NO. 22-1721

In The

United States Court Of Appeals

For The Fourth Circuit

MAXWELL KADEL; JASON FLECK; CONNOR THONEN-FLECK; JULIA MCKEOWN; MICHAEL D. BUNTING, JR.; C.B., by his next friends and parents; SAM SILVAINE; DANA CARAWAY,

Plaintiffs – Appellees,

v.

DALE FOLWELL, in his official capacity as State Treasurer of N.C.; DEE JONES, in her official capacity as executive Administrator of the N.C. State Health Plan for Teachers and State Employees,

Defendants – Appellants.

ON APPEAL FROM THE UNITED STATES DISTRICT COURT FOR THE MIDDLE DISTRICT OF NORTH CAROLINA AT GREENSBORO

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EXHIBIT 5

IN THE UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF ARKANSAS
CENTRAL DIVISION

DYLAN BRANDT, et al.,

PLAINTIFFS,

v. **No. 4:21-CV-00450-JM**

LESLIE RUTLEDGE, et al.,

DEFENDANTS.

DECLARATION OF DR. PATRICK W. LAPPERT

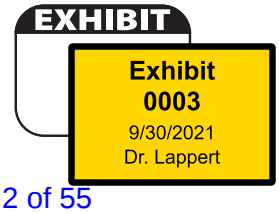
Pursuant to 28 U.S.C. 1746, I declare:

I. KNOWLEDGE, TRAINING, AND EXPERIENCE

1. **Education and Training:** I received my Bachelor of Arts in Biological Sciences at the University of California, Santa Barbara, 1979. There I was engaged in research in cell membrane physiology with Dr. Philip C. Laris, studying stoichiometry of the sodium: potassium ATPase pump. I received my M.D., Doctor of Medicine degree at the Uniformed Services University of the Health Sciences, 1983 at Bethesda, Md. I served my General Surgery Residency at the Naval Hospital Oakland/UC Davis East Bay Consortium, 1987-1991 and served as Chief Resident, Department of Surgery, Naval Hospital Oakland, 1990-1991. I also served a Plastic Surgery Residency at the University of Tennessee-Memphis, 1992-1994. My professional background, experience, and publications are described in more detail in my curriculum vitae, which is attached as Exhibit A to this declaration.

2. **Board Certifications in Medicine:** I have been Board Certified in Surgery (American Board of Surgery, 1992), in Plastic Surgery (American Board of Plastic Surgery, 1997; American Board of Plastic Surgery, 2008).

3. **Medical Staff Appointments:** I served as the Staff General Surgeon at the Naval Hospital Oakland, CA 1991-1992 and as Associate Professor of Surgery, UC Davis-East Bay,



1991-1992. I also served as a Plastic and Reconstructive Surgeon, Naval Medical Center, Portsmouth, Virginia, 1994-2002 and as Chairman, Department of Plastic and Reconstructive Surgery, Naval Hospital Portsmouth, Virginia, 1996-2002. I later served as Clinical Assistant Professor, Department of Surgery, Uniformed Services University of the Health Sciences, 1995-2002 and as Founding Director, Pediatric Cleft Palate and Craniofacial Deformities Clinic, Naval Hospital Portsmouth, Virginia, 1996-2002 also as the Founding Director, Wound Care Center, Naval Hospital Portsmouth, Virginia, 1995-2002. I have also served as a Staff Plastic Surgeon in Nebraska and Alabama.

4. **U.S. Surgeon General Service:** I served as a Specialty Leader, Plastic and Reconstructive Surgery, Office of the Surgeon General-USN, 1997-2002.

5. **Faculty Appointments:** I served as Teaching Faculty at Eastern Virginia Medical School, Division of Plastic Surgery, 1995-2002. I also served on the teaching faculty of the Via College of Osteopathic Medicine, 2017-2020.

6. **Military Service:** I served as an Aviation Officer Candidate, Naval Aviation Schools Command, NAS Pensacola, 1978 and was Commissioned an Ensign, MC, USNR 1979 and Commissioned as a Lieutenant, MC, USN 1983. I served as a Designated Naval Flight Surgeon, Naval Aerospace Medical Institute, 1985, and I was Assigned Marine Fighter/Attack Squadron-451, serving as Flight Surgeon, and serving as Radar Intercept Officer in the Marine F-4S Phantom, accumulating 235 flight hours, and trained for qualification as an Air Combat Tactics Instructor. I was deployed to the Western Pacific as UDP forward deployed fighter squadron in Korea, Japan, and the Philippines. I served in the US Navy for 24 years, and I served in the USMC for 3 years. I retired with the rank of Captain, USN in 2002.

7. **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 (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.

8. **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.

9. **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 transi-

tioners 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.

10. **Retained as an Expert Witness - Compensation - Bases for Opinions:** I have been retained as an expert witness by the State of Arkansas for the defense in connection with this litigation. I have actual knowledge of the matters stated in this declaration. I am being compensated at an hourly rate for actual time devoted, at the rate of $400 per hour including report drafting, travel, testimony, and consultation. My compensation does not depend on the outcome of this litigation. To formulate opinions in this case I have reviewed many scientific publications, case filings, and the plaintiffs' witness declarations.

11. **Expert Report Limitations:** My opinions and hypotheses in this matter are — as in all expert witness reports — subject to the limitations of documentary and related evidence, the impossibility of absolute predictions, as well as the limitations of social, biological, and medical science. All opinions are offered to a reasonable degree of medical certainty. I have not met with, nor personally interviewed, anyone in this case. As always, I have no expert opinions regarding the veracity of witnesses in this case. I have not yet reviewed all of the evidence in this case and my opinions are subject to change at any time as new information becomes available to me. Only the trier of fact can determine the credibility of witnesses and how scientific research may or may not be related to the specific facts of any particular case. In my opinion, a key role

of an expert witness is to help the court, lawyers, parties, and the public understand and apply reliable scientific, technical, and investigative principles, hypotheses, methods, and information.

II. GENDER AFFIRMING TREATMENTS ARE EXPERIMENTAL.

12. "Gender affirming" treatments remain experimental as the historic Branstrom study and National Reviews in England, Sweden, and Finland indicate. "Gender affirming" treatments (i.e., hormones and surgery) have not been proven effective, or even competently tested. Such "treatments" are not generally accepted by the relevant scientific community and have no documented error rates (See, Daubert/Kumho). Patients who experience a gender identity that is discordant with biological sex have an alarmingly high incidence of serious psychosocial morbidity including depression, anxiety, eating disorders, substance abuse, HIV infection, suicidality, and homelessness. Connolly, M. D., M. J. Zervos, C. J. Barone, C. C. Johnson, and 2nd C. L. Joseph. 2016. *'The Mental Health of Transgender Youth: Advances in Understanding.*" Journal of Adolescent Health 59:489–95. :10.1016/j.jadohealth.2016.06.012. While a need for effective treatment modalities is clear, there are currently significant deficiencies in our understanding of the etiology of this condition, of the risks and benefits of the current experimental (unproven, untested) medical interventions, and of the long-term success of various "affirmation" treatments in achieving the primary desired goal of reducing mental illness including reductions in suicide risk.

13. Multiple recent studies and reviews including the recent national science summaries and guidelines from England-NICE, Sweden, Finland, the Cochrane Review, the British Royal College of Psychiatrists and others all document significant deficits in our current understanding of these complex disorders and significant defects in the "low quality," contradictory, and controversial existing evidence. As we strive to provide real, effective, and sustained treat-

ment to patients who experience gender dysphoria within established ethical boundaries, it is essential that we properly and scientifically research the causes of gender dysphoria as well as conduct competent, properly conducted randomized clinical trials and long-term treatment outcome studies. These basic, foundational tasks — the tasks that make experimental procedures actual, proven treatments worthy of trust — have *never been accomplished in the highly controversial field of the transgender treatment industry*. Why? Suffering and vulnerable patients and their families continue to wait for this basic, foundational scientific work to be completed. Meanwhile, affirmation "treatments" are properly viewed as experimental. (See detailed citations in the "Notes" section of this report below).

14. The science and medical world have — in just the past few years — become increasingly aware of and deeply concerned about the glaring science and ethical defects of the transgender treatment industry. For example, the very recently released 2020 Finland national science review and guidelines documented "a lack of quality evidence to support the use of hormonal interventions in adolescents with gender dysphoria." The new strict Finnish guidance prioritizes psychological therapy over treatment with hormones or surgery, thus directly contradicting the non-science-based association protocols of WPATH. The 2020 Finland national science review and guidelines also document the ongoing lack of scientific basis for the transgender treatment industry, stating "Only limited research has been conducted on transgender identity and other gender identity conflicts, and comparative studies are very rare." In sum, the Finland National Science Review and Guidelines, like the new Sweden Review and Guidelines, the Cochrane Review, and other reviews, and the collapse and recantation of the 2020 Branstrom long-term treatment outcome study (which proved *no benefits* to these "treatments") claims, all

appear contrary to the opinions of plaintiffs' experts, WPATH, and the endorsements of professional associations. (See detailed citations in the "Notes" section of this report below).

15. Meanwhile, practitioners in this troubled field continue to offer defective research and politicized endorsements from politicized, union-like associations (WPATH, APA, ACP, etc.) rather than competent, credible, valid, and reliable peer-reviewed and published scientific evidence. The plaintiffs' experts failed to even discuss the serious defects and methodological limits of transgender medicine data and experimental practices. Fifty years of experimenting is enough. It is time for the transgender treatment industry to come up with real, competently constructed scientific evidence that they help more people than they hurt. As the recent national science reviews from England, Sweden, the Cochrane Review, and Finland have all noted, it is time to step back, slow down, and prudently investigate a range of approaches — including years of careful psychotherapy prior to experimental sterilizing "treatments" — to vulnerable patients struggling with gender discordance issues. (See detailed citations in the "Notes" section of this report below).

III. THE ETHICS OF PLASTIC SURGERY

A. "Chest Masculinization" in Natal Females is Not Ethically Equivalent to Mastectomies for Breast Cancer.

16. When mastectomy is performed for the management of breast cancer, or to mitigate the proven risk of developing breast cancer in women, it is done on the basis of objective diagnoses either by pathological examination of biopsy tissue, or as in the case of prophylactic mastectomy, on the basis of genetic analysis that shows known markers of increased risk of developing breast cancer. These tests (microscopic examination of tissue specimens, detection of cell surface markers with proven association with malignancy, and genetic screening of at-risk patients) have known positive predictive value for the diagnosis of breast cancer, and these tests

have known error rates that can be used when obtaining informed consent for mastectomy. The validity of these tests has been proven using scientific methodologies that produce high quality evidence in longitudinal population studies with control populations, and very long follow up. As the result, when a woman gives consent for mastectomy to control or prevent the potentially lethal disease, it is with a clear and proven evaluation of the risks and benefits that consent is obtained. Mastectomy is being performed based upon an objective diagnosis of a potentially lethal condition, and the surgical procedure has proven benefit in management of that condition.

17. In stark contrast, this is not the case when mastectomy is performed to "masculinize" the chest of girls and women who self-identify as transgender or who self-report symptoms of dysphoria. Otherwise healthy breasts are being removed on the basis of a diagnosis that is made by the patient since there are no tests with known error rates that can be used to predict who will benefit from this disfiguring and irreversible surgery. The claim is made that chest masculinization has proven benefit in reducing dysphoria and the associated risk of suicide. But published studies that make this claim of benefit offer evidence that is low to very low quality, typically small case collections with self-selection bias, very short follow up, and no case controls.

18. The best data presently available on the long-term effects of medical and surgical transitioning are long-term, longitudinal, population based studies. For example, Dehjne, et al., examined the putative long-term benefit of full transitioning (including hormonal and surgical treatments) found in the Swedish medical database. (See Long-Term Follow-Up of Transsexual Persons Undergoing Sex Reassignment Surgery: Cohort Study in Sweden; Cecilia Dhejne, Paul Lichtenstein, Marcus Boman, Anna L. V. Johansson, Niklas Långström, Mikael Landén; PLOS One February 22, 2011 https://doi.org/10.1371/journal.pone.0016885). That database includes

all persons in the Swedish medical system, from pre-natal to death. It reports all episodes of care and all demographic information in a uniform vocabulary. Furthermore, Sweden has been on the forefront of "gender affirmation" long before the American medical system seriously considered its claims. Because of the nature of Sweden's database, it is possible to study a cohort of patients that exactly matches the inquiry group with regards to age, sex, economic status, etc. It is possible to ask precisely such questions as, "What is the likelihood that a fully transitioned transgender male will be hospitalized for psychiatric illness when compared to the age/sex matched control group?" or "What is the relative risk of suicide in transgender persons, when compared to age/sex matched controls?"

19. Why are such longitudinal, population based studies superior to the case-collection/case series methodology? Because confounding variables such as age, sex, and self-selection biases are removed. In the flawed case-collection methodology, the reported cases are typically only those who return for follow up. You have no way of knowing if the patient had a good outcome or didn't return for follow up because they were in a psychiatric hospital, were incarcerated, or committed suicide. In the Swedish longitudinal study, the suicide is in the same database, as are the other issues of hospitalization, incarceration, and addiction treatment, among other rates of comorbidity. Thus the longitudinal population study can give us what is called a "hazard ratio" for a particular study population (patients who have completed transgender transition).

20. What did this Swedish study show us? It showed us that the risk of completed suicide in all transgender persons is *19.1 times higher* than in the control cohort. If you look only at patients who have transitioned — patients after "treatment" — from female to "male presentation," the risk of completed suicide is *40 times higher* than in the general population.

(Note: this finding is consistent with the historic Branstrom 10yr follow up study, which found no benefits to "transitioning treatments" but did note an increased risk of serious suicide attempts and anxiety disorders AFTER "treatment." (Correction to Bränström and Pachankis, Am J Psychiatry 177:8, August 2020; see detailed citations in the "Notes" section of this report below).

21. Another cautionary note was added to the literature review by the reputed Cochrane Review, a UK based international association of researchers who examine the quality of scientific evidence used in medical decision making. The Cochrane Review recently published findings concerning the medical evidence used to support the decision to give young women cross sex hormones as part of the transition process. The authors summarize the world literature review thus: "We found insufficient evidence to determine the efficacy or safety of hormonal treatment approaches for transgender women in transition. This lack of studies shows a gap between current clinical practice and clinical research." (Does hormone therapy help transgender women undergoing gender reassignment to transition? See, Haupt C, Henke M, Kutschmar A, Hauser B, Baldinger S, Saenz SR, Schreiber G., Cochrane Review, 28 Nov 2020).

22. Similar issues of very poor, low quality scientific support for chest masculinization surgery can be seen in a recent article by Tolstrup et al. published in the journal Aesthetic Plastic Surgery (See Anders Tolstrup, Dennis Zetner, Jacob Rosenberg, Outcome Measures in Gender-Confirming Chest Surgery: A Systematic Scoping Review, Aesthetic Plast Surg 2020 Feb;44(1):219-228. doi: 10.1007/s00266-019-01523-1. Epub 2019 Oct 29). The article reports a comprehensive review of the world literature concerning the efficacy of "gender confirming" chest surgery in transgender patients. The authors found 849 articles on the subject, published in peer reviewed medical journals. Of these 849 articles, only 47 could be included in the review. This means that only 5.5% of all the published, peer-reviewed transgender surgery articles

demonstrated even rudimentary scientific rigor. Of those 47 articles, the authors report that only 29 of the articles addressed mental health outcomes (3.4% of all the articles). What is startling is that the mental health outcomes were judged only on the basis of uncooroborated, untested, and unassessed patient subjective reporting with descriptors that varied so widely from article to article that results could not even be compared. The authors summarize by saying, "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." None of these negligent articles even bothered to examine rates of psychiatric hospitalization, substance abuse, self-harm behaviors, and suicide. This tells us that the main reason for performing these surgeries (psychological distress and suicide risk) isn't even evaluated with regard to efficacy.

23. An example of an article with very low quality data, reckless (now banned practices), and methodology, published in a "leading journal," and promoted as evidence for the efficacy of "chest masculinization" surgery makes this fact very clear. The lead author (Olson-Kennedy, a leading national advocate for the transgender treatment industry) is a board certified pediatrician who leads the gender clinic for the Los Angeles Children's Hospital. The article appeared in 2018 (See J. Olson-Kennedy, J. Warus, MD1, et al., *Chest Reconstruction and Chest Dysphoria in Transmasculine Minors and Young Adults; Comparisons of Nonsurgical and Postsurgical Cohorts*., JAMA Pediatr. 2018;172(5):431-436. doi:10.1001/jamapediatrics. 2017.5440). In their summary of findings, the authors reported that "chest dysphoria" is common among "trans males" (natal females seeking to present as males), and claimed that dysphoria is "decreased by surgery." They claim that regret for surgery is "rare." The article reports breast removal surgery on at least one girl aged *13 years*. (Note that this reckless, experimental

practice has now apparently been abandoned as unethical/experimentation on children by England, Sweden, and Finland). The average age of patients in the study 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 of the patients recruited from among visitors to the clinic (convenience sampling) there was an abundance of non-operated patients, so they were forced to reach out to all the post-surgical patients by phone. Twenty-six percent of the clinic's post-surgical patients could not be reached for various reasons including no working phone, or failure to respond to multiple messages. The 26% drop-out rate is never even questioned by these authors. Were surgical patients lost to follow up because of dissatisfaction, psychiatric hospitalization, or *suicide*? This problem is called "self-selection bias," and it is evidence of careless study design. Of the remaining 74% of patients, only 72% 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 — demonstrating multiple levels of confirmation bias — do not even ask such essential questions. (See detailed citations in the "Notes" section of this report below).

24. In the study, dysphoria was evaluated using what the author called "a novel measure," which amounted to a series of subjective questions about happiness that was in part designed by the adolescent test subjects themselves. Essentially, the methodology used an entirely unvalidated ("junk science") test instrument, with no known error rates and no proven predictive power. Furthermore, the post-surgical patients were administered the survey at widely 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 this obviously flawed sample, and yet the authors claim evidence of "negligible regret." This is a remarkable, misleading, and

deceptive 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 7 years post-surgery (Long-Term Follow-Up of Transsexual Persons Undergoing Sex Reassignment Surgery: Cohort Study in Sweden; Cecilia Dhejne, Paul Lichtenstein, Marcus Boman, Anna L. V. Johansson, Niklas Långström, Mikael Landén; PLOS One February 22, 2011 https://doi.org/10.1371/journal.pone.0016885). Surely the authors are familiar with the world literature on transgender outcomes?

25. Having deceptively or negligently promised in the introduction to their paper that "chest dysphoria" is reduced by surgery, at the conclusion the authors confessed to 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 confessed 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."

26. Finally, the authors did not even bother to validate their "Chest Dysphoria Scale." Such a "made-up" scale is unlikely to accurately represent distress or correlate with properly validated measures of quality of life, depression, anxiety, or functioning." Their own analysis at the conclusion or the paper directly contradicts their own deceptive claim made in their introduction.

27. This is the kind of "junk science" that is used to support transgender medicine and surgery. It was written by board certified physicians who practice in one of the nation's largest pediatric gender clinics and published in a peer-reviewed medical journal. It is essentially useless in making any clinical decisions regarding who should be offered surgery, what is the likelihood they will benefit from it, what is the likelihood they will regret their decision, and most importantly, whether their risk of suicide would be reduced.

28. Because of the very low quality scientific support for mastectomy in the management of gender dysphoria, valid consent would require that these procedures be described as experimental, would need the approval of ethics panels to monitor human experimentation, and would require the use of valid controls found in long-term, longitudinal population based study models. These are the kinds of patient protections now endorsed in England, Sweden and Finland but still ignored in the US environment where proper scientific critiques of such studies can get faculty "cancelled." (See detailed citations in the "Notes" section of this report below).

29. Even though the transgender treatment industry has been performing these surgeries for over 50 years, gender treatment centers continue to publish the same low quality, methodologically defective studies based upon collected cases that are degraded in value by self-selection bias, confirmation bias, and short-term follow-up, while continuing to deceptively claim that such defective research provides a sufficient scientific basis for performing irreversible, disfiguring, and ultimately sterilizing hormonal treatments and surgeries**.** (See detailed citations in the "Notes" section of this report below).

B. "Chest Masculinization" in Natal Females is Not Ethically Equivalent to Gynecomastectomy.

30. Gynecomastectomy is the surgical treatment of gynecomastia, a fairly common condition in which males develop female-type breast gland tissue. Proponents of "masculinization" mastectomy in natal females erroneously equate the ethics of removing healthy breast tissue from these patients with the removal of abnormal breast tissue in men (gynecomastia). In the case of gynecomastectomy in male patients, the operation is performed to remove the objectively diagnosed presence of female type glandular breast tissue present in a male patient. Physical examination demonstrates the presence of a dense retro-areolar mass which is tender and sometimes disfiguring. Pathological examination of the removed tissue will demonstrate the presence of female-type fibroglandular tissue in a male patient. This is an objectively abnormal condition. It should further be noted that in the absence of such abnormal, female-type fibroglandular tissue, chest recontouring is considered to be cosmetic, and is typically not paid for by third-party payors.

31. I have never read a peer reviewed journal article which discusses the indications for gynecomastectomy that included any claim to reduce major depression and suicide. This is because any male patient seeking removal of abnormal, female-type, breast tissue who reported suicidal ideation would be considered incompetent to give consent, and would require a psychiatric evaluation and treatment to manage suicidal thinking before being considered for surgery.

C. "Chest Masculinization" in Natal Females is Not Ethically Equivalent to Breast Reduction.

32. It should be obvious that "Chest Masculinization" surgery in natal females is not ethically equivalent to breast reduction surgery in non-transgender females. In the case of breast reduction for females with excessively large breasts (macromastia, or gigantomastia), the operation is performed to relieve a debilitating orthopedic complaint of neck, back, and shoulder pain

associated with the postural/mechanical effects of the weight of the breasts. These patients experience significant activity restriction and chronic pain that is not relieved by medical management or physical therapy. Furthermore, there is voluminous actuarial data, based upon many years of longitudinal population based study by medical insurance agencies that is used to predict who will benefit from surgery, and who will not. These physical, objective tests, based upon the actual measurement of the breasts, and the patient's overall body habitus, have known error rates that can be used to predict the likelihood that a breast reduction will relieve the orthopedic complaints of neck, back, and shoulder pain. When the tissue specimens are submitted to pathology, they are weighed in order to ensure that enough tissue has been removed so that there will be a very high likelihood that the surgery will relieve the orthopedic condition of neck, back, and shoulder pain (Accuracy of Predicted Resection Weights in Breast Reduction Surgery, Theodore A. Kung, MD, Raouf Ahmed, MBBS1 Christine O. Kang, MPH,1 Paul S. Cederna, MD, and Jeffrey H. Kozlow, MD; Plast Reconstr Surg Glob Open. 2018 Jun; 6(6): e1830.

33. Based upon that, adequate pre-operative consent can be obtained. The supporting data is based in very high quality methodology. There is no quality research data, no pre-operative test or study, and no known error rates, that can be used to predict the likelihood that any child suffering from gender dysphoria will benefit from the experimental procedures of mastectomy and chest "masculinization." As noted above, because of the very low quality data, transgender chest masculinization is at best experimental and at worst, should be viewed as a form of medical child abuse — it is important to note that Finland, Sweden, and the UK appar-

ently now all agree with this analysis, as they have all retreated from such reckless surgical procedures for minors — similar to what Arkansas's science-informed, responsible legislature has now done. (See detailed citations in the "Notes" section of this report below).

34. It is crucial to remember that "chest masculinization" of healthy breast tissue results in a complete loss of function, that this loss is two-fold (breast feeding and erotic sensibility), and the cause of the loss is two-fold (gland removal and severing of the intercostal nerve). (See Breast Reduction with Use of the Free Nipple Graft Technique; Stephen R. Colen, MD; Aesthetic Surgery Journal, (Breast Reduction with Use of the Free Nipple Graft Technique; Stephen R. Colen, MD; Aesthetic Surgery Journal, Volume 21, Issue 3, May 2001, Pages 261–271, https://doi.org/10.1067/maj.2001.116439.

35. If a patient who undergoes "chest masculinization" should regret the surgery, they do have the option of breast reconstruction. But all that will be produced is the appearance of a breast. The patient will have lost the function of breast feeding. Additionally, the most commonly performed "masculinization" surgery involves the removal of the nipples, and subsequent re-attachment in the form of a nipple graft. Those nipples will have lost their native nerve connections that provoke erotic sensibility. All that can be hoped for is the eventual random ingrowth of local skin sensation, but there will never be erotic sensation because the particular branch of the fourth intercostal nerve which communicates with particular centers in the brain responsible for oxytocin release and erotic provocation will have been permanently severed. This means that breast function has been completely and irreversibly sacrificed for the sake of producing a cosmetic result (a masculine appearing chest). This is the exact opposite of the goals of any reconstructive surgery. It must therefore be understood that "chest masculinization"

is a cosmetic procedure that has violated the most essential principle of cosmetic surgery: never sacrifice function for the sake of a cosmetic result.

D. Masculinizing and Feminizing Chest Surgeries are Not "Medically Necessary."

36. Supporters of "transitioning" treatments justify surgical treatment based upon "medical necessity." They claim that gender dysphoria can lead to debilitating anxiety and depression, as well as serious incidents of self-harm, including self-mutilation, suicide attempts, and suicide. Yet with only a single exception, in the studies they cite no measures are made of the effects of surgery on what is claimed to constitute the "medical necessity" for these procedures.

37. In contrast, the Branstrom study cited in detail in the Notes Section of this declaration documented no reliable benefits for transgender surgery/hormonal treatments and no reduction in suicide and even an *increase* in serious suicide attempts requiring hospitalization in patients receiving surgery. These recent, long-term, published, peer reviewed, credible research findings are quite contrary to the claims of supporters of "transitioning treatments" — as are the National Science Reviews in this area from England-NICE, Sweden, and Finland. (See detailed citations in the Notes section in this declaration).

38. Scientific rigor would demand an examination of such outcomes as: rates of substance abuse, psychiatric hospitalization, self-harm, or suicide, and how they were changed by surgery. One paper does ask these crucial questions concerning efficacy is a very comprehensive, long term, longitudinal population cohort study which actually shows the opposite of what plaintiffs' experts' claims for these patient outcomes. When followed beyond 8 years post operatively, this paper shows patients receiving plaintiffs 'experts' treatments have the same alarmingly high rates of hospitalization, substance abuse, self-harm, and completed suicide as persons

who have had no medical or surgical intervention. The fact that the citation is included by plaintiffs 'experts, but never discussed in his opinion regarding efficacy is troubling. In summary, on the issue of the safety and efficacy of these surgeries, the scientific support is very weak, while the scientific evidence rejecting the hypothesis of efficacy is remarkably strong (See Long-Term Follow-Up of Transsexual Persons Undergoing Sex Reassignment Surgery: Cohort Study in Sweden; Cecilia Dhejne, Paul Lichtenstein, Marcus Boman, Anna L. V. Johansson, Niklas Långström, Mikael Landén; PLOS One February 22, 2011 https://doi.org/10.1371/journal.pone.0016885

39. The surgical removal of the breasts, and the re-contouring of the chest through liposuction is a common procedure for women who seek to present as men. These operations are performed in both men and women, for a variety of reasons, are very safe, and typically performed in the outpatient setting. It is important to understand that the only way of distinguishing cosmetic breast surgery from "medically indicated" surgery is based upon the diagnosis of underlying pathology. For example, breast reduction may be cosmetic, or it may be medically indicated. In both cases, the patient presents with a complaint that her breast are too big. The distinction between cosmetic breast reduction and medically indicated breast reduction is based upon the presenting symptoms of orthopedic problems caused by the weight of the breasts, but even then, the weight of the removed tissue is factored into the objective verification that the surgery was "medically necessary."

40. The same issues are at stake in breast enhancement for men seeking to present as women. Cross-sex hormones will have caused varying degrees of gynecomastia (breast enlargement in men). Surgical enhancement procedures are exactly the same in both men and women.

Medically necessary surgery in women is based upon the diagnosis of an objective medical condition, such as Poland's syndrome (congenital absence of a breast), surgical absence of the breast following cancer care. In men, the objective diagnosis of gynecomastia might warrant surgery based upon medical necessity, but it would be a removal of tissue. A rare diagnosis of breast cancer in a man might warrant chest wall reconstruction after cancer care. On the other hand, cosmetic surgery of the breast is entirely about the subjective feelings of the patient, and that is all that we have in the case of the self-identified transgender patient.

41. In the case of transgender chest surgery, the diagnosis is based on the patient's subjective report of dysphoria, but the medical necessity is based on the expectation that surgery will relieve the patient of the risk of, among other things, major depression, self-harm behaviors, and suicide. None of the papers typically cited by supporters of "transitioning treatments" address themselves to the question of medical necessity for either masculinizing surgery, or feminizing surgery. They only address technical issues, management of complications, and subjective outcomes that employ precisely the same language that is used to assess cosmetic surgery of the breast. In summary, the medical necessity of transgender chest surgery is not supported by scientific evidence, and appears to be firmly in the category of cosmetic surgery.

E. Virtually All Transgender Patients are Born with Normal, Healthy Sex Organs and No Scientifically Validated Reason to Surgically Damage Them.

42. Sex is not "assigned at birth" but permanently "assigned" at conception by DNA. Medical technology can be used to determine a fetus's sex before birth. It is thus not scientifically correct to talk of doctors "assigning" the sex of a child at birth; almost anyone can accurately and reliably identify the sex of an infant by genital inspection with approx 99.9% accuracy. Every nucleated cell of an individual's body is chromosomally identifiably male or female—XY or XX. Claims that patients can — via hormonal and surgical treatments — obtain a

"sex change" or a "gender transition" process are misleading and scientifically impossible. In reality, the typical "transgender" gender discordant patient has normal healthy sex organs but struggles with gender discordant feelings and perceived identity — a psychiatric and not a medical problem.

F. **Detransitioners are Real and Surgeons Have No Diagnostic Tools to Identify Who They Will Be.**

43. The phenomenon of desistance or regret experienced later than adolescence or young adulthood, or among older transgender individuals, has to my knowledge not been quantified or well-studied. But it is a real phenomenon. I myself have worked with multiple individuals who have abandoned a trans female identity after living in it for years, and who would describe their experiences as "regret." More dramatically, a surgical group prominently active in the sexual reassignment field has published a report on a series of seven male-to-female patients requesting surgery to transform their surgically constructed female genitalia back to their original male form. See Djordjevic ML, Bizic MR, Duisin D, Bouman MB, Buncamper M. Reversal Surgery in Regretful Male-to-Female Transsexuals After Sex Reassignment Surgery. J Sex Med. 2016 Jun;13(6):1000-7. doi: 10.1016/j.jsxm.2016.02.173. Epub 2016 May 4. PMID: 27156012. Further, there is an increasingly visible online community of young women who have desisted after claiming a male gender identity at some point during their teen years. See, e.g., https://our-duty.group/2020/04/29/the-detransition-advocacy-network/. Given the rapid increase in the number of girls presenting to gender clinics within the last few years, the phenomena of regret and desistance by young women deserves careful attention and study.

44. Transgender surgeons have no objective, reliable means of evaluating the diagnostic error rate because there is no body of reliable scientific evidence that can be used to counsel the patient about what their risk of regret is. The ever growing population of de-transitioning

patients suggests that the error rate may be considerable, and the future medico-legal consequences may be proportionate.

45. Valid surgical consent requires that the surgeon is ultimately responsible for the accuracy of the diagnosis. For example, if an endocrinologist refers a patient for thyroidectomy because they have diagnosed a malignant thyroid nodule, the operating surgeon is still obliged to ensure the validity of the diagnosis. He has to entertain alternative diagnoses. Is it a benign nodule? Can it be treated with non-surgical means at lower risk to the patient? What do the scans show? What do the hormone levels show? Having evaluated all the alternative possibilities in the differential diagnosis, the surgeon can then counsel the patient and their family on the options of care, the likelihood of cure, and proper informed consent can be obtained.

46. But the transgender treatment industry, employing scientifically unsupported WPATH guidelines essentially (and unethically) excuse the surgeon from any responsibility for the diagnostic process or its consequences if the diagnosis is incorrect. The 7th edition of the WPATH guidelines requires only two letters written by psychologists, and a period of social transition. There is no action taken to verify the diagnosis on the part of the surgeon. The surgeon has no objective, reliable means by which to anticipate who might benefit or who might be harmed by surgery.

47. By the time a patient presents to a transgender surgeon, they have been the subject of affirmation processes that include everything from social transitioning, to hormonal manipulation. The surgeon is performing permanently life-altering surgical interventions to cure a psychological condition that was diagnosed by the patient, and sometimes the patient made the diagnosis before they even entered puberty. Since the abandonment of frontal lobotomies in 1967, there has been no other psychological-psychiatric condition for which surgery is performed, and

there is no other area of surgical care where the diagnostician is the patient themselves, and the surgeon has no objective, reliable means of confirming or rejecting the diagnosis.

G. **I Do Not Engage in Experimental Treatments Lacking Reliable, Credible Scientific Support.**

48. As multiple national science reviews and multiple peer reviewed science publications demonstrate, the relevant scientific community has never accepted the reliability, validity, safety or effectiveness of "gender affirmation" treatment procedures — including surgical procedures. Significant medical, ethical, and potential legal problems are created when health care providers employ experimental, unproven, treatment including surgical procedures. Due to the well-documented lack of scientific support and only low quality evidence of efficacy and safety, I will not personally engage in the delivery of experimental gender affirming medical interventions to patients of any age. I will not consider doing such invasive, potentially harmful surgical procedures — that can lead to life-long sterilization of vulnerable patients — until reliable, valid scientific research supports such methods.

49. The transgender treatment industry generates considerable income for hospitals, clinicians, and pharmaceutical companies. Members of the transgender treatment industry have a vested interest in believing that science has already justified their existence. Further, as sterilization is the expected adult outcome of endocrine and surgical treatments of the procedures undertaken in youth prior, the transgender treatment industry must have developed strong rationalizations to justify creating infertility. Will one day the medical profession look at support for transitioning youth in the same manner the eugenics movement is now regarded? (See, Hruz, PW, Mayer, LS, and McHugh, PR, "Growing Pains: Problems with Puberty Suppression in Treating Gender Dysphoria," The New Atlantis, Number 52, Spring 2017 pp. 3 -36 ; See also,

McHugh, P., Psychiatric Misadventures, The American Scholar, Vol. 62, No. 2 (Spring 1993), pp. 316-320

50. In summary, proponents of "affirmation care" for self-identified transgender patients have no body of quality scientific evidence that proves benefit from their interventions. They rely on low to very low quality data when they recommend affirmation therapy. Consensus statements by professional bodies are based upon the lowest category of evidence available. Advocates of "affirmation care" have no long term data to support their therapeutic recommendations, and they never compare their data to the historically proven approach of "watchful waiting." Advocates for "affirmation care" including medical and surgical intervention, have no objective test, with published error rates, that can be employed to determine who will benefit from their treatments. They rely only on subjective reporting by the patient. Transgender surgery, including "chest masculinization" does not meet the criteria for reconstructive surgery. Because the sole aim of the surgery is the claimed, but unsupported, emotional benefit, it is *by definition* aesthetic (feelings) or cosmetic (appearance) surgery. Chest "masculinization" surgery fails on professional moral grounds because informed consent is impossible (given that there is no way to predict who will benefit), and because function is utterly destroyed in order to achieve a counterfeit form.

IV. PLASTIC SURGERY IS CONCERNED WITH PSYCHOLOGY.

A. Why is Plastic Surgery Concerned with Psychology?

51. Plastic surgery has two areas of activity with broad overlap. The practice of plastic surgery includes reconstructive as well as aesthetic (often called cosmetic) surgery.

52. Reconstructive surgery is ordered to the establishment, or restoration, of normal body structures and their associated functions. The reconstructive process aims at deformities caused by trauma, disease or the management of disease such as cancer surgery, and congenital

deformities. The goal is the restoration of form and function. Sometimes functional restoration is given priority over form, as with the reconstruction of a hand injury in a man. Sometimes functional restoration is impossible, and all that can be offered is aesthetic, as with reconstruction of a facial wound that has resulted in the loss of an eye, where vision cannot be restored, and all that can be offered is a prosthetic eye.

53. Aesthetic (cosmetic) surgery on the other hand is surgery to modify the appearance of an area of the body that is functionally normal, and that has an appearance that, even though it is within the range of normal, causes some degree of annoyance or discomfort to the patient. (For example, prominent ears on a boy.) The ears are functionally normal, and their prominence may even be a recurring family trait, but their prominence is a daily annoyance to the boy; he may even have been given a pejorative nick name. A simple and safe procedure can be performed that reduces the prominence of his ears *without sacrificing any function,* and his daily annoyance is resolved. Form is changed within the range of normal, function is preserved, and the aesthetic (feelings) problem is solved.

54. In the clinical training of plastic surgeons, we learn to carefully evaluate aesthetic patients, not only for the sake of surgical planning, but because we have to understand their motivation for the surgery and how to anticipate potential complications. It is axiomatic in plastic surgery that the most avoidable complication in aesthetic surgery is disappointment and regret on the part of the patient. We are taught that disappointment is first and foremost managed by ensuring that the doctor understands what the patient is seeking to achieve, that the goal is worthy of pursuing, and that the surgeon is likely to achieve the goal.

55. Plastic surgeons are trained to recognize a particular subset of aesthetic patients who at first appear to be seeking some ordinary improvement in appearance, but upon further

evaluation discovers that the patient is seeking cosmetic surgery because they are convinced they are horribly disfigured — and *this* is the reason they feel alone, isolated and depressed. If such a patient has an otherwise normal physical appearance, then the diagnosis of Body Dysmorphic Disorder must be entertained. See (5) Body Dysmorphic Disorder, Andri S. Bjornsson, PhD, Elizabeth R. Didie, PhD, Katharine A. Phillips, MD; Dialogues Clin Neurosci. 2010 Jun; 12(2): 221–232; and Body Dysmorphic Disorder and Cosmetic Surgery Crerand, Canice E. Ph.D.; Franklin, Martin E. Ph.D.; Sarwer, David B. Ph.D. Plastic and Reconstructive Surgery: December 2006 - Volume 118 - Issue 7 - p 167e-180e.

56. Persons who suffer with this condition are seeking a physical explanation for a psychological wound. They are trying to explain their isolation, anxiety, depression, and despair by pointing to their appearance as the cause of their sorrows. Plastic surgeons learn that such patients may be elated at first with their surgery, but they return with complaints that "you didn't do the surgery right." They are disappointed because they still experience the anxiety, isolation, depression, and despair, which should not be surprising given the obvious fact that *you cannot heal a psychological wound with cosmetic surgery*.

57. Indeed, to offer cosmetic surgery to a person suffering from Body Dysmorphic Disorder is considered a failure of diagnosis. *To know that a person is suffering from body dysmorphic disorder, and to offer them surgery in spite of that knowledge is malpractice*. The surgeon is taking advantage of a psychologically vulnerable patient for the sake of financial gain. See Cosmetic Surgery and Body Dysmorphic Disorder – An Update B S. Higgins, MD and A. Wysong, MD, MS, Int J Womens Dermatolv. 4(1); March 2018.

58. Gender dysphoria is a diagnosis that is based upon the subjective reporting of the affected child. There is no objective test, with known error rates, that can be employed to confirm the diagnosis, or predict who will benefit from any putative therapeutic interventions. There is no chromosomal study, no genetic marker, no gene product, no hormonal abnormality, or any dynamic brain scan that can be used to confirm the diagnosis. Essentially, the transgender treatment industry is offering permanently life altering hormonal manipulation and irreversible surgery based upon a diagnosis that is made by an emotionally stressed adolescent, or even prepubertal child who is being socially transitioned. (See Deficiencies in Scientific Evidence for Medical Management of Gender Dysphoria Paul Hruz, MD, PhD. Linacre Quarterly 2020 Feb 87 (1)34-42. doi10.1177/0024363919873762. Epub 2019 Sep 20.)

B. **Gender Dysphoria or Gender Identity Disorder is a Logical Subcategory of Body Dysmorphic Disorder.**

59. Body dysmorphic disorder is a subcategory of obsessive compulsive disorder. What distinguishes gender identity disorder from other forms of body dysmorphic disorder is that the content of the obsessive thought is the sexed appearance of the patient. The obsessive thought is that they have the wrong genitalia, that they are really the other sex, and if they could change that, their anxiety, isolation, depression, and despair would resolve. Given that the patient is physically normal, and that the patient is seeking a change in appearance in order to resolve a feeling (aesthetic), all transgender surgery, by definition, is cosmetic surgery**.**

60. To call a "chest masculinization" mastectomy a "chest reconstruction" is not just an imprecision of language. It is intentional deception. Such mastectomy is in no way a restoration of form and function. It is rather the willful destruction of function for the purposes of producing a counterfeit form. What is more, because these mastectomies involve the irreversible destruction of normally functional parts, with associated loss of function, these operations violate

the first and most important principle of plastic surgery: It is bad surgical planning if you compromise function for the sake of a cosmetic result. In this case the compromise of function is actually a 100% loss.

C. There Are Multiple Pathways to Gender Dysphoria.

61. The diagnosis of "gender dysphoria" encompasses a diverse and controversial array of conditions, with widely differing pathways and characteristics depending on age of onset, the complexities introduced by co-occurring mental illnesses, social contagion and other environmental factors, among other things. Data from one population (e.g. adults, those struggling with complex mental illnesses) should not naively be assumed to be easily applicable to others (e.g. children, those changed by social contagion) and other factors. The developmental and mental health patterns for these groups are sufficiently different that data developed in connection with one of them cannot be assumed to be reliably applicable to another. See K. Zucker (2018), The Myth of Persistence: Response to "A Critical Commentary on Follow-Up Studies & 'Desistance 'Theories about Transgender & Gender Non-Conforming Children" by Temple Newhook et al., Intl J. of Transgenderism at 10, DOI: 10.1080/15532739.2018.1468293 ("Myth of Persistence").

V. OPINIONS REGARDING THE SHOCKING OMISSIONS OF PLAINTIFFS' REPORTS

62. As a physician and surgeon for decades, I have dedicated my life to helping the injured, the wounded, the sick, the vulnerable, and those in distress. As a physician and surgeon, I have a duty to carefully assess the available scientific research literature and determine what surgical procedures have been scientifically proven safe and effective for use on patients — and which procedures are still experimental, potentially dangerous, and may well do more harm than good for patients. Such an assessment requires the prudential review of scientific publications and my being familiar with the ongoing methodological and scientific debates in the field.

63. I have reviewed the plaintiffs' declarations from Drs. Adkins and Antommaria in this case. Those declarations demonstrate an stunning lack of knowledge or candor regarding the ongoing, raging, international scientific debates over the safety and effectiveness of "gender affirming" medical procedures. Those reports offer no proper disclosure of these controversies and demonstrate no apparent awareness of the serious methodological and ethical defects and controversies exposing the lack of scientific foundations for the transgender treatment industry. Over the past few years, multiple methodological exposes and national reviews in England (NICE), Sweden, and Finland, plus other reviews (e.g., Cochrane, Griffin, Carmichael, etc), have all raised urgent warnings and serious questions about the quality and the integrity of the scientific foundation for this very controversial field.

64. It is troubling that the plaintiffs' experts both appear to have significant financial and professional conflicts of interest as they themselves have reported in their appended curriculums vitae that much of their practices and incomes are derived from these experimental, unproven, potentially harmful methods and procedures of "gender affirmation transitioning" medical treatments. Further, not only their incomes but their professional reputations, academic positions, journal publications, and association memberships would all collapse if the transgender treatment industry collapsed due to widely noted missing evidence of safety and effectiveness.

