, and all of the literature cited by experts report only subjective data, which is typical of papers that address outcomes in cosmetic surgery.

107. Transgender surgery is, by definition, cosmetic surgery. The move towards surgery begins in the subjective life of the patient, is conducted with the aim of improving the subjective life of the patient, and outcomes are measured in subjective terms based in satisfaction surveys. Transgender surgery violates fundamental principle of cosmetic surgery, because it predictably destroys essential functions of the human person. It is not reconstructive surgery because the patient is physically healthy before the surgery, and has no definable deficit that can be objectively characterized to be the cause of the presenting complaint. There is no objective test to confirm the diagnosis of transgender, and no way to correctly select patients for surgery from among the young. The enterprise of gender affirmation medicine and surgery is based entirely in a consensus of expert opinion of low reliability because it is supported by unreliable scientific evidence. I declare, pursuant to 28 USC § 1746, under penalty of perjury that the foregoing is true and correct. Executed this 16th day of February, 2023.

<u>/s/ Patrick W. Lappert</u> Dr. Patrick W. Lappert, M.D.

#### Curriculum Vitae- Patrick W. Lappert, MD

#### **Education and Training :**

— Bachelor of Arts in Biological Sciences at the University of California, Santa Barbara, 1979. Research in cell membrane physiology with Dr. Philip C. Laris, studying stoichiometry of the sodium: potassium ATPase pump.

- M.D., Doctor of Medicine degree at the Uniformed Services University of the Health Sciences, 1983 at Bethesda, Md.

- General Surgery Residency at the Naval Hospital Oakland/ UC Davis East Bay Consortium, 1987-1991
- Chief Resident, Department of Surgery, Naval Hospital Oakland, 1990-1991.
- Plastic Surgery Residency at the University of Tennessee- Memphis, 1992-1994.

#### **Board Certifications in Medicine :**

- Board Certified in Surgery American Board of Surgery, 1992-2002
- Board Certified in Plastic Surgery American Board of Plastic Surgery, 1997-2018

#### **Medical Staff Appointments :**

- Staff General Surgeon at the Naval Hospital Oakland, CA 1991-1992
- Associate Professor of Surgery, UC Davis-East Bay, 1991-1992.
- Plastic and Reconstructive Surgeon, Naval Medical Center, Portsmouth, VA 1994-2002
- Chairman, Department of Plastic and Reconstructive Surgery, Naval Hospital Portsmouth, VA 1996-2002.
- Clinical Assistant Professor, Department of Surgery, Uniformed Services University of the Health Sciences, 1995-2002

- Founding Director, Pediatric Cleft Palate and Craniofacial Deformities Clinic, Naval Hospital Portsmouth, VA 1996-20002

- Founding Director, Wound Care Center, Naval Hospital Portsmouth, VA 1995-2002.

— Staff Plastic Surgeon in Nebraska, and Alabama.

#### **U.S.N. Surgeon General Service:**

- Specialty Leader, Plastic and Reconstructive Surgery, Office of the Surgeon General-USN, 1997-2002

#### **Faculty Appointments:**

- Teaching Faculty at Eastern Virginia Medical School, Division of Plastic Surgery, 1995-2002

#### **Military Service :**

- Aviation Officer Candidate, Naval Aviation Schools Command, NAS Pensacola, 1978
- Commissioned an Ensign, MC, USNR 1979 and Commissioned as a Lieutenant, MC, USN 1983 .
- Designated Naval Flight Surgeon, Naval Aerospace Medical Institute, 1985
- Flight Surgeon, Marine Fighter/ Attack Squadron-451

- Radar Intercept Officer in the Marine F-4S Phantom, accumulating 235 flight hours, and trained for qualification as an Air Combat Tactics Instructor.

- Deployed to the Western Pacific as UDP forward deployed fighter squadron in Korea, Japan, and the Philippines.

- Service in the US Navy for 24 years
- Service in the US Marine Corp. for 3 years.
- Retired with the rank of Captain, USN in 2002

#### **Military Awards:**

- Navy Commendation Medal For service with Marine Fighter/Attack Squadron 451
- Meritorious Unit Citation- 3rd award
- Humanitarian Service Medal For service in the aftermath of the Loma Prieta earthquake.

#### **Publications - Peer Reviewed Medical Journals :**

- Lappert PW. Peritoneal Fluid in Human Acute Pancreatitis. Surgery. 1987 Sep;102(3):553-4

— Toth B, Lappert P. Modified Skin Incisions for Mastectomy: The Need for Plastic Surgical Input in Preoperative Planning. J Plastic and Reconstructive Surgery. 1991; 87: 1048-53

- Lappert P. Patch Esophagoplasty. J Plastic and Reconstructive Surgery. 1993; 91 (5): 967-8

— Smoot E C III, Bowen D G, Lappert P, Ruiz J A. Delayed development of an ectopic frontal sinus mucocele after pediatric cranial trauma. *J Craniofacial Surg.* 1995;6(4):327–331.

- Lappert PW. Scarless Fetal Skin Repair: "Unborn Patients" and "Fetal Material". J Plastic and Reconstructive Surgery. 1996 Nov;98(6):1125

- Lappert PW, Lee JW. Treatment of an isolated outer table frontal sinus fracture using endoscopic reduction and fixation. Plastic and Reconstructive Surgery 1998;102(5):1642-5.

#### **Publications - Medical Textbooks:**

— Wound Management in the Military. Lappert PW, Weiss DD, Eriksson E. Plastic Surgery: Indications, Operations, and Outcomes, Vol. 1; 53-63. Mosby. St. Louis, MO 2000

**Operations and Clinical Experience - Consultations and Discussions :** As a physician and surgeon, I have treated many thousands of patients in 7 states and 4 foreign nations. My practice has included Primary Care, Family Medicine, Aerospace Medicine, General Surgery, Reconstructive Surgery for combat injured, cancer reconstructive surgeries including extensive experience with microvascular surgery, Pediatric Congenital Deformity, and the care of chronic wounds. I have practiced in rural medicine, urban trauma centers, military field hospitals, university teaching hospitals, and as a solo private practitioner. In my private practice I have had occasion to treat many self-identified transgender patients for skin pathologies related to their use of high dose sex steroids, laser therapies for management of facial hair both in transitioners and detransitioners. I have performed breast reversal surgeries for detransitioning patients. My practice is rated as "LGBTQ friendly" on social media. I have consulted with families with children who are experiencing gender discordance. I have given many presentations to professional meetings of educators and counselors on the subject of transgender, and the present state of the science and treatment. I have discussed the scientific issues relevant to the case with many physicians and experts over a number of years and also discussed related issues with parents and others.