65. The following are among the shocking errors, omissions, and failures of the plaintiffs' expert reports.

A. Failure to Disclose Multiple International Controversies and the Poor Quality of the Evidence

66. The plaintiffs' experts failed to properly disclose and discuss the international debates and controversies surrounding transgender affirmation methods and procedures discussed above. Indeed, it is difficult to imagine a more inaccurate summary of the state of the embattled,

experimental transgender treatment industry that that reflected in their reports. (See detailed citations in the "Notes" section of this report below).

67. The plaintiffs' experts failed to properly disclose and discuss multiple peer-reviewed, published exposés of significant methodological defects in research on transgender affirmation methods and procedures. Further, the plaintiffs' experts failed to properly disclose and discuss recent scientific studies and reviews including the Cochrane Review, the Carmichael study, the Griffin review and the devastating scientific critiques of the ill-fated and recanted Branstrom, et al. study, including the many multiple, detailed, methodologically sophisticated letters to the editor. (See detailed citations in the "Notes" section of this report below).

B. **Failure to Acknowledge Comorbidities**

68. Plaintiffs' experts fail to recognize how the existence of comorbidities complicate the treatment of gender dysphoric patients. It is well established in peer-reviewed medical literature that children who experience gender discordance have a very high likelihood of major anxiety disorders, major clinical depression, self-harming behaviors such as cutting, substance abuse. They also have a greater than 30% likelihood of being on the autism spectrum. Under the "affirmation care" model, these issues are more often than not ignored, ascribing all of the child's problems to their self-diagnosed gender dysphoria. (See Elevated rates of autism, other neurodevelopmental and psychiatric diagnoses, and autistic traits in transgender and gender-diverse individuals, Varun Warrier, David M. Greenberg, Elizabeth Weir, Clara Buckingham, Paula Smith, Meng-Chuan Lai, Carrie Allison & Simon Baron-Cohen ; Nature Communications volume 11, Article number: 3959 (2020), https://www.nature.com/articles/s41467-020-17794-1.

C. Failure to Acknowledge the Radically Changing Patient Demographics and Problems for the "Affirmative" Model

69. Plaintiffs' experts fail to recognize that the demographics of transgender patients have seen a radical transformation in the last several years. Historically, the condition was rare (less than 0.2% of children), had initial presentation in pre-puberty, was almost exclusively boys, and showed a desistance (i.e., abandonment of cross-sex self-identification) rate of over 80% by mid-adolescence, and over 90% when followed into adulthood. See A Follow-Up Study of Boys With Gender Identity Disorder; Devita Singh, Susan J. Bradley, and Kenneth J. Zucker, Front. Psychiatry, 29 March 2021.

70. Currently, the majority of newly diagnosed transgender children are natal females (over 50%), initial presentation is in early adolescence to young adulthood, and some reports have the overall prevalence rate rising to somewhere between 2 and 10% of school age children. See Evidence for a Change in the Sex Ratio of Children Referred for Gender Dysphoria: Data From the Gender Identity Development Service in London (2000-2017) Nastasja M de Graaf , Polly Carmichael , Thomas D Steensma , Kenneth J Zucker, J Sex Med 2018 Oct;15(10):1381-1383 and also Characteristics of Referrals for Gender Dysphoria Over a 13-Year Period Melinda Chen, M.D., John Fuqua, M.D., and Erica A. Eugster, M.D J Adolesc Health. 2016 Mar; 58(3): 369–371. doi: 10.1016/j.jadohealth.2015.11.010). This means that the diagnosis among females has risen by nearly 50-fold in the last five years (See Gender dysphoria in adolescence: current perspectives, Riittakerttu Kaltiala- Heino, Hannah Bergman, Marja Työläjärvi, and Louise Frisén; Adolesc Health Med Ther. 2018; 9: 31–41. Published online 2018 Mar 2. doi: 10.2147/AHMT.S135432).

71. Additionally, there appear to be "outbreaks" of clusters of adolescent females that are connected either by school, or social media that suddenly appear. This was first reported by

Dr. Lisa Littman of Brown University in her 2018 paper which coined the diagnostic term of Rapid Onset Gender Dysphoria. (See Parent reports of adolescents and young adults perceived to show signs of a rapid onset of gender dysphoria, Littman, L. PLOS One, August 16, 2018; https://doi.org/10.1371/journal.pone.0202330). She found evidence suggesting that these subjects developed transgender self-identification through a social contagion process that included highly rehearsed speech to be used when speaking to psychologists, counselors, pediatricians, and surgeons. A moment's reflection on this single fact should be enough to dissuade anyone from the idea that transgender self-identification is a biologically determined condition. Has there been a mass mutation in the human genome that would cause a fifty-fold increase among girls? Is there some substance abroad in the world that has radically and swiftly altered childhood brain development? The numbers of affected children would easily place this in the category of a pandemic, given the geographic range of the condition in the western world.

72. The transgender treatment industry has not shown the slightest interest in examining alternative causes, and it offers precisely the same treatment model to children whether they experience gender dysphoria from their first days of character formation in early childhood or at age 14 when their psychosexual development is under the tremendous pressures of puberty. All patients are given "affirmation care" in spite of the fact that we are dealing with wildly different psychological processes. The only variation in treatment plan, from the youngest patient to the oldest, is where along that single line of care they are brought in: social transition, puberty blockers, cross-sex hormones, then surgery.

73. Psychological evaluation and treatment, even of the known psychological comorbidities such as depression and anxiety, bipolar disorder, etc., is a priori decried by the American Psychological Association and other political allies as "conversion therapy," even if the therapy

is used to reduce depression and anxiety. Therapists are *barred* by "political correctness" from seeking alternative causal explanations and thus less able to avoid confirmation bias. Properly exploring the possibility of alternative diagnoses, such as anxiety disorder, major depression, or autism spectrum, even though part of the standard of care, is labelled as" trans-phobic."

74. Because the alternative causal explanations identify disorders that are far more treatable, cross-sex identification may, for many patients, be treatable using safe, proven methodologies such as Cognitive Behavioral Therapy (CBT). Instead, "affirmation" advocates claim that CBT — the most tested and validated form of psychotherapy for depression and anxiety relief — is nothing more than" conversion therapy", or even "psychological torture." (See APA Resolution on Gender Identity Change Efforts Feb. 2021 https://www.apa.org/about/policy/resolution-gender-identity-change-efforts.pdf). The transgender treatment industry maintains emotional chaos in these vulnerable patients, giving rise to a continuing "need" for irreversible, sterilizing, unproven, controversial "transitioning" treatments.

D. The Existence of the "Watchful Waiting" Model of Care

75. Plaintiffs' expert witnesses failed to acknowledge even the very existence of the "watchful waiting" model of care.

76. Historically, Gender Identity Disorder (now called Gender Dysphoria) was recognized as a sub-category of Obsessive Compulsive Disorder where the child has a persistent, intrusive thought that they are the wrong sex. This makes sense because the content of the thought meets the three criteria of a delusional thought: It is 1) held with absolute certainty, 2) unpersuadable by contrary evidence, and 3) impossible. In the case of the gender discordant child, the content of the delusional thought relates to their sexed self. These children typically presented in pre-puberty, and care were directed at several important issues: Experiences or perceptions that have provoked fear or anxiety (e.g. child abuse including sexual assault) that might be causing

the child to seek safety in the opposite sex presentation; misinterpretation of family dynamics that may have caused a desire to be the other sex; actual abuse events that may have provoked and habituated the obsessive thought.

77. Individual and family counseling directs the child's thoughts and coping processes in the direction of the truth of their nature, which includes their biological sex. Historically, this "watchful waiting" approach resulted in a complete resolution of symptoms in 80% of children by mid-adolescence, and over 90% resolution by early adulthood. (See Psychosexual outcome of gender-dysphoric children. Madeleine S. C. Wallien, P. Cohen-Kettenis 2008 Psychology, Medicine Journal of the American Academy of Child and Adolescent Psychiatry 10.1097/CHI.0b013e31818956b9; and A Follow-up Study of Girls with Gender Identity Disorder, Kelley D Drummond 1, Susan J Bradley 2, Michele Peterson-Badali 1, Kenneth J Zucker; Dev Psychol. 2008 Jan;44(1):34-45. doi: 10.1037/0012-1649.44.1.34).

78. The "watchful waiting" approach is based upon a recognition that at the heart of the transgender process lies a psychological problem, and this perspective finds strong support in both its natural history (80+% resolution without medical or surgical intervention), and the fact that no objective test, having known error rates, has yet been found that can affirm or reject a "transgender" diagnosis.

79. In contrast to the highly successful results of "watchful waiting," we have the presently regnant "affirmation" model. Under the "affirmation" model, the treating physician is essentially forbidden to consider the transgender condition to be a psychological disturbance apart from the unhappiness and associated impaired social functioning caused by the discordance between their objective biological sex and their interior sense of their gender. Treating profes-

sionals, including pediatricians, endocrinologists, psychologists, and surgeons are strongly discouraged from examining alternate theories concerning the diagnosis and causes, such as clinical anxiety apart from gender discordance, major depression, or the social contagion model of causation. The affirmation model proposes that the child's interior sense of their gender is "their true self," and that the problem demands that the appearance of the body must be radically changed so that it "aligns" with the child's subjective sense of being the opposite sex.

80. The startling difference in outcomes between "watchful waiting" and "affirmation" provides a compelling counter argument to the WPATH guidelines. As stated above, "watchful waiting," which includes individual and family counseling, yields successful resolution of gender discordance by natural maturation in over 80% of children by mid adolescence, and over 90% by young adulthood. This is in stark contrast, with "affirmation care" where we find that children who are enrolled in gender clinics are nearly 100% likely to persist in their cross-sex self-identification through childhood into adulthood. Essentially, at least 80% of affected children who would have resolved their problem and gone onto gender congruence, are instead trapped in the transgender treatment enterprise. The proponents of "affirmation care" have no proven test, with known error rates, by which to distinguish the 90% that will resolve their problem from the 10% that will experience persistence of symptoms into adulthood. The probability of misdiagnosis — the error rate for this process — is 90%. This places the transgender treatment enterprise, including endocrinologists and surgeons, in the category of gross malpractice.

81. Plaintiffs' experts claim that in the case of transgender patients, it would be unethical to randomize patients into control groups and treatment groups, given the high rate of self-harm. This is a specious argument for two reasons. First, randomized case/control studies are

not the only alternative to unreliable, retrospective, biased collected case reports with short follow up on which the transgender industry rests. Longitudinal, population based, long term data is available in the world literature that allows us to evaluate the claims made by the gender affirmation treatment model. (See Long-Term Follow-Up of Transsexual Persons Undergoing Sex Reassignment Surgery: Cohort Study in Sweden; Cecilia Dhejne, Paul Lichtenstein, Marcus Boman, Anna L. V. Johansson, Niklas Långström, Mikael Landén; PLOS One February 22, 2011 https://doi.org/10.1371/journal.pone.0016885). In fact, that long-term population based data is very the reason why the Tavistock Institute in London and the Karolinska Institute Hospital in Sweden — in a dramatic change — have *restricted* the use of puberty blockers, cross-sex hormones, and transgender surgery in minors. The famed Swedish hospital's new patient protections require the involvment of research monitoring to protect children from "transitioning" experimental procedures. (See detailed citations in the "Notes" section of this report below).

82. Essentially, the "control group" already exists in the world literature, however the transgender treatment industry ignores this control group, and continues to publish low-quality case-collection studies without controls, with short follow up and massive self-selection biases.

83. Secondly, there is a very long history of results from the "watchful waiting" model against which the "affirmation model" can be compared. But Plaintiffs' experts entirely ignore this data which shows that the historically proven "watchful waiting" model has a "cure" rate of approximately 90%. The "affirmation care" model hasn't even proven basic efficacy, much less high rates of efficacy, given the low to very low quality evidence that they continue to rely on. Its proponents publish only subjective results to which they assign numerical values using unproven test instruments that have no known error rates or predictive value. (E.g., as noted

above, the historic Branstrom study and recantation documented no reliable benefits to patients in a 10yr+ follow-up study.) (See detailed citations in the "Notes" section of this report below).

E. Failure to Acknowledge that Relying on "Consensus Statements" is Not Relying on Evidence.

84. As can be seen in the Complaint in this case and the plaintiffs' expert reports, the primary supports for the "affirmative" approach are the repeated references to "consensus statements" from medical and other associations and the WPATH guidelines. It should be noted that the quality of scientific evidence in medicine can be graded based upon the methodology employed. The methodology of professional consensus seeking is in the lowest category. (See The Levels of Evidence and their role in Evidence-Based Medicine Patricia B. Burns, MPH, Rod J. Rohrich, MD, and Kevin C. Chung, MD, MS. Plast Reconstr Surg. 2011 Jul; 128(1): 305–310.)

85. It should further be noted that consensus statements from such organizations as the American Pediatric Association and the Endocrine Society are not obtained by polling the membership of the entire society, but are instead the product of consensus seeking methodology applied to a very small, self-selected sample of members that happen to be on that particular policy committee. Nonetheless, the "consensus statement" is incorrectly presented as though there is majority if not universal agreement by pediatricians and endocrinologists.

86. Furthermore, WPATH intentionally mis-labels its guidelines, calling them "Standards of Care" (See http://www.wpath.org/publications/soc). Guidelines are a suggested course of treatment that may or may not produce the desired results, and are therefore not mandatory. Labeling their document as "Standards of Care" implies that they are proven treatment methods of very high efficacy that must be adhered to in order to achieve a known and positive outcome, and that deviations from the "standards of care" has a high probability of a poor outcome, and possible legal consequences.. Given that the guidelines offer no scientifically verified

evidence that their outcomes are consistently and overwhelmingly positive, this is a clear misrepresentation of their actual value. For this reason, whenever the acronym "WPATH" is used in conjunction with the words "standards of care," the author of such words is intentionally misleading the reader.

87. The WPATH guidelines also seek to define a "professional" in transgender health. In order to be classified as a "professional" you must simply agree with what the WPATH documents state. (See WPATH Standards of Care section VI p.13 – section VII p.33 (defining the "professional" in terms of compliance with WPATH "standards of care")). This is more characteristic of a cult than a scientific body. Science demands unflinching, ongoing, debate and re-evaluation of hypotheses, quality of data, methodologies, and best practices. In contrast, WPATH demands consensus and compliance with a single, unproven model of care, even when the patients have wildly differing presentations (pre-pubertal vs. adult, co-morbid association with other illness such as autism spectrum etc.).

88. As it happens, among the lead authors of the WPATH guidelines, and their board members, are physicians and surgeons whose practices largely depend on the revenue stream found in transgender services. (WPATH Standards of Care. Pp.109-112 (describing the composition of the committee members, and their consensus methodology used in generating the document)). Essentially, they are saying, "mastectomy is justified in transgender teenage natal females because I said so in the WPATH document that I wrote." This is a classic *ipse dixit* opinion.

VI. CONCLUDING OPINIONS

89. There are no currently no competently conducted, long-term, peer-reviewed published, reliable and valid, research studies documenting the number or percentage of patients receiving gender affirming medical interventions who are helped by such procedures.

90. There are no long-term, peer-reviewed published, reliable and valid, research studies documenting the number or percentage of patients receiving gender affirming medical interventions who are injured or harmed by such procedures.

91. There are no long-term, peer-reviewed published, reliable and valid, research studies documenting the reliability and validity of assessing gender identity by relying solely upon the expressed desires of a patient.

92. There are no long-term, peer-reviewed published, reliable and valid, research studies documenting any valid and reliable biological, medical, surgical, radiological, psychological, or other objective assessment of gender identity or gender dysphoria.

93. A currently unknown percentage and number of patients reporting gender dysphoria suffer from mental illness(es) that complicate and may distort their judgments and perceptions of gender identity.

94. A currently unknown percentage and number of patients reporting gender dysphoria are suffering social contagion and social pressure processes brought on by a peer group, social media, YouTube role modeling, and/or family dynamics.

95. Patients suffering from gender dysphoria or related issues have a right to be protected from experimental, potentially harmful treatments lacking reliable and valid, peer reviewed, published, long-term scientific evidence of safety and effectiveness.

96. It would be a serious violation of licensing rules, ethical rules, and professional standards of care for a health care professional to provide gender transition or related procedures to any patient without first properly obtaining informed consent including informing the patient and/or guardian(s) of the lack of valid and reliable on the long-term risks and benefits of "affirmative" treatments.

97. A large percentage of children (over 80% in some studies) who questioned their gender identity will, if left alone, develop an acceptance of their natal (biological) sex.

98. Medical treatments may differ significantly by sex according to chromosomal assessment but not gender identity. Misinforming physicians of a patient's biological sex can have deleterious effects on treatment for medical conditions.

99. Affirmation medical treatments — hormones and surgery — for gender dysphoria and "transitioning" have not been accepted by the relevant scientific communities (biology, genetics, neonatolgy, medicine, psychology, etc.).

100. "Gender affirmation" assessments and treatments — hormones and surgery — for gender dysphoria and "transitioning" have no known, peer reviewed and published error rates.

101. Political advocates, activist physicians, and medical organizations that operate by voting methodologies (e.g., WPATH, the American Medical Association, the American Academy of Pediatrics, the American Endocrine Society) are not the relevant scientific community, they are politically active professional organizations. These organizations operate via consensus-seeking methodology (voting) and are easily swayed by political ideologies rather than evidence-based scientific methodologies.

102. Experts in legal cases have an ethical obligation to honestly, fairly, and accurately disclose and discuss the international controversies regarding the safety, effectiveness, reliability, and credibility of the gender transition industry. It is astonishing that in their expert declarations, Plaintiffs' experts failed to disclose and discuss the serious controversies, complex issues, debates, and contrary national science review recommendations in this field. It is difficult to imagine a more inaccurate summary of the state of the embattled, experimental transgender treatment industry. (See detailed citations in Notes section below).

VII. RESEARCH NOTES

To assist in my testimony in this case, I include my notes, references and citations documenting the depth and breadth of the serious controversies in this field. Over the past few years, the glaring defects in the research foundations of the gender transition industry have been exposed for all the world to see.

See, Vrouenraets et al, Early Medical Treatment of Children and Adolescents With Gender Dysphoria: An Empirical Ethical Study, Journal of Adolescent Health 57 (2015) 367e373. …"no consensus exists whether to use these early medical interventions." The study shows that there is no agreement concerning the causes of gender dysphoria, which give rise to very different treatment strategies that are at times in diametric opposition. As a result of this confusion of explanations, "consensus" regarding treatment is ipso facto impossible. Results: Seven themes give rise to different, and even opposing, views on treatment: (1) the lack of an explanatory model for GD; (2) the unknown nature of GD (normal variation?, social construct?, or mental illness?); (3) the role of physiological puberty in developing gender identity; (4) the role of comorbidity [with severe mental illnesses] ; (5) unknown possible physical or psychological effects of (refraining from) early medical interventions; (6) child competence and decision making authority [to give truly informed consent to be sterilized for experimental procedures?]; and (7) the role of social context …how GD is perceived. Strikingly, the guidelines are debated both for being too liberal and for being too limiting. Conclusions: As long as debate remains on these seven themes and only limited long-term data are available, there will be no consensus on treatment. Therefore, more systematic interdisciplinary and (worldwide) multi-center research is required. It is striking that plaintiffs' experts somehow both failed to properly report this ongoing international debate within their claimed filed of expertise.

See, Dhejne et al. (2011), Long-Term Follow-Up of Transsexual Persons Undergoing Sex Reassignment Surgery: Cohort Study in Sweden, PLOS ONE 6(2) e16885 ("Long Term"); See also, R. K. Simonsen et al. (2016), Long-Term Follow-Up of Individuals Undergoing Sex Reassignment Surgery: Psychiatric Morbidity & Mortality, Nordic J. of Psychiatry 70(4). Swedish follow-up study of patients who underwent sex-reassignment surgery over a 30-year period found a suicide rate in the post-Sex Reassignment Surgery (SRS) population 19.1 times greater — after affirmation treatment — than that of the controls; both studies demonstrated elevated mortality rates from medical and psychiatric conditions.

See, Carmichael P, Butler G, Masic U, et al. Short-term outcomes of pubertal suppression in a selected cohort of 12 to 15 year old young people with persistent gender dysphoria in the UK. medRxiv 2020.12.01.20241653. Self-harm did NOT improve and "no changes in psychological function," meaning no improvement. (Also, "YSR [Youth Self Report] data at 36 months (n = 6) were not analyzed." No significant effect on their psychological function, thoughts of self-harm, or body image, a study has found… children experienced reduced growth in height and bone strength by the time they finished their treatment at age 16. The findings, from a study of 44 children treated by the Gender Identity Development Service (GIDS) run by the Tavistock and Portman NHS Foundation Trust in London, have emerged as the trust prepares to appeal against a High Court ruling that led NHS England to pause referrals of under 16s for puberty blockers.

Demographics**:** no biological explanation. The radical change in patient demographics from early onset in boys to teen girls with rapid onset— has been termed late-, adolescent-, or

rapid-onset gender dysphoria — has now been seen in every gender clinic in the western world, and there has been a huge surge in the number of cases. "National College Health Assessment: ACHA-NCHA s://www.acha.org/NCHA/ACHANCHA_Data/Publications_and_Reports/NCHA/Data/Publications_and_Reports.aspx?hkey=d5fb767c-d15d-4efc-8c41-3546d92032c5 See, Kaltiala-Heino, Riittakerttu, Hannah Bergman, Marja Työläjärvi, and Louise Frisen. "Gender Dysphoria in Adolescence: Current Perspectives." Adolescent Health, Medicine and Therapeutics Volume9 (March 2018): 31–41. https://doi.org/10.2147/AHMT.S135432 See, Vries, Annelou L.C. de. "Challenges in Timing Puberty Suppression for Gender-Nonconforming Adolescents." Pediatrics 146, no. 4 (October 2020): e2020010611. https://doi.org/10.1542/peds.2020-010611. See, Zucker, Kenneth J. "Adolescents with Gender Dysphoria: Reflections on Some Contemporary Clinical and Research Issues." Archives of Sexual Behavior 48, no. 7 (October 2019): 1983–92. https://doi.org/10.1007/s10508-019-01518-8.

Great Britain (NICE), Deborah Cohen and Hannah Barnes, Evidence for puberty blockers use very low, says NICE at https://www.bbc.com/news/health-56601386 [“The evidence for using puberty blocking drugs to treat young people struggling with their gender identity is "very low", an official review has found. The National Institute of Health and Care Excellence (NICE) said existing studies of the drugs were small and "subject to bias and confounding"

See, Asscheman H, Giltay EJ, Megens JA, et al. A long-term follow-up study of mortality in transsexuals receiving treatment with cross-sex hormones. *Eur J Endocrinol.* 2011;164:635-642. *"There is no evidence that transition reduces suicide when we look past 10 years, and there is some suggestion that* **suicide rates may actually increase** *after the transition*

honeymoon phase is over," says Malone, stressing the importance of providing proper evaluation and appropriate psychological treatment for any suicidal tendencies. (Supports the Branson conclusions after recantation and correction).

Sweden - Review of Gender dysphoria in children and adolescents: an inventory of the literature, SBU Policy Support no 307, 2019 www.sbu.se/en • registrator@sbu.se Contact SBU: Jan Adolfsson, Medical Advisor, Project Manager, jan.adolfsson@sbu.se, English Proofreading: Project group and Jan Adolfsson, SBU [" No relevant randomized controlled (treatment outcome) trials in children and adolescents were found."] ; See, also e.g., FINLAND Issues Strict Guidelines for Treating Gender Dysphoria at https://genderreport.ca/finland-strict-guidelines-for-treating-gender-dysphoria/. In 2020, Finland reportedly became the first country in the world to issue new guidelines for this group of patients when it concluded similarly to the UK High Court that there is a lack of quality evidence to support the use of hormonal interventions in adolescents with gender dysphoria…. they also issued the guideline ordering "No surgical interventions are allowed for children under the age of 18".). As the *methodological quality of the studies was already poor* based on the type of study, thus no actual quality assessment or determination of the degree of evidence was performed."] ;

See, Cochrane Review (See, Haupt, C., Henke, M. et. al., Cochrane Database of Systematic Reviews Review - Intervention, Antiandrogen or estradiol treatment or both during hormone therapy in transitioning transgender women, 28 November 2020.)

See, Griffin, L., Clyde, K., Byng, R., Bewley, S., Sex, gender and gender identity: a re-evaluation of the evidence. BJPsych Bulletin (2020) doi:10.1192/bjb.2020.73, Cambridge University Press, 21 July 2020, the authors noted the hazardous error of mandating "affirmation treatments" — thus requiring the negligent practice of Confirmation Bias — rather than properly and carefully exploring alternative hypotheses — the standard, required ethical, medical standard of practice. As Griffin discussed, "Attempts to properly explore, formulate and treat coexisting mental illness in gender dysphoric populations, including that relating to childhood trauma, might be considered tantamount to 'conversion therapy'. Although mental illness is overrepresented in the trans population it is important to note that gender non-conformity itself is not a mental illness or disorder. As there is evidence that many psychiatric disorders persist despite positive affirmation and medical transition, it is puzzling why transition would come to be seen as a key goal rather than other outcomes, such as improved quality of life and reduced morbidity. When the phenomena related to identity disorders and the evidence base are uncertain, it might be wiser for the profession to admit the uncertainties. Taking a supportive, exploratory (psychotherapy) approach with gender-questioning patients should not be considered conversion therapy." In addition, Griffin et al wrote: "Transgender support groups have emphasized the risk of suicide. After controlling for coexisting mental health problems, studies show an increased risk of suicidal behaviour and self-harm in the transgender population, although underlying causality has not been convincingly demonstrated.

See, Dyer, C., Puberty blockers do not alleviate negative thoughts in children with gender dysphoria, finds study BMJ 2021; 372 doi: *https://doi.org/10.1136/bmj.n356* (Published 08 February 2021), BMJ 2021;372:n356 (Puberty blockers used to treat children aged 12 to 15 who

have severe and persistent gender dysphoria had no significant effect on their psychological function, thoughts of self-harm, or body image, a study has found. However, as expected, the children experienced reduced growth in height and bone strength by the time they finished their treatment at age 16)

See, Bränström and Panchankis long term surgical results. NO benefit (data suggests and suggests an increased risk of serious suicide attempts). See, Kalin, N.H., Reassessing Mental Health Treatment Utilization Reduction in Transgender Individuals After Gender-Affirming Surgeries: A Comment by the Editor on the Process by the Editor-in-Chief The American Journal of Psychiatry, Am J Psychiatry 2020; 177:7 64; doi: 10.1176/appi.ajp.2020.20060803; See also, Anckarsäter, H., and Gillberg, C., Methodological Shortcomings Undercut Statement in Support of Gender-Affirming Surgery, Am J Psychiatry 2020; 177:764–765; doi: 10.1176/appi.ajp.2020.19111117.

See, e.g., Wold, A. (M.D., Ph.D.) Gender-Corrective Surgery Promoting Mental Health in Persons With Gender Dysphoria Not Supported by Data Presented in Article, Am J Psychiatry 2020; 177:768; doi: 10.1176/appi.ajp.2020.19111170. [among the individuals examined in the Branstrom study discussed here, the risk of being hospitalized for a suicide attempt was 2.4 times HIGHER if they had undergone gender-corrective surgery than if they had not…. the data presented in the Branstrom article do not support the conclusion that surgery is beneficial to mental health in individuals with gender dysphoria."]

"Therefore, … the data in the article … *OVERTURNS the authors' stated conclusions, suggesting that sex reassignment surgery is in fact associated with INCREASED mental health*

treatment See, Ring, A. (PhD) and Malone, W. , Confounding Effects on Mental Health Observations After Sex Reassignment Surgery, Am J Psychiatry 2020; 177:768–769; doi: 10.1176/appi.ajp.2020.19111169.

See, See, Van Mol, A., Laidlaw, M. K., Grossman, M., McHugh, P., Gender-Affirmation Surgery Conclusion Lacks Evidence, Am J Psychiatry 177:8, August 2020 ajp.psychiatryonline.org 765. "The study confirms the strong association between psychiatric morbidity and the experience of incongruity between gender identity and biological sex. However, the study does NOT demonstrate that either hormonal treatment or surgery has ANY effect on this morbidity. It seems that the main message of this article is that the incidence of mental health problems and suicide attempts is especially HIGH in the year AFTER the completion of gender-affirming surgery [It is telling that the authors somehow ignored this most essential finding] …" See, Curtis, D., Study of Transgender Patients: Conclusions Are Not Supported by Findings, Am J Psychiatry 2020; 177:766; doi: 10.1176/appi.ajp.2020.19111131.

See, Malone, W. and Roman, S., Calling Into Question Whether Gender-Affirming Surgery Relieves Psychological Distress, Am J Psychiatry 2020; 177:766–767; doi: 10.1176/appi.ajp.2020.19111149. "Bränström and Pachankis study on mental health treatment and suicide attempts … is misleading because the study design is flawed." "The authors first found what was already known … the rate of psychiatric morbidity is much higher in persons with gender dysphoria compared with the general population (both before AND after "transitioning"). The authors then explored if the risk for mental health treatment changes as a function of years since starting HORMONAL treatment. They find NO effect (odds ratio = 1.0), but they do find a trend toward INCREASED risk of suicide attempts as a function of years since starting

[gender affirmation] HORMONAL treatment. They somehow failed to publish this essential finding.

See, Landén, M. (M.D., Ph.D.) The Effect of Gender-Affirming Treatment on Psychiatric Morbidity Is Still Undecided, Am J Psychiatry 2020; 177:767–768; doi: 10.1176/appi.ajp.2020.19111165. This conclusion is not supported by the data presented in the article.

See, Bränström, R. and Pachankis, J., Toward Rigorous Methodologies for Strengthening Causal Inference in the Association Between Gender-Affirming Care and Transgender Individuals 'Mental Health: Response to Letters, Am J Psychiatry 2020; 177:769–772; doi: 10.1176/appi.ajp.2020.20050599.

2020 - Sweden, following a national review of transgender science, published a new guideline that is NOT consistent with WPATH protocols nor the opinions of the plaintiffs' experts in this case. https://genderreport.ca/finland-strict-guidelines-for-treating-gender-dysphoria/ The Swedish National Guidelines appear quite contrary to the opinions of Plaintiffs Experts and WPATH.

2020 - Finland following a review of transgender science, became the first country in the world to issue new guidelines for this group of patients when it concluded similarly to the UK High Court that *there is* ***a*** lack of quality evidence to support the use of hormonal interventions in adolescents with gender dysphoria. This new Finnish guidance prioritizes psychological therapy over treatment with hormones or surgery and suggests different care plans for early-onset vs late-onset childhood gender dysphoria. The 2020 Finland guidelines state "Only limited research

has been conducted on transgender identity and other gender identity conflicts, and comparative studies are very rare."] The Finland National Guidelines appear quite contrary to the opinions of Plaintiffs Experts and WPATH.

See, https://genderreport.ca/finland-strict-guidelines-for-treating-gender-dysphoria/ Finland Clinical Guidelines and Conclusions Three reports were created by COHERE in Finland. The report "Medical treatment methods for dysphoria associated with variations in gender identity in minors – recommendation" clarifies the roles of different healthcare providers in a situation where a minor is uncertain about their gender identity. They also produced general recommendations for the treatment of transgender people, which applies to adults. And interestingly, a third and separate set of recommendations for the treatment of gender dysphoria related to non-binary people and people with gender identities other than opposite-sex gender identities.

I declare under penalty of perjury that the foregoing is true and correct.

Executed on July 8, 2021.

Patrick W. Lappert, MD

Curriculum Vitae

Patrick W. Lappert, MD
Board Certified in Surgery and Plastic Surgery
Decatur, AL 35603

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, in

— Board Certified in Plastic Surgery — American Board of Plastic Surgery, 1997; American Board of Plastic Surgery, 2008.

Medical Staff Appointments :

EXHIBIT A

— 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. 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. P!astic 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.

EXHIBIT 6

IN THE UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF ARKANSAS
CENTRAL DIVISION

DYLAN BRANDT, ET AL **PLAINTIFFS**

V. **4:21CV00450 JM**

LESLIE RUTLEDGE, ET AL **DEFENDANTS**

SUPPLEMENTAL ORDER

After further consideration, the Court supplements the ruling made at the conclusion of the July 21, 2021 hearing to include the following findings:

On April 6, 2021, the Arkansas Legislature passed House Bill 1570, Act 626 of the 93rd General Assembly of Arkansas, to be codified at Ark. Code Ann. §§ 20-9-1501 to 20-9-1504 and 23-79-164 ("Act 626"). Act 626 prohibits a physician or other healthcare provider from providing or referring any individual under the age of 18 for "gender transition procedures."

> "Gender transition procedures" means the process in which a person goes from identifying with and living as a gender that corresponds to his or her biological sex to identifying with and living as a gender different from his or her biological sex, and may involve social, legal, or physical changes;
>
> (6)(A) "Gender transition procedures" means any medical or surgical service, including without limitation physician's services, inpatient and outpatient hospital services, or prescribed drugs related to gender transition that seeks to:
>
> (i) Alter or remove physical or anatomical characteristics or features that are typical for the individual's biological sex; or
>
> (ii) Instill or create physiological or anatomical characteristics that resemble a sex different from the individual's biological sex, including without limitation medical services that provide puberty-blocking drugs, cross-sex hormones, or other mechanisms to promote the development of feminizing or masculinizing features in the opposite biological sex, or genital or nongenital gender reassignment surgery performed for the purpose of assisting an individual with a gender transition.

AR LEGIS 626 (2021), 2021 Arkansas Laws Act 626 (H.B. 1570). The Defendants asserts that Arkansas has a compelling government interest in protecting the health and safety of its citizens, particularly "vulnerable" children who are gender nonconforming or who experience distress at identifying with their biological sex. *Id.*

Plaintiffs are minors, Dylan Brandt, Sabrina Jennen, Brooke Dennis, Parker Saxton (the "Patient Plaintiffs"), their parents, Joanna Brandt, Lacey and Aaron Jennen, Amanda and Shayne Dennis, Donnie Saxton (the "Parent Plaintiffs") and their healthcare providers, Dr. Michele Hutchison, and Dr. Kathryn Stambough (the "Physician Plaintiffs"). Plaintiffs have filed suit claiming the Act violates the Equal Protection Clause, Due Process Clause, and the First Amendment. They seek a preliminary injunction to enjoin Defendants and their successors in office from enforcing Act 626 during the pendency of this litigation. Plaintiffs contend that Act 626 categorically prohibits transgender adolescents with gender dysphoria from treatment, that the patient, their parents, and their medical providers agree, is medically necessary and in the adolescent's best interest. They allege that the Act singles out individuals in need of medically necessary gender-affirming care solely because the individual's gender identity does not conform to their assigned sex at birth.

I. Rule 12(b)(1) Motion to Dismiss

As stated on the record, the Court finds that the Patient and Parent Plaintiffs have standing under the Equal Protection Clause to challenge Act 626's prohibition of "gender transition procedures" as that term is defined in Ark. Code Ann. §§ 20-9-1501(6). They also have standing to challenge the Act's authorization of private rights of action. "Where an unconstitutional statute provides for enforcement both through official acts and private suits, Plaintiffs with standing to seek an injunction against the official acts may also challenge the

constitutionality of private suits." *See Planned Parenthood of Se. Pa. v. Casey*, 505 U.S. 833, 887-88 (1992).

The Court finds that Physician Plaintiffs have standing in their own right to challenge the Act's unequal treatment between healthcare providers who provide gender-affirming care to transgender patients, which would be prohibited by Act 626, and other healthcare providers, who provide all other medically accepted care, including gender-affirming care to non-transgender patients, which is not prohibited. *See Am. Coll. of Obstetricians & Gynecologists v. U.S. Food & Drug Admin.*, 472 F. Supp. 3d 183, 206 (D. Md. 2020).

The Court finds that Physician Plaintiffs have third-party standing to challenge Act 626 on behalf of their patients based upon the Supreme Court's opinion in *June Med. Serv's. LLC v. Russo*, 140 S. Ct. 2103, 2118-2119 (2020) ("[W]e have generally permitted plaintiffs to assert third-party rights in cases where the 'enforcement of the challenged restriction against the litigant would result indirectly in the violation of third parties' rights.'") (quoting *Kowalski v. Tesmer*, 543 U.S. 125, 130 (2004)). Further, Physician Plaintiffs have alleged a close relationship with their patients and a hindrance to their patients' ability to protect their interests because of the risk of discrimination and their patients' desire to protect their privacy. *See Singleton v. Wulff*, 428 U.S. 106, 117 (1976) (patient may be "chilled" from asserting their rights "by a desire to protect the very privacy of [their] decision from the publicity of a court suit.").

II. Preliminary Injunction

"The primary function of a preliminary injunction is to preserve the status quo until, upon final hearing, a court may grant full, effective relief." *Ferry-Morse Seed Co. v. Food Corn, Inc.*, 729 F.2d 589, 593 (8th Cir. 1984). The Court considers four factors in evaluating Plaintiffs' request for a preliminary injunction: (1) the likelihood of success on the merits; (2) the likelihood

of irreparable harm in the absence of an injunction; (3) the balance of equities; and (4) the public interest. *Sanborn Mfg. Co., Inc. v. Campbell Hausfeld/Scott Fetzer Co*., 997 F.2d 484, 485-86 (8th Cir. 1983). "When the government is a party, these last two factors merge." *Nken v. Holder*, 556 U.S. 418, 435 (2009)).

A. Equal Protection

To analyze Plaintiffs' facial challenge to Act 626, the Court must determine what level of scrutiny applies and whether Act 626 survives that scrutiny. The Court concludes that heightened scrutiny applies to Plaintiffs' Equal Protection claims because Act 626 rests on sex-based classifications and because "transgender people constitute at least a quasi-suspect class." *Grimm v. Gloucester Cty. Sch. Bd.*, 972 F.3d 586, 607 (8th Cir. 2020); *accord Bostock v. Clayton County*, 140 S. Ct. 1731, 1741 (2020) (discrimination for being transgender is discrimination "on the basis of sex"). Defendants argue that Act 626 does not specifically refer to transgender individuals. It does, however, refer to gender transition which is only sought by transgender individuals. *See Bray v. Alexandria Women's Health Clinic*, 506 U.S. 263, 270 (1993) ("Some activities may be such an irrational object of disfavor that, if they are targeted, and if they also happen to be engaged in exclusively or predominantly by a particular class of people, an intent to disfavor that class can readily be presumed.").

Under heightened scrutiny, Act 626 must be substantially related to a sufficiently important governmental interest. A policy subject to intermediate scrutiny must be supported by an "exceedingly persuasive justification." *United States v. Virginia*, 518 U.S. 515, 531 (1996). The policy must serve important governmental objectives, and the government must show "that the discriminatory means employed are substantially related to the achievement of those objectives." *Id.* at 533 (citation omitted).

Defendants contend that Act 626 is substantially related to the State's important governmental objectives of protecting vulnerable children from experimental treatment and regulating the ethics of the medical profession. Defendants contend that there is a lack of credible scientific evidence that gender-transition procedures improve children's health. They also contend that the consequences of performing these procedures on Arkansas children are too great to allow physicians and healthcare providers to continue performing them. Defendants state that the Arkansas General Assembly passed Act 626 in response to a recent judicial ruling of the U.K. High Court of Justice of England and Wales and an Arizona district court. *See Bell v. Tavistock and Portman Nat'l Health Serv. Found. Trust*, [2020] EWHC (Admin) 3274; *Hennessy-Waller v. Snyder*, 2021 WL 1192842, at *1 (D. Ariz. Mar. 30, 2021).

In *Tavistock*, the U.K. High Court considered the "narrow" issue of whether "a child or young person under the age of 16 [can] achieve *Gillick* [1] competence in respect of the decision to take PBs [puberty blockers] for GD [gender dysphoria]" *Id*. at ¶133. Although Defendants argue that this case is evidence that the U.K. Court is on the forefront of ethics by banning all gender transitioning procedures, *Tavistock* does not categorically prohibit individuals from all "gender transition procedures." The U.K. Court merely concluded that it is "unlikely" that a 13-year-old or under would be competent to give *Gillick* consent to puberty blockers and doubtful that a 14- or 15-year-old could give consent. However, a 16-year-old or older is presumed to have the ability to consent to these procedures. Act 626 prohibits anyone under the age of 18 from receiving treatment without regard to informed consent.

[1] *Gillick* refers to a U.K. High Court case where the House of Lords held by a majority that a doctor could lawfully give contraceptive advice and treatment to a girl aged under 16 if she had sufficient maturity and intelligence to understand the nature and implications of the proposed treatment and provided that certain conditions were satisfied. *See Gillick v. West Norfolk and Wisbech Health Authority* [1986] AC 112.

The Arizona district court case, *Hennessy-Waller v. Snyder*, which is on appeal to the Ninth Circuit Court of Appeals, denied plaintiffs' motion to enjoin the director of the Arizona Health Care Cost Containment System "from further enforcement of" a regulation that excludes gender reassignment surgery from Arizona's Medicaid coverage and to "order AHCCCS to cover male chest reconstruction surgery for D.H. and John." *Hennessy-Waller v. Snyder*, 2021 WL 1192842, at *1 (D. Ariz. Mar. 30, 2021). The *Hennessy-Waller* plaintiffs are not prohibited from all gender-transition treatments and their healthcare providers are not prohibited from providing gender-transition treatments to them. The Court does not find either "authority" to be persuasive or precedential.

Plaintiffs argue that Act 626 does not protect children. Instead, it bans potentially life-saving treatment to transgender adolescents given in accordance with widely accepted medical protocols for treatment of adolescent gender dysphoria.[2] The consensus recommendation of medical organizations is that the only effective treatment for individuals at risk of or suffering from gender dysphoria is to provide gender-affirming care.[3] According to the Medical Organizations, the goal of gender-affirming care is to provide patients who struggle with their gender identity the time and support they need to resolve that struggle and to mitigate the distress

[2] Wylie C. Hembree et al., *Endocrine Treatment of Gender-Dysphoric/Gender-Incongruent Persons: An Endocrine Soc'y Clinical Practice Guideline*, 1029110 J. Clinical Endocrinology & Metabolism, Vol. 103, Issue 11, pgs. 3869-3903 (Nov. 2017) [hereinafter "Endocrine Soc'y Clinical Guidelines"]; Eli Coleman et al., *The World Professional Association for Transgender Health. Standards of Care for the Health of Transsexual, Transgender, and Gender Nonconforming People* 13, 19 (7th ed. 2012), https://www.wpath.org/media/cms/Documents/SOC%20v7/SOC%20V7_English2012.pdf?_t=1613669341 [hereinafter "WPATH Standards of Care"].

[3] *See* Brief for American Medical Association, American Pediatric Society, American Academy of Pediatrics, American Academy of Child and Adolescent Psychiatry, American Psychiatric Association, American Association of Physicians for Human Rights Inc, American College of Osteopathic Pediatricians, Arkansas Chapter of the American Academy of Pediatrics, Arkansas Council on Child and Adolescent Psychiatry, Arkansas Psychiatric Society, Association of Medical School Pediatric Department Chairs, Endocrine Society, National Association of Pediatric Nurse Practitioners, Pediatric Endocrine Society, Society for Adolescent Health and Medicine, Society for Pediatric Research, Society of Pediatric Nurses, and World Professional Association for Transgender Health (the "Medical Organizations") as Amici Curiae Supporting Plaintiffs at ECF No. 30, p.16.

that can be associated with that condition.[4] Gender-affirming care seeks to minimize the incongruence between a transgender person's gender identity and their sex assigned at birth, thereby minimizing or eliminating gender dysphoria. *Id.* In addition, Plaintiffs argue that the State's contention that gender transition treatments cause irreversible and dangerous consequences is belied by the fact that the same medical treatments banned for transgender adolescents for "gender transition" by Act 626 are permitted for non-transgender adolescents for any other purpose, including to bring their bodies into alignment with their gender.

At this point in the proceedings, the Court finds that Act 626 is not substantially related to protecting children in Arkansas from experimental treatment or regulating the ethics of Arkansas doctors and Defendant's purported health concerns regarding the risks of gender transition procedures are pretextual. The State's reliance on the U.K. High Court's ruling is not credible. If the State's health concerns were genuine, the State would prohibit these procedures for all patients under 18 regardless of gender identity. The State's goal in passing Act 626 was not to ban a treatment. It was to ban an outcome that the State deems undesirable. In other words, Defendants' rationale that the Act protects children from experimental treatment and the long-term, irreversible effects of the treatment, is counterintuitive to the fact that it allows the same treatment for cisgender minors as long as the desired results conform with the stereotype of their biological sex.

The Court finds the Act's ban of services and referrals by healthcare providers is not substantially related to the regulation of the ethics of the medical profession in Arkansas. Gender-affirming treatment is supported by medical evidence that has been subject to rigorous study. Every major expert medical association[5] recognizes that gender-affirming care for

[4] *See* Brief for Medical Organizations as Amici Curiae, *supra* note 3, ECF No. 30 at 16-17.
[5] *See* Brief for Medical Organizations as Amici Curiae, *supra* note 3. ECF No. 30 at 16.

transgender minors may be medically appropriate and necessary to improve the physical and mental health of transgender people. Act 626 prohibits most of these treatments. Further, the State's goal of ensuring the ethics of Arkansas healthcare providers is not attained by interfering with the patient-physician relationship, unnecessarily regulating the evidence-based practice of medicine and subjecting physicians who deliver safe, legal, and medically necessary care to civil liability and loss of licensing.[6] If the Act is not enjoined, healthcare providers in this State will not be able to consider the recognized standard of care for adolescent gender dysphoria. Instead of ensuring that healthcare providers in the State of Arkansas abide by ethical standards, the State has ensured that its healthcare providers do not have the ability to abide by their ethical standards which may include medically necessary transition-related care for improving the physical and mental health of their transgender patients. The Court finds that Act 626 cannot withstand heightened scrutiny and based on the record would not even withstand rational basis scrutiny if it were the appropriate standard of review. Plaintiffs are, therefore, likely to succeed on the merits of their Equal Protection claim.

Next, the Court finds that Plaintiffs will suffer irreparable harm if Act 626 is not enjoined. The Act will cause irreparable physical and psychological harms to the Patient Plaintiffs by terminating their access to necessary medical treatment. Plaintiffs who have begun puberty blocking hormones will be forced to stop the treatments which will cause them to undergo endogenous puberty. Plaintiffs who will soon enter puberty will lose access to puberty blockers. In each case, Patient Plaintiffs will have to live with physical characteristics that do not

[6] *See* Statement, American Academy of Family Physicians, American Academy of Pediatrics, American College of Obstetricians and Gynecologists, American College of Physicians, American Osteopathic Association, and American Psychiatric Association, *Frontline Physicians Call on Politicians to End Political Interference in the Delivery of evidence Based Medicine*, (May 15, 2019), https://www.acog.org/news/news-releases/2019/05/frontline-physicians-call-on-politicians-to-end-political-interference-in-the-delivery-of-evidence-based-medicine.

conform to their gender identity, putting them at high risk of gender dysphoria and lifelong physical and emotional pain. Parent Plaintiffs face the irreparable harm of having to watch their children experience physical and emotional pain or of uprooting their families to move to another state where their children can receive medically necessary treatment. Physician Plaintiffs face the irreparable harm of choosing between breaking the law and providing appropriate guidance and interventions for their transgender patients.

The Court finds that the State's interest in enforcing Act 626 during the pendency of this litigation pales in comparison to the certain and severe harm faced by Plaintiffs. The "State has no interest in enforcing laws that are unconstitutional. . .." *Little Rock Fam. Plan. Servs. v. Rutledge*, 397 F. Supp. 3d 1213, 1322 (E.D. Ark. 2019), *aff'd in part, appeal dismissed in part and remanded*, 984 F.3d 682 (8th Cir. 2021). Because Plaintiffs have demonstrated at least at this preliminary stage that they are likely to prevail on the issue of Act 626's unconstitutionality, an injunction preventing the State from enforcing the Act does not irreparably harm the State.

B. Due Process

The Due Process Clause of the Fourteenth Amendment forbids states to "deprive any person of life, liberty, or property, without due process of law...." U.S. Const. amend. XIV, § 1. The Clause also includes a substantive component that "provides heightened protection against government interference with certain fundamental rights and liberty interests." *Washington v. Glucksberg*, 521 U.S. 702, 719-20 (1997). "The liberty interest at issue in this case—the interest of parents in the care, custody, and control of their children—is perhaps the oldest of the fundamental liberty interests recognized by this Court." *Troxel v. Granville*, 530 U.S. 57, 65 (2000); *see also Kanuszewski* v. *Mich. Dep't of Health and Human Serv's*, 927 F.3d 396, 419 (6th Cir. 2019) ("[P]arents' substantive due process right to make decisions concerning the care,

custody, and control of their children includes the right to direct their children's medical care."). Parents are presumed to be acting in the best interest of their children. *Parham v. J.R.*, 442 U.S. 584, 602 (1979).

The Court finds that the Parent Plaintiffs have a fundamental right to seek medical care for their children and, in conjunction with their adolescent child's consent and their doctor's recommendation, make a judgment that medical care is necessary. So long as a parent adequately cares for his or her children, "there will normally be no reason for the State to inject itself into the private realm of the family to further question the ability of that parent to make the best decisions concerning the rearing of that parent's children." *Troxel*, 530 U.S. at 68-69.

Strict scrutiny is the appropriate standard of review for infringement of a fundamental parental right. *Glucksberg*, 521 U.S. at 719-20. In applying strict scrutiny, the Court finds that Defendants have not met their burden of showing that Arkansas has a compelling state interest in infringing upon parents' fundamental right to seek medical care for their children, or that Act 626 is narrowly tailored to serve that interest. As stated, the State has not shown that Act 626 serves the stated goal of protecting Arkansas's children. The goal in this context is pretextual because Act 626 allows the same treatments for cisgender minors that are banned for transgender minors as long as the desired results conform with the stereotype of the minor's biological sex. Based on these findings, the State could not withstand either heightened scrutiny or rational basis review.

The Court finds that Plaintiffs have shown irreparable harm. The State suffers little harm from maintaining the status quo through the litigation of this case. The risk of irreparable harm to the Plaintiffs tips the balance of equities in favor of a preliminary injunction of Act 626.

C. First Amendment

Plaintiffs claim that Act 626 prevents healthcare professionals from speaking, and their patients and parents from hearing, about medically accepted treatments for gender dysphoria in violation of their First Amendment rights. Defendants argue that Act 626 is not a regulation of speech but rather a regulation of professional conduct. Further, they argue that the Act does not restrict any right to receive information.

The Court finds that Act 626's ban on referrals by healthcare providers is a regulation of speech. The Supreme Court has held that "the creation and dissemination of information are speech within the meaning of the First Amendment." *Sorrell v. IMS Health Inc.*, 564 U.S. 552, 570 (2011) (citing *Bartnicki v. Vopper*, 532 U.S. 514, 527 (2001) ("[I]f the acts of 'disclosing' and 'publishing' information do not constitute speech, it is hard to imagine what does fall within that category, as distinct from the category of expressive conduct")). "[A] State may not, under the guise of prohibiting professional misconduct, ignore constitutional rights." *Nat'l Ass'n for Advancement of Colored People v. Button*, 371 U.S. 415, 439 (1963); *see also Nat'l Inst. of Fam. & Life Advocs. v. Becerra*, 138 S. Ct. 2361, 2371–72 (2018) ("[T]his Court has not recognized 'professional speech' as a separate category of speech. Speech is not unprotected merely because it is uttered by 'professionals.'").

The Court further finds that Act 626 is a content and viewpoint-based regulation because it restricts healthcare professionals only from making referrals for "gender transition procedures," not for other purposes. As such, it is "presumptively unconstitutional" and is subject to strict scrutiny. *Reed v. Town of Gilbert*, 576 U.S. 155, 163 (2015). To meet the strict scrutiny standard, Defendants assert that Arkansas has a compelling interest in protecting children from experimental gender-transition procedures and safeguarding medical ethics.

However, the Supreme Court has held that the government does not have a legitimate interest in protecting against the "fear that people [will] make bad decisions if given truthful information." *Thompson v. W. States Med. Ctr.*, 535 U.S. 357, 374 (2002); *see also Brown v. Entm't. Merch. Ass'n*, 564 U.S. 786, 794 (2011) (while states can protect children from harm, that "does not include a free-floating power to restrict the ideas to which children may be exposed"). In this case, the State believes that a transgender adolescent who, along with their parents and health care providers, decides to receive gender transition treatment is making a bad decision. The State believes it can keep these individuals from getting this treatment if healthcare providers are not allowed to refer their patients to providers in other states who can prescribe the treatment. Because the Court finds that Act 626 cannot survive strict scrutiny or even rational scrutiny, Plaintiffs are likely to succeed on the merits of their First Amendment claim.

The Court also finds that Plaintiffs will suffer irreparable harm if Act 626 is not enjoined. "It is well-established that "[t]he loss of First Amendment freedoms, for even minimal periods of time, unquestionably constitutes irreparable injury." *Powell v. Noble*, 798 F.3d 690, 702 (8th Cir. 2015) (*Elrod v. Burns*, 427 U.S. 347, 373 (1976)). The balance of equities so favors the Plaintiffs that justice requires the Court to preserve the status quo until the merits of the case are determined.

III. Rule 12(b)(6) Motion to Dismiss

As for the Defendants motion to dismiss for failure to state a claim, it is inherent in the Court's decision to grant the preliminary injunction that the Plaintiffs have stated claims for violations of their Equal Protection, Due Process, and First Amendment rights.

IV. Conclusion

Defendants and successors in office are enjoined from enforcing any provision of House Bill 1570, Act 626 of the 93rd General Assembly of Arkansas, to be codified at Ark. Code Ann. §§ 20-9-1501 to 20-9-1504 and 23-79-164 during the pendency of the litigation of this case.

IT IS SO ORDERED this 2nd day of August, 2021.

James M. Moody Jr.
United States District Judge

EXHIBIT 7

OPEN

PRS GLOBAL OPEN

SPECIAL TOPIC

Levels of Evidence in Plastic and Reconstructive Surgery Research: Have We Improved Over the Past 10 Years?

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Cormac W. Joyce, FRCS
Sean M. Carroll, FRCS, MD

Summary: Levels of evidence (LOE) aid in the critical appraisal of evidence by ranking studies based on limitation of its design. Analyzing LOE provides insight into application of evidence-based medicine. The aim of this study is to determine if the quality of evidence in plastic surgery research has improved over the past 10 years. Systematic review of research published in *Plastics and Reconstructive Surgery* journal over the years, 10-year period (2008, 2013, 2018), was performed. LOE for each article was determined using the American Society of Plastic Surgeons (ASPS) guidelines. Each level was calculated as percentage of publications per year and compared yearly and between different topics. Eight hundred eighty-four studies were included in the final analysis. The LOE of the research improved over the study period. Level 4 evidence was the most frequent published (50.6%, 447/884), with a decline from 63.2% in 2008 to 41.3% in 2018. Level 1 evidence improved each year and accounted for 2.1% of all research in 2018. Aesthetic surgery was the most frequent published topic with upper limb research demonstrating an 18.5% increase in high-quality evidence over the study period. Increased awareness of evidence-based medicine has improved the quality of plastic surgery research over the past decade. It is vital this continues to provide gold standard patient care. *(Plast Reconstr Surg Glob Open 2019;7:e2408; doi: 10.1097/GOX.0000000000002408; Published online 30 September 2019.)*

INTRODUCTION

Advances in technology, improved understanding of disease pathogenesis, and superior interventions have enhanced plastic surgery patients' outcomes over the past decade.[1,2] To support these advancements, up to date research endeavors are mandatory. The resultant increase in studies has generated an overwhelming amount of evidence. To assist clinicians in critical appraisal of this evidence, a conceptual tool known as evidence-based medicine (EBM) was developed.[3]

Levels of evidence (LOE) is the foundation of EBM. It is a hierarchical appraisal system which grades research (levels 1–5) based on inherent limitations of study methodology.[4] LOE enables clinicians to rapidly appraise evidence before translating into clinical practice.[5] It is also a reliable method of evaluating the quality of evidence published. High-quality research is a prerequisite in maintaining optimal patient care. The aim of this study is to determine if the quality of evidence in plastic surgery research has improved over the past 10 years.

METHODOLOGY

A systematic review of published research articles was performed in *Plastic and Reconstructive Surgery* (PRS) journal. Articles were selected from this journal, as it is the highest impact factor plastic surgery journal, publishing on a wide variety of plastic surgery topics. To evaluate any trends, articles were initially reviewed from 3 years, covering a 10-year period (2008, 2013, 2018). Editorials, letters, announcements, reflections, book reviews, Continuing Medical Education (CME) articles were excluded from this study. Review articles and laboratory studies (animal, cadaver, basic science) were included in the initial review but excluded from the final analysis, as no LOE can be allocated to these studies.

Each clinical article was allocated an LOE based upon published American Society of Plastic Surgeons (ASPS) guidelines.[6] First, the research aim was broadly divided into 3 categories: therapeutic, risk, and diagnostic. Within these

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categories, evidence was ranked from 1 to 5 mirroring the hierarchal research pyramid. This ranking is based upon the probability that the research design has reduced the potential bias. Highest quality evidence (level 1) is produced from randomized control trials or systematic reviews/meta-analysis of these. Articles of limited study design with biases, such as expert opinions, are ranked the lowest (level 5).

Two authors (C.M.S., C.W.J.) independently evaluated published research articles. Discrepancies in the assignment of LOE were discussed with the senior author (S.M.C.). Information obtained from the articles included year of publication, topic, study design, and LOE. Each LOE was expressed as percentage of the overall publications that year and to the other years. Study design was also assessed. Further analysis on the different topics published in the journal was performed. The percentage of higher-level evidence (levels 1 and 2) was calculated for each topic and compared over the 10-year period.

RESULTS

Two thousand six hundred sixty-four articles were published in the PRS journal in the years 2008, 2013, 2018. By applying the inclusion criteria, a total of 1,369 articles were reviewed. Review articles and laboratory studies accounted for 14.7% and 20.7% of the remaining articles. These were excluded from the final analysis as they are not part of LOE hierarchy. A LOE rank was applied to 884 articles (2008 = 313, 2013 = 291, 2018 = 280) (Fig. 1).

Therapeutic studies were the most frequent research aim, accounting for 83.6% of all research. Level 4 evidence was the greatest level published across the years (50.6%, 447/884). There was a decline in the percentage of level 4 evidence from 63.2% in 2008 to 41.3% in 2018. Twelve publications accounted for level 1 evidence, with 11 of these published in the past 5 years (Table 1).

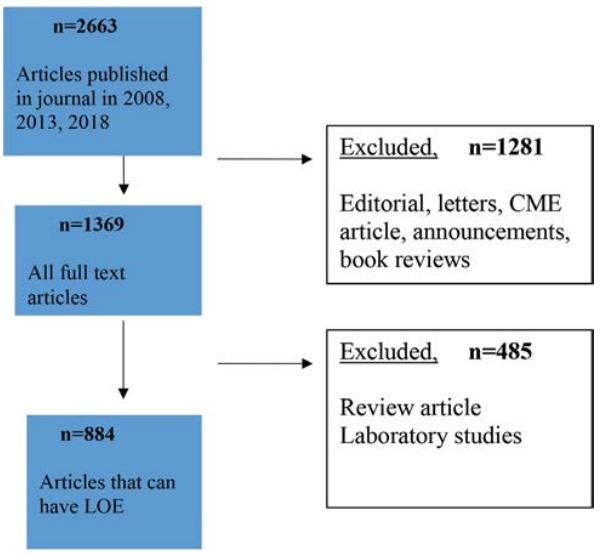

Fig. 1. Flow diagram of study methodology. CME indicates continuing medical education; LOE, levels of evidence.

Table 1. Percentage of Each Level of Evidence Published per Year

Levels of Evidence	2008	2013	2018
1	0.3	1.7	2.1
2	6.3	11.3	13.6
3	19.6	33.3	34.5
4	63.2	45.5	41.7
5	11.3	8.5	7.9

Table 2. Evaluation of Each Study Methodology Used in Research, per Year

	2008 n (%)	2013 n (%)	2018 n (%)
Systematic review/meta analysis	5 (1.1)	21 (4.6)	15 (3.2)
Randomized control trials	8 (1.7)	5 (1.1)	18 (3.8)
Cohort study	4 (0.9)	10 (2.2)	8(1.7)
Case–control	44 (9.7)	75 (16.7)	93 (19.9)
Case series	219 (48.3)	156 (34.7)	123 (26.3)
Case report	10 (2.2)	9 (2.0)	9 (1.2)
Expert opinion	25 (5.5)	15 (1.1)	12 (2.1)
Review article	45 (9.3)	61 (15.8)	99 (22.2)
Laboratory study	96 (21.1)	97 (21.6)	90 (19.3)
	n = 453	n = 449	n = 467

Table 3. Percentage Comparison of High-quality Evidence (Levels 1 and 2) per Plastic Surgery Topic, per Year

Topics	2008	2013	2018
Aesthetics	6.3	6.2	15.3
Breast	19.2	13.7	18.7
Craniofacial	1.5	8.3	8.5
Upper limb	11.5	11.1	25

Case series was the most common study design (36.4%, 498/1,369). This study designed decreased over time from 48.3% in 2008 to 25.5% in 2018. Case–control studies increased from 9.7 % to 19.9% (Table 2).

Aesthetic (21.6%), breast (17.3%), craniofacial (4.2%), and upper limb surgery were the most frequently published topics in PRS journal. The percentage of higher LOE (levels 1 and 2) published in these topics over the years is seen in Table 3. The largest percentage increase over the 10-year period was demonstrated by upper limb surgery (18.5%).

DISCUSSION

The application of EBM involves merging individual clinical experience with the best scientific evidence.[7] The interrogation of EBM into plastic surgery practice has been limited.[8] By evaluating trends in LOE of published research, the utilization of EBM principles can be measured. This study has shown that the LOE in plastic surgery research has improved over the past decade. There has been a growth in levels 1, 2, and 3 evidence, with a reduction in the publication in lower-quality evidence. In 2018, high-quality evidence (levels 1 and 2) accounted for 15.7% of all plastic surgery research. This was marginally lower than orthopedic literature (21.6%),[9] but higher than neurosurgical (10.3%)[10] and maxillofacial research (2%).[11] Within the PRS journal, up-

per limb and aesthetics surgery demonstrated the largest increase in high-quality evidence over the 10-year period.

Case series are the backbone of surgical research. By evaluating a similar group of patients undergoing a common intervention, this study design replicates everyday surgical practice.[12] The absence of a control group justifiably ranks this design at the lower end of the evidence pyramid. Despite this, case series are vital. They may be the only feasible and ethical study methodology obtainable, as seen with craniofacial surgery.[13] In our study, craniofacial research accounted for the lowest percentage publication (8.4%) of high-quality evidence, with no improvement over the past 5 years. The rarity of craniofacial pathology coupled with a small number of patients makes it difficult to produce higher quality research. Case–control studies are an upgrade from case series, with the addition of a control group significantly reducing study bias.[14] Case –control studies increased in our study period. In a specialty where obtaining high-quality evidence is challenging, the evolution from case series to case–control studies is an important indicator of EBM application.

The concept of LOE was originally described 50 years ago.[15] Yet, its application in plastic surgery research has been underwhelming,[16] with lack of awareness a probable reason.[17] To overcome this, PRS journal, in 2011, made it mandatory for authors submitting manuscripts to attach an LOE rating. This is then displayed as a small pyramidal graphic on the abstract page, providing immediate context for the reader. This editorial policy could account for the greater increase in LOE between 2008 and 2013, in comparison to the past 5 years of this study. Other journals have a similar requirement, but the LOE is allocated by the editorial board, out of fear of authors over infiltrating their own research.[18] However, good interobserver and intraobserver reliability has been reported when grading LOE.[19] By placing the responsibility of LOE ranking with the submitting author, knowledge of EBM has improved along with the quality of evidence published.

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EXHIBIT 8

AMERICAN SOCIETY OF PLASTIC SURGEONS

Exhibit 0007 9/30/2021 Dr. Lappert

Advocacy / Advocacy News

State Focus on Gender Affirmation Intensifies

Thursday, February 25, 2021

Policy around transgender care has recently gained considerable attention amid a growing trend of legislation carrying serious professional, financial or criminal penalties for the provision of gender affirmation care. Conversely, although less extensively, efforts to expand coverage for transgender services among both public and third-party payer programs are also taking place.

This period of focused conversation centered on transgender care has been marked by both significant challenges and notable gains in the fight for full access to medically necessary affirming health care.

Background

Gender affirmation is a developing field of medical and surgical practice in which plastic surgeons play a pivotal role, leading the field in many of the physical transformative procedures often involved in gender affirmation.

Like many conditions, gender dysphoria and the process of gender affirmation requires a multidisciplinary approach. Physical, psychological and psychosocial treatment are all components of the gender affirmation process. These components of care – and particularly psychological assessment of gender dysphoria – often begin in childhood and early adolescence. Legislation that seeks to criminalize gender therapy targets this part of the care continuum.

A growing legislative trend

State legislation designed to criminalize gender affirming care first emerged in 2016. The frequency of such bills increased in the years that followed, but 2020 was a particularly active year, seeing six states with bills introduced on the issue. The volume and intent of the legislation between 2016 and 2020 resulted in transgender advocacy groups classifying the bills as "hostile." Last year was also notable because it marked the first instance in which one of the aforementioned bills successfully passed a state legislative chamber.

In 2020, the South Dakota House of Representatives passed legislation prohibiting gender-affirming care for minors and leveling serious consequences for physicians found in violation of the law, including possible jail time. The state's Senate ultimately defeated the bill and prevented it from being enacted into law, but the relative success of the legislation was concerning and may have inspired a number of similar bills that would soon follow.

Less than three months into 2021, 11 pieces of legislation attempting to criminalize gender affirmation therapies have been introduced in 10 states. Alabama, Indiana, Iowa, Mississippi, Missouri, Montana, New Hampshire, Oklahoma, Texas and Utah have each introduced bills seeking to regulate the practice of medicine by banning certain procedures for minors and criminalizing the actions of health care providers who elect to administer gender affirmation care.

While the legislative concepts vary by state, the common threads include a prohibition of gender affirmation care for minors, identification of specific procedures and therapies that cannot be performed by the state's health care practitioners and a stipulation that it is illegal for a minor's parents or guardians to consent to the procedures. Penalties for health care providers, guardians and even school counselors found in violation of the laws vary widely and range from a fine of up to $500,000, to notifying child protective services and even classification of the guilty party as a felon.

Efforts to expand coverage

Contrary to the disturbing trend of legislation looking so severely at limiting gender-affirming care that it seeks to make criminals out of some of those involved, concerted efforts are also underway to expand coverage for the transgender community.

In one notable example, Aetna announced in January the expansion of its coverage for gender-affirming surgeries for transgender women. The insurer now covers gender-affirming breast augmentation in most plans, bringing coverage for the procedure into alignment with coverage for other surgeries common in transgender patients, such as breast removal or gender-reassignment.

Additionally, several states have worked to expand gender affirmation coverage. On February 12, ASPS wrote a letter in support of an emergency rule from the Wisconsin Department of Health Services that would repeal current restrictions and expand coverage for transgender Medicaid members. Similar amendments were proposed to the Washington Administrative Code and received the support of the Society via public comment in late January after ASPS involvement in the development of the policy that dates back to 2018.

ASPS involvement

ASPS firmly believes that plastic surgery services can help gender dysphoria patients align their bodies with whom they know themselves to be and improve their overall mental health and well-being. In 2021, the Society has actively opposed legislation seeking to criminalize actions by physicians and guardians when minors receive gender affirmation surgery in Missouri, Montana and Alabama and is readying engagement in other states where the issue has emerged. ASPS will continue its efforts to advocate across state legislatures for full access to medically necessary transition care.

RELATED

- **ASPS Maintains Support for ELSA in 117th Congress**
- **Attacks on MOC Reemerge**
- **Register Today: 2021 ASPS Virtual Advocacy Summit**
- **ASPS Responds to a Wave of Scope of Practice Expansion Bills**
- **ASPS Executive Committee Approves 2021 Policy Priorities**

EXHIBIT 9

BlueCross BlueShield of North Carolina

An independent licensee of the Blue Cross and Blue Shield Association

Corporate Medical Policy

Gender Affirmation Surgery and Hormone Therapy

File Name:	gender_affirmation_surgery_and_hormone_therapy
Origination:	7/2011
Last CAP Review:	5/2020
Next CAP Review:	5/2021
Last Review:	3/2021

Description of Procedure or Service

Gender Dysphoria (GD) is the formal diagnosis used by professionals to describe persons who experience significant gender dysphoria (discontent with their biological sex and/or birth gender). Although it is a psychiatric classification, GD is not medically classified as a mental illness.

In the U.S., the American Psychiatric Association (APA) permits a diagnosis of gender dysphoria in adolescents and adults if the diagnostic criteria in the Diagnostic and Statistical Manual of Mental Disorders, 5th Edition, (DSM-5™) are met. The criteria are:

A. A marked incongruence between one's experienced/expressed gender and assigned gender, of at least six month's duration, as manifested by at least **two** of the following:

   1. A marked incongruence between one's experienced/expressed gender and primary and/or secondary sex characteristics (or in young adolescents, the anticipated secondary sex characteristics); **OR**
   2. A strong desire to be rid of one's primary and/or secondary sex characteristics because of a marked incongruence with one's experienced/expressed gender (or in young adolescents, a desire to prevent the development of the anticipated secondary sex characteristics; **OR**
   3. A strong desire for the primary and/or secondary sex characteristics of the other gender; **OR**
   4. A strong desire to be of the other gender (or some alternative gender different from one's assigned gender); **OR**
   5. A strong desire to be treated as the other gender (or some alternative gender different from one's assigned gender); **OR**
   6. A strong conviction that one has the typical feelings and reactions of the other gender (or some alternative gender different from one's assigned gender); **AND**

B. The condition is associated with clinically significant distress or impairment in social, occupational, or other important areas of functioning.

Gender dysphoria is a medical condition when the elements of the condition noted above are present. Gender affirmation surgery is one treatment option. Gender Affirmation Surgery is not a single procedure, but part of a complex process involving multiple medical, psychiatric, and surgical modalities performed in conjunction with each other to help the candidate for gender affirmation achieve successful behavioral and medical outcomes. Before undertaking gender affirmation surgery, candidates need to undergo important medical and psychological evaluations, and begin medical/hormonal therapies and behavioral trials to confirm that surgery is the most appropriate treatment choice. Gender affirmation surgery presents significant medical and psychological risks, and the results are irreversible.

******Note: This Medical Policy is complex and technical. For questions concerning the technical language and/or specific clinical indications for its use, please consult your provider.***

Gender Affirmation Surgery and Hormone Therapy

Policy

Services for gender affirmation surgery and hormone therapy may be considered medically necessary when the criteria below are met.

Please see the following section "Benefits Application" regarding specific benefit and medical management requirements.

Benefits Application

Gender affirmation surgery and hormone therapy may be specifically excluded under some health benefit plans. Please refer to the Member's Benefit Booklet for availability of benefits.

When benefits for gender affirmation surgery and hormone therapy are available, coverage may vary according to benefit design. Some benefit designs for gender affirmation surgery may include benefits for pelvic and/or breast reconstruction. Member benefit language specific to gender affirmation should be reviewed before applying the terms of this medical policy. This medical policy relates only to the services or supplies described herein.

Prior review and certification are required by most benefit plans, and when required, must be obtained or services will not be covered. Some benefit plans provide coverage without a requirement for prior approval or medical necessity review. Please refer to the Member's Benefit Booklet for specific prior approval or medical necessity review requirements.

If prior authorization and medical necessity review are required for hormone therapy, and related surgical procedures for the treatment of gender dysphoria, the medical criteria and guidelines shown below will be utilized to determine the medical necessity for the requested procedure or treatment.

When Gender Affirmation Surgery and Hormone Therapy is covered

Gender affirmation surgery and hormone therapy may be considered medically necessary when all the following candidate criteria are met and supporting provider documentation is provided:

Candidate Criteria for Adults and Adolescents age 18 years and Older for Gender Affirmation Surgery

1. The candidate is at least 18 years of age; and
2. Has been diagnosed with gender dysphoria, including meeting all of the following indications:
    a. A strong conviction to live as some alternative gender different from one's assigned gender.
        - Typically accompanied by the desire to make the physical body as congruent as possible with the identified sex through surgery and hormone treatment; and
    b. The new gender identity has been present for at least 6 months; and
    c. If significant medical or mental health concerns are present, they must be reasonably well-controlled; and
    d. The gender dysphoria causes clinical or social distress or impairment in social, occupational, or other important areas of functioning.

3. For those candidates without a medical contraindication, the candidate has undergone a minimum of 12 months of continuous hormonal therapy that is (Note: for those candidates requesting female to male surgery see item 4. below):
    a. Recommended by a mental health professional and

b. Provided under the supervision of a physician; and the supervising physician indicates that the patient has taken the hormones as directed.

4. For candidates requesting female to male surgery only:
   a. When the initial requested surgery is solely a mastectomy, the treating physician may indicate that no hormonal treatment (as described in criteria 3. above) is required prior to performance of the mastectomy. In this case, the 12 month requirement for hormonal treatment will be waived only when all other criteria contained in this policy and in the member's health benefit plan are met.
5. The candidate has completed a minimum of 12 months of successful continuous full time real-life experience in their new gender, with no returning to their original gender. This requirement must be demonstrated by living in their new gender while:
   a. Maintaining part- or full-time employment; or
   b. Functioning as a student in an academic setting; or
   c. Functioning in a community-based volunteer activity as applicable. (For those candidates not meeting this criteria, see item 6. below.)
6. If the candidate does not meet the 12 month time frame criteria as noted in item 5. above, then the treating clinician must submit information indicating why it would be clinically inappropriate to require the candidate to meet these criteria. When submitted, the criteria in item 5. will be waived unless the criteria noted in item 5. above are specified as required in the candidate's health benefit plan.

Provider Documentation Criteria for Gender Affirmation Surgery:

The treating clinicians must provide the following documentation. The documentation must be provided in letters from the appropriate clinicians and contain the information noted below.

1. The letters must attest to the psychological aspects of the candidate's gender dysphoria.
   a. One of the letters must be from a licensed behavioral health professional with an appropriate degree (Ph.D., M.D., L.C.S.W., Ed.D., D.Sc., D.S.W., psychiatric physician assistant, Psy.D, or psychiatric nurse practitioner under the supervision of a psychiatrist) with established competence and clinical expertise in the assessment and treatment of gender dysphoria, who is capable of adequately evaluating if the candidate has any co-morbid psychiatric conditions. When patients with gender dysphoria are also diagnosed with severe psychiatric disorders and impaired reality testing (e.g., psychotic episodes, bipolar disorder, dissociative identity disorder, borderline personality disorder) an effort must be made to improve these conditions with psychotropic medications and/or psychotherapy before surgery is contemplated. Reevaluation by a mental health professional qualified to assess and manage psychotic conditions should be conducted prior to surgery, describing the patient's mental status and readiness for surgery. It is preferable that this mental health professional be familiar with the patient. No surgery should be performed while a patient is actively psychotic.

   b. One of the letters must be from the candidate's established physician or behavioral health provider. The letter or letters must document the following:
      1. Whether the author of the letter is part of a gender dysphoria treatment team and/or follows current WPATH Standards of Care or Endocrine Society Guidelines for the Endocrine Treatment of Gender-Dysphoric/ Gender-Incongruent Persons for evaluation and treatment of gender dysphoria; and
      2. The initial and evolving gender, sexual, and other psychiatric diagnoses (if applicable); and
      3. The duration of their professional relationship including the type evaluation that the candidate underwent; and
      4. The eligibility criteria that have been met by the candidate according to the above Standards of Care; and
      5. The physician or mental health professional's rationale for hormone therapy and/or surgery; and
      6. The degree to which the candidate has followed the treatment and experiential requirements to date and the likelihood of future compliance; and

7. The extent of participation in psychotherapy throughout the 12 month real-life trial, (if such therapy is recommended by a treating medical or behavioral health practitioner) and
8. That during the 12 month, real-life experience (for candidates not meeting the 12 month candidate criteria as noted in 6 and 7, the letter should still comment on the candidates ability to function and experience in the desired gender role), persons other than the treating therapist were aware of the candidate's experience in the desired gender role and could attest to the candidate's ability to function in the new role.
9. Demonstrable progress on the part of the candidate in consolidating the new gender identity, including improvements in the ability to handle:
   - Work, family, and interpersonal issues
   - Behavioral health issues, should they exist.

c. If the letters specified in 1a and 1b above come from the same clinician, then a letter from a second physician or behavioral health provider familiar with the candidate corroborating the information provided by the first clinician is required.

d. For members requesting surgical treatment, a letter of documentation must be received from the treating surgeon. If one of the previously described letters is from the treating surgeon, then it must contain the documentation noted in the section below. All letters from a treating surgeon must confirm that:
   1. The candidate meets the "candidate criteria" listed in this policy and
   2. The treating surgeon feels that the candidate is likely to benefit from surgery and
   3. The surgeon has personally communicated with the treating mental health provider or physician treating the candidate, and
   4. The surgeon has personally communicated with the candidate and the candidate understands the ramifications of surgery, including:
      - The required length of hospitalizations,
      - Possible complications of the surgery, and
      - The post-surgical rehabilitation requirements of the various surgical approaches and the planned surgery.

Candidate Criteria for Children and Adolescents under Age 18 years

Pubertal delay and gender affirming hormone therapy may be considered medically necessary when all the following candidate criteria are met and supporting provider documentation is provided:

Candidate Criteria (based on World Professional Association for Transgender Health (WPATH) Standards of Care):

1. The patient has been diagnosed with gender dysphoria, including meeting all of the following indications:
   a. A strong conviction to live as some alternative gender different from one's assigned gender,
      - Typically accompanied by the desire to make the physical body as congruent as possible with the identified sex through surgery and hormone treatment; and
   b. Any co-existing psychological, medical, or social problems that could interfere with treatment (e.g., that may compromise treatment adherence) have been addressed, such that the adolescent's situation and functioning are stable enough to start treatment; and
   c. The gender dysphoria causes clinical or social distress or impairment in social, occupational, or other important areas of functioning.

2. The candidate has completed a minimum of 12 months of successful continuous full time real-life experience in their new gender, with no returning to their original gender. This requirement must be demonstrated by living in their new gender while:
   a. Maintaining part- or full-time employment; or
   b. Functioning as a student in an academic setting; or
   c. Functioning in a community-based volunteer activity as applicable. (For those candidates not meeting this criteria, see item 3. below.)

3. If the candidate does not meet the 12 month time frame criteria as noted in item 2. above, then the treating clinician must submit information indicating why it would be clinically inappropriate to require the candidate to meet these criteria. When submitted, the criteria in item 2. will be waived unless the criteria noted in item 2. above are specified as required in the candidate's health benefit plan.

Provider Documentation Criteria for Pubertal Delay and Gender Affirming Hormonal Therapy:

The treating clinicians must provide the following documentation. The documentation must be provided in letters from the appropriate clinicians and contain the information noted below.

1. The letters must attest to the psychological aspects of the candidate's gender dysphoria
   a. One of the letters must be from a licensed behavioral health professional with an appropriate degree (Ph.D., M.D., Ed.D., D.Sc., D.S.W., psychiatric physician assistant, Psy.D, or psychiatric nurse practitioner under the supervision of a psychiatrist) with established competence and clinical expertise in the assessment and treatment of gender dysphoria, who is capable of adequately evaluating if the candidate has any co-morbid psychiatric conditions.
   b. One of the letters must be from the candidate's established physician or behavioral health provider. The letter or letters must document the following:
      1. Whether the author of the letter is part of a gender dysphoria treatment team and/or follows current WPATH Standards of Care or Endocrine Society Guidelines for the Endocrine Treatment of Gender-Dysphoric/ Gender-Incongruent Persons for evaluation and treatment of gender dysphoria; and
      2. The initial and evolving gender, sexual, and other psychiatric diagnoses (if applicable); and
      3. The duration of their professional relationship including the type evaluation that the candidate underwent; and
      4. The eligibility criteria that have been met by the candidate according to the above Standards of Care; and
      5. The physician or mental health professional's rationale for hormone therapy; and
      6. The degree to which the candidate has followed the treatment and experiential requirements to date and the likelihood of future compliance; and
      7. The extent of participation in psychotherapy throughout the 12 month real-life trial, (if such therapy is recommended by a treating medical or behavioral health practitioner); and
      8. That during the 12 month, real-life experience (for candidates not meeting the 12 month candidate criteria as noted in 6 and 7, the letter should still comment on the candidates ability to function and experience in the desired gender role), persons other than the treating therapist were aware of the candidate's experience in the desired gender role and could attest to the candidate's ability to function in the new role.

Prepubertal children do not require medical or surgical treatment, but do require mental health services as listed above.

Criteria for Adolescents Entering Puberty

Adolescents, having reached puberty (tanner 2), and who have met eligibility and readiness criteria can be treated with GnRH analogues.

The definition of puberty is having reached Tanner stage 2/5 and/or having LH, estradiol levels or testosterone levels, within the pubertal range. These LH, estradiol and testosterone ranges are well-known and published and are broken down by biological male vs. biological female Tanner stage, and nocturnal and diurnal levels. Adolescents are ***eligible*** for GnRH treatment, (for suppression of puberty) by these eligibility criteria: (same for adults)

1. Have an established diagnosis for GD based on DSM V or ICD-10 criteria;
2. Have experienced puberty to at least Tanner stage 2, which can be confirmed by pubertal levels of LH, estrogen or testosterone;
3. Have experienced pubertal changes that resulted in an increase of their gender dysphoria;
4. Do not suffer from psychiatric comorbidity (that interferes with the diagnostic work-up or treatment);

5. Have adequate psychological and social support during treatment, to include having parental/guardian consent;
6. Demonstrate knowledge and understanding of the expected outcomes of GnRH analogue treatment, cross-sex hormone treatment, and gender affirmation surgeries, as well as the medical and social risks and benefits of gender affirmation; and have been counseled regarding fertility options.

Criteria for Postpubertal Adolescents under the Age of 18 Years
Post-pubertal adolescents under age 18 must meet the same criteria and documentation requirements for treatment as listed above for adults. If those criteria are met, they are eligible for gender affirmation hormonal treatment and treatment for menstrual suppression when gender affirming hormones are not successful in eliminating menses.

Gender affirmation surgery is rarely appropriate for patients under the age of 18. Requests for mastectomy for female to male transgender individuals age 17 or older may be considered only in exceptional circumstances on an individual consideration basis.

A limited number of electrolysis or laser hair removal sessions are considered medically necessary to prepare for approved genital surgery when the surgeon makes a recommendation documented in the medical record.

When Gender Affirmation Surgery and Hormone Therapy are not covered

Gender Affirmation Surgery and hormone therapy are non-covered benefits when the member does not have benefits for the services requested contained in their health benefit plan.

Gender Affirmation Surgery and hormonal therapy are considered not medically necessary for plans offering gender affirmation services when the candidate criteria and provider documentation criteria are not met.

Gender Affirmation Surgery Exclusions:

Services and procedures that are considered Cosmetic in all benefit plans are considered non-covered benefits, including but not limited to:

- Cosmetic services that may be used for gender affirmation, including, but not limited to, procedures such as: plastic surgery of the nose; face lift; lip enhancement; facial bone reduction; plastic surgery of the eyelids; liposuction of the waist; reduction of the thyroid cartilage; hair removal ; hair transplants; and surgery of the larynx, including shortening of the vocal cords; chin implants; nose implants, and lip reduction.
- Fertility preservation, including but not limited to: sperm banking and embryonic freezing.

Autologous tissue flap breast reconstructions are considered not medically necessary for gender affirmation surgery.

Policy Guidelines

Gender affirmation surgery and hormone therapy candidate criteria and care standards are based, in part, on the World Professional Association for Transgender Health (WPATH) and Endocrine Society Guidelines for Endocrine Treatment of Gender-Dysphoric/ Gender-Incongruent Persons.

Billing/Coding/Physician Documentation Information

This policy may apply to the following codes. Inclusion of a code in this section does not guarantee that it will be reimbursed. For further information on reimbursement guidelines, please see Administrative Policies on the

Blue Cross Blue Shield of North Carolina web site at www.bcbsnc.com. They are listed in the Category Search on the Medical Policy search page.

ICD-10 diagnosis codes: F64.0, Z87.890

Applicable codes: 17380, 19304, 19316, 19318, 19324, 19325, 19340, 54400, 54401, 54405, 54406, 54408, 54410, 54411, 54415, 54416, 54417, 54660, 55175, 55180, 55970, 55980, 56800, 56805, 57291, 57292, 57295, 57296, 57335, C1813, C2622, J1950, J3315, J9217, J9219, J9226.

Applicable non-covered procedure codes, including, but not limited to: 11950, 11951, 11952, 11954, 15775, 15776, 15780, 15781, 15782, 15783, 15786, 15787, 15788, 15789, 15792, 15793, 15820, 15821, 15822, 15823, 15824, 15825, 15826, 15828, 15829, 15830, 15832, 15833, 15834, 15835, 15836, 15837, 15838, 15839, 15876, 15877, 15878, 15879, 21120, 21121, 21122, 21123, 21125, 21127, 21208, 21210, 21270, 30400, 30410, 30420, 30430, 30435, 30450, 67900, 92507, 92508.

BCBSNC may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful, but are not sufficient documentation unless all specific information needed to make a medical necessity determination is included.

Scientific Background and Reference Sources

Diagnostic and Statistical Manual of Mental Disorders Fourth Edition. Text Revision (DSM-IV-TR). American Psychiatric Association. American Psychiatric Association, Inc. July 2000

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Medical Director review, July 2011

The World Professional Association for Transgender Health; Standards of Care for the Health of Transsexual, Transgender, and Gender Nonconforming People; 7th Version; July 2012. Accessed at http://www.wpath.org/site_page.cfm?pk_association_webpage_menu=1351&pk_association_webpage=4655 on 9/21/2016.

Specialty Matched Consultant Advisory Panel 12/2012

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Specialty Matched Consultant Advisory Panel 9/2016

Senior Medical Diector review 9/2016

Specialty Matched Consultant Advisory Panel 5/2017

Specialty Matched Consultant Advisory Panel 5/2018

Specialty Matched Consultant Advisory Panel 6/2019

The World Professional Association for Transgender Health; Standards of Care for the Health of Transsexual, Transgender, and Gender Nonconforming People; 7th Version; July 2012. Accessed at https://www.wpath.org/media/cms/Documents/SOC%20v7/Standards%20of%20Care_V7%20Full%20Book_English.pdf on 4/27/2020

Specialty Matched Consultant Advisory Panel 5/2020

Medical Director review 7/2020

Medical Director review 9/2020

Hembree WC, Cohen-Kettenis P, et al. Endocrine Treatment of Gender-Dysphoric/Gender-Incongruent Persons: An Endocrine Society Clinical Practice Guideline. J Clin Endocrinol Metab. November 2017, 102(11):3869-3903. Accessed at https://academic.oup.com/jcem/article/102/11/3869/4157558 on 9/25/2020.

Medical Director review 3/2021

Policy Implementation/Update Information

7/19/11 New policy developed. When benefits for gender reassignment surgery are available, coverage may vary. Some benefit plans provide coverage without a requirement for prior approval or medical necessity review. Benefits for upper and/or lower body gender reassignment procedures vary by benefit plan. If prior authorization and medical necessity review are required for hormone therapy, breast augmentation surgery (mammoplasty), and mastectomy for the treatment of gender identity disorders, the medical criteria and guidelines outlined in the policy will be utilized to determine the medical necessity for the requested procedure or treatment. (adn)

9/18/12 Added diagnosis codes 302.0, 302.5, 302.50 – 302.53, 302.6, 302.85, 302.9, 313.82, 752.7 to Billing/Coding section. (sk)

1/1/13 Reference added. Specialty Matched Consultant Advisory Panel review 12/4/12. No change to policy statement. (sk)

7/1/13 ICD-10 diagnosis codes added to Billing/Coding section. (sk)

10/29/13 Reference added. Replaced DSM-IV TR criteria with DSM-5™ criteria. Removed "Sex change surgical procedures other than breast augmentation surgery (mammoplasty) and mastectomy" from the When Not Covered section. Added "pelvic reconstruction" to the When Covered section. Applicable Service Codes removed from Billing/Coding section. Senior Medical Director review. (sk)

Gender Affirmation Surgery and Hormone Therapy

7/1/14 Removed ICD-10 effective date from Billing/Coding section. (sk)

12/9/14 Reference added. Specialty Matched Consultant Advisory Panel review 11/24/14. No change to policy statement. (sk)

12/30/15 Specialty Matched Consultant Advisory Panel review 11/18/2015. (sk)

9/30/16 Specialty Matched Consultant Advisory Panel review 9/2016. Policy re-titled to Gender Confirmation Surgery and Hormone Therapy. Information regarding coverage of services for adolescents added to the "When Covered" section. Fertility preservation, including but not limited to: sperm banking and embryonic freezing added to Non-covered section. ICD 9 codes removed from Billing/Coding section. ICD 10 codes, covered codes and non-covered codes added to Billing/Coding section. Policy noticed 10/1/2016 for policy effective date 1/1/2017. (sk)

6/30/17 Specialty Matched Consultant Advisory Panel review 5/31/2017. (sk)

6/29/18 Specialty Matched Consultant Advisory Panel review 5/23/2018. (sk)

7/16/19 Specialty Matched Consultant Advisory Panel review 6/28/2019. (sk)

6/23/20 Reference added. Specialty Matched Consultant Advisory Panel review 5/20/2020. (sk)

8/25/20 Medical Director review. Provider Documentation Criteria updated to include "licensed" behavioral health professional, and "with established competence and clinical expertise in the assessment and treatment of gender dysphoria". (sk)

11/10/20 Medical Director review. Policy title changed from "Gender Confirmation Surgery and Hormone Therapy" to "Gender Affirmation Surgery and Hormone Therapy". The word "confirmation" changed to "affirmation" throughout the policy. In the When Covered section, Candidate Criteria for Adults and Adolescents age 18 years and older, criteria 2, wording changed from "the desire to live and be accepted as a member of the opposite sex" to "A strong conviction to live as some alternative gender different from one's assigned gender". In the When Covered section, Candidate Criteria for Children and Adolescents under age 18 years, criteria 1a, wording changed from "the desire to live and be accepted as a member of the opposite sex" to "A strong conviction to live as some alternative gender different from one's assigned gender". When Covered section updated to include information on medically necessary hair removal prior to genital surgery. References updated. (sk)

3/23/21 Medical Director review. Removed "That the candidate has, intends to, or is in the process of acquiring a legal gender-identity appropriate name change and" from the list of Provider Documentation Criteria for Gender Affirmation Surgery. (sk)

EXHIBIT 10

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(https://www.aetna.com/)

Gender Affirming Surgery

Clinical Policy Bulletins | Medical Clinical Policy Bulletins

Number: 0615

Policy

Aetna considers gender affirming surgery medically necessary when all of the following criteria are met:

I. Requirements for breast removal:

A. Single letter of referral from a qualified mental health professional (see Appendix); *and*
B. Persistent, well-documented gender dysphoria (see Appendix); *and*
C. Capacity to make a fully informed decision and to consent for treatment; *and*
D. For members less than 18 years of age, completion of one year of testosterone treatment; *and*
E. If significant medical or mental health concerns are present, they must be reasonably well controlled.

Note: A trial of hormone therapy is not a pre-requisite to qualifying for a mastectomy in adults.

II. Requirements for breast augmentation (implants/lipofilling):

Policy History

Last Review
01/12/2021
Effective: 05/14/2002
Next Review: 06/24/2021

Review History

Definitions

Additional Information

Clinical Policy Bulletin Notes

State Information

California

Exhibit 0030
9/30/2021
Dr. Lappert

A. Single letter of referral from a qualified mental health professional (see Appendix); *and*
B. Persistent, well-documented gender dysphoria (see Appendix); *and*
C. Capacity to make a fully informed decision and to consent for treatment; *and*
D. Member is 18 years of age or older; *and*
E. Completion of one year of feminizing hormone therapy prior to breast augmentation surgery (unless the member has a medical contraindication or is otherwise medically unable to take hormones); *and*
F. If significant medical or mental health concerns are present, they must be reasonably well controlled.

Note: More than one breast augmentation is considered not medically necessary. This does not include the medically necessary replacement of breast implants (see CPB 0142 - Breast Implant Remova (../100_199/0142.html)l).

III. Requirements for gonadectomy (hysterectomy and oophorectomy or orchiectomy):

A. Two referral letters from qualified mental health professionals, one in a purely evaluative role (see appendix); *and*
B. Persistent, well-documented gender dysphoria (see Appendix); *and*
C. Capacity to make a fully informed decision and to consent for treatment; *and*
D. Age 18 years or older; *and*
E. If significant medical or mental health concerns are present, they must be reasonably well controlled; *and*
F. Twelve months of continuous hormone therapy as appropriate to the member's gender goals (unless the member has a medical contraindication or is otherwise unable or unwilling to take hormones).

IV. Requirements for genital reconstructive surgery (i.e., vaginectomy, urethroplasty, metoidioplasty, phalloplasty, scrotoplasty, placement of a testicular prosthesis and erectile prosthesis,

penectomy, vaginoplasty, labiaplasty, and clitoroplasty)

A. Two referral letters from qualified mental health professionals, one in a purely evaluative role (see appendix); *and*
B. Persistent, well-documented gender dysphoria (see Appendix); *and*
C. Capacity to make a fully informed decision and to consent for treatment; *and*
D. Age 18 years and older; *and*
E. If significant medical or mental health concerns are present, they must be reasonably well controlled; *and*
F. Twelve months of continuous hormone therapy as appropriate to the member's gender goals (unless the member has a medical contraindication or is otherwise unable or unwilling to take hormones); *and*
G. Twelve months of living in a gender role that is congruent with their gender identity (real life experience).

Note on gender specific services for the transgender community:

Gender-specific services may be medically necessary for transgender persons appropriate to their anatomy. Examples include:

1. Breast cancer screening may be medically necessary for transmasculine persons who have not undergone chest masculinization surgery;
2. Prostate cancer screening may be medically necessary for transfeminine persons who have retained their prostate.

Aetna considers gonadotropin-releasing hormone medically necessary to suppress puberty in trans identified adolescents if they meet World Professional Association for Transgender Health (WPATH) criteria (see CPB 0501 - Gonadotropin-Releasing Hormone Analogs and Antagonists (../500_599/0501.html)).

Aetna considers reversal of gender affirming surgery for gender dysphoria not medically necessary.

Aetna considers the following procedures that may be performed as a component of a gender transition as cosmetic (not an all-inclusive list) (see also CPB 0031 - Cosmetic Surgery (../1_99/0031.html)):

- Abdominoplasty
- Blepharoplasty
- Body contouring (liposuction of waist)
- Brow lift
- Calf implants
- Cheek/malar implants
- Chin/nose implants
- Collagen injections
- Construction of a clitoral hood
- Drugs for hair loss or growth
- Face lifting
- Facial bone reduction
- Facial feminization and masculinization surgery
- Feminization of torso
- Forehead lift
- Jaw reduction (jaw contouring)
- Hair removal (e.g., electrolysis, laser hair removal) (Exception: A limited number of electrolysis or laser hair removal sessions are considered medically necessary for skin graft preparation for genital surgery)
- Hair transplantation
- Lip enhancement
- Lip reduction
- Liposuction
- Masculinization of torso
- Mastopexy
- Neck tightening
- Nipple reconstruction
- Nose implants
- Pectoral implants
- Pitch-raising surgery
- Removal of redundant skin
- Rhinoplasty
- Skin resurfacing (dermabrasion/chemical peel)

- Tracheal shave (reduction thyroid chondroplasty)
- Voice modification surgery (laryngoplasty, cricothyroid approximation or shortening of the vocal cords)
- Voice therapy/voice lessons.

Background

Gender dysphoria refers to discomfort or distress that is caused by a discrepancy between an individual's gender identity and the gender assigned at birth (and the associated gender role and/or primary and secondary sex characteristics). A diagnosis of gender dysphoria requires a marked difference between the individual's expressed/experienced gender and the gender others would assign him or her, and it must continue for at least six months. This condition may cause clinically significant distress or impairment in social, occupational or other important areas of functioning.

Gender affirming surgery is performed to change primary and/or secondary sex characteristics. For transfeminine (assigned male at birth) gender transition, surgical procedures may include genital reconstruction (vaginoplasty, penectomy, orchidectomy, clitoroplasty), breast augmentation (implants, lipofilling), and cosmetic surgery (facial reshaping, rhinoplasty, abdominoplasty, thyroid chondroplasty (laryngeal shaving), voice modification surgery (vocal cord shortening), hair transplants) (Day, 2002). For transmasculine (assigned female at birth) gender transition, surgical procedures may include mastectomy, genital reconstruction (phalloplasty, genitoplasty, hysterectomy, bilateral oophorectomy), mastectomy, and cosmetic procedures to enhance male features such as pectoral implants and chest wall recontouring (Day, 2002).

The criterion noted above for some types of genital surgeries – i.e., that patients engage in 12 continuous months of living in a gender role that is congruent with their gender identity – is based on expert clinical consensus that this experience provides ample opportunity for patients to experience and socially adjust in their desired gender role, before undergoing irreversible surgery (Coleman, et al., 2011).

It is recommended that transfeminine persons undergo feminizing hormone therapy (minimum 12 months) prior to breast augmentation surgery. The purpose is to maximize breast growth in order to obtain better surgical (aesthetic) results.

In addition to hormone therapy and gender affirming surgery, psychological adjustments are necessary in affirming sex. Treatment should focus on psychological adjustment, with hormone therapy and gender affirming surgery being viewed as confirmatory procedures dependent on adequate psychological adjustment. Mental health care may need to be continued after gender affirming surgery. The overall success of treatment depends partly on the technical success of the surgery, but more crucially on the psychological adjustment of the trans identified person and the support from family, friends, employers and the medical profession.

Nakatsuka (2012) noted that the third versions of the guideline for treatment of people with gender dysphoria (GD) of the Japanese Society of Psychiatry and Neurology recommends that feminizing/masculinizing hormone therapy and genital surgery should not be carried out until 18 years old and 20 years old, respectively. On the other hand, the sixth (2001) and the seventh (2011) versions of the standards of care for the health of transsexual, transgender, and gender non-conforming people of World Professional Association for Transgender Health (WPATH) recommend that transgender adolescents (Tanner stage 2, [mainly 12 to 13 years of age]) are treated by the endocrinologists to suppress puberty with gonadotropin-releasing hormone (GnRH) agonists until age 16 years old, after which gender-affirming hormones may be given. A questionnaire on 181 people with GID diagnosed in the Okayama University Hospital (Japan) showed that female to male (FTM) trans identified individuals hoped to begin masculinizing hormone therapy at age of 15.6 +/- 4.0 (mean +/- S.D.) whereas male to female (MTF) trans identified individuals hoped to begin feminizing hormone therapy as early as age 12.5 +/- 4.0, before presenting secondary sex characters. After confirmation of strong and persistent trans gender identification, adolescents with GD should be treated with gender-affirming hormone or puberty-delaying hormone to prevent developing undesired sex

characters. These treatments may prevent transgender adolescents from attempting suicide, suffering from depression, and refusing to attend school.

Spack (2013) stated that GD is poorly understood from both mechanistic and clinical standpoints. Awareness of the condition appears to be increasing, probably because of greater societal acceptance and available hormonal treatment. Therapeutic options include hormone and surgical treatments but may be limited by insurance coverage because costs are high. For patients seeking MTF affirmation, hormone treatment includes estrogens, finasteride, spironolactone, and GnRH analogs. Surgical options include feminizing genital and facial surgery, breast augmentation, and various fat transplantations. For patients seeking a FTM gender affirmation, medical therapy includes testosterone and GnRH analogs and surgical therapy includes mammoplasty and phalloplasty. Medical therapy for both FTM and MTF can be started in early puberty, although long-term effects are not known. All patients considering treatment need counseling and medical monitoring.

Leinung and colleagues (2013) noted that the Endocrine Society's recently published clinical practice guidelines for the treatment of transgender persons acknowledged the need for further information on transgender health. These investigators reported the experience of one provider with the endocrine treatment of transgender persons over the past 2 decades. Data on demographics, clinical response to treatment, and psychosocial status were collected on all transgender persons receiving gender-affirming hormone therapy since 1991 at the endocrinology clinic at Albany Medical Center, a tertiary care referral center serving upstate New York. Through 2009, a total 192 MTF and 50 FTM transgender persons were seen. These patients had a high prevalence of mental health and psychiatric problems (over 50 %), with low rates of employment and high levels of disability. Mental health and psychiatric problems were inversely correlated with age at presentation. The prevalence of gender affirming surgery was low (31 % for MTF). The number of persons seeking treatment has increased substantially in recent years. Gender-affirming hormone therapy achieves very good results in FTM persons and is most successful in MTF persons when initiated at younger ages. The authors concluded that transgender persons seeking hormonal therapy are being seen with increasing

frequency. The dysphoria present in many transgender persons is associated with significant mood disorders that interfere with successful careers. They stated that starting therapy at an earlier age may lessen the negative impact on mental health and lead to improved social outcomes.

Meyer-Bahlburg (2013) summarized for the practicing endocrinologist the current literature on the psychobiology of the development of gender identity and its variants in individuals with disorders of sex development or with transgenderism. Gender reassignment remains the treatment of choice for strong and persistent gender dysphoria in both categories, but more research is needed on the short-term and long-term effects of puberty-suppressing medications and cross-sex hormones on brain and behavior.

Irreversible Surgical Interventions for Minors

The World Professional Association for Transgender Health (WPATH) recommendations version 7 (Coleman, et al., 2011) states, regarding irreversible surgical interventions, that "[g]enital surgery should not be carried out until (i) patients reach the legal age of majority in a given country, and (ii) patients have lived continuously for at least 12 months in the gender role that is congruent with their gender identity. The age threshold should be seen as a minimum criterion and not an indication in and of itself for active intervention." The WPATH guidelines state that "Chest surgery in FtM patients could be carried out earlier, preferably after ample time of living in the desired gender role and after one year of testosterone treatment. The intent of this suggested sequence is to give adolescents sufficient opportunity to experience and socially adjust in a more masculine gender role, before undergoing irreversible surgery. However, different approaches may be more suitable, depending on an adolescent's specific clinical situation and goals for gender identity expression."

Note on Breast Reduction/Mastectomy and Nipple Reconstruction

The CPT codes for mastectomy (CPT codes 19303 and 19304) are for breast cancer, and are not appropriate to bill for reduction mammaplasty for female to male (transmasculine) gender affirmation surgery. CPT 2020

states that “Mastectomy procedures (with the exception of gynecomastia [19300]) are performed either for treatment or prevention of breast cancer.” CPT 2020 also states that "Code 19303 describes total removal of ipsilateral breast tissue with or without removal of skin and/or nipples (eg, nipple-sparing), for treatment or prevention of breast cancer.” There are important differences between a mastectomy for breast cancer and a mastectomy for gender reassignment. The former requires careful attention to removal of all breast tissue to reduce the risk of cancer. By contrast, careful removal of all breast tissue is not essential in mastectomy for gender reassignment. In mastectomy for gender reassignment, the nipple areola complex typically can be preserved.

Some have tried to justify routinely billing CPT code 19350 for nipple reconstruction at the time of mastectomy for gender reassignment based upon the frequent need to reduce the size of the areola to give it a male appearance. However, the nipple reconstruction as defined by CPT code 19350 describes a much more involved procedure than areola reduction. The typical patient vignette for CPT code 19350, according to the AMA, is as follows: “The patient is measured in the standing position to ensure even balanced position for a location of the nipple and areola graft on the right breast. Under local anesthesia, a Skate flap is elevated at the site selected for the nipple reconstruction and constructed. A full-thickness skin graft is taken from the right groin to reconstruct the areola. The right groin donor site is closed primarily in layers.”

The AMA vignette for CPT code 19318 (reduction mammaplasty) clarifies that this CPT code includes the work that is necessary to reposition and reshape the nipple to create an aesthetically pleasing result, as is necessary in female to male breast reduction. "The physician reduces the size of the breast, removing wedges of skin and breast tissue from a female patient. The physician makes a circular skin incision above the nipple, in the position to which the nipple will be elevated. Another skin incision is made around the circumference of the nipple. Two incisions are made from the circular cut above the nipple to the fold beneath the breast, one on either side of the nipple, creating a keyhole shaped skin and breast incision. Wedges of skin and breast tissue are removed until the desired size is achieved. Bleeding vessels may be ligated or cauterized. The physician elevates the nipple and its pedicle of subcutaneous tissue to its new position and sutures the nipple pedicle

with layered closure. The remaining incision is repaired with layered closure" (EncoderPro, 2019). CPT code 19350 does not describe the work that that is being done, because that code describes the actual construction of a new nipple.

Thus, Aetna considers nipple reconstruction, as defined by CPT code 19350, as cosmetic/not medically necessary for mastectomy for transmasculine gender reassignment, and that CPT code 19318 includes the extra work that may be necessary to reshape the nipple and create an aesthetically pleasing male chest.

Vulvoplasty versus Vaginoplasty as Gender-Affirming Genital Surgery for Transgender Women

Jiang and colleagues (2018) noted that gender-affirming vaginoplasty aims to create the external female genitalia (vulva) as well as the internal vaginal canal; however, not all patients desire nor can safely undergo vaginal canal creation. These investigators described the factors influencing patient choice or surgeon recommendation of vulvoplasty (creation of the external appearance of female genitalia without creation of a neovaginal canal) and evaluated the patient's satisfaction with this choice. Gender-affirming genital surgery consults were reviewed from March 2015 until December 2017, and patients scheduled for or who had completed vulvoplasty were interviewed by telephone. These investigators reported demographic data and the reasons for choosing vulvoplasty as gender-affirming surgery for patients who either completed or were scheduled for surgery, in addition to patient reports of satisfaction with choice of surgery, satisfaction with the surgery itself, and sexual activity after surgery. A total of 486 patients were seen in consultation for trans-feminine gender-affirming genital surgery: 396 requested vaginoplasty and 39 patients requested vulvoplasty; 30 Patients either completed or are scheduled for vulvoplasty. Vulvoplasty patients were older and had higher body mass index (BMI) than those seeking vaginoplasty. The majority (63 %) of the patients seeking vulvoplasty chose this surgery despite no contraindications to vaginoplasty. The remaining patients had risk factors leading the surgeon to recommend vulvoplasty. Of those who completed surgery, 93 % were satisfied with the surgery and their decision for vulvoplasty. The authors concluded that this was the first study of factors impacting a patient's choice of or a

surgeon's recommendation for vulvoplasty over vaginoplasty as gender-affirming genital surgery; it also was the first reported series of patients undergoing vulvoplasty only.

Drawbacks of this study included its retrospective nature, non-validated questions, short-term follow-up, and selection bias in how vulvoplasty was offered. Vulvoplasty is a form of gender-affirming feminizing surgery that does not involve creation of a neovagina, and it is associated with high satisfaction and low decision regret.

Autologous Fibroblast-Seeded Amnion for Reconstruction of Neo-vagina in Transfeminine Reassignment Surgery

Seyed-Forootan and colleagues (2018) stated that plastic surgeons have used several methods for the construction of neo-vaginas, including the utilization of penile skin, free skin grafts, small bowel or recto-sigmoid grafts, an amnion graft, and cultured cells. These researchers compared the results of amnion grafts with amnion seeded with autograft fibroblasts. Over 8 years, these investigators compared the results of 24 male-to-female transsexual patients retrospectively based on their complications and levels of satisfaction; 16 patients in group A received amnion grafts with fibroblasts, and the patients in group B received only amnion grafts without any additional cellular lining. The depths, sizes, secretions, and sensations of the vaginas were evaluated. The patients were monitored for any complications, including over-secretion, stenosis, stricture, fistula formation, infection, and bleeding. The mean age of group A was 28 ± 4 years and group B was 32 ± 3 years. Patients were followed-up from 30 months to 8 years (mean of 36 ± 4) after surgery. The depth of the vaginas for group A was 14 to 16 and 13 to 16 cm for group B. There was no stenosis in neither group. The diameter of the vaginal opening was 34 to 38 mm in group A and 33 to 38 cm in group B. These researchers only had 2 cases of stricture in the neo-vagina in group B, but no stricture was recorded for group A. All of the patients had good and acceptable sensation in the neo-vagina; 75 % of patients had sexual experience and of those, 93.7 % in group A and 87.5% in group B expressed satisfaction. The authors concluded that the creation of a neo-vaginal canal and its lining with allograft amnion and seeded autologous fibroblasts is an effective method for imitating a normal vagina. The size of neo-vagina, secretion, sensation, and orgasm was good and proper.

More than 93.7 % of patients had satisfaction with sexual intercourse. They stated that amnion seeded with fibroblasts extracted from the patient's own cells will result in a vagina with the proper size and moisture that can eliminate the need for long-term dilatation. The constructed vagina has a 2-layer structure and is much more resistant to trauma and laceration. No cases of stenosis or stricture were recorded. Level of Evidence = IV. These preliminary findings need to be validated by well-designed studies.

Pitch-Raising Surgery in Transfeminine Persons

Van Damme and colleagues (2017) reviewed the evidence of the effectiveness of pitch-raising surgery performed in male-to-female transsexuals. These investigators carried out a search for studies in PubMed, Web of Science, Science Direct, EBSCOhost, Google Scholar, and the references in retrieved manuscripts, using as keywords "transsexual" or "transgender" combined with terms related to voice surgery. They included 8 studies using cricothyroid approximation, 6 studies using anterior glottal web formation, and 6 studies using other surgery types or a combination of surgical techniques, leading to 20 studies in total. Objectively, a substantial rise in post-operative fundamental frequency was identified. Perceptually, mainly laryngeal web formation appeared risky for decreasing voice quality. The majority of patients appeared satisfied with the outcome. However, none of the studies used a control group and randomization process. The authors concluded that future research needs to investigate long-term effects of pitch-raising surgery using a stronger study design.

Azul and associates (2017) evaluated the currently available discursive and empirical data relating to those aspects of trans-masculine people's vocal situations that are not primarily gender-related, and identified restrictions to voice function that have been observed in this population, and made suggestions for future voice research and clinical practice. These researchers conducted a comprehensive review of the voice literature. Publications were identified by searching 6 electronic databases and bibliographies of relevant articles. A total of 22 publications met inclusion criteria. Discourses and empirical data were analyzed for factors and practices that impact on voice function and for indications of voice function-related problems in trans-masculine people.

The quality of the evidence was appraised. The extent and quality of studies investigating trans-masculine people's voice function was found to be limited. There was mixed evidence to suggest that trans-masculine people might experience restrictions to a range of domains of voice function, including vocal power, vocal control/stability, glottal function, pitch range/variability, vocal endurance, and voice quality. The authors concluded that more research into the different factors and practices affecting trans-masculine people's voice function that took account of a range of parameters of voice function and considered participants' self-evaluations is needed to establish how functional voice production can be best supported in this population.

Facial Feminization Surgery

Raffaini and colleagues (2016) stated that gender dysphoria refers to the discomfort and distress that arise from a discrepancy between a person's gender identity and sex assigned at birth. The treatment plan for gender dysphoria varies and can include psychotherapy, hormone treatment, and gender affirmation surgery, which is, in part, an irreversible change of sexual identity. Procedures for transformation to the female sex include facial feminization surgery, vaginoplasty, clitoroplasty, and breast augmentation. Facial feminization surgery can include forehead re-modeling, rhinoplasty, mentoplasty, thyroid chondroplasty, and voice alteration procedures. These investigators reported patient satisfaction following facial feminization surgery, including outcome measurements after forehead slippage and chin re-modeling. A total of 33 patients between 19 and 40 years of age were referred for facial feminization surgery between January of 2003 and December of 2013, for a total of 180 procedures. Surgical outcome was analyzed both subjectively through questionnaires administered to patients and objectively by serial photographs. Most facial feminization surgery procedures could be safely completed in 6 months, barring complications. All patients showed excellent cosmetic results and were satisfied with their procedures. Both frontal and profile views achieved a loss of masculine features. The authors concluded that patient satisfaction following facial feminization surgery was high; they stated that the reduction of gender dysphoria had psychological and social benefits and significantly affected patient outcome. The level of evidence of this study was IV.

Morrison and associates (2018) noted that facial feminization surgery encompasses a broad range of cranio-maxillofacial surgical procedures designed to change masculine facial features into feminine features. The surgical principles of facial feminization surgery could be applied to male-to-female transsexuals and anyone desiring feminization of the face. Although the prevalence of these procedures is difficult to quantify, because of the rising prevalence of transgenderism (approximately 1 in 14,000 men) along with improved insurance coverage for gender-confirming surgery, surgeons versed in techniques, outcomes, and challenges of facial feminization surgery are needed. These researchers appraised the current facial feminization surgery literature. They carried out a comprehensive literature search of the Medline, PubMed, and Embase databases was conducted for studies published through October 2014 with multiple search terms related to facial feminization. Data on techniques, outcomes, complications, and patient satisfaction were collected. A total of 15 articles were selected and reviewed from the 24 identified, all of which were either retrospective or case series/reports. Articles covered a variety of facial feminization procedures. A total of 1,121 patients underwent facial feminization surgery, with 7 complications reported, although many articles did not explicitly comment on complications. Satisfaction was high, although most studies did not use validated or quantified approaches to address satisfaction. The authors concluded that facial feminization surgery appeared to be safe and satisfactory for patients. These researchers stated that further studies are needed to better compare different techniques to more robustly establish best practices; prospective studies and patient-reported outcomes are needed to establish quality-of-life (QOL) outcomes for patients.

Reversal of Gender Affirming Surgery for Gender Dysphoria

The WPATH Standards of Care (SOC) for the Health of Transsexual, Transgender, and Gender Nonconforming Peoples describe reversible and irreversible interventions, and the ideal order and timing of these approaches. Surgery as an intervention is considered irreversible by WPATH.

Appendix

DSM 5 Criteria for Gender Dysphoria in Adults and Adolescents

I. A marked incongruence between one's experienced/expressed gender and assigned gender, of at least 6 months duration, as manifested by two or more of the following:

   A. A marked incongruence between one's experienced/expressed gender and primary and/or secondary sex characteristics (or, in young adolescents, the anticipated secondary sex characteristics)
   B. A strong desire to be rid of one's primary and/or secondary sex characteristics because of a marked incongruence with one's experienced/expressed gender (or, in young adolescents, a desire to prevent the development of the anticipated secondary sex characteristics)
   C. A strong desire for the primary and/or secondary sex characteristics of the other gender
   D. A strong desire to be of the other gender (or some alternative gender different from one's assigned gender)
   E. A strong desire to be treated as the other gender (or some alternative gender different from one's assigned gender)
   F. A strong conviction that one has the typical feelings and reactions of the other gender (or some alternative gender different from one's assigned gender)

II. The condition is associated with clinically significant distress or impairment in social, occupational, or other important areas of functioning.

Format for referral letters from Qualified Health Professional: (From SOC-7)

1. Client's general identifying characteristics; *and*
2. Results of the client's psychosocial assessment, including any diagnoses; *and*
3. The duration of the mental health professional's relationship with the client, including the type of evaluation and therapy or counseling to date; *and*

4. An explanation that the WPATH criteria for surgery have been met, and a brief description of the clinical rationale for supporting the patient's request for surgery; *and*
5. A statement about the fact that informed consent has been obtained from the patient; *and*
6. A statement that the mental health professional is available for coordination of care and welcomes a phone call to establish this.

Note: There is no minimum duration of relationship required with mental health professional. It is the professional's judgment as to the appropriate length of time before a referral letter can appropriately be written. A common period of time is three months, but there is significant variation in both directions. When two letters are required, the second referral is intended to be an evaluative consultation, not a representation of an ongoing long-term therapeutic relationship, and can be written by a medical practitioner of sufficient experience with gender dysphoria.

Note: Evaluation of candidacy for gender affirmation surgery by a mental health professional is covered under the member's medical benefit, unless the services of a mental health professional are necessary to evaluate and treat a mental health problem, in which case the mental health professional's services are covered under the member's behavioral health benefit. Please check benefit plan descriptions.

Characteristics of a Qualified Mental Health Professional: (From SOC-7)

1. Master's degree or equivalent in a clinical behavioral science field granted by an institution accredited by the appropriate national accrediting board. The professional should also have documented credentials from the relevant licensing board or equivalent; *and*
2. Competence in using the Diagnostic Statistical Manual of Mental Disorders and/or the International Classification of Disease for diagnostic purposes; *and*
3. Ability to recognize and diagnose co-existing mental health concerns and to distinguish these from gender dysphoria; *and*
4. Knowledgeable about gender nonconforming identities and expressions, and the assessment and treatment of gender dysphoria; *and*

5. Continuing education in the assessment and treatment of gender dysphoria. This may include attending relevant professional meetings, workshops, or seminars; obtaining supervision from a mental health professional with relevant experience; or participating in research related to gender nonconformity and gender dysphoria.

CPT Codes / HCPCS Codes / ICD-10 Codes

Information in the [brackets] below has been added for clarification purposes. Codes requiring a 7th character are represented by "+":

Code	Code Description
CPT codes covered if selection criteria are met:	
Laser hair removal - no specific code	
17380	Electrolysis epilation, each 30 minutes
19318	Reduction mammaplasty
19324 - 19325	Mammaplasty, augmentation
19340	Immediate insertion of breast prosthesis following mastopexy, mastectomy or in reconstruction
19342	Delayed insertion of breast prosthesis following mastopexy, mastectomy or in reconstruction
53430	Urethroplasty, reconstruction of female urethra
54125	Amputation of penis; complete
54400 - 54417	Penile prosthesis
54520	Orchiectomy, simple (including subcapsular), with or without testicular prosthesis, scrotal or inguinal approach
54660	Insertion of testicular prosthesis (separate procedure)
54690	Laparoscopic, surgical; orchiectomy
55175	Scrotoplasty; simple
55180	complicated
55970	Intersex surgery; male to female [a series of staged procedures that includes male genitalia removal, penile dissection, urethral transposition, creation of vagina and labia with stent placement]

Code	Code Description
55980	female to male [a series of staged procedures that include penis and scrotum formation by graft, and prostheses placement]
56625	Vulvectomy simple; complete
56800	Plastic repair of introitus
56805	Clitoroplasty for intersex state
56810	Perineoplasty, repair of perineum, nonobstetrical (separate procedure)
57106 - 57107, 57110 - 57111	Vaginectomy
57291 - 57292	Construction of artificial vagina
57335	Vaginoplasty for intersex state
58150, 58180, 58260 - 58262, 58275 - 58291, 58541 - 58544, 58550 - 58554	Hysterectomy
58570 - 58573	Laparoscopy, surgical, with total hysterectomy
58661	Laparoscopy, surgical; with removal of adnexal structures (partial or total oophorectomy and/or salpingectomy)
58720	Salpingo-oophorectomy, complete or partial, unilateral or bilateral
CPT codes not covered for indications listed in the CPB [considered cosmetic]:	
Tracheal shave - no specific code:	
11950 - 11954	Subcutaneous injection of filling material (e.g., collagen)
15200	Full thickness graft, free, including direct closure of donor site, trunk; 20 sq cm or less [nipple reconstruction]
15775	Punch graft for hair transplant; 1 to 15 punch grafts
15776	Punch graft for hair transplant; more than 15 punch grafts
15780 - 15787	Dermabrasion

Code	Code Description
15788 - 15793	Chemical peel
15820 - 15823	Blepharoplasty
15824 - 15828	Rhytidectomy [face-lifting]
15830 - 15839	Excision, excessive skin and subcutaneous tissue (includes lipectomy); abdomen, infraumbilical panniculectomy
15876 - 15879	Suction assisted lipectomy
17380	Electrolysis epilation, each 30 minutes
19301	Mastectomy, partial (eg, lumpectomy, tylectomy, quadrantectomy, segmentectomy)
19303	Mastectomy, simple, complete
19316	Mastopexy
19350	Nipple/areola reconstruction
21087	Nasal prosthesis
21120 - 21123	Genioplasty
21125 - 21127	Augmentation, mandibular body or angle; prosthetic material or with bone graft, onlay or interpositional (includes obtaining autograft)
21193	Reconstruction of mandibular rami, horizontal, vertical, C, or L osteotomy; without bone graft
21194	with bone graft (includes obtaining graft)
21195	Reconstruction of mandibular rami and/or body, sagittal split; without internal rigid fixation
21196	with internal rigid fixation
21208	Osteoplasty, facial bones; augmentation (autograft, allograft, or prosthetic implant)
21210	Graft, bone; nasal, maxillary or malar areas (includes obtaining graft)
21270	Malar augmentation, prosthetic material
30400 - 30420	Rhinoplasty; primary
30430 - 30450	Rhinoplasty; secondary

Code	Code Description
67900	Repair of brow ptosis (supraciliary, mid-forehead or coronal approach)
92507	Treatment of speech, language, voice, communication, and/or auditory processing disorder; individual
92508	Treatment of speech, language, voice, communication, and/or auditory processing disorder; group, two or more individuals
Other CPT codes related to the CPB:	
11980	Subcutaneous hormone pellet implantation (implantation of estradiol and/or testosterone pellets beneath the skin)
+90785	Interactive complexity (List separately in addition to the code for primary procedure)
90832 - 90838	Psychotherapy
96372	Therapeutic, prophylactic, or diagnostic injection (specify substance of drug); subcutaneous or intramuscular
HCPCS codes covered if selection criteria are met:	
C1813	Prosthesis, penile, inflatable
C2622	Prosthesis, penile, non-inflatable
J1071	Injection, testosterone cypionate, 1 mg
J3121	Injection, testosterone enanthate, 1 mg
J3145	Injection, testosterone undecanoate, 1 mg
J1950	Injection, leuprolide acetate (for depot suspension), per 3.75 mg
J9202	Goserelin acetate implant, per 3.6 mg
J9217	Leuprolide acetate (for depot suspension), 7.5 mg
J9218	Leuprolide acetate, per 1 mg
J9219	Leuprolide acetate implant, 65 mg
S0189	Testosterone pellet, 75 mg
HCPCS codes not covered for indications listed in the CPB:	
G0153	Services performed by a qualified speech-language pathologist in the home health or hospice setting, each 15 minutes
S9128	Speech therapy, in the home, per diem
ICD-10 codes covered if selection criteria are met:	
F64.0 - F64.1	Transexualism and dual role transvestism

Code	Code Description
F64.8	Other gender identity disorders
F64.9	Gender identity disorder, unspecified
Z87.890	Personal history of sex reassignment
ICD-10 codes not covered for indications listed in the CPB:	
F64.2	Gender identity disorder of childhood

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EXHIBIT 11

Medical Coverage Policy

Effective Date **5/18/2021**
Next Review Date **3/15/2022**
Coverage Policy Number **0266**

Treatment of Gender Dysphoria

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INSTRUCTIONS FOR USE

The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Each coverage request should be reviewed on its own merits. Medical directors are expected to exercise clinical judgment and have discretion in making individual coverage determinations. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

Exhibit 0031 9/30/2021 Dr. Lappert

Overview

This Coverage Policy addresses treatment of gender dysphoria. Gender dysphoria is defined as discomfort or distress that is caused by a discrepancy between a person's gender identity and the person's assigned sex at birth (World Professional Association for Transgender Health, [WPATH], 2012).

Coverage Policy

Coverage for treatment of gender dysphoria varies across plans. Coverage of drugs for hormonal therapy, as well as whether the drug is covered as a medical or a pharmacy benefit, varies across plans. Refer to the customer's benefit plan document for coverage details. In addition, coverage for treatment of gender dysphoria, including gender reassignment surgery and related services may be governed by state and/or federal mandates.[1]

Unless otherwise specified in a benefit plan, the following conditions of coverage apply for treatment of gender dysphoria and/or gender reassignment surgery and related procedures, including all applicable benefit limitations, precertification, or other medical necessity criteria.

Medically necessary treatment for an individual with gender dysphoria may include ANY of the following services, when services are available in the benefit plan:

- Behavioral health services, including but not limited to, counseling for gender dysphoria and related psychiatric conditions (e.g., anxiety, depression)
- Hormonal therapy, including but not limited to androgens, anti-androgens, GnRH analogues*, estrogens, and progestins (Prior authorization requirements may apply).
  ***Note:** If use in adolescents, individual should have reached Tanner stage 2 of puberty prior to receiving GnRH agonist therapy.
- Laboratory testing to monitor prescribed hormonal therapy
- Age-related, gender-specific services, including but not limited to preventive health, as appropriate to the individuals biological anatomy (e.g., cancer screening [e.g., cervical, breast, prostate]; treatment of a prostate medical condition)
- Gender reassignment and related surgery (see below)**.**

Gender Reassignment Surgery

Gender reassignment surgery is considered medically necessary treatment of gender dysphoria when the individual is age 18 years or older and when the following criteria are met.

Note: For New York regulated benefit plans (e.g., insured): case-by-case review by a medical director for individuals under the age of 18 years of age will be given.

- **For reconstructive chest surgery (i.e., initial mastectomy, breast augmentation):** one letter of support from a qualified mental health professional

  NOTE: The Women's Health and Cancer Rights Act (WHCRA), 29 U.S. Code § 1185b requires coverage of certain post-mastectomy services related to breast reconstruction and treatment of physical complications from mastectomy including nipple-areola reconstruction.

- **For hysterectomy, salpingo-oophorectomy, orchiectomy:**
  - documentation of at least 12 months of continuous hormonal sex reassignment therapy, AND recommendation for sex reassignment surgery (i.e., genital surgery) by two qualified mental health professionals with written documentation submitted to the physician performing the genital surgery. If the first referral is from the individual's psychotherapist, the second referral should be from a person who has only had an evaluative role with the individual. Two separate letters, or one letter signed by both [for example, if practicing within the same clinic] are required.

[1] New York regulated benefit plans do not include exclusions or plan language that limit coverage.

- **For reconstructive genital surgery:**
  - documentation of at least 12 months of continuous hormonal sex reassignment therapy, AND
  - recommendation for sex reassignment surgery (i.e., genital surgery) by two qualified mental health professionals with written documentation submitted to the physician performing the genital surgery (If the first referral is from the individual's psychotherapist, the second referral should be from a person who has only had an evaluative role with the individual. Two separate letters, or one letter signed by both [for example, if practicing within the same clinic] are required AND
  - documentation the individual has lived for at least 12 continuous months in a gender role that is congruent with their gender identity

Table 1: Gender Reassignment Surgery: Covered Under Standard Benefit Plan Language

The procedures listed below are considered medically necessary under standard benefit plan language when the above listed criteria for gender reassignment surgery have been met, unless specifically excluded in the benefit plan language.

Procedure	CPT / HCPCS codes (This list may not be all inclusive)
Female to Male reconstructive genital surgery:	55980
Vaginectomy**/colpectomy	57110
Vulvectomy	56625
Metoidioplasty	58999
Phalloplasty	58999
Electrolysis of donor site tissue to be used for phalloplasty	17380
Penile prosthesis (noninflatable / inflatable), including surgical correction of malfunctioning pump, cylinders, or reservoir	54400, 54401, 54405, C1813, C2622
Urethroplasty /urethromeatoplasty	53430, 53450
Hysterectomy and salpingo-oophorectomy	58150, 58260, 58262, 58291, 58552, 58554, 58571, 58573, 58661
Scrotoplasty	55175, 55180
Insertion of testicular prosthesis	54660
Replacement of tissue expander with permanent prosthesis testicular insertion	11970
Testicular expanders, including replacement with prosthesis, testicular prosthesis	11960, 11970, 11971, 54660
Female to Male reconstructive chest surgery:	
Initial mastectomy	19303
Nipple-areola reconstruction (related to mastectomy or post mastectomy reconstruction)	19350*
Breast reduction	19318
Pectoral implants	L8600, 17999
Male to Female reconstructive genital surgery:	55970
Vaginoplasty**, (e.g, construction of vagina with/without graft, colovaginoplasty)	57291, 57292, 57335
Electrolysis of donor site tissue to be used to line the vaginal canal for vaginoplasty	17380
Penectomy	54125
Vulvoplasty, (e.g., labiaplasty, clitoroplasty, penile skin inversion)	56620, 56805
Repair of introitus	56800
	44145, 55899

Coloproctostomy Orchiectomy	54520, 54690
Male to Female reconstructive chest surgery: Initial breast reconstruction including augmentation with implants	 15771-15772 (when specific to breast), 19325, 19340, 19342, C1789

***Note: CPT 19318 (breast reduction) includes the work necessary to reposition and reshape the nipple and areola. Therefore, CPT 19350 (nipple and areola reconstruction) is considered integral to CPT 19318. Thus, these two codes cannot be billed together for "mastectomy" for the purpose of gender reassignment. However, 19350 would be covered if requested along with 19303 as per the federal mandate.**

****Note: For individuals considering hysterectomy/salpingo-oophorectomy, orchiectomy, vaginectomy or vaginoplasty procedures a total of 12 months continuous hormonal sex reassignment therapy is required.**

Table 2: Gender Reassignment Surgery: Other Procedures

The procedures listed below are considered not medically necessary under standard benefit plan language. However, some benefit plans may expressly cover some or all of the procedures listed below for gender reassignment surgery.

Note: For New York regulated benefit plans (e.g., insured):The procedures listed below will be further reviewed on a case-by-case basis by a medical director with particular consideration given to whether the proposed procedure(s) advance an individual's ability to properly present and function in the identified gender role.

Facial Feminization/Masculinization Procedures	CPT/HCPCS Code
Blepharoplasty	15820, 15821, 15822, 15823
Brow lift	67900
Cheek/malar implants	17999
Chin/nose implants, chin recontouring	21210, 21270, 30400, 30410, 30420, 30430 30435, 30450
Collagen injections	11950, 11951, 11952, 11954
Face lift	15824, 15825, 15826, 15828, 15829
Forehead reduction and contouring	21137
Facial bone reduction (osteoplasty)	21209
Hair removal/hair transplantation	15775, 15776, 17380
Jaw reduction, contouring, augmentation	21120, 21121, 21122, 21123, 21125, 21127
Laryngoplasty	31599
Lip lift and lip filling	40799
Rhinoplasty	21210, 21270, 30400, 30410, 30420, 30430, 30435, 30450
Skin resurfacing (e.g., dermabrasion, chemical peels)	15780, 15781, 15782, 15783, 15786, 15787, 15788, 15789, 15792, 15793
Thyroid reduction chondroplasty	31750
Neck tightening	15825
Electrolysis, other than when performed pre-vaginoplasty as outlined above	17380
Removal of redundant skin when performed as part of facial reconstruction	15830, 15832, 15833, 15834, 15835, 15836 15837, 15838, 15839
Suction assisted lipoplasty, lipofilling, and/or liposuction	15830, 15832, 15833, 15834, 15835, 15836, 15837, 15838, 15839, 15876, 15877, 15878, 15879
Voice therapy/voice lessons	92507
Voice modification surgery	31599, 31899

General Background

The causes of gender dysphoria and the developmental factors associated with them are not well-understood. Treatment of individuals with gender dysphoria varies, with some treatments involving a change in gender expression or body modification. The term "transsexual" refers to an individual whose gender identity is not congruent with their genetic and/or assigned sex and usually seeks hormone replacement therapy (HRT) and possibly gender-affirmation surgery to feminize or masculinize the body and who may live full-time in the crossgender role. Transsexualism is a form of gender dysphoria. Other differential diagnoses include, but are not limited to, partial or temporary disorders as seen in adolescent crisis, transvestitism, refusal to accept a homosexual orientation, psychotic misjudgments of gender identity and severe personality disorders (Becker, et al., 1998). Individuals that are transsexual, transgender, or gender nonconforming (i.e., gender identity differs from the cultural norm) may experience gender dysphoria.

Treatment of gender dysphoria is unique to each individual and may or may not involve body modification. Some individuals require only psychotherapy, some require a change in gender roles/expression, and others require hormone therapy and/or surgery to facilitate a gender transition.

Behavioral Health Services

Licensing requirements and scope of practice vary by state for healthcare professionals. The recommended minimum credentials for a mental health professional to be qualified to evaluate or treat adult individuals with gender dysphoria has been defined in the literature. There is some consensus that in addition to general licensing requirements, a minimum of a Master's or more advanced degree from an accredited institution, an ability to recognize and diagnose coexisting mental health concerns, and an ability to distinguish such conditions from gender dysphoria is required.

Mental health professionals play a strong role in working with individuals with gender dysphoria as they need to diagnose the gender disorder and any co-morbid psychiatric conditions accurately, counsel the individual regarding treatment options, and provide psychotherapy (as needed) and assess eligibility and readiness for hormone and surgical therapy. For children and adolescents, the mental health professional should also be trained in child and adolescent developmental psychopathology.

Once the individual is evaluated, the mental health professional provides documentation and formal recommendations to medical and surgical specialists. Documentation for hormonal and/or surgery should be comprehensive and include the extent to which eligibility criteria have been met (i.e., confirmed gender dysphoria, capacity to make a fully informed decision, age ≥ 18 years or age of majority, and other significant medical or behavioral health concerns are well-controlled), in addition to the following:

- individual's general identifying characteristics
- the initial and evolving gender, sexual and psychiatric diagnoses
- details regarding the type and duration of psychotherapy or evaluation the individual received
- the mental health professional's rationale for hormone therapy or surgery
- the degree to which the individual has followed recommended medical management and likelihood of continued compliance
- whether or not the mental health professional is a part of a gender team

Psychiatric care may need to continue for several years after gender reassignment surgery, as major psychological adjustments may continue to be necessary. Other providers of care may include a family physician or internist, endocrinologist, urologist, plastic surgeon, general surgeon and gynecologist. The overall success of the surgery is highly dependent on psychological adjustment and continued support.

After diagnosis, the therapeutic approach is individualized but generally includes three elements: sex hormone therapy of the identified gender, real life experience in the desired role, and surgery to change the genitalia and other sex characteristics.

Hormonal Therapy

For both adults and adolescents, hormonal treatment for gender dysphoria must be administered and monitored by a qualified healthcare practitioner as therapy requires ongoing medical management, including physical

examination and laboratory evaluation studies to manage dosage, side effects, etc. Lifelong maintenance is usually required.

Adults: Prior to and following gender reassignment surgery, individuals undergo hormone replacement therapy, unless medically contraindicated. Biological males are treated with estrogens and anti-androgens to increase breast size, redistribute body fat, soften skin, decrease body hair, and decrease testicular size and erections. Biological females are treated with androgens such as testosterone to deepen voice, increase muscle and bone mass, decrease breast size, increase clitoris size, and increase facial and body hair. In both sexes hormone replacement therapy (HRT) may be effective in reducing the adverse psychologic impact of gender dysphoria. Hormone therapy is usually initiated upon referral from a qualified mental health professional or a health professional competent in behavioral health and gender dysphoria treatment specifically. Twelve months of continuous hormone therapy (gender appropriate) is required prior to hysterectomy and salpingo-oophorectomy and orchiectomy.

Adolescents: For some adolescents the onset of puberty may worsen gender dysphoria. For these individuals puberty-suppressing hormones (e.g., GnRH analogues) may be provided to individuals who have reached at least Tanner stage 2 of sexual development (Hembree, et al., 2009; World Professional Association for Transgender health [WPATH], 2012). Consistent with adult hormone therapy, treatment of adolescents involves a multidisciplinary team, however when treating an adolescent a pediatric endocrinologist should be included as a part of the team. Pre-pubertal hormone suppression differs from hormone therapy used in adults and may not be without consequence; some pharmaceutical agents may cause negative physical side effects (e.g., height, bone growth).

Gender Reassignment Surgery

The term "gender reassignment surgery," also known as sexual reassignment surgery, gender confirming surgery or gender affirmation surgery, may be part of a treatment plan for gender dysphoria. The terms may be used to refer to either the reconstruction of male or female genitalia specifically, or the reshaping by any surgical procedure of a male body into a body with female appearance, or vice versa in order for an individual to function socially in the role to which they identify. Such procedures that tend to display outward appearance generally include facial procedures, chest reconstructive procedures as well as some genital reconstructive procedures (e.g.,phalloplasty).

Gender identity disorder does not persist into adolescence in most children (Hembree, et al., 2009). Evidence suggests that 75-80% of prepubertal children do not turn out to be transgender in adolescence (Hembree, et al., 2009). According to WPATH (2007) persistence of gender dysphoria from adolescence into adulthood is much higher. Performing gender reassignment surgery prior to age 18, or the legal age to give consent, is not recommended by professional societies (American College of Obstetricians and Gynecology [ACOG], 2017; WPATH, 2012; American Psychiatric Association (APA), 2012, Endocrine Society, 2009). Gender reassignment surgery is intended to be a permanent change (non-reversible), establishing congruency between an individual's gender identity and physical appearance. Therefore, a careful and accurate diagnosis is essential for treatment and can be made only as part of a long-term diagnostic process involving a multidisciplinary specialty approach that includes an extensive case history; gynecological, endocrine and urological examination; and a clinical psychiatric/psychological examination. Individuals who choose to undergo gender reassignment surgery must be fully informed regarding treatment options with confirmation from the mental health professional that the individual is considered a candidate for surgical treatment.

Twelve months of continuous hormone therapy is required prior to irreversible genital surgery unless medically contraindicated. Contraindications to hormonal therapy include but are not limited to hypercoagulability conditions, known coronary artery disease, liver disease, and venous thromboembolism.

In addition, prior to surgery the individual identified with gender dysphoria must undergo a "real life experience". During this time the individual adopts the new or evolving gender role and lives in that role for at least 12 continuous months as part of the transition pathway. This process assists in confirming the person's desire for gender role change, ability to function in this role long-term, as well as the adequacy of his/her support system. During the real life experience a person would be expected to maintain their baseline functional lifestyle, participate in community activities, and provide an indication that others are aware of the change in gender role. Some individuals may not be able to continuously live in the gender role for which they identify, for example, concerns surrounding one's employment environment may preclude an individual from meeting this requirement.

In such instances the clinician must confirm the individual has had a satisfactory social role change prior to surgery.

Other Associated Surgical Procedures

Services Otherwise Medically Necessary: Age appropriate gender-specific services that would otherwise be considered medically necessary remain medically necessary services for transgender individuals, as appropriate to their biological anatomy. Examples include (but are not limited to):

- for female to male transgender individuals (e.g., who have not undergone a mastectomy, breast cancer screening)
- for male to female transgender individuals who have retained their prostate cancer screening or treatment of a prostate condition.

Reversal of Gender Reassignment: Gender reassignment surgery is considered an irreversible intervention. Although infrequent, surgery to reverse a partially or fully completed gender reassignment (reversal of surgery to revise secondary sex characteristics), may be necessary as a result of a complication (i.e., infection) or other medical condition necessitating surgical intervention.

Masculinization/Feminization Procedures: Various other surgical procedures may be performed as part of gender reassignment surgery, for example masculinization or feminization procedures. When performed as part of gender reassignment surgery some procedures are performed to assist with improving culturally appropriate male or female appearance characteristics and may be considered not medically necessary. Please refer to the applicable benefit plan document for terms, conditions, and limitations of coverage in addition to the applicable Cigna Medical Coverage Policy for conditions of coverage.

Professional Society/Organization

American College of Obstetricians and Gynecologists (ACOG): ACOG published a Committee Opinion in 2017 for the care of transgender adolescents. Within this document regarding surgical management ACOG notes transgender male patients may undergo phalloplasty when one reaches the age of majority, and a transgender female patient may undergo vaginoplasty when one reaches the age of majority. In addition the authors acknowledge the Endocrine Society guidelines (Hembree, et al., 2009) which state that an individual is at least age 18 years for genital reconstructive surgery (ACOG, 2017).

American Psychiatric Association (APA): In 2012 the APA published a task force report on treatment of gender identity disorder. Within this document, regarding adolescents specifically, the authors state the evidence is inadequate to develop a guideline regarding the timing of sex reassignment surgery. However the task force acknowledges the Endocrine Society guidelines (Hembree, et al., 2009) and that given the irreversible nature of surgery, for adolescents most clinicians advise waiting until the individual has attained the age of legal consent and a degree of independence (APA, 2012).

WPATH Standards of Care: The World Professional Association for Transgender Health (WPATH) promotes standards of health care for individuals through the articulation of “Standards of Care for the Health of Transsexual, Transgender, and Gender Nonconforming People” (WPATH, 2012, Version 7). Although there is no recent update, WPATH standards of care are based on scientific evidence and expert consensus and are commonly utilized as a clinical guide for individuals seeking treatment of gender disorders.

Endocrine Society: In 2009 the Endocrine Society published a clinical practice guideline for endocrine treatment of transsexual persons (Hembree, et al., 2009). As part of this guideline, the endocrine society recommends that transsexual persons consider genital sex reassignment surgery only after both the physician responsible for endocrine transition therapy and the mental health professional find surgery advisable; that surgery be recommended only after completion of at least one year of consistent and compliant hormone treatment; and that the physician responsible for endocrine treatment medically clear the individual for sex reassignment surgery and collaborate with the surgeon regarding hormone use during and after surgery.

Use Outside of the US: Several other countries including the United Kingdom offer treatment options for individuals with gender dysphoria. Treatments are similar to those offered in the United States.

Medicare Coverage Determinations

	Contractor	Policy Name/Number	Revision Effective Date
NCD	National	No National Coverage Determinatin	
LCD		No Local Coverage Determination	

Note: Please review the current Medicare Policy for the most up-to-date information.

Coding/Billing Information

Note: 1) This list of codes may not be all-inclusive.
2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

Table 1: Gender Reassignment Surgery: Covered Under Standard Benefit Plan Language

Intersex Surgery: Female to Male

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT®* Codes	Description
55980	Intersex surgery, female to male
11960	Insertion of tissue expander(s) for other than breast, including subsequent expansion
11970	Replacement of tissue expander with permanent implant
11971	Removal of tissue expander without insertion of implant
17380†	Electrolysis epilation, each 30 minutes
17999††	Unlisted procedure, skin, mucous membrane and subcutaneous tissue
19303	Mastectomy, simple, complete
19318	Breast reduction
19350†††	Nipple/areola reconstruction
53430	Urethroplasty, reconstruction of female urethra
53450	Urethromeatoplasty, with mucosal advancement
54400	Insertion of penile prosthesis; non-inflatable (semi-rigid)
54401	Insertion of penile prosthesis; inflatable (self-contained)
54405	Insertion of multi-component, inflatable penile prosthesis, including placement of pump, cylinders, and reservoir
54660	Insertion of testicular prosthesis (separate procedure)
55175	Scrotoplasty; simple
55180	Scrotoplasty; complicated
56625	Vulvectomy simple; complete
57110	Vaginectomy, complete removal of vaginal wall
58150	Total abdominal hysterectomy (corpus and cervix), with or without removal of tube(s), with or without removal of ovary(s)
58260	Vaginal hysterectomy, for uterus 250 g or less
58262	Vaginal hysterectomy, for uterus 250 g or less; with removal of tube(s), and/or ovary(s)
58291	Vaginal hysterectomy, for uterus greater than 250 g; with removal of tube(s) and/or ovary(s)
58552	Laparoscopy, surgical, with vaginal hysterectomy, for uterus 250 g or less; with removal of tube(s) and/or ovary(s)
58554	Laparoscopy, surgical, with vaginal hysterectomy, for uterus greater than 250 g; with removal of tube(s) and/or ovary(s)
58571	Laparoscopy, surgical, with total hysterectomy, for uterus 250 g or less; with removal of tube(s) and/or ovary(s)
58573	Laparoscopy, surgical, with total hysterectomy, for uterus greater than 250 g; with removal of tube(s) and/or ovary(s)
58661	Laparoscopy, surgical; with removal of adnexal structures (partial or total oophorectomy and/or salpingectomy)
58999††††	Unlisted procedure, female genital system (nonobstetrical)

†Note: Considered medically necessary when performed as electrolysis of donor site tissue to be used for phalloplasty.

††Note: Considered medically necessary when used to represent pectoral implants.

†††Note: Considered medically necessary when performed as part of a mastectomy or breast reconstruction procedure following a mastectomy. Considered integral and/or not covered when performed with reduction mammoplasty.

††††Note: Considered medically necessary when used to report metoidioplasty with phalloplasty.

HCPCS Codes	Description
C1813	Prosthesis, penile, inflatable
C2622	Prosthesis, penile, non-inflatable
L8600	Implantable breast prosthesis, silicone or equal

Intersex Surgery: Male to Female

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT®* Codes	Description
55970	Intersex surgery; male to female
15771†	Grafting of autologous fat harvested by liposuction technique to trunk, breasts, scalp, arms, and/or legs; 50 cc or less injectate
15772†	Grafting of autologous fat harvested by liposuction technique to trunk, breasts, scalp, arms, and/or legs; each additional 50 cc injectate, or part thereof (List separately in addition to code for primary procedure)
17380††	Electrolysis epilation, each 30 minutes
19325	Breast augmentation with implant
19340	Insertion of breast implant on same day of mastectomy (ie, immediate)
19342	Insertion or replacement of breast implant on separate day from mastectomy
44145	Colectomy, partial; with coloproctostomy (low pelvic anastomosis)
54125	Amputation of penis; complete
54520	Orchiectomy, simple (including subcapsular), with or without testicular prosthesis, scrotal or inguinal approach
54690	Laparoscopy, surgical; orchiectomy
55899†††	Unlisted procedure, male genital system
56620	Vulvectomy simple; partial
56800	Plastic repair of introitus
56805	Clitoroplasty for intersex state
57291	Construction of artificial vagina; without graft
57292	Construction of artificial vagina; with graft
57335	Vaginoplasty for intersex state

HCPCS Codes	Description
C1789	Prosthesis, breast (implantable)

†Note: Considered medically necessary when used to report liposuction techniques specific to breast augmentation.

††Note: Considered medically necessary when performed as electrolysis of donor site tissue to be used to line the vaginal canal for vaginoplasty.

†††**Note: Considered medically necessary when used to report coloproctostomy.**

ICD-10-CM Diagnosis Codes	Description
F64.0	Transsexualism
F64.1	Dual role transvestism
F64.2	Gender identity disorder of childhood
F64.8	Other gender identity disorders
F64.9	Gender identity disorder, unspecified
Z87.890	Personal history of sex reassignment

Table 2: Gender Reassignment Surgery: Other Procedures

Generally considered not medically necessary when performed as a component of gender reassignment even when coverage for gender reassignment surgery exists, unless subject to a coverage mandate or specifically listed as available in the applicable benefit plan document.

Note: For New York regulated benefit plans (e.g., insured): Subject to case by case review by a medical director.

CPT®* Codes	Description
11950	Subcutaneous injection of filling material (eg, collagen); 1 cc or less
11951	Subcutaneous injection of filling material (eg, collagen); 1.1 to 5.0 cc
11952	Subcutaneous injection of filling material (eg, collagen); 5.1 to 10.0 cc
11954	Subcutaneous injection of filling material (eg, collagen); over 10.0 cc
15775	Punch graft for hair transplant; 1 to 15 punch grafts
15776	Punch graft for hair transplant; more than 15 punch grafts
15780	Dermabrasion; total face (eg, for acne scarring, fine wrinkling, rhytids, general keratosis)
15781	Dermabrasion; segmental, face
15782	Dermabrasion; regional, other than face
15783	Dermabrasion; superficial, any site (eg, tattoo removal)
15786	Abrasion; single lesion (eg, keratosis, scar)
15787	Abrasion; each additional 4 lesions or less (List separately in addition to code for primary procedure)
15788	Chemical peel, facial; epidermal
15789	Chemical peel, facial; dermal
15792	Chemical peel, nonfacial; epidermal
15793	Chemical peel, nonfacial; dermal
15820	Blepharoplasty, lower eyelid
15821	Blepharoplasty, lower eyelid with extensive herniated fat pad
15822	Blepharoplasty, upper eyelid
15823	Blepharoplasty, upper eyelid; with excessive skin weighting down lid
15824	Rhytidectomy, forehead
15825	Rhytidectomy; neck with platysmal tightening (platysmal flap, P-flap)
15826	Rhytidectomy; glabellar frown lines
15828	Rhytidectomy; cheek, chin, and neck
15829	Rhytidectomy; superficial musculoaponeurotic system (SMAS) flap
15830	Excision, excessive skin and subcutaneous tissue (includes lipectomy); abdomen, infraumbilical panniculectomy
15832	Excision, excessive skin and subcutaneous tissue (includes lipectomy); thigh
15833	Excision, excessive skin and subcutaneous tissue (includes lipectomy); leg
15834	Excision, excessive skin and subcutaneous tissue (includes lipectomy); hip
15835	Excision, excessive skin and subcutaneous tissue (includes lipectomy); buttock
15836	Excision, excessive skin and subcutaneous tissue (includes lipectomy); arm
15837	Excision, excessive skin and subcutaneous tissue (includes lipectomy); forearm or hand

CPT®* Codes	Description
15838	Excision, excessive skin and subcutaneous tissue (includes lipectomy); submental fat pad
15839	Excision, excessive skin and subcutaneous tissue (includes lipectomy); other area
15847	Excision, excessive skin and subcutaneous tissue (includes lipectomy), abdomen (eg, abdominoplasty) (includes umbilical transposition and fascial plication) (List separately in addition to code for primary procedure)
15876	Suction assisted lipectomy; head and neck
15877	Suction assisted lipectomy; trunk
15878	Suction assisted lipectomy; upper extremity
15879	Suction assisted lipectomy; lower extremity
17380	Electrolysis epilation, each 30 minutes
17999†	Unlisted procedure, skin, mucous membrane and subcutaneous tissue
19324	Mammaplasty, augmentation; without prosthetic implant (Code deleted 12/31/2020)
21120	Genioplasty; augmentation (autograft, allograft, prosthetic material)
21121	Genioplasty; sliding osteotomy, single piece
21122	Genioplasty; sliding osteotomies, 2 or more osteotomies (eg, wedge excision or bone wedge reversal for asymmetrical chin)
21123	Genioplasty; sliding, augmentation with interpositional bone grafts (includes obtaining autografts)
21125	Augmentation, mandibular body or angle; prosthetic material
21127	Augmentation, mandibular body or angle; with bone graft, onlay or interpositional (includes obtaining autograft)
21137	Reduction forehead; contouring only
21209	Osteoplasty, facial bones; reduction
21210	Graft, bone; nasal, maxillary or malar areas (includes obtaining graft)
21270	Malar augmentation, prosthetic material
30400	Rhinoplasty, primary; lateral and alar cartilages and/or elevation of nasal tip
30410	Rhinoplasty, primary; complete, external parts including bony pyramid, lateral and alar cartilages, and/or elevation of nasal tip
30420	Rhinoplasty, primary; including major septal repair
30430	Rhinoplasty, secondary; minor revision (small amount of nasal tip work)
30435	Rhinoplasty, secondary; intermediate revision (bony work with osteotomies)
30450	Rhinoplasty, secondary; major revision (nasal tip work and osteotomies)
31599††	Unlisted procedure, larynx
31750	Tracheoplasty; cervical
31899†††	Unlisted procedure, trachea, bronchi
40799††††	Unlisted procedure, lips
67900	Repair of brow ptosis (supraciliary, mid-forehead or coronal approach)
92507	Treatment of speech, language, voice, communication, and/or auditory processing disorder; individual

†**Note: Generally not medically necessary when used to report cheek and malar implants or fat transfers performed in conjunction with gender reassignment surgery, even when coverage for gender reassignment surgery exists.**

††**Note: Generally not medically necessary when used to report laryngoplasty and/or voice modification surgery performed in conjunction with gender reassignment surgery, even when coverage for gender reassignment surgery exists.**

†††**Note: Generally not medically necessary when used to report voice modification surgery performed in conjunction with gender reassignment surgery, even when coverage for gender reassignment surgery exists.**

††††**Note: Generally not medically necessary when used to report lip reduction/enhancement performed in conjunction with gender reassignment surgery, even when coverage for gender reassignment surgery exists.**

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EXHIBIT 12

United Healthcare®

Exhibit 0032 9/30/2021 Dr. Lappert

UnitedHealthcare® Commercial *Medical Policy*

Gender Dysphoria Treatment

Policy Number: 2021T0580J
Effective Date: April 1, 2021

➲ Instructions for Use

Table of Contents Page

Related Commercial Policies

- Blepharoplasty, Blepharoptosis and Brow Ptosis Repair
- Botulinum Toxins A and B
- Cosmetic and Reconstructive Procedures
- Gonadotropin Releasing Hormone Analogs
- Habilitative Services and Outpatient Rehabilitation Therapy
- Panniculectomy and Body Contouring Procedures
- Rhinoplasty and Other Nasal Surgeries

Community Plan Policy

- Gender Dysphoria Treatment

Coverage Rationale

➲ See Benefit Considerations

Notes:
- This Medical Policy does not apply to individuals with ambiguous genitalia or disorders of sexual development.
- This Medical Policy does not apply to self-funded and fully insured group policies in California. Refer to the Benefit Interpretation Policy titled Gender Dysphoria (Gender Identity Disorder) Treatment: CA.

Surgical treatment for Gender Dysphoria may be indicated for individuals who provide the following documentation:
- For breast surgery, a written psychological assessment from at least one Qualified Behavioral Health Provider experienced in treating Gender Dysphoria* is required. The assessment must document that an individual meets all of the following criteria:
  - Persistent, well-documented Gender Dysphoria
  - Capacity to make a fully informed decision and to consent for treatment
  - Must be at least 18 years of age (age of majority)
  - Favorable psychosocial-behavioral evaluation to provide screening and identification of risk factors or potential postoperative challenges
- For genital surgery, a written psychological assessment from at least two Qualified Behavioral Health Providers experienced in treating Gender Dysphoria*, who have independently assessed the individual, is required. The assessment must document that an individual meets all of the following criteria:
  - Persistent, well-documented Gender Dysphoria
  - Capacity to make a fully informed decision and to consent for treatment
  - Must be at least 18 years of age (age of majority)
  - Favorable psychosocial-behavioral evaluation to provide screening and identification of risk factors or potential postoperative challenges
  - Complete at least 12 months of successful continuous full-time real-life experience in the desired gender

  - Complete 12 months of continuous cross-sex hormone therapy appropriate for the desired gender (unless medically contraindicated)
- Treatment plan that includes ongoing follow-up and care by a Qualified Behavioral Health Provider experienced in treating Gender Dysphoria*

When the above criteria are met, the following surgical procedures to treat Gender Dysphoria are medically necessary and covered as a proven benefit:

- Bilateral mastectomy or breast reduction*
- Clitoroplasty (creation of clitoris)
- Hysterectomy (removal of uterus)
- Labiaplasty (creation of labia)
- Laser or electrolysis hair removal in advance of genital reconstruction prescribed by a physician for the treatment of Gender Dysphoria
- Metoidioplasty (creation of penis, using clitoris)
- Orchiectomy (removal of testicles)
- Penectomy (removal of penis)
- Penile prosthesis
- Phalloplasty (creation of penis)
- Salpingo-oophorectomy (removal of fallopian tubes and ovaries)
- Scrotoplasty (creation of scrotum)
- Testicular prostheses
- Urethroplasty (reconstruction of female urethra)
- Urethroplasty (reconstruction of male urethra)
- Vaginectomy (removal of vagina)
- Vaginoplasty (creation of vagina)
- Vulvectomy (removal of vulva)

*When bilateral mastectomy or breast reduction is performed as a stand-alone procedure, without genital reconstruction procedures, completion of hormone therapy prior to the breast procedure is not required.

Certain ancillary procedures, including but not limited to the following, are considered cosmetic and not medically necessary, when performed as part of surgical treatment for Gender Dysphoria:

Refer to the Benefit Considerations section as member specific benefit plan language may vary.

Note: For fully insured group policies in New York, refer to the Benefit Considerations section for more information.

- Abdominoplasty (also refer to the Coverage Determination Guideline titled Panniculectomy and Body Contouring Procedures)
- Blepharoplasty (also refer to the Coverage Determination Guideline titled Blepharoplasty, Blepharoptosis and Brow Ptosis Repair)
- Body contouring (e.g., fat transfer, lipoplasty, panniculectomy) (also refer to the Coverage Determination Guideline titled Panniculectomy and Body Contouring Procedures)
- Breast enlargement, including augmentation mammaplasty and breast implants
- Brow lift
- Calf implants
- Cheek, chin and nose implants
- Injection of fillers or neurotoxins (also refer to the Medical Benefit Drug Policy titled Botulinum Toxins A and B)
- Face/forehead lift and/or neck tightening
- Facial bone remodeling for facial feminization
- Laser or electrolysis hair removal not related to genital reconstruction
- Hair transplantation
- Lip augmentation
- Lip reduction

- Liposuction (suction-assisted lipectomy) (also refer to the Coverage Determination Guideline titled Panniculectomy and Body Contouring Procedures)
- Mastopexy
- Pectoral implants for chest masculinization
- Rhinoplasty (also refer to the Coverage Determination Guideline titled Rhinoplasty and Other Nasal Surgeries)
- Skin resurfacing (e.g., dermabrasion, chemical peels, laser)
- Thyroid cartilage reduction/reduction thyroid chondroplasty/trachea shave (removal or reduction of the Adam's apple)
- Voice modification surgery (e.g., laryngoplasty, glottoplasty or shortening of the vocal cords)
- Voice lessons and voice therapy

Documentation Requirements

Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The documentation requirements outlined below are used to assess whether the member meets the clinical criteria for coverage but do not guarantee coverage of the service requested.

CPT Codes*	Required Clinical Information
Gender Dysphoria Treatment	
14000, 14000, 14001, 14041, 15734, 15738, 15750, 15757, 15758, 15820, 15821, 15822, 15823, 15830, 15847, 15877, 17999, 19303, 19316, 19318, 19325, 19340, 19342, 19350, 21121, 21123, 21125, 21127, 21137, 21138, 21139, 21172, 21175, 21179, 21180, 21208, 21209, 21210, 30400, 30410, 30420, 30430, 30435, 30450, 53410, 53430, 54125, 54520, 54660, 54690, 55175, 55180, 55970, 55980, 56625, 56800, 56805, 57110, 57335, 58150, 58180, 58260, 58262, 58290, 58291, 58541, 58542, 58543, 58544, 58550, 58552, 58553, 58554, 58570, 58571, 58572, 58573, 58661, 58720, 58940, 64856, 64892, 64896, 67900	Medical notes documenting the following: • The history of medical conditions requiring treatment or surgical intervention • A well-defined physical/physiologic abnormality resulting in a medical condition that requires treatment • Recurrent or persistent functional deficit caused by the abnormality • Clinical studies/tests addressing the physical/physiologic abnormality confirming its presence and degree to which it causes impairment • Color photos, where applicable, of the physical and/or physiological abnormality • Physician plan of care with proposed procedures and whether this request is part of a staged procedure; indicate how the procedure will improve and/or restore function • For CPT codes 58260, 58262, 58290 and 58291, provide the additional information: o The history of medical conditions requiring treatment or surgical intervention o Physician plan of care with proposed procedures and whether this request is part of a staged procedure o A written psychological assessment from at least two Qualified Behavioral Health Providers experienced in treating Gender Dysphoria, who have independently assessed the individual. The assessment should include all of the following: ▪ The member is capable to make a fully informed decision and to consent for treatment ▪ The member must be at least 18 years of age (age of majority) ▪ If significant medical or mental health concerns are present, they must be reasonably well controlled ▪ The member has completed at least 12 months of successful continuous full-time real-life experience in the desired gender ▪ The member has completed 12 months of continuous cross-sex hormone therapy appropriate for the desired gender (unless medically contraindicated) o A treatment plan that includes ongoing follow-up and care by a Qualified Behavioral Health Provider experienced in treating Gender Dysphoria

**For code descriptions, see the Applicable Codes section.*

Definitions

Gender Dysphoria in Adolescents and Adults: A disorder characterized by the following diagnostic criteria (Diagnostic and Statistical Manual of Mental Disorders, 5th edition [DSM-5]):

A. A marked incongruence between one's experienced/expressed gender and assigned gender, of at least 6 months' duration, as manifested by at least two of the following:
   1. A marked incongruence between one's experienced/expressed gender and primary and/or secondary sex characteristics [(or in young adolescents, the anticipated secondary sex characteristics)].
   2. A strong desire to be rid of one's primary and/or secondary sex characteristics because of a marked incongruence with one's experienced/expressed gender [or in young adolescents, a desire to prevent the development of the anticipated secondary sex characteristics)].
   3. A strong desire for the primary and/or secondary sex characteristics of the other gender.
   4. A strong desire to be of the other gender (or some alternative gender different from one's assigned gender).
   5. A strong desire to be treated as the other gender (or some alternative gender different from one's assigned gender).
   6. A strong conviction that one has the typical feelings and reactions of the other gender (or some alternative gender different from one's assigned gender).

B. The condition is associated with clinically significant distress or impairment in social, occupational or other important areas of functioning.

Gender Dysphoria in Children: A disorder characterized by the following diagnostic criteria (Diagnostic and Statistical Manual of Mental Disorders, 5th edition [DSM-5]):

A. A marked incongruence between one's experienced/expressed gender and assigned gender, of at least 6 months' duration, as manifested by at least six of the following (one of which must be criterion A1):
   1. A strong desire to be of the other gender or an insistence that one is the other gender (or some alternative gender different from one's assigned gender).
   2. In boys (assigned gender), a strong preference for cross-dressing or simulating female attire; or in girls (assigned gender), a strong preference for wearing only typical masculine clothing and a strong resistance to the wearing of typical feminine clothing.
   3. A strong preference for cross-gender roles in make-believe play or fantasy play.
   4. A strong preference for the toys, games or activities stereotypically used or engaged in by the other gender.
   5. A strong preference for playmates of the other gender.
   6. In boys (assigned gender), a strong rejection of typically masculine toys, games and activities and a strong avoidance of rough-and-tumble play; or in girls (assigned gender), a strong rejection of typically feminine toys, games and activities.
   7. A strong dislike of ones' sexual anatomy.
   8. A strong desire for the primary and/or secondary sex characteristics that match one's experienced gender.

B. The condition is associated with clinically significant distress or impairment in social, school or other important areas of functioning.

Qualified Behavioral Health Provider:

- Recommended minimum credentials for behavioral health providers working with adults presenting with gender dysphoria (World Professional Association for Transgender Health [WPATH] Guidelines, version 7, 2012):
  - A minimum of a master's degree or its equivalent in a clinical behavioral science field. This degree should be granted by an institution accredited by the appropriate national or regional accrediting board. The behavioral health provider should have documented credentials from a relevant licensing board;
  - Competence in using the current version of the Diagnostic Statistical Manual of Mental Disorders (DSM) and/or the International Classification of Diseases (ICD) for assessment and diagnostic purposes;
  - Ability to recognize and diagnose coexisting mental health concerns and to distinguish these from gender dysphoria;
  - Documented supervised training and competence in psychotherapy or counseling;
  - Knowledgeable about gender nonconforming identities and expressions, and the evaluation and treatment of gender dysphoria;
  - Continuing education in the assessment and treatment of gender dysphoria;
  - Develop and maintain cultural competence to facilitate their work with transsexual, transgender, and gender nonconforming clients.

- Recommended minimum credentials for behavioral health providers working with children or adolescents presenting with gender dysphoria (WPATH Guidelines, version 7, 2012):
  - Meet the competency requirements for behavioral health providers working with adults, as outlined above;
  - Trained in childhood and adolescent developmental psychopathology;
  - Competent in diagnosing and treating the ordinary problems of children and adolescents.

Applicable Codes

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this policy does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

CPT Code	Description
11950	Subcutaneous injection of filling material (e.g., collagen); 1 cc or less
11951	Subcutaneous injection of filling material (e.g., collagen); 1.1 to 5.0 cc
11952	Subcutaneous injection of filling material (e.g., collagen); 5.1 to 10.0 cc
11954	Subcutaneous injection of filling material (e.g., collagen); over 10.0 cc
14000	Adjacent tissue transfer or rearrangement, trunk; defect 10 sq cm or less
14001	Adjacent tissue transfer or rearrangement, trunk; defect 10.1 sq cm to 30.0 sq cm
14041	Adjacent tissue transfer or rearrangement, forehead, cheeks, chin, mouth, neck, axillae, genitalia, hands and/or feet; defect 10.1 sq cm to 30.0 sq cm
15734	Muscle, myocutaneous, or fasciocutaneous flap; trunk
15738	Muscle, myocutaneous, or fasciocutaneous flap; lower extremity
15750	Flap; neurovascular pedicle
15757	Free skin flap with microvascular anastomosis
15758	Free fascial flap with microvascular anastomosis
15769	Grafting of autologous soft tissue, other, harvested by direct excision (e.g., fat, dermis, fascia)
15771	Grafting of autologous fat harvested by liposuction technique to trunk, breasts, scalp, arms, and/or legs; 50 cc or less injectate
15772	Grafting of autologous fat harvested by liposuction technique to trunk, breasts, scalp, arms, and/or legs; each additional 50 cc injectate, or part thereof (List separately in addition to code for primary procedure)
15773	Grafting of autologous fat harvested by liposuction technique to face, eyelids, mouth, neck, ears, orbits, genitalia, hands, and/or feet; 25 cc or less injectate
15774	Grafting of autologous fat harvested by liposuction technique to face, eyelids, mouth, neck, ears, orbits, genitalia, hands, and/or feet; each additional 25 cc injectate, or part thereof (List separately in addition to code for primary procedure)
15775	Punch graft for hair transplant; 1 to 15 punch grafts
15776	Punch graft for hair transplant; more than 15 punch grafts
15780	Dermabrasion; total face (e.g., for acne scarring, fine wrinkling, rhytids, general keratosis)
15781	Dermabrasion; segmental, face
15782	Dermabrasion; regional, other than face
15783	Dermabrasion; superficial, any site (e.g., tattoo removal)
15788	Chemical peel, facial; epidermal
15789	Chemical peel, facial; dermal
15792	Chemical peel, nonfacial; epidermal

CPT Code	Description
15793	Chemical peel, nonfacial; dermal
15819	Cervicoplasty
15820	Blepharoplasty, lower eyelid
15821	Blepharoplasty, lower eyelid; with extensive herniated fat pad
15822	Blepharoplasty, upper eyelid
15823	Blepharoplasty, upper eyelid; with excessive skin weighting down lid
15824	Rhytidectomy; forehead
15825	Rhytidectomy; neck with platysmal tightening (platysmal flap, P-flap)
15826	Rhytidectomy; glabellar frown lines
15828	Rhytidectomy; cheek, chin, and neck
15829	Rhytidectomy; superficial musculoaponeurotic system (SMAS) flap
15830	Excision, excessive skin and subcutaneous tissue (includes lipectomy); abdomen, infraumbilical panniculectomy
15832	Excision, excessive skin and subcutaneous tissue (includes lipectomy); thigh
15833	Excision, excessive skin and subcutaneous tissue (includes lipectomy); leg
15834	Excision, excessive skin and subcutaneous tissue (includes lipectomy); hip
15835	Excision, excessive skin and subcutaneous tissue (includes lipectomy); buttock
15836	Excision, excessive skin and subcutaneous tissue (includes lipectomy); arm
15837	Excision, excessive skin and subcutaneous tissue (includes lipectomy); forearm or hand
15838	Excision, excessive skin and subcutaneous tissue (includes lipectomy); submental fat pad
15839	Excision, excessive skin and subcutaneous tissue (includes lipectomy); other area
15847	Excision, excessive skin and subcutaneous tissue (includes lipectomy), abdomen (e.g., abdominoplasty) (includes umbilical transposition and fascial plication) (List separately in addition to code for primary procedure)
15876	Suction assisted lipectomy; head and neck
15877	Suction assisted lipectomy; trunk
15878	Suction assisted lipectomy; upper extremity
15879	Suction assisted lipectomy; lower extremity
17380	Electrolysis epilation, each 30 minutes
17999	Unlisted procedure, skin, mucous membrane and subcutaneous tissue
19303	Mastectomy, simple, complete
19316	Mastopexy
19318	Breast reduction
19325	Breast augmentation with implant
19340	Insertion of breast implant on same day of mastectomy (i.e., immediate)
19342	Insertion or replacement of breast implant on separate day from mastectomy
19350	Nipple/areola reconstruction
21120	Genioplasty; augmentation (autograft, allograft, prosthetic material)
21121	Genioplasty; sliding osteotomy, single piece
21122	Genioplasty; sliding osteotomies, 2 or more osteotomies (e.g., wedge excision or bone wedge reversal for asymmetrical chin)
21123	Genioplasty; sliding, augmentation with interpositional bone grafts (includes obtaining autografts)
21125	Augmentation, mandibular body or angle; prosthetic material

CPT Code	Description
21127	Augmentation, mandibular body or angle; with bone graft, onlay or interpositional (includes obtaining autograft)
21137	Reduction forehead; contouring only
21138	Reduction forehead; contouring and application of prosthetic material or bone graft (includes obtaining autograft)
21139	Reduction forehead; contouring and setback of anterior frontal sinus wall
21172	Reconstruction superior-lateral orbital rim and lower forehead, advancement or alteration, with or without grafts (includes obtaining autografts)
21175	Reconstruction, bifrontal, superior-lateral orbital rims and lower forehead, advancement or alteration (e.g., plagiocephaly, trigonocephaly, brachycephaly), with or without grafts (includes obtaining autografts)
21179	Reconstruction, entire or majority of forehead and/or supraorbital rims; with grafts (allograft or prosthetic material)
21180	Reconstruction, entire or majority of forehead and/or supraorbital rims; with autograft (includes obtaining grafts)
21208	Osteoplasty, facial bones; augmentation (autograft, allograft, or prosthetic implant)
21209	Osteoplasty, facial bones; reduction
21210	Graft, bone; nasal, maxillary or malar areas (includes obtaining graft)
21270	Malar augmentation, prosthetic material
21899	Unlisted procedure, neck or thorax
30400	Rhinoplasty, primary; lateral and alar cartilages and/or elevation of nasal tip
30410	Rhinoplasty, primary; complete, external parts including bony pyramid, lateral and alar cartilages, and/or elevation of nasal tip
30420	Rhinoplasty, primary; including major septal repair
30430	Rhinoplasty, secondary; minor revision (small amount of nasal tip work)
30435	Rhinoplasty, secondary; intermediate revision (bony work with osteotomies)
30450	Rhinoplasty, secondary; major revision (nasal tip work and osteotomies)
31599	Unlisted procedure, larynx
31899	Unlisted procedure, trachea, bronchi
53410	Urethroplasty, 1-stage reconstruction of male anterior urethra
53430	Urethroplasty, reconstruction of female urethra
54125	Amputation of penis; complete
54400	Insertion of penile prosthesis; non-inflatable (semi-rigid)
54401	Insertion of penile prosthesis; inflatable (self-contained)
54405	Insertion of multi-component, inflatable penile prosthesis, including placement of pump, cylinders, and reservoir
54406	Removal of all components of a multi-component, inflatable penile prosthesis without replacement of prosthesis
54408	Repair of component(s) of a multi-component, inflatable penile prosthesis
54410	Removal and replacement of all component(s) of a multi-component, inflatable penile prosthesis at the same operative session
54411	Removal and replacement of all components of a multi-component inflatable penile prosthesis through an infected field at the same operative session, including irrigation and debridement of infected tissue
54415	Removal of non-inflatable (semi-rigid) or inflatable (self-contained) penile prosthesis, without replacement of prosthesis

CPT Code	Description
54416	Removal and replacement of non-inflatable (semi-rigid) or inflatable (self-contained) penile prosthesis at the same operative session
54417	Removal and replacement of non-inflatable (semi-rigid) or inflatable (self-contained) penile prosthesis through an infected field at the same operative session, including irrigation and debridement of infected tissue
54520	Orchiectomy, simple (including subcapsular), with or without testicular prosthesis, scrotal or inguinal approach
54660	Insertion of testicular prosthesis (separate procedure)
54690	Laparoscopy, surgical; orchiectomy
55175	Scrotoplasty; simple
55180	Scrotoplasty; complicated
55970	Intersex surgery; male to female
55980	Intersex surgery; female to male
56625	Vulvectomy simple; complete
56800	Plastic repair of introitus
56805	Clitoroplasty for intersex state
57110	Vaginectomy, complete removal of vaginal wall;
57335	Vaginoplasty for intersex state
58150	Total abdominal hysterectomy (corpus and cervix), with or without removal of tube(s), with or without removal of ovary(s)
58180	Supracervical abdominal hysterectomy (subtotal hysterectomy), with or without removal of tube(s), with or without removal of ovary(s)
58260	Vaginal hysterectomy, for uterus 250 g or less
58262	Vaginal hysterectomy, for uterus 250 g or less; with removal of tube(s), and/or ovary(s)
58290	Vaginal hysterectomy, for uterus greater than 250 g
58291	Vaginal hysterectomy, for uterus greater than 250 g; with removal of tube(s) and/or ovary(s)
58541	Laparoscopy, surgical, supracervical hysterectomy, for uterus 250 g or less
58542	Laparoscopy, surgical, supracervical hysterectomy, for uterus 250 g or less; with removal of tube(s) and/or ovary(s)
58543	Laparoscopy, surgical, supracervical hysterectomy, for uterus greater than 250 g
58544	Laparoscopy, surgical, supracervical hysterectomy, for uterus greater than 250 g; with removal of tube(s) and/or ovary(s)
58550	Laparoscopy, surgical, with vaginal hysterectomy, for uterus 250 g or less
58552	Laparoscopy, surgical, with vaginal hysterectomy, for uterus 250 g or less; with removal of tube(s) and/or ovary(s)
58553	Laparoscopy, surgical, with vaginal hysterectomy, for uterus greater than 250 g
58554	Laparoscopy, surgical, with vaginal hysterectomy, for uterus greater than 250 g; with removal of tube(s) and/or ovary(s)
58570	Laparoscopy, surgical, with total hysterectomy, for uterus 250 g or less
58571	Laparoscopy, surgical, with total hysterectomy, for uterus 250 g or less; with removal of tube(s) and/or ovary(s)
58572	Laparoscopy, surgical, with total hysterectomy, for uterus greater than 250 g
58573	Laparoscopy, surgical, with total hysterectomy, for uterus greater than 250 g; with removal of tube(s) and/or ovary(s)

CPT Code	Description
58661	Laparoscopy, surgical; with removal of adnexal structures (partial or total oophorectomy and/or salpingectomy)
58720	Salpingo-oophorectomy, complete or partial, unilateral or bilateral (separate procedure)
58940	Oophorectomy, partial or total, unilateral or bilateral
64856	Suture of major peripheral nerve, arm or leg, except sciatic; including transposition
64892	Nerve graft (includes obtaining graft), single strand, arm or leg; up to 4 cm length
64896	Nerve graft (includes obtaining graft), multiple strands (cable), hand or foot; more than 4 cm length
67900	Repair of brow ptosis (supraciliary, mid-forehead or coronal approach)
92507	Treatment of speech, language, voice, communication, and/or auditory processing disorder; individual
92508	Treatment of speech, language, voice, communication, and/or auditory processing disorder; group, 2 or more individuals

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Diagnosis Code	Description
F64.0	Transsexualism
F64.1	Dual role transvestism
F64.2	Gender identity disorder of childhood
F64.8	Other gender identity disorders
F64.9	Gender identity disorder, unspecified
Z87.890	Personal history of sex reassignment

Description of Services

Gender Dysphoria is a condition in which there is a marked incongruence between an individual's experienced/expressed /alternative gender and assigned gender (DSM-5). Treatment options include behavioral therapy, psychotherapy, hormone therapy, and surgery for gender transformation. Surgical treatments for Gender Dysphoria may include the following: clitoroplasty, hysterectomy, labiaplasty, mastectomy, orchiectomy, penectomy, phalloplasty or metoidioplasty (alternative to phalloplasty), placement of testicular and/or penile prostheses, salpingo-oophorectomy, scrotoplasty, urethroplasty, urethroplasty, vaginectomy, vaginoplasty and vulvectomy.

Other terms used to describe surgery for Gender Dysphoria include sex transformation surgery, sex change, sex reversal, gender change, transsexual surgery, transgender surgery, and sex reassignment.

Benefit Considerations

Coverage Information

Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service.

This medical policy does not apply to self-funded and fully insured group policies in California. Refer to the Benefit Interpretation Policy titled Gender Dysphoria (Gender Identity Disorder) Treatment: CA.

Unless otherwise specified, if a plan covers treatment for Gender Dysphoria, coverage includes psychotherapy, cross-sex hormone therapy, puberty suppressing medications and laboratory testing to monitor the safety of hormone therapy. This benefit also includes certain surgical treatments listed in the Coverage Rationale section. Refer to the Drug Policy titled Gonadotropin Releasing Hormone Analogs.

Limitations and Exclusions

Certain treatments and services are not covered. Examples include, but are not limited to:

- Treatment received outside of the United States
- Reproduction services, including, but not limited to, sperm preservation in advance of hormone treatment or Gender Dysphoria surgery, cryopreservation of fertilized embryos, oocyte preservation, surrogate parenting, donor eggs, donor sperm and host uterus (see the Reproduction exclusion in the member specific benefit plan document)
- Transportation, meals, lodging or similar expenses
- Cosmetic procedures (refer to the Coverage Determination Guideline titled Cosmetic and Reconstructive Procedures and the Coverage Rationale section). See below for additional information on New York fully insured group policies.
- Reversal of genital surgery or reversal of surgery to revise secondary sex characteristics

Coverage does not apply to members who do not meet the indications listed in the Coverage Rationale section above.

For Fully Insured Group Policies in New York Only

Certain ancillary procedures may be considered cosmetic and not medically necessary when performed as part of surgical treatment for Gender Dysphoria. Clinical review for medical necessity of ancillary procedures is conducted on a case-by-case basis.

Clinical Evidence

Scandurra et al. (2019) performed a systematic review assessing the health of nonbinary and genderqueer (NBGQ) individuals compared to binary transgender (BT) and cisgender individuals. Eleven studies were included in the review. Results related to the difference in health between NBGQ and BT were mixed, with some finding a better health status while others a worse one. Results related to the differences in health between NBGQ and cisgender individuals highlighted higher health needs in NBGQ individuals compared with cisgender counterparts. The authors noted the need for research expansion in terms of both methodology and research contents.

Wernick et al. (2019) conducted a systematic review of the psychological benefits of gender-affirming surgery. Thirty-three studies were included in the analysis. Overall, most of the studies comparing pre- and post-operative data on quality of life, body image/satisfaction, and overall psychological functioning among individuals with gender dysphoria suggested that gender-affirming surgery leads to multiple, significant psychological benefits. Of the studies comparing psychological well-being between individuals who did or did not undergo surgery, most demonstrated a trend of better mental health among individuals who underwent surgery compared with those who did not. The authors encouraged future research to focus on standardizing the assessment of psychological functioning pre- and post-gender-affirming surgery to gather longitudinal data that will allow for more definitive conclusions to be made about factors that contribute to the psychological benefits of surgery.

Cohen et al. (2019) conducted a systematic review of surgical options and associated outcomes for transmasculine top surgery. Twenty-two studies were included (n=2447). The authors reported that future research is needed to improve patient selection, surgical decision making, and patient-reported outcomes for different chest contouring techniques.

Mahfouda et al. (2019) conducted a systematic review of the available published evidence on gender-affirming cross-sex hormone (CSH) and surgical interventions in transgender children and adolescents, amalgamating findings on mental health outcomes, cognitive and physical effects, side-effects, and safety variables. The small amount of available data suggest that when clearly indicated in accordance with international guidelines, gender-affirming CSHs and chest wall masculinization in transgender males are associated with improvements in mental health and quality of life. Evidence regarding surgical vaginoplasty in transgender females younger than age 18 years remains extremely scarce and conclusions cannot yet be drawn regarding its risks and benefits in this age group. Further research on an international scale is urgently warranted to clarify long-term outcomes on psychological functioning and safety.

Dreher et al. (2018) conducted a systematic review and meta-analysis to evaluate the epidemiology, presentation, management, and outcomes of neovaginal complications in the MtF transgender reassignment surgery patients. Selected studies reported on 1,684 patients with an overall complication rate of 32.5% and a reoperation rate of 21.7% for non-esthetic reasons. The most common complication was stenosis of the neo-meatus (14.4%). Wound infection was associated with an increased risk of all

tissue-healing complications. Use of sacrospinous ligament fixation (SSL) was associated with a significantly decreased risk of prolapse of the neovagina. The authors concluded that gender-affirmation surgery is important in the treatment of gender dysphoric patients, but there is a high complication rate in the reported literature. Variability in technique and complication reporting standards makes it difficult to assess the accurately the current state of MtF gender reassignment surgery. Further research and implementation of standards is necessary to improve patient outcomes.

Manrique et al (2018) conducted a systematic review of retrospective studies on the outcomes of MtF vaginoplasty to minimize surgical complications and improve patient outcomes for transgender patients. Forty-six studies met the authors eligibility criteria. A total of 3716 cases were analyzed. The results showed the overall incidence of complications as follows: 2% fistula, 14% stenosis and strictures, 1% tissue necrosis, and 4% prolapse. Patient-reported outcomes included a satisfaction rate of 93% with overall results, 87% with functional outcomes, and 90% with esthetic outcomes. Ability to have orgasm was reported in 70% of patients. The regret rate was 1%. The authors concluded that multiple surgical techniques have demonstrated safe and reliable means of MtF vaginoplasty with low overall complication rates and with a significant improvement in the patient's quality of life. Studies using different techniques in a similar population and standardized patient-reported outcomes are required to further analyze outcomes among the different procedures and to establish best-practice guidelines.

Van Damme et al. (2017) conducted a systematic review of the effectiveness of pitch-raising surgery performed in MtF transsexuals. Twenty studies were included: eight using cricothyroid approximation, six using anterior glottal web formation and six using other surgery types or a combination of surgical techniques. A substantial rise in postoperative frequency was identified. The majority of patients seemed satisfied with the outcome. However, none of the studies used a control group and randomization process. Further investigation regarding long-term results using a stronger study design is necessary.

Gaither et al. (2017) retrospectively reviewed the records of 330 MtF patients from 2011 to 2015, to assess surgical complications related to primary penile inversion vaginoplasty. Complications included granulation tissue, vaginal pain, wound separation, labial asymmetry, vaginal stenosis, fistula formation, urinary symptoms including spraying stream or dribbling, infection, vaginal fissure or vaginal bleeding. Median age at surgery was 35 years, and median follow-up in all patients was 3 months. The results showed that 95 of the patients presented with a postoperative complication with the median time to a complication being 4.4 months. Rectoneovaginal fistulas developed in 3 patients, and 30 patients required a second operation. Age, body mass index and hormone replacement therapy were not associated with complications. The authors concluded that penile inversion vaginoplasty is a relatively safe procedure. Most complications due to this surgery develop within the first 4 months postoperatively. Age, body mass index and hormone replacement therapy are not associated with complications and, thus, they should not dictate the timing of surgery.

An ECRI special report systematically reviewed the clinical literature to assess the efficacy of treatments for gender dysphoria. The authors identified limited evidence from mostly low-quality retrospective studies. Evidence on gender reassignment surgery was mostly limited to evaluations of MtF individuals undergoing vaginoplasty, facial feminization surgery and breast augmentation. Outcomes included mortality, patient satisfaction, physical well-being, psychological-related outcomes, quality of life, sexual-related outcomes, suicide and adverse events. Concluding remarks included the need for standardized protocols and prospective studies using standardized measures for correct interpretation and comparability of data (ECRI, 2016).

Morrison et al. (2016) conducted a systematic review of the facial feminization surgery literature. Fifteen studies were included, all of which were either retrospective or case series/reports. The studies covered a variety of facial feminization procedures. A total of 1121 patients underwent facial feminization surgery, with seven complications reported, although many studies did not explicitly comment on complications. Satisfaction was high, although most studies did not use validated or quantified approaches to address satisfaction. The authors noted that further studies are needed to better compare different techniques to more robustly establish best practices. Prospective studies and patient-reported outcomes are needed to establish quality of life outcomes for patients.

Frey et al. (2016) conducted a systematic review of metoidioplasty and radial forearm flap phalloplasty (RFFP) in FtM transgender genital reconstruction. Eighteen studies were included: 7 for metoidioplasty and 11 for RFFP. The quality of evidence was low to very low for all included studies. In studies examining metoidioplasty, the average study size and length of follow-up were 54 patients and 4.6 years, respectively (1 study did not report [NR]). Eighty-eight percent underwent a single-stage reconstruction, 87% reported an aesthetic neophallus (3 NR) and 100% reported erogenous sensation (2 NR). Fifty-one percent of patients reported successful intercourse (3 NR) and 89% of patients achieved standing micturition (3 NR). In studies examining RFFP, the average study size and follow-up were 60.4 patients and 6.23 years, respectively (6 NR). No patients

underwent single-stage reconstructions (8 NR). Seventy percent of patients reported a satisfactorily aesthetic neophallus (4 NR) and 69% reported erogenous sensation (6 NR). Forty-three percent reported successful penetration of partner during intercourse (6 NR) and 89% achieved standing micturition (6 NR). Compared with RFFP, metoidioplasty was significantly more likely to be completed in a single stage, have an aesthetic result, maintain erogenous sensation, achieve standing micturition and have a lower overall complication rate. The authors reported that, although the current literature suggests that metoidioplasty is more likely to yield an "ideal" neophallus compared with RFFP, any conclusion is severely limited by the low quality of available evidence.

Using a retrospective chart review, Buncamper et al. (2016) assessed surgical outcome after penile inversion vaginoplasty. Outcome measures were intraoperative and postoperative complications, reoperations, secondary surgical procedures and possible risk factors. Of 475 patients who underwent the procedure, 405 did not have additional full-thickness skin grafts while 70 did have grafts. Median follow-up was 7.8 years. The most frequently observed intraoperative complication was rectal injury (2.3 percent). Short-term postoperative bleeding that required transfusion (4.8 percent), reoperation (1.5 percent) or both (0.4 percent) occurred in some cases. Major complications were three (0.6 percent) rectoneovaginal fistulas, which were successfully treated. Revision vaginoplasty was performed in 14 patients (2.9 percent). Comorbid diabetes was associated with a higher risk of local infection, and use of psychotropic medication predisposed to postoperative urinary retention. Successful vaginal construction without the need for secondary functional reoperations was achieved in the majority of patients.

Bouman et al. (2016) prospectively assessed surgical outcomes of primary total laparoscopic sigmoid vaginoplasty in 42 transgender women with penoscrotal hypoplasia. Mean follow-up time was 3.2 ± 2.1 years. The mean operative duration was 210 ± 44 minutes. There were no conversions to laparotomy. One rectal perforation was recognized during surgery and immediately oversewn without long-term consequences. The mean length of hospitalization was 5.7 ± 1.1 days. One patient died as a result of an extended-spectrum beta-lactamase-positive necrotizing fasciitis leading to septic shock, with multiorgan failure. Direct postoperative complications that needed laparoscopic reoperation occurred in three cases (7.1 percent). In seven cases (17.1 percent), long-term complications needed a secondary correction. After 1 year, all patients had a functional neovagina with a mean depth of 16.3 ± 1.5 cm.

Despite the significant increase in genital gender affirming surgery (GAS) within the past 50 years, there is limited data regarding hair removal practices in preparation for genital GAS. Genital gender affirming surgery (GAS) involves reconstruction of the genitals to match a patient's identified sex. The use of hair-bearing flaps in this procedure may result in postoperative intra-vaginal and intra-urethral hair growth and associated complications, including lower satisfaction with genital GAS. In 2016 Zhang et al conducted a literature review, recommendations from experience, and a practical laser hair removal (LHR) approach to hair removal prior to genital GAS.

Horbach et al. (2015) conducted a systematic review of vaginoplasty techniques in MtF individuals with gender dysphoria. Twenty-six studies were included (mostly retrospective case series of low to intermediate quality). Outcome of the penile skin inversion technique was reported in 1,461 patients and bowel vaginoplasty in 102 patients. Neovaginal stenosis was the most frequent complication in both techniques. Sexual function and patient satisfaction were overall acceptable, but many different outcome measures were used. Quality of life was only reported in one study. Comparison between techniques was difficult due to the lack of standardization. The authors concluded that the penile skin inversion technique is the most researched surgical procedure. Outcome of bowel vaginoplasty has been reported less frequently but does not seem to be inferior. The available literature is heterogeneous in patient groups, surgical procedure, outcome measurement tools and follow-up. There is a need for prospective studies with standardized surgical procedures, larger patient groups and longer follow-up periods. Uniformity in outcome measurement tools such as validated questionnaires and scores for sexual function and quality of life is mandatory for correct interpretation and comparability of data.

A Hayes report concluded that, overall, the quality of the evidence on gender reassignment surgery for gender dysphoria was very low (Hayes, 2014; updated 2020). The evidence suggests positive benefits, but because of serious limitations, permits only weak conclusions. Limitations include small sample sizes, retrospective data, lack of randomization and control and a lack of objective and validated outcome measures.

- Patients who underwent chest/breast or genital surgery were generally pleased with the aesthetic results.
- Following gender reassignment surgery, patients reported decreased gender dysphoria, depression and anxiety and increased quality of life.
- The majority of gender reassignment surgery patients were sexually active, but the ability to orgasm varied across studies.
- Complications of surgery following gender reassignment surgery were common and could be serious.

- Rates of regret of surgery and suicide were very low following gender reassignment surgery.
- Data were too sparse to draw conclusions regarding whether gender reassignment surgery conferred additional benefits to hormone therapy alone.
- Data were too sparse to draw conclusions regarding whether outcomes vary according to which surgeries were performed.

Bouman et al. (2014) conducted a systematic review of surgical techniques and clinical outcomes of intestinal vaginoplasty. Twenty-one studies were included (n=894). All studies had a retrospective design and were of low quality. Prevalence and severity of procedure-related complications were low. The main postoperative complication was introital stenosis, necessitating surgical correction in 4.1% of sigmoid-derived and 1.2% of ileum-derived vaginoplasties. Neither diversion colitis nor cancer was reported. Sexual satisfaction rate was high, but standardized questionnaires were rarely used. Quality of life was not reported. The authors concluded that prospective studies, using standardized measures and questionnaires, are warranted to assess functional outcomes and quality of life.

Djordjevic et al. (2013) evaluated 207 patients who underwent single-stage metoidioplasty, comparing two different surgical techniques of urethral lengthening. The procedure included lengthening and straightening of the clitoris, urethral reconstruction and scrotoplasty with implantation of testicular prostheses. Buccal mucosa graft was used in all cases for dorsal urethral plate formation and joined with one of the two different flaps: longitudinal dorsal clitoral skin flap (n=49) (group 1) and labia minora flap (n=158) (group 2). The median follow-up was 39 months. The total length of reconstructed urethra ranged from 9.1 to 12.3 cm in group 1 and from 9.4 to 14.2 cm in group 2. Voiding while standing was significantly better in group 2 (93%) than in group 1 (87.82%). Urethral fistula occurred in 16 patients in both groups. Overall satisfaction was noted in 193 patients. The authors concluded that combined buccal mucosa graft and labia minora flap was the method of choice for urethroplasty in metoidioplasty, minimizing postoperative complications.

In a non-randomized study, Dhejne et al. (2011) evaluated mortality, morbidity and criminal rates after gender reassignment surgery in 324 individuals (MtF n=191; FtM n=133). Random population controls (10:1) were matched by birth year and birth sex or reassigned final sex. The authors reported substantially higher rates of overall mortality, death from cardiovascular disease and suicide, suicide attempts and psychiatric hospitalizations in sex-reassigned individuals (both MtF/FtM) compared to a healthy control population. FtMs had a higher risk for criminal convictions.

Murad et al. (2010) conducted a systematic review to evaluate the effects of hormone therapy on patients undergoing gender reassignment surgery. The authors identified 28 eligible studies, all of which were observational and most lacked controls. These studies enrolled 1833 participants with gender dysphoria (1093 MtF; 801 FtM). After gender reassignment surgery, individuals reported improvement in gender dysphoria (80%), psychological symptoms (78%), sexual function (72%) and quality of life (80%). The authors concluded that very low quality evidence suggests that gender reassignment, that includes hormonal interventions, is likely to improve gender dysphoria, psychological functioning and comorbidities, sexual function and overall quality of life.

Sutcliffe et al. (2009) systematically reviewed five individual procedures for MtF gender reassignment surgery: clitoroplasty, labiaplasty, orchiectomy, penectomy and vaginoplasty. Further evaluations were made of eight surgical procedures for FtM gender reassignment surgery: hysterectomy, mastectomy, metoidioplasty, phalloplasty, salpingo-oophorectomy, scrotoplasty/placement of testicular prostheses, urethroplasty and vaginectomy. Eighty-two published studies (38 MtF; 44 FtM) were included in the review. For MtF procedures, the authors found no evidence that met the inclusion criteria concerning labiaplasty, penectomy or orchiectomy. A large amount of evidence was available concerning vaginoplasty and clitoroplasty procedures. The authors reported that the evidence concerning gender reassignment surgery in both MtF and FtM individuals with gender dysphoria has several limitations including lack of controlled studies, lack of prospective data, high loss to follow-up and lack of validated assessment measures. Some satisfactory outcomes were reported, but the magnitude of benefit and harm for individual surgical procedures cannot be estimated accurately using the current available evidence.

World Professional Association for Transgender Health (WPATH)

WPATH, formerly known as the Harry Benjamin International Gender Dysphoria Association, is an advocacy group devoted to transgender health. WPATH guidelines (2012) present eligibility and readiness criteria for transition-related treatment, as well as competencies of health care providers.

WPATH describes the transition from one gender to another in the following three stages:

- Living in the gender role consistent with gender identity

- The use of cross-sex hormone therapy after living in the new gender role for a least three months
- Gender-affirmation surgery after living in the new gender role and using hormonal therapy for at least 12 months

Clinical Practice Guidelines

American Academy of Pediatrics (AAP)

In a 2018 policy statement entitled Ensuring Comprehensive Care and Support for Transgender and Gender- Diverse Children and Adolescents, the AAP states the following regarding surgery: Surgical approaches may be used to feminize or masculinize features, such as hair distribution, chest, or genitalia, and may include removal of internal organs, such as ovaries or the uterus (affecting fertility). These changes are irreversible. Although current protocols typically reserve surgical interventions for adults, they are occasionally pursued during adolescence on a case-by case basis, considering the necessity and benefit to the adolescent's overall health and often including multidisciplinary input from medical, mental health, and surgical providers as well as from the adolescent and family.

American College of Obstetrics and Gynecology (ACOG)

An ACOG committee opinion (2017; reaffirmed 2020) provides guidance on health care for transgender adolescents. The document makes the following recommendations regarding surgery:

- Obstetrician-gynecologists should understand gender identity and be able to treat transgender patients or refer them appropriately for medical and surgical therapeutic options.
- Surgical management for transgender male patients is typically reserved for patients 18 years and older.
- For transgender male patients, phalloplasty may be performed when the patient reaches the age of majority.
- Transgender female patients who choose to undergo surgery for a neovagina may have vaginoplasty after the age of majority.
- Transgender patients should be counseled about fertility and fertility preservation prior to surgical treatment.

A separate ACOG committee opinion (2011; reaffirmed 2019) provides guidance on health care for transgender individuals. The document makes the following recommendations regarding surgery:

- Obstetrician-gynecologists should assist or refer transgender individuals for routine treatment and screening as well as hormonal and surgical therapies.
- Hormonal and surgical therapies should be managed in consultation with health care providers with expertise in specialized care and treatment of transgender persons.

Endocrine Society

Endocrine Society practice guidelines (Hembree et al., 2017) addressing endocrine treatment of gender-dysphoric/ gender-incongruent persons makes the following recommendations regarding surgery for sex reassignment and gender confirmation:

- Suggest that clinicians delay gender-affirming genital surgery involving gonadectomy and/or hysterectomy until the patient is at least 18 years old or legal age of majority in his or her country (Recommendation based on low quality evidence).
- A patient pursue genital gender-affirming surgery only after the mental health practitioner (MHP) and the clinician responsible for endocrine transition therapy both agree that surgery is medically necessary and would benefit the patient's overall health and/or well-being (Strong recommendation based on low quality evidence).
- Surgery is recommended only after completion of at least one year of consistent and compliant hormone treatment unless hormone therapy is not desired or medically contraindicated (Ungraded Good Practice Statement).
- The physician responsible for endocrine treatment medically clears individual for surgery and collaborates with the surgeon regarding hormone use during and after surgery (Ungraded Good Practice Statement).
- Recommend that clinicians refer hormone treated transgender individuals for genital surgery when (Strong recommendation based on very low quality evidence):
  - The individual has had a satisfactory social role change
  - The individual is satisfied about the hormonal effects
  - The individual desires definitive surgical changes
- Suggest that clinicians determine the timing of breast surgery for transgender males based upon the physical and mental health status of the individual. There is insufficient evidence to recommend a specific age requirement (Recommendation based on very low quality evidence)

U.S. Food and Drug Administration (FDA)

This section is to be used for informational purposes only. FDA approval alone is not a basis for coverage.

Gender transformation surgeries are procedures, and therefore, not subject to FDA regulation. However, medical devices, drugs, biologics, or tests used as a part of these procedures may be subject to FDA regulation. See the following website to search by product name. Available at: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm. (Accessed August 12, 2020)

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Policy History/Revision Information

Date	Summary of Changes
04/26/2021	Template Update • Replaced content sub-heading titled “Professional Societies” with “Clinical Practice Guidelines” in *Clinical Evidence* section • Removed *CMS* section • Replaced reference to “MCG™ Care Guidelines” with “InterQual® criteria” in *Instructions for Use*
04/01/2021	Coverage Rationale • Added notation to indicate this Medical Policy does not apply to self-funded and fully insured group policies in California; refer to the California-specific Benefit Interpretation Policy titled *Gender Dysphoria (Gender Identity Disorder) Treatment* Supporting Information

Date	Summary of Changes
	• Archived previous policy version 2021T0580i

Instructions for Use

This Medical Policy provides assistance in interpreting UnitedHealthcare standard benefit plans. When deciding coverage, the member specific benefit plan document must be referenced as the terms of the member specific benefit plan may differ from the standard plan. In the event of a conflict, the member specific benefit plan document governs. Before using this policy, please check the member specific benefit plan document and any applicable federal or state mandates. UnitedHealthcare reserves the right to modify its Policies and Guidelines as necessary. This Medical Policy is provided for informational purposes. It does not constitute medical advice.

This Medical Policy may also be applied to Medicare Advantage plans in certain instances. In the absence of a Medicare National Coverage Determination (NCD), Local Coverage Determination (LCD), or other Medicare coverage guidance, CMS allows a Medicare Advantage Organization (MAO) to create its own coverage determinations, using objective evidence-based rationale relying on authoritative evidence (Medicare IOM Pub. No. 100-16, Ch. 4, §90.5).

UnitedHealthcare may also use tools developed by third parties, such as the InterQual® criteria, to assist us in administering health benefits. UnitedHealthcare Medical Policies are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice.

EXHIBIT 13

TRANSGENDER "TRANSITION" PROCEDURES PERFORMED ON MINORS
ANSWERS TO QUESTIONS AND INFORMATION FOR JOINT INTERIM COMMITTEE

Submitted by Rep. Rex P. Shipp

June 10, 2021

Part I - Evaluating the scope of the challenge

1. What is biological sex dysphoria?

Biological sex dysphoria is the feeling of discomfort or distress that might occur in people whose gender identity differs from their biological sex or sex-related physical characteristics.

"The medical diagnosis is gender dysphoria. A biological male feeling and believing himself to be a girl and the distress that accompanies these feelings and beliefs is an example of gender dysphoria (previously known as gender identity disorder).

There are billions of neurons that make the brain. Neurons are very specialized cells that transmit and store information. The control center, if you will, of every cell in the body is the nucleus, which contains DNA. The DNA is wound up into specialized units called chromosomes. There are 46 chromosomes in every human cell. Two of these are specialized chromosomes called sex chromosomes. Assuming normal development, females have two X chromosomes, and males have one X and one Y chromosome. These sex chromosomes are present in every cell in the body. They remain in the cells from conception until death and do not change." Michael K. Laidlaw, M.D.

Historically, biological sex dysphoria primarily affected a very small percentage of biologically male children who were first diagnosed at a very young age (generally, under the age of five). More recently, however, a growing number of pre-teen and early teen females (primarily) are experiencing what has come to be called Rapid Onset Gender Dysphoria (ROGD).

"In my clinical practice I find that social media, internet exposure to pornography, and childhood sexual abuse are often contributing factors to ROGD in my clients ages 10-13. For my client base, the "coming out" is linked to access to the internet or getting their own cell phone where when they google "feeling uncomfortable about your body" google will tell you all about gender dysphoria and being transgender. Other factors can include undiagnosed autistic spectrum and other learning disabilities causing social anxiety." Sheri Golden, Ph.D.

A distraction frequently raised in the context of this issue is the tiny percentage of people who suffer from disorders of sexual development (DSD), sometimes referred to as an intersex condition. Those in whom sexual anatomy is ambiguous or clearly conflicts with their chromosomal make-up are rare, estimated by one expert as "occurring in fewer than 2 out of every 10,000 live births." The vast majority of "transgender" individuals are not "intersexed."

Any proposed legislation would be carefully written and should not inhibit the normal and traditional treatment of these chromosomal birth defects.

2. How many Utah children experience biological sex dysphoria or Utah adolescents experience rapid onset gender dysphoria?

There are no medical records available that would show how many children see pediatricians because their parents express concerns about any gender confusion their child might be experiencing. Nor are there records that would show how many who do so are advised that that ambiguity in gender expression or feelings is fairly common in children, and that the wisest course is "watchful waiting" because the feelings will resolve themselves in most cases. Nor are there records that would show how many parents have concerns but never report those concerns to anyone. Even if records were available, it still would be particularly difficult to establish or estimate a number because a child's gender expression or emotional feelings about his or her biological gender are not fixed and can change over time.

Rapid onset gender dysphoria in teens is unquestionably a social phenomenon. Often driven by social media and the need to be noticed or to be "trendy," teens sometimes identify as a sexual or gender minority for a season. However, we have no research studies to follow how this changes over time. This very fluidity in identity is a fundamental feature of adolescence and illustrates the dangers of making life decisions based on what could well be a temporary enthrallment.

Reliable research on sexual or gender issues in children and adolescents – particularly in individual states like Utah – is essentially nonexistent. Further, identifying randomly selected subjects, employing reliable and reasonably accurate survey methodology, and following the research subjects over time would be extraordinarily difficult. In addition, for a number of reasons, an attempted survey of even a large sample of school-age children and adolescents could easily yield inaccurate or misleading results in either direction. Voluntary response rates would vary and likely would be considerably less than 100 percent even among the survey sample population, for reasons ranging from individual reluctance to parental objection.

We do know from other evidence (e.g. *Examining Health Outcomes for People Who Are Transgender*, 2019) that there has been an increase in adolescents reporting gender dysphoria of over 1,000 percent in the United States and 4,000 percent in Great Britain over the last decade. Another primary indicator is the number of gender clinics that have begun operation within the last five years. In Utah there has been a five-fold increase in the number of prescriptions for testosterone to girls under the age of 18 in the last five reporting years according to information in the Utah Controlled Substances Database. (As discussed further below, there is no medical reason to administer testosterone to girls; the only possible reason is for gender "transition.")

Evidently, an increasing number of physicians and mental health professionals believe there is money to be made by specializing in this area. New gender clinics are springing up almost overnight. For example, Planned Parenthood is now offering transgender services in the vast majority of its facilities, and has expanding its advertising from its traditional focus on abortion services to include "transgender" pharmaceutical and medical conversion therapies. This indicates that the problem affects a significant number of youth and is increasing.

3. How many Utah children and adolescents are undergoing various forms of "gender affirming" pharmaceutical or medical (surgical) conversion therapies?

Transgender "affirming" processes begin with social transition (changes in name, clothing, public presentation, etc.) and then progress to early pharmaceutical interventions – puberty blocking drugs – to stop normal adolescent development. The next transition phase is administering what are popularly called cross-sex hormones (boys receiving abnormally large doses of estrogen, or girls being injected with large doses of testosterone). The final phase is "sex reassignment" surgeries, in which healthy breasts are removed from females and healthy genitals from males, along with a variety of additional surgical procedures to construct artificial male or female genitalia to "reshape" the body to artificially resemble the body of an opposite-sex individual.

The unregulated nature of these experimental processes and the growing number of unregulated venues where these procedures are available make it impossible to know at what age, in what number, or to what degree gender conversion therapies are taking place in Utah.

a. Puberty blockers:

"Puberty blockers are gonadotropin releasing hormone agonists (GnRHa) which basically chemically castrate either sex at the level of the brain, thus suppressing ("blocking") the formation of either testosterone or estrogen. They are FDA approved for use in precocious (premature) puberty and for treatment of prostate cancer, both being disease states. They are not FDA approved for treatment of gender dysphoria, where their use in otherwise physically healthy minors is experimental, not proven safe, not proven effective, not proven to reduce suicides, and is something to which a minor does not have the competence to consent." Andre Van Mol, M.D.

There are proper medical and FDA-approved uses for puberty blockers with children in certain rare cases such as precocious puberty, idiopathic short stature, endometriosis, or sex hormone-stimulated cancers. (The most common puberty blockers are gonadotropin-releasing hormone agonists (GnRHa) such as Lupron.) The legislation being suggested includes express exceptions for all of the known medical conditions for which these drugs are proper FDA-approved treatment.

"By current protocol, children with gender dysphoria are given these powerful hormones at around age eleven. This is too young for them to understand the implications of what will happen to their minds and bodies. Time is required for maturity of the developing adolescent mind, and hormones play an important role in this development." Michael K. Laidlaw, M.D.

For children experiencing biological sex dysphoria (transgender feelings), there is nothing under current law restricting or limiting physicians, psychiatrists, licensed physician assistants, and even nurse practitioners from prescribing puberty blockers to stop the normal developmental process. Under current law, GnRHa and similar drugs are not controlled substances. There is no mandatory reporting system for prescriptions filled for these drugs.

b. Cross-sex hormones ("masculinizing" or "feminizing" drugs)

By "masculinizing" drugs, we understand the question to refer to administration of testosterone or other androgens to minor females. By "feminizing" drugs, we understand the question to refer to administration of estrogen or compounds with estrogenic effect to minor males.

The next step in "affirming" gender transition of minors for those who first took puberty blockers is the administration of cross-sex hormones. The male hormone testosterone is given to biological females who wish to present themselves as male, in order to give them more masculine physical characteristics (such as facial and body hair and deepening of the voice). The female hormone estrogen is given to biological males who wish to present themselves as female, in order to give them more feminine characteristics such as enlarged breasts. In effect, the cross-sex hormones are used to initiate an artificial partial puberty corresponding to the desired gender identity. In this situation, there may be pressure to start cross-sex hormones at even younger ages, so that the child does not remain in an artificial pre-pubescent state while his or her peers are continuing to develop more adult sexual characteristics.

"*There is no such thing as 'trans puberty.' What happens is that [an] abnormal, pathologic state . . . is induced*." Michael K. Laidlaw, M.D.

Testosterone is a Schedule III controlled substance. (Utah Code Ann. § 58-37-4(2)(c)(vi)(Z).) Consequently, every retail, institutional, and outpatient hospital pharmacy, and every in-state and out-of-state mail order pharmacy, is legally required to report every dispensing of this substance to the Utah Controlled Substance Database (CSD). (Utah Code Ann. § 58-37f-203(3).) The CSD is not accessible by the public. However, we understand from a former legislator who obtained the information from the CSD that more than 550 prescriptions for testosterone issued to minor females were filled in 2019, and that this number is more than a five-fold increase over 5 years before. There is no medical reason to prescribe testosterone to a female other than to facilitate gender "transition."

Estrogen is not a controlled substance, and there is no mandatory reporting system for prescriptions filled for estrogen. Therefore, the number of minor males for whom estrogen was prescribed to facilitate gender "transition" is unknown.

c. Sex reassignment surgeries

"Sex reassignment surgery" is a massive misrepresentation of what these operations actually do. You can't change a person's sex. All that is happening is that the patient is undergoing an intentional mutilation in order to create a counterfeit appearance of the other sex. Nearly 100% of children who are enrolled in "gender clinics" are pushed along from puberty blockers, to wrong sex hormones, to top surgery, and then to bottom surgery, because at each step, the hoped for resolution of their anxiety only finds temporary effect, so the next step is encouraged." Patrick Lappert, M.D.

There are a variety of medical procedures and surgeries that are undertaken in an attempt to make female bodies appear more male, and male bodies to appear more female. Healthy bodies are declared to be "wrong" and are treated as mere material to be mastered and reshaped. These range from the actual removal of healthy breasts and genitals to plastic surgery to construct a more masculine or feminine sounding or appearing body.

"Typically, surgery turning a male into a trans-female involves dissecting the penis, turning the skin inside out, and placing it into a surgically created cavity to create a false vagina. After surgery, a dilator has to be placed in this artificial vagina to keep it from collapsing. Since he still has a small child-sized penis (because of puberty blockers), he does not have enough skin to line the false vagina. Potential remedies include sewing in a section of intestine along with the penis skin to make the false vagina. Once he has surgery to remove his testicles he will be forever infertile, with no chance to produce biological offspring." Michael K. Laidlaw, M.D.

While we have no reporting requirements that would show how many of these various procedures are taking place in Utah, or the age of the patients on whom they are performed, the Internet is replete with the pictures and stories of minor children who have undergone these procedures.

4. How many Utah minors who begin treatment for biological sex dysphoria with puberty blocking drugs subsequently move on to cross-sex hormones and sex reassignment surgeries?

Transgender "affirming" advocates and clinics outline in their publications and websites a step-by-step process that begins with social transitioning, moves to drug and hormone treatment, and concludes with surgical procedures. If one accepts the worldview that an individual can be born as a male with a female brain or as a female with a male brain (*i.e.*, transgender is something you are and not just a dysphoria about biological sex that you experience), then advancing toward becoming your authentic self is the logical goal. Current research from Great

Britain and Sweden suggests that individuals who are socially affirmed in a new transgender identity and begin puberty blockers almost always proceed to cross-sex hormones and surgical transition.

The entire transgender affirming process is so new, so medically experimental, so irreversible in its effects, and so lacking in longitudinal (long term) research that much of the eventual consequences of this socially-driven phenomenon are completely unknown. That is precisely why it is so potentially harmful. Regardless of the number of Utah children affected, be it 5 or 50 or 500, every child and adolescent should be protected from these "adults only" procedures.

5. How are social awareness, population growth, and the evolving understanding of appropriate treatment for gender dysphoria likely to affect the estimates above?

Different parties have vastly different views on what constitutes "appropriate treatment for gender dysphoria." As a nation-wide (and world-wide) social phenomenon, public and even professional awareness is changing rapidly.

We believe the appropriate treatment for children and adolescents is competent and caring counseling by an adept mental health professional. Medical professionals in the United Kingdom, Finland, and most recently Sweden have declared that the permanent, irreversible chemical or surgical damage to the healthy bodies of minors cannot be justified as a wise or sensible approach to what is scientifically a mental health issue. We hope that this growing awareness and Utah's willingness to protect vulnerable children and adolescents will be the foundation for an "evolving understanding of appropriate treatment."

"As a family therapist for over 25 years, as well as educating on gender identity development for nearly 20 years, I have found that when children are confused about their gender, there are usually underlying factors that need to be addressed. Offering to change a child's body, instead of addressing his or her mind, completely ignores the underlying issues. Hormones and amputation of body parts are neither safe, nor effective solutions. However, individual and family therapy (talk therapy) have been shown to be effective with many of these children. Not only is this a safer option, but it addresses the deeper issues." Julie Hamilton, Ph.D., LMFT

Professional perception of what constitutes appropriate treatment for biological sex dysphoria depends primarily on the professional's "worldview" of the issue. Transgenderism is based on the idea that a person can be born into the "wrong body" (*i.e.*, that someone born male can have a "female brain," and vice versa). "Affirming" mental health professionals and physicians accept and advocate that position. Consequently, they favor drug, hormonal, and surgical interventions to try to re-fashion the body to align with internally-perceived gender. However, there is no scientific evidence for this underlying proposition. There is no evidence that there is anything different about a transgender female's brain or body from that of any other male. There is no evidence that there is anything different about a transgender male's brain or body from that of any other female. Persons experiencing biological sex dysphoria are having a

mental or emotional experience—albeit a very painful and difficult and often persistent one—which may arise from any of a number of causes or contributing factors particular to the individual.

It is for this reason that medical professionals are becoming more reluctant to undertake medical procedures on people whose bodies do not present medical issues. Mental health and medical professionals who do not accept transgenderism's underlying assumption—which is an ideological proposition, not a scientific fact or evidence-based scientific hypothesis—believe that these emotional challenges should be addressed through therapeutic counseling procedures.

Part II – Assessing the treatment options

1. **What are the short- and long-term potential benefits and harms of addressing gender dysphoria in minors with medical intervention?**

   a. Puberty blockers:

"Puberty blockers (GnRHa or PB) cause infertility (blocking sperm and egg development) as long as they are used, and their reversibility after discontinuation is not assured. If puberty blockers are followed by cross-sex hormones, sterility is assured. Puberty blockers inhibit and compromise bone density development precisely during life's greatest period of increase for such. This may lead to early osteoporosis. Genitalia are arrested in an underdeveloped stage and sexual dysfunction is also noted (for males: erectile, orgasmic and ejaculatory impairment; for females: a menopausal-like state is induced).

The Lupron package insert warns of mood swings, depression, suicidal ideation and attempts. Brain development milestones are hindered with unknown long-term effects, and the puberty time frame shared with peers is forever sacrificed. Numerous studies show that initiation of puberty blockers selects persistence of gender dysphoria over its natural desistance. Therefore, puberty blockers are not "buying time" or "pause buttons" to "wait and see," but are gateway drugs to cross sex hormones and possible gender reassignment surgery, along with all of their shortcomings.

Their use in otherwise physically healthy minors is experimental, not proven safe, and not proven effective. Thus ruled the United Kingdom's High Court in Bell v Tavistock (Dec 2020), which led to the NHS amending service specifications for Gender Identity Development Services for children and adolescents. Likewise, Sweden's famed Karolinska Hospital issued a similar policy change effective April 1, 2021. Puberty blockade will no longer be allowed for minors under 16, and only under court order (UK) or in a closely monitored clinical trial (Sweden) for those under 18." Andre Van Mol, M.D.

The legislation being suggested includes express exceptions for all of the known medical conditions for which these drugs are the proper FDA-approved treatment. The FDA has not approved use of puberty blockers for treatment of biological sex dysphoria. Use of GnRHa for this purpose is still highly experimental.

Current Utah law does nothing to protect children from physicians, physician assistants, or even nurse practitioners from prescribing these drugs, even though the medical practitioner may have little or no experience or specialty training in the physical or psychological consequences of prescribing these drugs, or knowledge of the current medical research.

Delaying puberty in a child who has confused or dysphoric feelings about his or her biological sex may bring a very temporary perception of relieved stress in delaying physical development that the child thinks he or she does not want, and with which the child is, in the immediate moment, uncomfortable. However, if the confused feelings don't actually represent reality—in other words, if a child with confused feelings has not actually been "born into the wrong body"—prescribing medications can only "mask" or distract from the exploration of underlying problems or sources of the confused feelings.

Transgender activists argue that use of puberty blockers is harmless. They say that their effects are fully reversible if a minor stops taking them. Making any such claims for experimental treatments about which there is little longitudinal medical research is speculative at best and irresponsible at worst. Notably, last year the United Kingdom's National Health Service (NHS) backed away from previous categorical statements that effects of puberty blockers are fully reversible; new NHS statements are much more cautious.

The biggest concern, however, is that in the overwhelming majority of cases, children who are socially transitioned and placed on puberty blockers progress to the next phase of "transition," that is, the administration of cross-sex hormones.

b. Cross-sex hormones

Cross-sex hormones – large doses of feminizing hormones (estrogen) given to biological boys places them at increased risk for blood clots, high triglycerides, cardiovascular disease, high blood pressure, and diabetes. Large doses of masculinizing hormones (testosterone) given to biological girls places them at increased risk for high red blood cells, high cholesterol, cardiovascular disease, high blood pressure, diabetes, and destabilization of certain psychiatric disorders.

The effect of administering cross-sex hormones after puberty blockers is permanent sterilization. A young person who has taken puberty blockers will have already prevented the development of the reproductive system to the point where viable sperm or eggs would be produced in the first place. Indeed, the medical disclosure forms patients or their parents are required to sign before these treatments can proceed emphasize this.

Individuals who have already undergone natural puberty will generally be rendered infertile, at least temporarily, by the administration of cross-sex hormones, which inhibit ovulation in biological females and the production of sperm in biological males. While claims that either puberty blockers or cross-sex hormones alone are "fully reversible" are questionable, the use of both amounts to what some have called "chemical castration."

c. Sex reassignment surgery

It is very important to understand the reality of attempted sex-change surgical procedures. For females, this involves mastectomies, hysterectomies, removal of the ovaries, chest and facial masculinization procedures, and construction of artificial male genitalia from other tissues. For males, attempted sex-change surgery involves orchiectomy (removal of the testes); reduction and reconstruction of the penis to form an artificial clitoris; construction of an artificial vagina and artificial vulva; breast augmentation surgery, and facial feminization procedures. These procedures are irreversible and cause permanent sterilization.

Life-long pharmaceutical treatment and very often repeated medical interventions will be necessary because of the extreme nature of these hormonal and surgical procedures.

"Elective mastectomy to masculinize a young woman's chest (sometimes as young as 13-year-old girls) is the intentional removal of normal tissue in hopes of satisfying a disordered subjective feeling. It cannot be equated to the removal of normal breast tissue in a girl with abnormally large breasts because this latter case is based upon the diagnosis of an orthopedic problem (neck, back, and shoulder pain limiting physical activity). There is an objective medical condition, and 3rd party payment requires reporting of the weights of the specimens in order to confirm the mechanical effects of the weight of the breast, and to distinguish this operation from a cosmetic procedure to make the girl look better. In the case of boys having breast tissue removed, here again we have an objective medical diagnosis of gynecomastia (breast glandular tissue in a boy is not normal).

In the case of transgender masculinization, the diagnosis is subjective, the diagnosis is made by the child, and the doctor has no way of confirming or refuting the diagnosis, and has no way of predicting if the child will benefit. There are no peer reviewed publications to support the procedure, only small studies, typically single center, with massive self-selection bias, and no long term follow up to show benefit. The best studies, which are longitudinal population based studies show that persons who have completed transition surgeries, when followed long term, have a 19-fold higher incidence of completed suicide.

Mastectomy is irreversible. All that can be offered to the ever growing population of females with transition regret is the construction of breast mounds. They will never be able to breast feed (so they have lost a human capacity) and in most cases will have lost erotic sensibility. They will always have large chest scars in most cases." Patrick Lappert, M.D.

Again, there is no medically defensible reason to cut off or mutilate healthy body parts or destroy healthy body functions in response to what is actually an emotional or mental health issue. None of these procedures address the underlying causes of the confused feelings for the individual involved. As with administration of cross-sex hormones, performing these procedures on a minor who does not have the maturity or judgment to make such life-long irreversible decisions for himself or herself is not justifiable.

In short, from a medical perspective, all of these procedures are only harmful and damaging.

The only arguable benefit from this damage is a perception of continued partial relief from distressed and conflicted feelings. How long such perceived relief lasts will vary according to the individual case because the underlying causes of the confused feelings will go unaddressed.

This is especially true for minors, who are at an age at which conflicted emotions on any number of issues are common, and for whom the emotional maturation and developmental processes are not complete. To permanently sterilize a minor at this stage of life, when the minor does not have the maturity and judgment to make the decision for himself or herself, is unjustifiable.

2. What are the short- and long-term potential benefits and harms of addressing gender dysphoria in minors with non-medical (counseling and support) interventions?

Children and adolescents experiencing either biological sex dysphoria or later-occurring rapid onset gender dysphoria are experiencing authentic confusion and distress. Ignoring these genuine symptoms of angst is risky and potentially dangerous. A process of acknowledgement, counseling, evaluation, and support directed by competent mental health professionals is the appropriate approach.

"In young children, for example, parents can be taught how to genuinely "affirm," i.e., learn to recognize their child's innate goodness and communicate their delight in his or her being. In time affirmation by others helps one to affirm oneself as one is, and as one has the potential to be(come). Family and parental therapy may be a tremendous help for enabling parents to affirm their child as s/he is now, even if s/he is discordant about his/her biological sex and how s/he would like to live as a gendered being. Fundamentally, parents can learn to unconditionally love their child." Philip Sutton, Ph.D.

Experiences of biological sex dysphoria in teens are taking place in a developmental season where incidents of childhood trauma, normal identity exploration, peer influence and various emotional conflicts or intellectual misunderstandings (to cite just a few examples) can effect an evolving sense of self. Understanding and evaluating these potential developmental factors requires both time and professional competence. There should be no rush to reach hypothetical and premature psychological conclusions, or to move toward experimental and

dangerous medical interventions which are clearly life-changing and irreversible.

"The research indicates that approximately 90% of dysphoric patients resolve dysphoria by their late 20s. Past peer reviewed research has shown that dysphoria in children can be resolved via psychotherapy, which indicates dysphoria is environmentally based. And yet…many medical doctors and therapists approve of and perform permanent removal of healthy body parts in order to supposedly relieve dysphoria. The research is already showing increased transgender treatment regret in some areas of the world. But the damage to their bodies is permanent in operative cases. Authentic and compassionate psychotherapy treatments must be adopted by our professions." David Pickup, LMFT

Since research clearly demonstrates that a very high percentage of children experiencing biological sex dysphoria will resolve their confusion in favor of their biological sex by the time they reach adulthood, surely a counseling approach makes more sense and does not foreclose "transition" opportunities for adults who eventually pursue a medical option.

3. How should potential harms and benefits be weighed in treatment decisions?

As a matter of general principle, of course, potential harms and benefits should be weighed in any treatment decision. But inherent in that is the imperative necessity of an accurate and truthful understanding, and honest and logical analysis, of the factors involved. In addition, we must consider the ability of children and adolescents to understand these potential harms and benefits and offer truly "informed consent".

"During the past decade, research on neurological maturity shows that the human brain is not finally "mature" until the mid-20's (25 is often given as the average.) It is simply not possible for pre-pubescent and pubescent girls and boys to truly understand the serious short and long-term (life-long) consequences of taking puberty blockers and cross-sex hormones. These boys and girls are simply humanly unable to understand the gravity of such decisions. This is even more true for the amputation of primary and secondary sexual organs. " Philip Sutton, Ph.D.

We must keep the following in mind:

There is no scientific or medical evidence to clearly establish any biological explanation for biological sex dysphoria. We are left to conclude that this is a very real emotional and psychological condition. This is a mental health, not a medical, condition.

Experimental, life-altering pharmaceutical and surgical procedures are a decision to artificially alter the body to meet a mental image the individual may have of himself or herself and to regulate challenging emotions. This process will require life-long medical treatments to force the natural body to accept these synthetically-imposed alterations.

Both a decision to go forward with or to postpone medical "transition" may have emotional consequences. The difference is that children and adolescents who postpone medical interventions and pursue the family and mental health counseling route can always pursue medical interventions as adults should they choose to do so for themselves. Children and adolescents who are permitted by adults to pursue medical transition can never "un-ring the bell." They can never really undo the damage to their body that these procedures will do.

Sadly, parents are sometimes misinformed about the long-term consequences to their children of medical interventions, or receive inadequate support from mental health professionals to assist their children while they pursue a "supportive counseling" approach.

Sometimes parents are misled into believing that a failure to support childhood biological sex transition processes will lead to an increased suicide risk for those they love. They need to know that there is no reliable research to support the idea that these medical transition procedures prevent suicide. While there may be some evidence that biological sex dysphoria increases distress in certain individuals, there is absolutely no research that demonstrates that children who follow a counseling process for their dysphoria are any more suicidal than those who follow a medical transition process. Experts agree that suicide is most likely to be associated with some form of ongoing mental illness.

"Ninety percent of suicides are associated with a psychiatric condition. The risk of suicide coincides of course with the high prevalence of mental illness in this group of people. Depression, for example, is present in at least 50 percent of those who commit suicides." Michael K. Laidlaw, MD

In fact

"Using quotes from the following studies done through NIH/NCBI to answer these concerns.

*'Approximately 58% of transgender patients had at least one DSM-5 diagnosis, most frequently Major Depressive Disorder. (13.6% cisgender) * NIH/NCBI November 2020.' Clearly this is a population at risk and in need of therapeutic counseling and perhaps medication to address these illnesses. Any type of medical transitioning will complicate diagnostic evaluation and treatment. Therefore, rather than reducing suicide risk, medical procedures involving hormone therapy and surgery have the potential to increase the risk because of missed diagnosis and complications of medications.*

*It seems that transitioning in and of itself is does not remove the risk of suicide in this population. As found in the study from *NIH/NCBI June 2020, "Suicide risk in transgender people is higher than in the general population and seems to occur during every stage of transitioning." Therefore the act of transitioning does not prevent the risk of suicide."* Steven Johnson, Ph.D. and Dale Johnson, M.S.

4. **To what extent have long-term outcomes, including physical health, mental health, satisfaction, and regret, been tracked in individuals receiving various treatments for gender dysphoria? What do those studies indicate?**

Again, the entire transgender "affirming" process is so new, so medically experimental, so irreversible in its effects, and lacking in longitudinal (long term) research that much of the eventual consequences of this socially driven phenomenon are completely unknown. That is precisely why it is so potentially harmful and exactly why we should not be preforming these irreversible pharmaceutical and medical conversion therapies on minors.

Part III – Clinical Guidelines

1. **Are the guidelines published by the World Professional Association for Transgender Health and the Endocrine Society and other published information adequate to guide professionals in their care of minors experiencing biological sex dysphoria?**

Twelve years ago a review of more than 100 international medical studies of post-operative transgender patients by the University of Birmingham Aggressive Research Intelligence Facility found "no robust scientific evidence that gender reassignment surgery is clinically effective . . . Research from the US and Holland suggests that up to a fifth of patients regret changing sex."

In regards to children and adolescents there are almost no scientific outcome studies whatsoever.

We must again return to the concern that there has been too little longitudinal research for scientifically-minded organizations to offer authoritative guidelines for either medical or mental health professionals. For example, even when small studies have been conducted, the results are often based on a minority of the participants because, as *The Guardian* newspaper in Great Britain reported, "The results of many gender reassignment studies are unsound because researchers lost track of more than half of the participants. For example, in a five-year study of 727 post-operative transsexuals published, 495 people dropped out for unknown reasons."

Additionally, how do you set medical guidelines without understanding the many psychological conditions that may be affecting the emotional stability of the client? According to one study (*Psychiatric Axis I Comorbidities among Patients with Gender Dysphoria*, 2014) Fifty-seven (62.7%) patients had at least one psychiatric comorbidity. Major depressive disorder (33.7%), specific phobia (20.5%), and adjustment disorder (15.7%) were the three most prevalent disorders. Consistent with most of earlier research, the majority of patients with gender dysphoria had psychiatric Axis I comorbidity.

The Endocrine Society Guidelines published in 2017 advocated for "watchful waiting" as the standard of care for gender dysphoria. The Society noted, "In some forms of Gender dysphoria/ gender incongruence, psychological interventions may be useful and sufficient."

Taking a conservative approach to treatment is justified because, as Professor Kenneth Zucker (of the Toronto Gender Clinic) notes, ". . . the field suffers from a vexing problem: There are no randomized controlled trials of different approaches, so the front-line clinician has to rely on lower-order levels of evidence in deciding on what optimal approach to treatment might be."

The so called "World Professional Association for Transgender Health," or WPATH, is simply a self-selected group individuals who are a political advocacy organization for "affirming" transgender procedures. WPATH is not a scientific or medical organization, and its membership is not restricted to medical or mental health professionals and scientists. No national government or international legal body officially appointed or recognizes WPATH. Nor is it accountable to any recognized body of scientists or medical researchers.

WPATH's views are by no means accepted objective standards, as demonstrated by the policies of the national medical associations in the United Kingdom, Sweden and Norway who oppose pharmaceutical and surgical procedures for children or young adolescents.

In simple terms, organizations who refuse to acknowledge the following concept have a divergent "worldview" that cannot be reconciled with those of us who do:

"Sex as defined by biology and reproductive function cannot be changed. While hormonal and surgical procedures may enable some individuals to "pass" as the opposite gender during some or all of their lives, such procedures carry with them physical, psychological, and social risks, and no procedures can enable an individual to perform the reproductive role of the opposite sex." Stephen B. Levine, M.D.

Part IV – Utah policy

1. **Should any particular treatments for gender dysphoria be limited to adults and emancipated minors? Why or why not?**

For reasons discussed above, cross-sex hormone treatments and surgical interventions for purposes of "transition" or attempted sex change should be limited to adults who have the maturity and judgment (and legal capacity) to make these decisions for themselves. As Stephen B. Levine, M.D. noted in his article published in the Journal of Sex & Marital Therapy, *Informed Consent for Transgendered Patients:*

> All of these patients should be helped by their clinicians to grapple with four relevant questions. Their answers provide the professional with a judgment about how realistic the patient is being:
> 1. What benefits do you expect that the consolidation of this identity, gender transition, hormones, or surgery will provide?

2. What do you understand of the social, educational, vocational, and psychological risks of this identity consolidation and gender role transition?
3. What do you understand about the common and rare, short- and long-term medical and health risks of hormone and surgical interventions?
4. What have you considered the nature of your life will be in 10 to 20 years?

Clearly children and adolescents cannot provide informed consent. The suggested legislation would apply only to procedures performed on minors. Adults are free to choose to undertake these procedures on their own bodies, regardless of whether other individuals personally would agree with that choice.

2. is there statutory, regulatory, or case law you believe the committee should be particularly mindful of?

Yes. In 2019, the Legislature enacted a law prohibiting female genital mutilation on minors (HB 430, Chapter 398 of the 2019 General Session). It was aimed at the practice of genital mutilation of young girls followed in some African Muslim cultures that has found its way to the United States.

Utah Code Ann. § 76-5-701(1) defines "female genital mutilation" comprehensively and with great specificity. Under paragraph (f), it includes "any other actions intended to alter the structure or function of the female genitalia for non-medical reasons." Female-to-male "bottom surgery" certainly alters the structure and function of female genitalia, in addition to involving specific procedures identified in some of the preceding paragraphs of that subsection. Subsection (2) provides that female genital mutilation is child abuse for mandatory reporting purposes under § 62A-4a-403.

Section 76-5-702(1) then makes performing a female genital mutilation on a minor female, giving permission for such a procedure on a minor female, or removing or facilitating the removal of a minor female from the state for the purpose of facilitating such a procedure a second degree felony. Subsection (2) provides that it is not a defense that the practice is required as a matter of religion or custom or that the girl's parent or guardian consented to it. Subsection (3) then provides that a surgical procedure is not a violation of the section defining female genital mutilation if it is necessary for medical reasons or if it is "requested for sex reassignment surgery by the person on whom it is performed."

Under subsection (4), a medical professional who is convicted of a violation will have his or her license revoked. Additionally, section 76-5-704 creates a civil right of action by the victim of female genital mutilation for damages.

Given that these sections apply only to procedures performed on minors, it appears that mutilating a minor girl's genitals as part of surgical "transition" (or consenting to or facilitating

such a procedure for that purpose) is exempt from the criminal sanctions as long as the minor girl requests the procedure.

The exception for sex reassignment surgery was in the bill as originally introduced. We have not been able to find any relevant legislative history regarding that exception. Given the apparent absence of discussion on the issue, it may be that the sponsors were looking at the "sex reassignment surgery" exception as a way to address the rare true "intersex" birth situation for which surgery may be medically appropriate. Or (without any offense to the sponsors or drafters intended) it could be that the provision was not well thought-through in the context of the bill's exclusive application to minors.

As a matter of public policy, it is difficult to understand why performing these procedures, or a parent's consenting to these procedures, is criminalized if it is for reasons of religious conviction, but it's OK if the minor girl is emotionally confused or delusional at the moment.

The version of the suggested legislation considered in the general session earlier this year would not have criminalized performing attempted sex-change surgery on a minor female (assuming the parents consented), but would have defined performing such procedures on a minor as unprofessional conduct that could lead to revoking the medical license of the surgeon performing the procedure. If a measure such as the suggested legislation is enacted, the exemption from criminal prosecution in section 76-5-702(3) could remain unchanged. However, to avoid ambiguity, the legislation should provide specifically for the possibility of professional discipline notwithstanding the exemption from criminal sanction. It should also provide that the private right of action in section 76-5-704 applies and that parental consent is not a defense to a private right of action.

We express appreciation to these noted professionals who contributed to this report:

Chauncey Adams, Ph.D. - Dr. Adams is a Clinical Psychologist with more than thirty years' experience in private practice, served as a psychology consultant in the Washington County school district, and as a the Behavioral Medicine Clinical Director, and former Chair of the Psychiatry Department at the IHC St. George Regional Medical Center. He is a graduate of Brigham Young University, a Member of the American Psychological Association, and a past Board Member of the Utah Psychological Association

Shirley E. Cox, D.S.W. – Dr. Cox has spent many years in private practice and 27 years as a social work educator at Weber State, University of Nevada, Las Vegas, and Brigham Young University. She has received numerous awards for her teaching and community practice including: the Liberal Arts

Outstanding Faculty Award, the Morris Committee on Excellence in Teaching Award, the NASW Nevada Chapter Social Worker of the Year. Her individual and jointly authored publications appear in outlets such as: The Journal of International Social Work and the Journal of Social Work Education.

Michelle Cretella, M.D. - Dr. Cretella received her medical degree from the University of Connecticut School of Medicine and she completed her internship and residency in pediatrics at the Connecticut Children's Medical Center. She practiced pediatrics with a special interest in behavioral health for 15 years and now serves as the Executive Director of the American College of Pediatricians (ACPeds). Dr. Cretella is a peer reviewer for the Journal of American Physicians and Surgeons, Issues in Law and Medicine, and the International Journal of Behavioural and Healthcare Research.

Sheri L. Golden, Ph.D. – Dr. Golden holds a PhD in Counselor Education and Supervision, and an MS in Human Services and Mental Health Counseling, with a specialization in Human Sexuality, from Capella University. Dr. Golden practices as a licensed professional counselor at Steeple Counseling LLC, and is the Director of Counselor Education at The Steeple Institute.

Julie Harren Hamilton, Ph.D. - Dr. Hamilton is a licensed marriage and family therapist with a private practice in south Florida. A graduate of Nova Southeastern University, she is a former Assistant Professor of Psychology in the Graduate Counseling Psychology Department of Palm Beach Atlantic University. She is a former president of the Palm Beach Association for Marriage and Family Therapy.

Geoffrey Heath, J.D., LL.M. – Mr. Heath graduated from the University of Utah, the University of Michigan Law School, and received an LL.M. degree from George Washington University. He is a former supervisory attorney and administrative judge of an Executive department of the Federal government.

Paul W. Hruz, M.D., Ph.D. – Dr. Hruz is an associate professor of pediatrics, endocrinology, and diabetes and an associate professor of cell biology and physiology at Washington University School of Medicine in St. Louis. A graduate of Marquette University, he received both his Ph.D. and his M.D. from the Medical College of Wisconsin.

Dale Johnson, M.S. - Received her undergraduate degree at Salisbury University and received a Master's degree in counseling from Johns Hopkins University. She worked for many years as a school counselor and served as the Department Chair for a staff of 15 where they served over 2000 "high risk" high schools students annually. Dale now acts as a Court Appointed Special Advocate.

Steve Johnson, Ph.D. – Dr. Johnson received his M.A. from the University of Nebraska at Omaha and his Ph.D. at the University of Illinois (dissertation on cognitive dissonance). He is a member of the National Register of Health Service Providers in Psychology and was in private practice in clinical psychology for almost 40 years. During those same years he served as a school psychologist specializing in emotionally and behaviorally disrupted adolescents, conducted cognitive and personality testing, parent and staff training and therapeutic groups. He has taught at George Mason and Western Maryland Universities.

Patrick Lappert, M.D. – Dr. Lappert has been practicing in the field of Plastic Surgery for over 25 years. He completed his undergraduate studies in Biology at the University of California, Santa Barbara, his medical degree at the Uniformed Services University School of Medicine and his general surgery residency at the Naval Hospital Oakland, and is Board Certified in General Surgery. Dr. Lappert completed his Plastic Surgery Residency at the University of Tennessee-Memphis and is Board Certified

by the American Board of Plastic Surgery. He was the former Chief of Plastic Surgery at the largest military hospital in the world (Naval Hospital Portsmouth, VA).

Michael K. Laidlaw, M.D. – Dr. Laidlaw is a board-certified physician in private practice for almost two decades specializing in Endocrinology, Diabetes, and Metabolism. He is a graduate of the University of Southern California School of Medicine, and is a member of the Endocrine Society and the National Board of Physicians and Surgeons.

Stephen B. Levine, M.D. – Dr. Levine earned his M.D. from Case Western Reserve University School of Medicine in and serves as a Clinical Professor of Psychiatry there. His clinical practice is with the University Hospitals of Cleveland Sexual Dysfunction Clinic (presently called The Center for Marital and Sexual Health). He received the Masters and Johnson Lifetime Achievement Award from the Society of Sex Therapy and Research and is a Distinguished Life Fellow of the American Psychiatric Association.

Paul McHugh, M.D. – Dr. McHugh is a psychiatrist, researcher, educator and currently the University Distinguished Service Professor of Psychiatry at the Johns Hopkins University School of Medicine and the author, co-author, or editor of seven books in his field. He graduated from Harvard College and Harvard Medical School. He served as the Chairman of the Department of Psychiatry at the University of Oregon and as the Henry Phipps Professor of Psychiatry and the director of the Department of Psychiatry and Behavioral Science at the Johns Hopkins University. At the same time, he was psychiatrist-in-chief at the Johns Hopkins Hospital.

David H. Pickup, L.M.F.T. – Mr. Pickup holds a Master's Degree in Psychology and is a Doctoral Candidate in Psychology at California Southern University. He is a member of the American Psychological Association and the California Association of Marriage and Family Therapists and is in private practice with offices in California and Texas. He regularly speaks at regional, national, and international conferences on subjects related to human sexuality.

David Clarke Pruden, Sr., M.S. – Mr. Pruden graduated from the University of Utah and Utah State University in Family and Human Development. He is currently the Managing Editor of the Journal of Human Sexuality and an author and speaker on adolescent resilience and sexuality. He was a former adjunct faculty member at USU and Provo College and in his long career served as the Executive Director of the Utah Republican Party and the Director of the Utah Newspaper Association.

Philip M. Sutton, Ph.D. – Dr. Sutton is a licensed psychologist in Michigan, and a licensed marriage and family therapist and clinical social worker in Indiana. He earned his Master of Science in the clinical psychology program and Ph.D. in the marriage and family therapy program at Purdue University and earned a BA in philosophy at the University of Notre Dame. He has been in practice as a clinical psychologist for more than thirty years.

Andre Van Mol, M.D. – Dr. Van Mol is a board-certified family physician with more than 20 years in private practice and is the co-chair of the American College of Pediatrician's Committee on Adolescent Sexuality. His education included the University of Southern California, the Medical College of Wisconsin, Charleston Naval Hospital, and the Naval Aerospace Medical Institute. He is a diplomate of the American Board of Family Practice.

Quentin Van Meter, M.D. – Dr. Van Meter graduated from the College of William and Mary, the Medical College of Virginia and completed his pediatric endocrinology fellowship at Johns Hopkins Hospital. After a 20-year career in the Navy Medical Corps he developed his own full-time private practice. He is an adjunct associate professor of Pediatrics at Emory University School of Medicine and an Associate Clinical Professor of Pediatrics at Morehouse Schools of Medicine.

Addendum A – Detransition Statements

Below is just a small sampling of stories among hundreds of examples you will find on the Internet. For example, go to YouTube and search "detransition" to listen to the many individuals speaking very candidly about their transition stories. To understand the scope of this growing problem, then consider the many more individuals who are too humiliated or traumatized to share their stories, or who just want to move on.

No matter where you are, there are aspects that are dangerous and terrifying about being a woman. And if we don't change that now, then we are just going to continue on this path of changing women and losing women to wanting to be a man because they cannot possibly survive in this society.

Pushing a person like myself in that direction and encouraging that person to take medical steps, I think was a very dangerous thing. Um, I was not told about much of the long-term effects from my therapist. After almost five years on testosterone, I started to experience liver and kidney failure. However, I was not prepared or told even that kidney and liver damage could be related to cross-sex hormones.

I felt like all these success stories were out there this whole time and why was I not doing it right? Why was everything out of control? Why was I not fixed? And when I was reading the stories of these detransition women, I realized it's because transitioning can't fix you.

Rachel Foster - See full interview at: https://youtu.be/w8taOdnXD6o

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I was about 17 when I had the word for transgender. I felt different before that but I didn't have like a particular word for it and I took intro to psych in high school and, you know, during that time, as a teenager, obviously, everybody goes through like changes and doesn't quite understand themselves. And I happened to be also autistic… A thing about autism is that, um, at least for high functioning, autism will tend to have like obsessions. So when they get into something it's like really into something, um, and they'll do all sorts of like research and, and it can like really, and they convince themselves also. And so I convinced myself that, uh, that I was absolutely trans, like that's what I needed to do…

I started seeing a gender therapist specifically because I'm really, um, resourceful with the internet. And so all I did was like Google gender therapist in Calgary and that was how that happened. After like three sessions I got my, um, permission slip or whatever for transitioning, medically for hormones. And so I started in 2013 on testosterone and it wasn't until 2015 or 2016, actually that I had any surgery. I had a top surgery and unfortunately I had a hysterectomy and oophorectomy, so, uh, I can't have babies. Top surgery I did in May of 2016 and the hysterectomy and oophorectomy I did in 2017. I ended up going through with it and, you know, really regretting it.

I think that up until recently there, haven't been like a lot of detransitoners speaking out, and I think it's important for the trans community, for people considering transitioning and for people who have like doubts in their minds who have already transitioned to hear our stories…

Ashira – See full Interview at: https://youtu.be/i0EFPv1_jdI

My first feelings of doubt. I can't really pinpoint the first thought that I ever had, but it was after my transition had finished. And that was when I changed all of my legal documents. And I felt like I could breathe after that, like I was done, let's live my life the way it was supposed to for the first time. And it was, there was a strong sense of relief in the, in the immediate, you know, and after four years of effort. I started having real doubts was in April of 2019 around my 21st birthday…

I've already done everything that I set out to do. And yet I still feel this dissonance and the dissonance was actually more apparent than the dissonance that I felt before my initial transition. And that was deeply, deeply concerning to me because transition is supposed to correct that initial dissonance. I hated my body now…

And when my voice started to change, I was elated when I got top surgery, I was elated. And so naturally because I was elated after each step, I thought, you know, this meant that I was going in the right direction. But when it was finished, I was left, incomplete, broken. I was suicidal. I couldn't even say the words. I regret my transition. I couldn't bear to hear myself say it. It was the, it was the unthinkable. It was my greatest nightmare.

Daisy – See full video at: https://youtu.be/R_KD46_Ophg

When I was 16 in high school, I thought that I might be a trans man so socially I transitioned about a year. And then when I was 17, I went on to a hormone replacement therapy and I was on that until I was 19. And then I got off of it and I detransitioned fully.

The therapist and the medical staff without being presented enough risks… like if they're not aware of a lot of detransitioners out there and the possibility of detransitioning, then they're going to just be like, oh, well, this person just has gender dysphoria so it's just allowed them to go and fully transitioned. If you've been on hormone replacement therapy you're going through your third puberty and that's kind of traumatic. It's very intense.

Willow – See full video at: https://youtu.be/d-z4H4NvGjw

Billy Burleigh took cross-sex hormones and getting surgeries to change his outward appearance after a difficult childhood and being sexually assaulted by his swim coach. He did his best to live as a woman but ultimately the truth of his biology won out. Billy hopes that by sharing his story, he will help others avoid the damaging and expensive procedures he endured.
https://youtu.be/55IR8taw2Ig

Sydney Wright started cross-sex hormones shortly after she turned 18 and almost died from the effects of testosterone. As she matured she realized she wanted to transition as a result of childhood trauma and internalized homophobia.
https://vimeo.com/481533780

Hacsi Horvath had a traumatic childhood and in a deep depression grabbed hold of the idea that he was actually a woman as a way to start a new life. After years on cross-sex hormones and genital mutilating surgery, he realized it was a mistake.
https://youtu.be/qbCX8XgvBMI

Laura Perry detransitioned after being on cross-sex hormones and having her breasts removed. She has spoken out widely about the harms of the gender industry.
https://www.youtube.com/watch?v=ucdLlJi8j50

EXHIBIT 14

LOCAL NEWS

Alabama bill that would criminalize treatment for transgender minors headed to full Alabama Senate

A Gadsden police officer testified about getting care for his transgender daughter, which would be outlawed by the proposed legislation.

Author: **Micah Danney (alreporter.com)**
Published: **3:02 PM CST February 14, 2021**
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MONTGOMERY, Alabama — The Alabama Senate Health Committee on Wednesday approved a bill that would outlaw puberty-blocking medications and gender-affirming care for minors, giving it a favorable report in an 11-2 vote. An Alabama House committee heard testimony in a public hearing on a companion bill, but the committee did not vote on the measure.

The legislation would also prevent school faculty from encouraging minors to not tell their parents or legal guardians that they do not identify as their biological sex, and would require that faculty divulge that information to parents and guardians.

During the House hearing, some members questioned why the bill was assigned to them instead of the House Health Committee.

They heard from four speakers who supported the bill and four who opposed it. There were medical professionals on both sides, with those in favor saying the bill would protect children from reckless medical procedures and those against saying it would deny life-saving health care to minors at high risk for self-harm and suicide.

Others have had personal experience.

Speaking against the bill was David Fuller, a sergeant with the Gadsden Police Department. He spoke about raising his transgender daughter, who was assigned male gender at birth but seemed different from a young age and struggled with depression and other emotional issues. She revealed her gender dysphoria to him when she was 16.

“I mean, I was probably like you guys — I didn’t like this. I didn’t understand this,” he said. “I was ignorant to it.”

As he began to learn about it, he discovered the statistic that half of transgender teens try to kill themselves, he said. It terrified him. Then he learned that the suicide risk returns almost to normal for teens who are supported by their families and communities — and who have access to health care. Studies have shown that gender-affirming care, such as puberty blockers, is linked with lower suicide risk for transgender people.

After his daughter shared her suicidal thoughts, Fuller took her to specialists at the University of Alabama at Birmingham. He said they were keen to slow down any talk of medical treatment like puberty-blockers or hormone therapy. Most importantly, he said, they provided support and information about options that could be pursued overtime at a delicate and critical time for his family, which he credited with saving his daughter’s life.

“They made us feel like we weren’t alone, that we were normal in an abnormal situation, and that they could help us,” Fuller said.

One voice in favor was Walt Heyer, an author and traveling speaker who has become known in some Christian circles for his story of living as a woman for eight years before transitioning back to a man. He regrets that decision and period of his life, he said. Heyer said that confusion in minors about gender identity can start early and lead to medical decisions that have lasting consequences, so he supports the bill’s blanket ban on medical treatments.

Another speaker opposed to the bill was Dr. Morissa Ladinsky, a Birmingham pediatrician who has experience working with transgender youth. She said that they may assert their gender identity anywhere from preschool to puberty or later, and any treatment that affirms that identity is long-term and involves “lengthy informed consent” with all parents.

No irreversible treatments are allowed on minors, she said. Puberty-blocking medications can be reversed and surgeries are not performed on children.

“Folks, there are not pediatricians traveling around Alabama just writing hormone prescriptions for minors,” she said.

Ladinsky accused the bill of unfairly criminalizing pharmacists for filling the prescriptions that it would outlaw. Pharmacists rarely, if ever, know the reason a drug is prescribed, she said.

“This bill tells truly vulnerable youth, those facing gender dysphoria, that you are going to make their health care a crime,” she said. “It invades the sacred domain of parenting, reaches into the practice of medicine and shuts down the parent voice in medical decision-making.”

Dr. Patrick Lappert, a Decatur plastic surgeon, spoke in favor of the bill. He cited a Swedish study that found an increase in suicide rates and other mental health issues among transgender people in adulthood, apparently contrary to the notion that early medical treatment had saved them.

Sweden has a universal database for medical records, which Lappert said makes its data most reliable in tracking the health of transgender people longterm. A 30-year study in Sweden

published in 2011 found that participants who had sex-reassignment surgery went on to have significantly higher rates of mortality, suicidal behavior and psychiatric morbidity than the general population. The researchers concluded that "sex reassignment, although alleviating gender dysphoria, may not suffice as treatment for transsexualism, and should inspire improved psychiatric and somatic care after sex reassignment for this patient group."

But a 50-year survey published in 2010 found that out of 767 respondents, just 2 percent expressed regret about their reassignment surgery. Among participants who underwent non-surgical treatments like puberty-blockers, less than 2 percent expressed regret. More recent research has found that mental health gets better and continues later in life the earlier that medical treatment addresses gender dysmorphia.

Lappert, who has spoken against the use of medicine and surgery for transgender people as a Catholic deacon in his local diocese, said that the vast majority of teens who present themselves as being in the wrong body "have gotten over the idea" once they reach early adulthood. When a committee member questioned Lappert's medical expertise on the issue, Lappert said that he would not treat a person seeking guidance for their gender dysphoria but would refer them to a qualified mental health professional.

Responding to further questions from the committee, Fuller took issue with what he said was implied by Lappert's mentioning of the Swedish study.

"I'll tell you why that happens: It is terribly hard to be a transgender person in this world, on this planet, anywhere. And God forbid in Alabama — here we are legislating against the health care these kids need," Fuller said.

The Human Rights Campaign, a national group that advocates for LGBTQ rights, issued a statement on Wednesday saying that the bill is part of a seven-state, coordinated push for legislation by a national campaign.

"These bills are not addressing any real problem, and they're not being requested by constituents," the group said. "Rather, this effort is being driven by national far-right organizations attempting to sow fear and hate."

Dillon Nettles, director of policy and advocacy at the ACLU of Alabama, issued a statement on the Senate Health Committee's passage of the bill:

"Alabama lawmakers are once again threatening the healthcare choice of everyday Alabamians. By passing SB10 out of the Senate Health committee today, children across Alabama are at risk of losing life-preserving care due to their identity and the government.

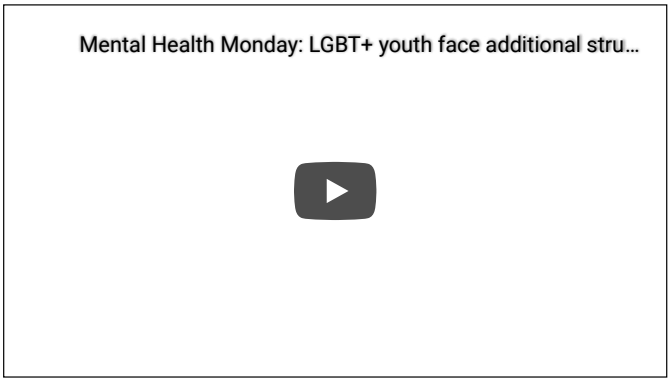
"This legislation also puts Alabama's doctors at risk of being charged with a Class C felony simply for performing their duties by supporting the health and well-being of transgender children.

"This legislation is wholly dangerous and irresponsible, particularly at a time when the importance of qualified and non-exclusionary medical professionals is more evident than ever, and children are already struggling under the circumstances of this pandemic."

The bill is expected to go to a full vote in the Senate. It will be on the House Judiciary Committee's agenda again in two weeks.

This story originally appeared in the Alabama Political Reporter.

IN OTHER NEWS: Mental Health Monday: LGBT+ youth face additional struggles during pandemic



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In LGBTQ-friendly fashion, Biden White House website now allows choice of pronouns

LGBTQ community disproportionately affected by pandemic, report finds

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Mental Health Monday: LGB…

EXHIBIT 15


U.S. NAVAL HOSPITAL SHIP
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Dr. Lappert

Transgender Surgery & Christian Anthropology

COURAGE
A Roman Catholic Apostolate

Deacon Patrick W. Lappert, MD
Birmingham in Alabama
256-303-8509

The Challenge

- "Male and female He created them" has been replaced by a confusion of exceptional cases.
- Aggressive re-characterization of the nature of the human person.
  - Academia, entertainment, law, and even at church.

Finally and above all, man has made stupendous progress in the domination and rational organization of the forces of nature, such that *he* ***tends to extend this domination*** *to his own total being;* ***to his body***, to psychical life, to social life, and even to the laws which regulate the transmission of life. ~ Humanae vitae 2

The Challenge

- Understand the subject.
- Fluent in the language.
- No shocking surprises.
- Patient, but insisting upon the truth

Human Nature

- The human person: body and spirit together comprising a single nature.
  - By our nature we are made for *the other*.
  - Possessed of an intellect by which we can know the good, the true, and the beautiful.
  - Possessed of a will by which we can choose the good, the true, and the beautiful; *the moral life*.

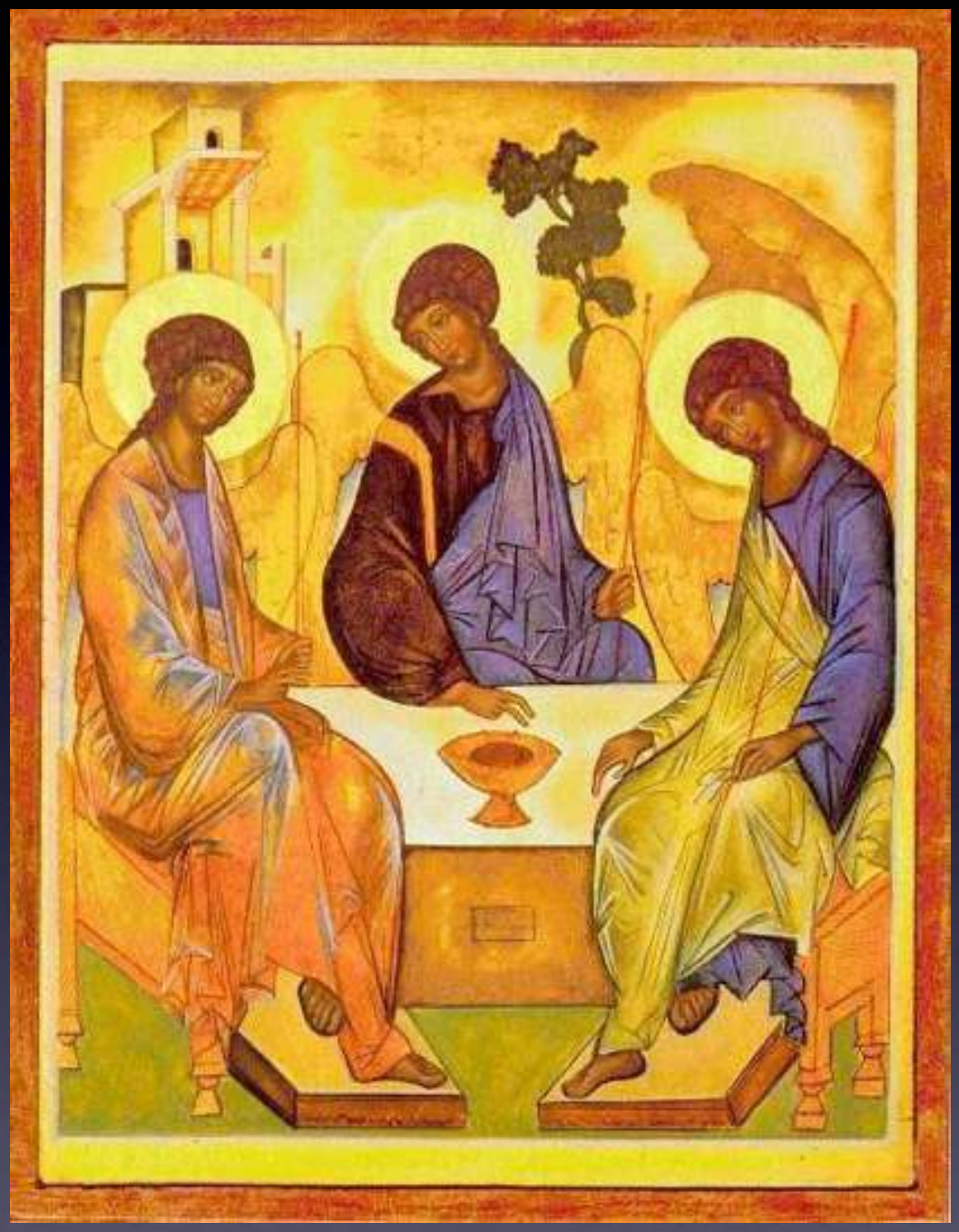
Human nature

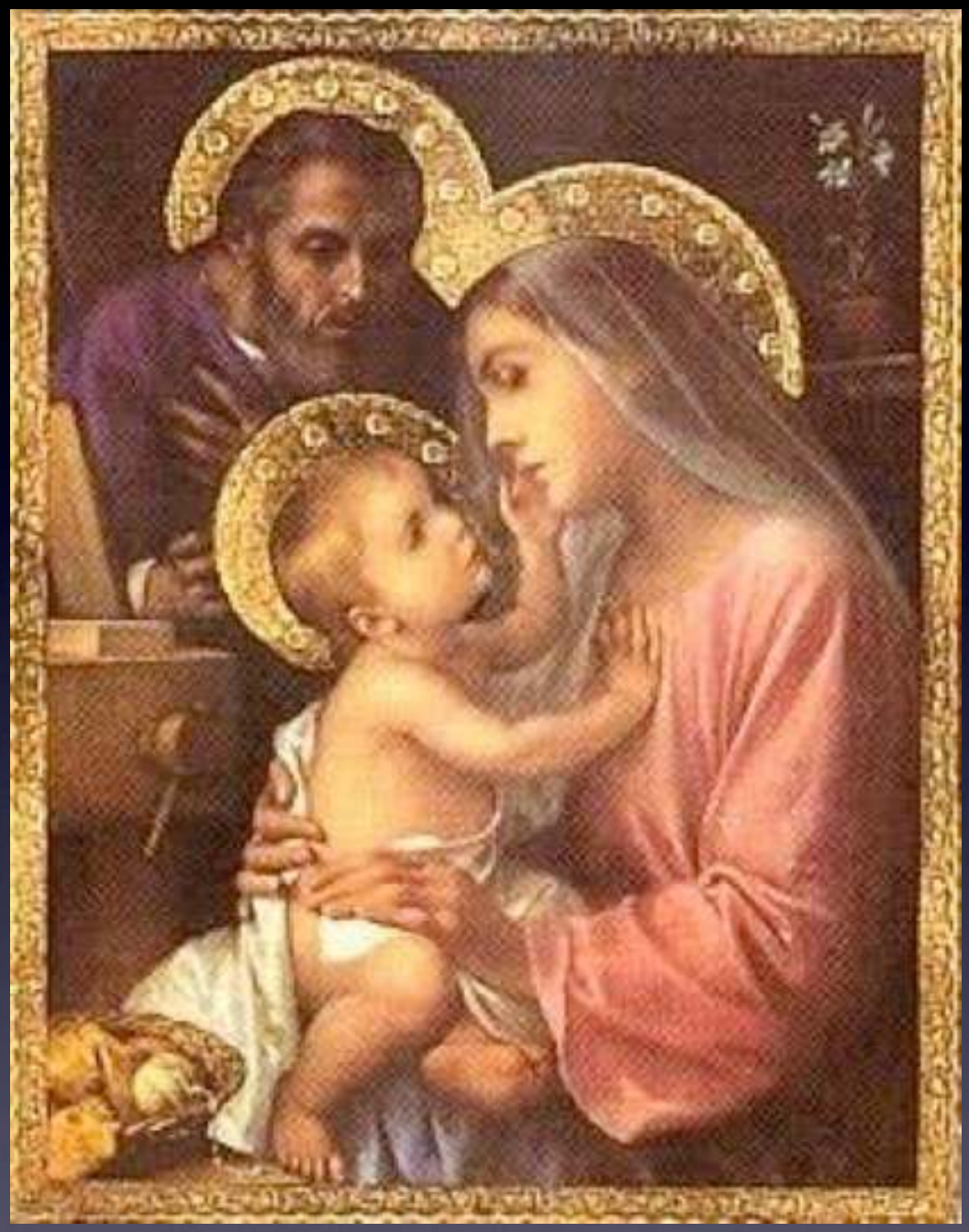
- The moral life: built upon foundational truths.
- Not arbitrary.
- Not repressive, but rather affirming of the intrinsic dignity of the person.

What is a human being?

Human Nature

- The human body
  - The "reproductive system", and the fulness of humanity.
- Dimorphism and complementarity.
- The human family is in our nature.





The Image and Likeness of God

Human Nature

- Why must we consider first the *nature* of the human person?
  - Defines the "end" of medical and surgical care.
  - Human nature is that which is perfected by the life of grace.
  - That which is perfectly realized in the Incarnation of Jesus Christ.

Modern "Gender"

- A confusion of biology, psychology, and political science.
  - Use of biology to explain psychology
  - Political terms to explain the emotional life.
  - Shifting from biological determinism, to freedom of expression.
  - Language of "science" counterpoised with rejection of scientific evidence as "tool of oppression".

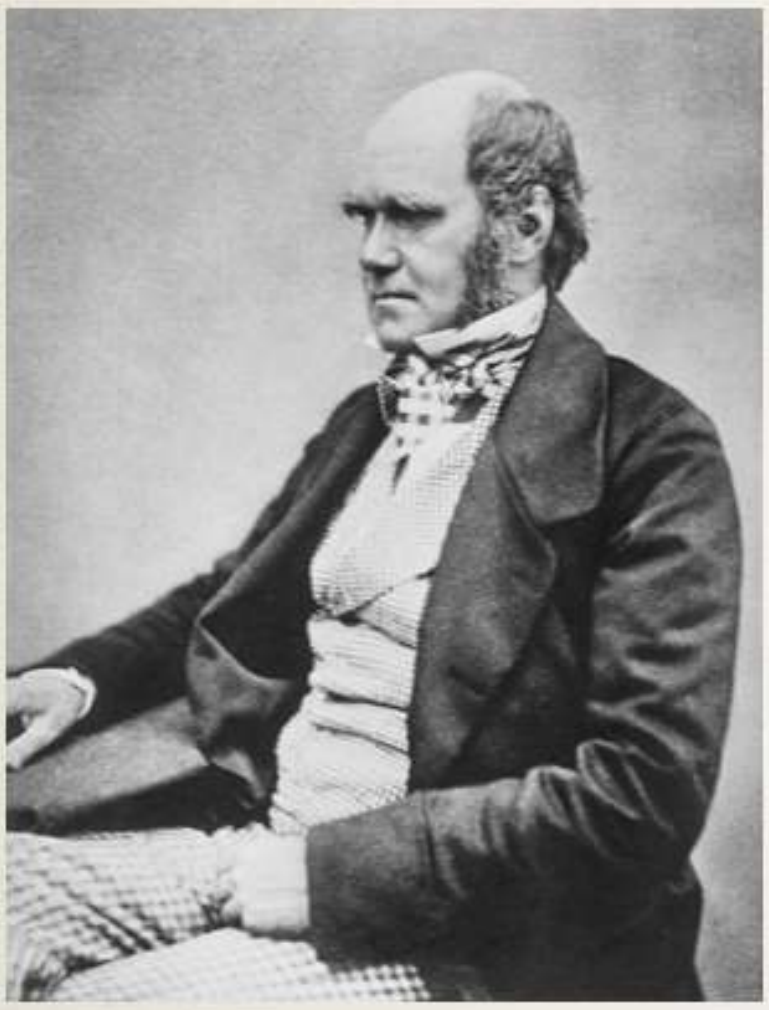
"Great Expectations"

- Science (separate from faith): A "pure" thing.
  - Deeper, "more evolved"
- Technology: domination of nature
  - Capability to modify the person in any way that "choice" demands.
- *Progress*: irresistible power of history leading to liberation from the oppression of the past. Transgenders no longer *"outcasts"*!

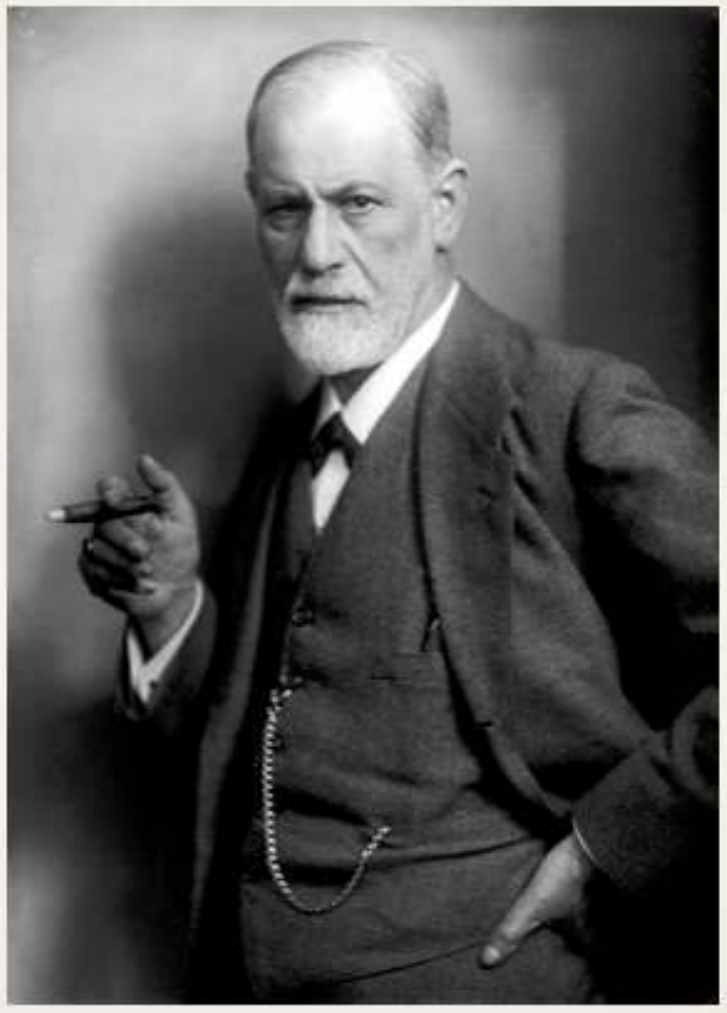
Transgender Language

- Outgrowth of "gender identity" principles.
- Relationship to the "sexual revolution".
- The divorce of the two aspects of human sexual union.
- Catholic anthropology vs. materialistic anthropology.

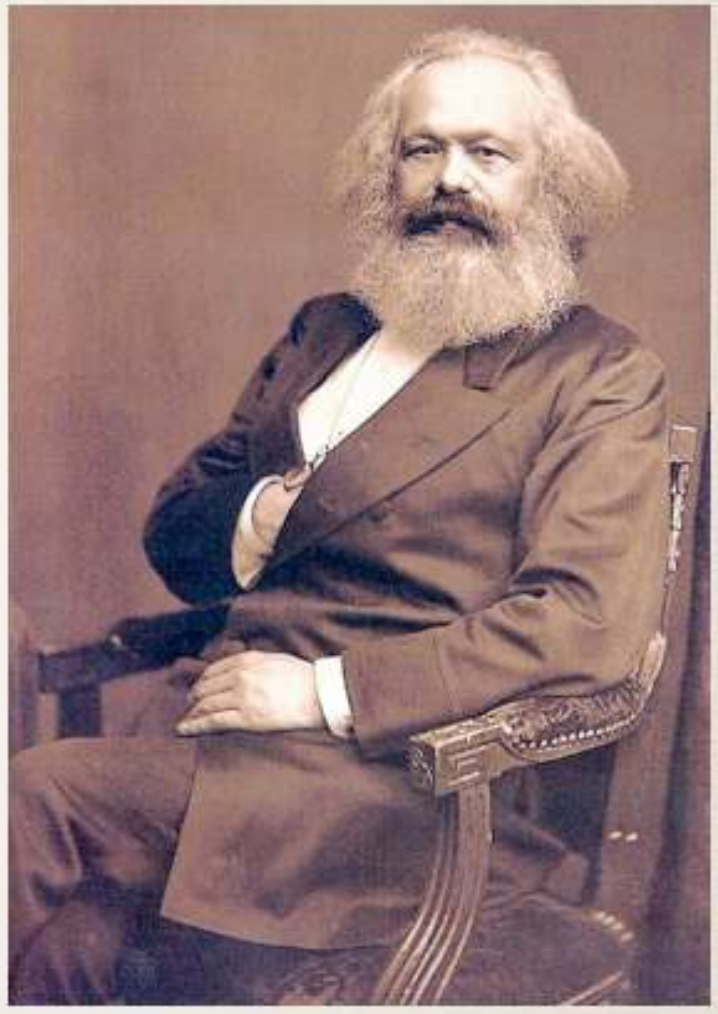
The 3 Stranded Rope



Charles Darwin



Sigmund Freud



Karl Marx

The human person is materially caused, materially driven, and his highest aim and happiness is materially defined.

Psychological Language

- Seeking to give a complete explanation of human behavior, without recourse to theology.
- Man as merely a particularly complicated animal.
  - Inherent drives common to animal life.
    - Assorted coping mechanisms to deal with the frustration of those drives. Some are pathological = neurosis / psychosis
  - "The Pleasure Principle" ~ Freud

Psychological Language

- The search for "pleasure" is the central instinct:
- Sexual pleasure seen as the zenith.
- The central element in character development:
  - Sexual drive, and sexual experiences are seen as the prime movers in the development of personality and social capacities.
  - Good (pleasurable) experiences = good personality development.

Psychological Language

- Human sexuality is viewed from the standpoint of the *one person*, *their needs*, and the satisfaction of those needs.
- Any moral perspective on human sexuality seen as an arbitrary social restriction, or *"taboo"*, without foundational truth.
- Belief that much psychopathology can be avoided by changing society, and ignoring moral questions.

Modern Sexuality Sumarized

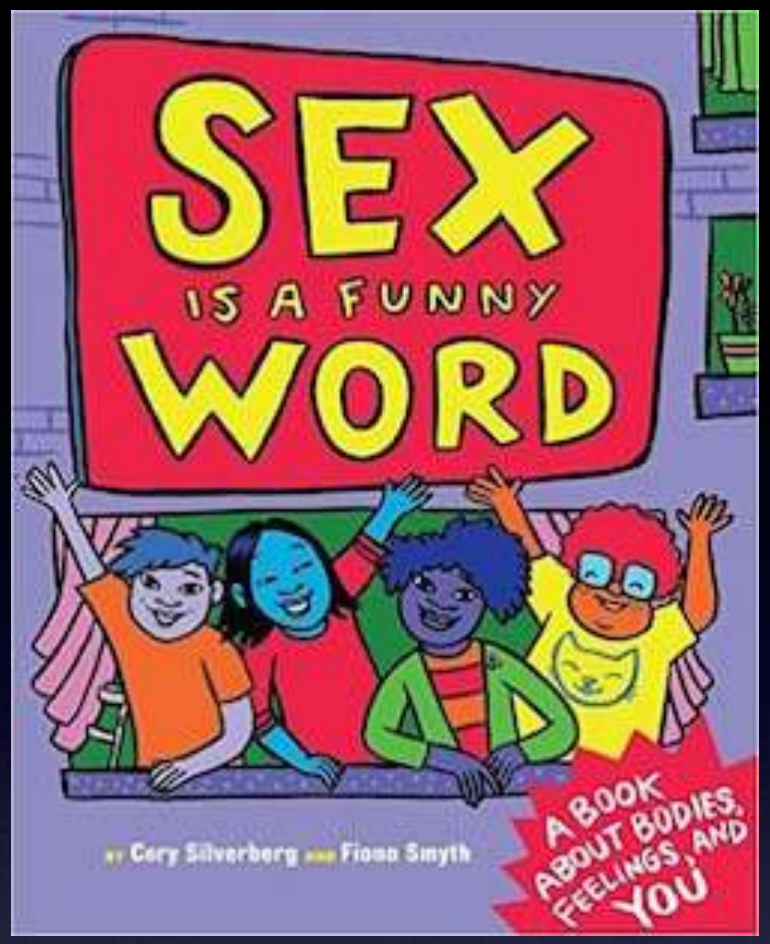
(Lappert's Axioms)

"Adult sexuality" is an endlessly variable, *personal* expression of *individuality*, the purpose of which is to produce joy for that person. It sometimes involves other people, and with alarming frequency, is known to produce other people.

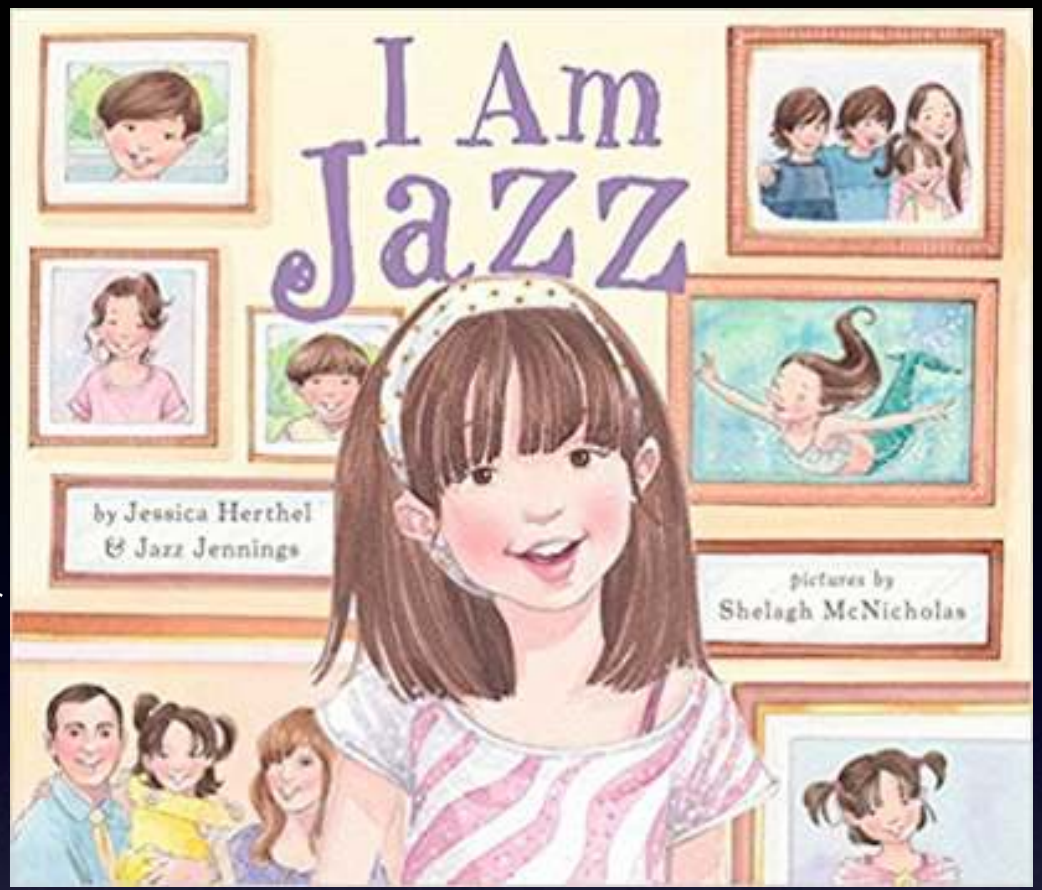
Modern Sexuality Sumarized

(Lappert's Axioms)

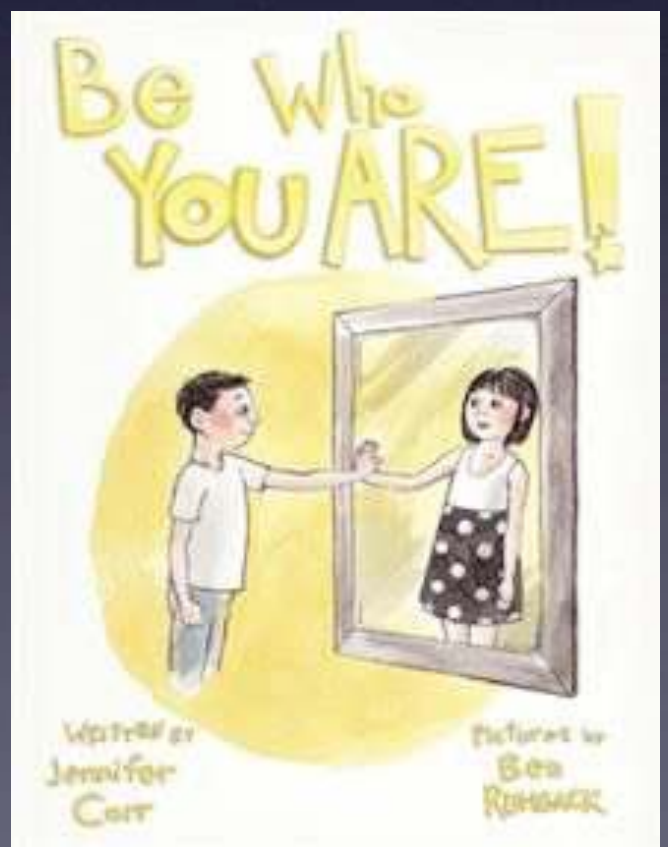
"Adult sexuality", is the developmental result of "childhood sexuality", just as adult language is the developmental result of childhood language. For this reason, it has become the habit of psychologists, and teachers to talk to children about "adult" sexual activity.



Recommended for
7- 10 y.o. children



Recommended for
4- 8 y.o. children

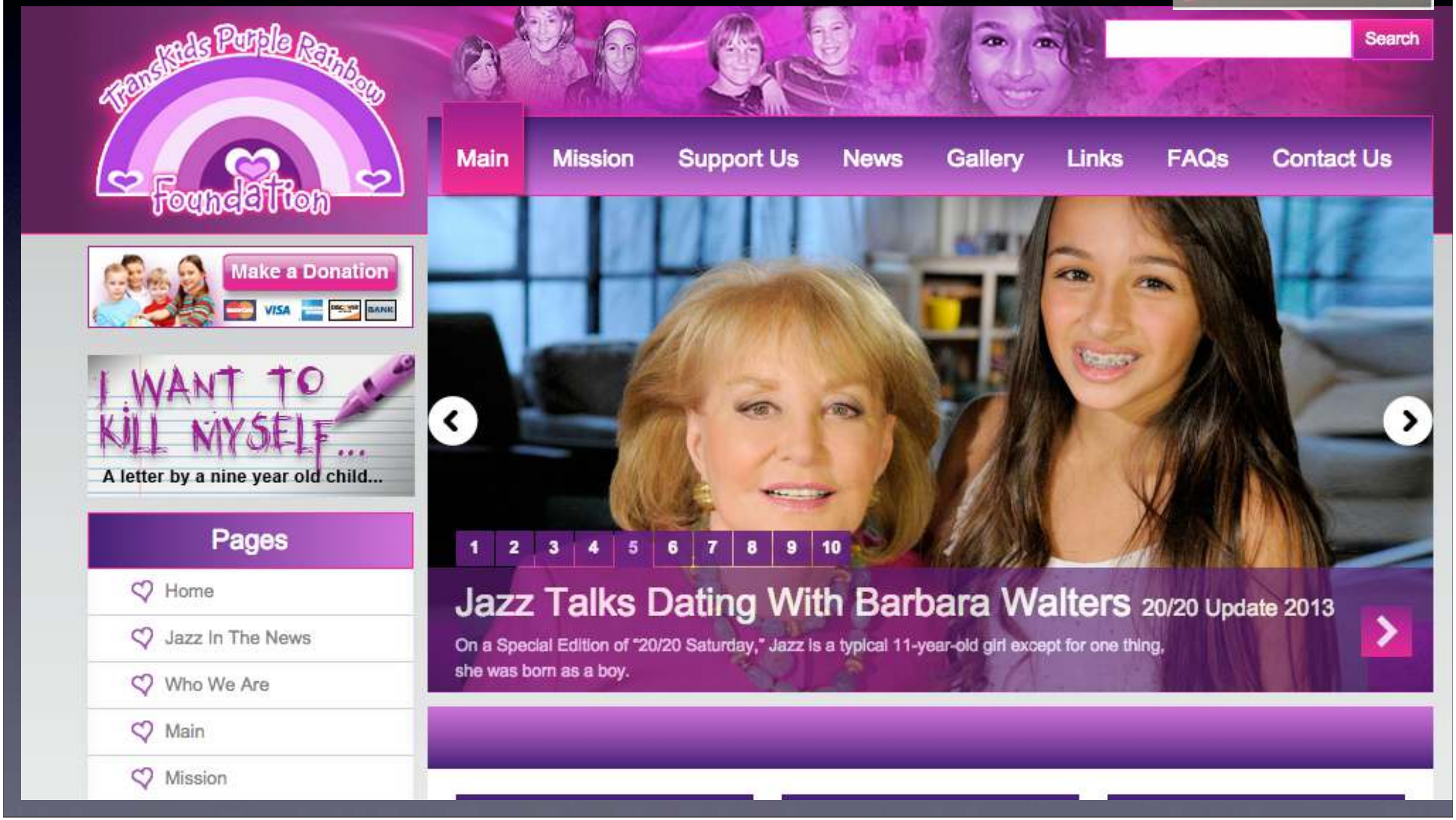


Recommended fo
9 y.o. children

JA2775


"I like to say that
I'm a girl stuck
in a boy's body."
Lia, age 9
#GrowingUpTrans
pbs.org/frontline
FRONTLINE

Shaping the Conversation, & Grooming a Generation



Making Life Better with Plastic Surgery

- When you "don't feel right, because something "doesn't look right".
  - Aesthetics or Reconstruction

Managing the Unseen Wound

- Profound sorrow, anger, anxiety.
- Seeking a material (aesthetic) explanation and remedy.

Body Dysmorphic Disorders

- Broad category of disorders of misperception about physical appearance
  - Anorexia
  - BDD/ Aesthetic surgery patients
  - Seeking limb amputations etc.

Science
Neurophilosophy

The science and ethics of voluntary amputation

Should amputation be offered as a treatment to people suffering from Body Integrity Identity Disorder?

Mo Costandi

Wednesday 30 May 2012
13.07 EDT

Body Dysmorphic Disorder

- Type of Obsessive- Compulsive Disorder
  - Depressive presentation
  - Social isolation. "Outcast"
- Treatment
  - SSRIs, Cognitive-Behavioral Therapy

Gender Dysphoria

- The unhappiness associated with the condition because:
  - "I don't look the way I know I should"
  - "The world does not accept me as I know I really am"
- Social isolation due to:
  - Incongruous behavior
  - Secret life with associated shame.

Transgender

- Obsessive thinking with varying degrees of "dysphoria"
- Perceiving something that is not objectively there:
- Delusional thinking
- Errors of assumption

Criteria For Delusion

- Karl Jaspers in *General Psychopathology* (1913) The criteria are:
  - certainty (held with absolute conviction)
  - incorrigibility (not changeable by compelling counterargument or proof to the contrary)
  - impossibility or falsity of content (implausible, bizarre or patently untrue)

Co-morbidities:

- Alcohol and drug abuse, depression, incarceration, homelessness, high rate of suicidal ideation.
- Variable in Expression:
  - Private stress management by cross-dressing
  - Public, anonymous cross-sex persona, including sexual contact (sometimes prostitution).
- Transitioning in stages.

Biological Language

- Seeks to establish the material causation for the psychological instincts/ drives
  - Genetic, neuroanatomic, endocrine, etc.
- Seeks to understand the biological basis for "gender"
  - Sexual dimorphism/ polymorphism vs. social construct and learned behaviors

Biological Language

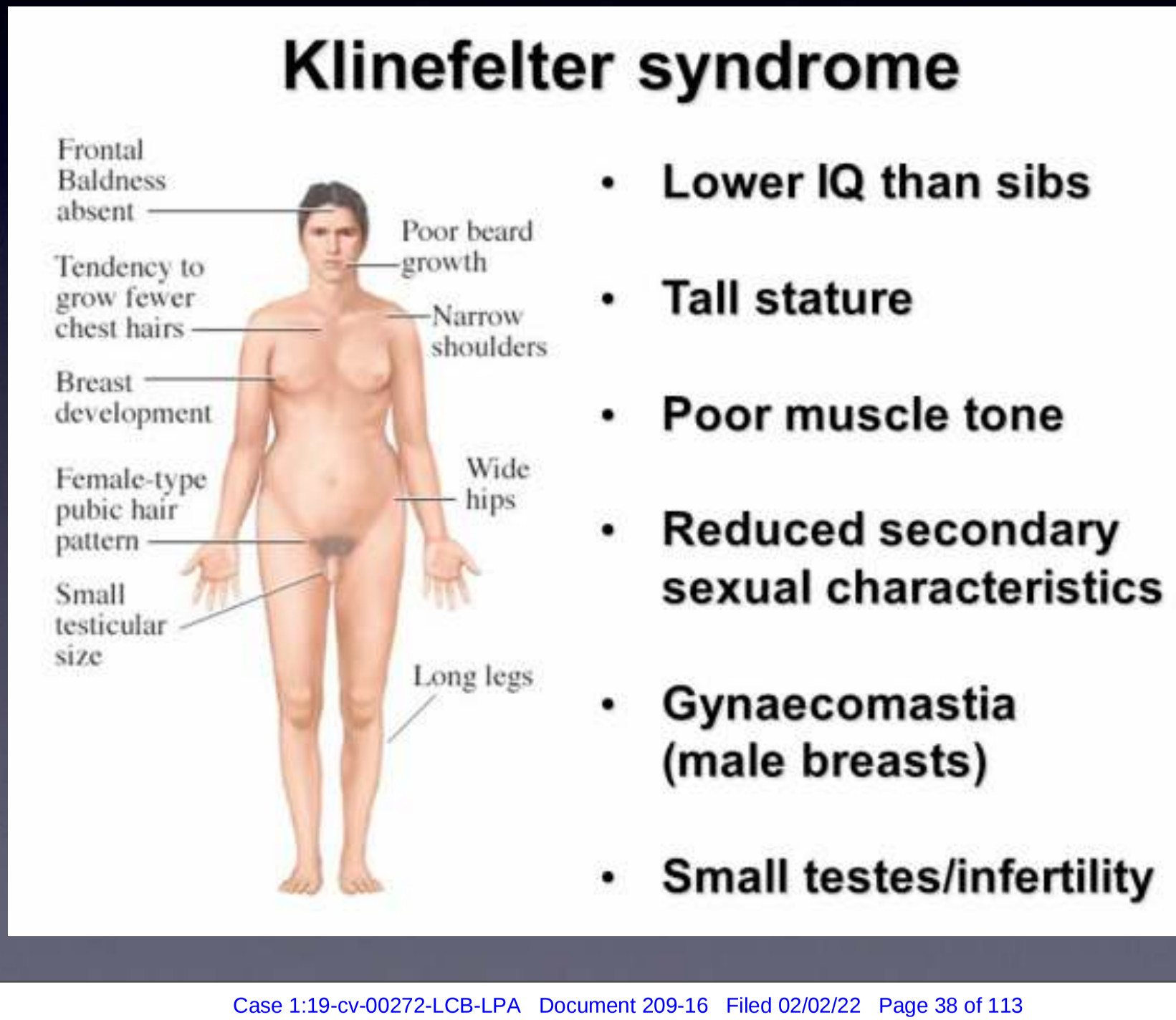
- "Evolution" words applied to human sexual functioning.
  - Searching for the "adaptive advantage" of fruitless sexual activity.
    - The problem of reconciling a Darwinian view of the human person, and a putative inherited behavior that is annoyingly maladaptive.
- The hope: genetic trait of animal life would silence moral arguments.

Biological Determinism
vs.
The Moral Life

Biological Language

- "Isn't there a genetic explanation for "transgender?"
- "We learned in school that there are many genetically caused examples of people who are somewhere in between "man" and "woman".
  - Klinefelter's Syndrome
  - Androgen Insensitivity Syndrome (AIS)
- "That is what I have. I am "intersex", and I choose to be....."

Biological "Intersex"
(Hermaphroditism)



Clinical Support for Intersex Persons

- Multidisciplinary: Pediatrics, Geneticists, Pediatric Surgery, Urology, Psychology.
- Assessment: Including genital ambiguity, problems with voiding etc.
- Planning based upon “sexual assignment”.

Gender Assignment Surgery
(ambiguous genitalia)

- Seeks to remedy structural problems that interfere with voiding.
- Seeks to establish an arrangement of tissue that would make sexual intercourse possible.
- Make reproduction possible only in cases of structural problems of shape, size, and patency.

So…is it biological?

- Genetic, like Klinefelter or AIS?
  - No genetic marker, no mutation.
    - Normal male or female karyotype
- Hormonal?
  - Hormone levels entirely normal for age/sex matched controls
- Anatomical?
  - Brain scans: MRI, PET Scan etc.
    - No structure/ activity that mimics opposite sex.

Nature v. Nurture

- Speculation among "sexologists" working in Intersex Clinics.
  - "Gender Identity" is:
    - Malleable, or "fluid"
    - Socially determined
    - Typically produced by "repressive" processes

The "Science" of Gender

Dr. Harry Benjamin

Dr. Alfred Kinsey

Dr. John Money

Nature v. Nurture

- Difficulty in separating the vague and as yet not demonstrated genetic influences from social / cultural influences.
- Database skewed by selection bias among genetically / developmentally abnormal patients.

The Twin Study

- The "gold standard" for exclusion of biological determinism (genetic).
- Monozygotic twins raised in different social circumstances.

The Index Case

John Money, PhD

Sexologist in the Intersex Clinic

Johns Hopkins

-Convinces parents to raise their son as a girl.

-"Socialize" strenuously as a girl

-Castrate, and administer estrogen

-Ultimately use reconstructive surgery to produce a neo-vagina.

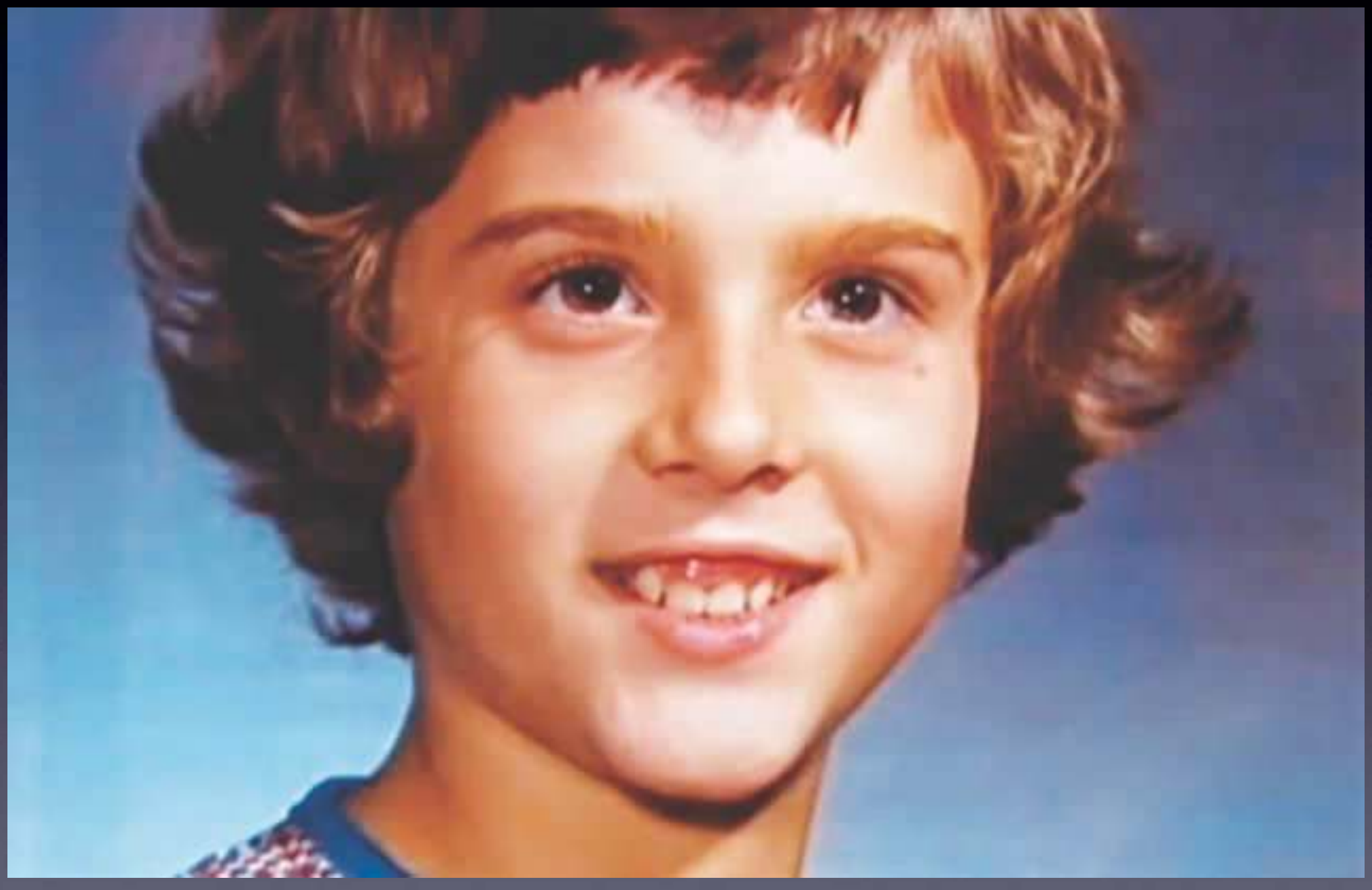
Published Results in "Peer Reviewed Journals"

- Papers and presentations based upon "long term follow up".
- "Successful" in every way.
- Torrent of "scientific literature" re: gender roles/ identity etc.
- Political dimension

John Money, PhD

The Reimer Twins

"Brenda" Reimer



"Scientific" Basis of Gender Politics

- Gender "assignment" is a process of repression.
- Forces persons into "binary" model of sexual expression.
- Sexual expression is a form of political expression.
- "Dr. Money's twin study proves this conclusively!"

Annual Visits to John Money, PhD

- Expected result further drives the intervention.
- Photographs them as he "instructs" them in "sex-play".
- Fear and anxiety

Truth

- Was eventually given the truth at age 15.
- Enthusiastically embraces boyhood.

The Experiment is Ended

- Hormone replacement due to castration.
- Surgical efforts
- The silence of John Money, PhD

David the Man

Husband, and adoptive father of three children

David the Man

- Battle with depression.
- Financial difficulties
- Wife leaves him after 14 years.
- Brother dies of drug overdose.

David Reimer 1965- 2004

The Nexus

- Catholic Anthropology

&

- Plastic/ Reconstructive Surgery

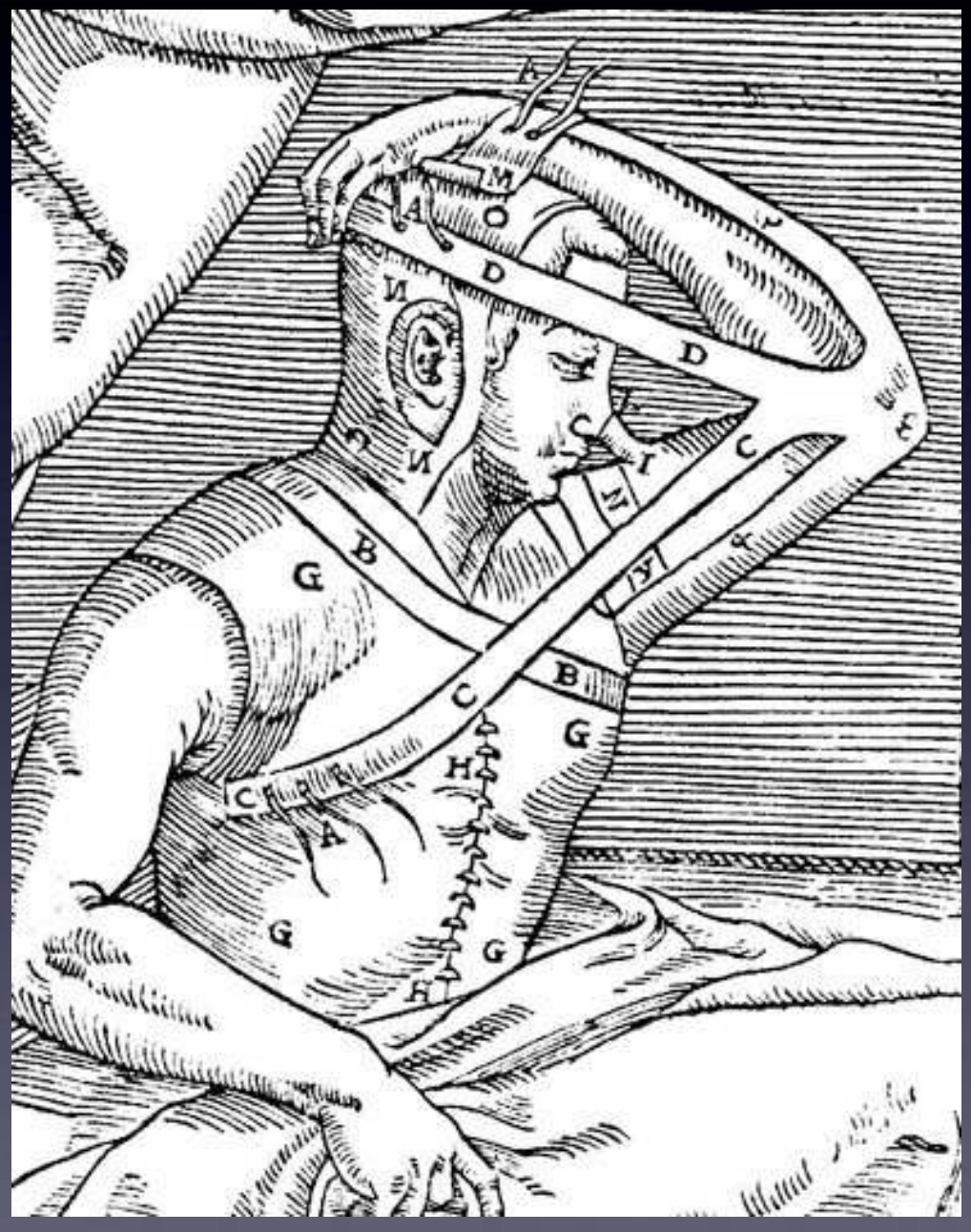
A Quick Review of Plastic Surgery

- The oldest form of surgery
- Ear reconstruction- India
- Nasal reconstruction- Italy
- Restoration of the social outcast.

Sushruta- 7th Century BC India

The Mutillation of Emperor Justinian II *"Rhinotmetos"* 695 AD

History-



Plastic & Reconstructive Surgery

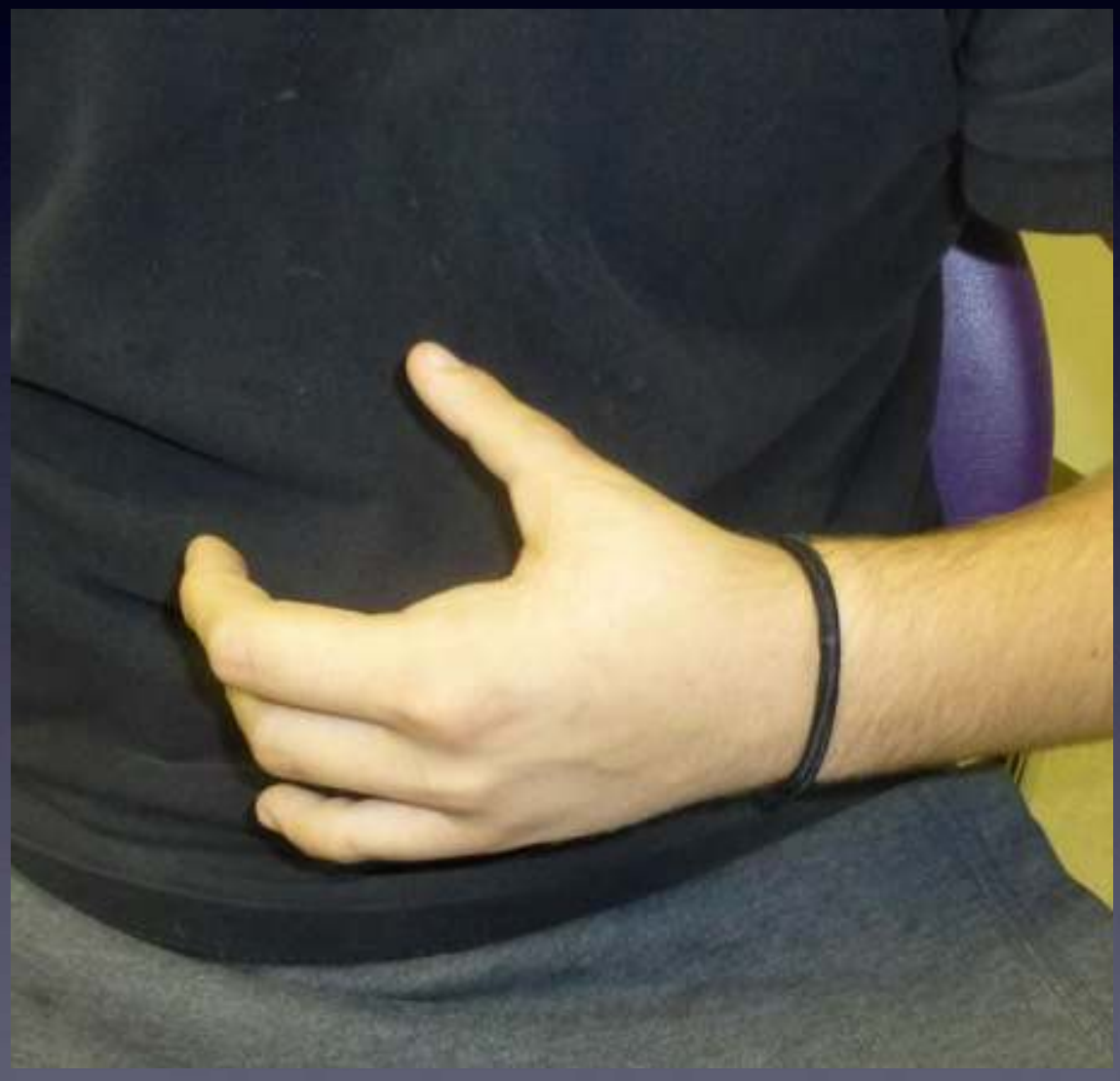
- Basic Principles:
  - Establishment or Restoration
    - Form and Function
  - Based upon a thorough understanding of the nature of the missing or injured part, and its relationship to the person.
  - Directed at the "perfection" of the nature of the human person.

Restoration

- Lost due to trauma, or surgical management of malignancy, infection, etc.
- Missing at birth, due to developmental anomalies, or in-utero events.

Missing from trauma

- Adult male: traumatic amputation of non-dominant thumb
- Needs prehensile, helping hand with good grip and fine "key pinch" functions.

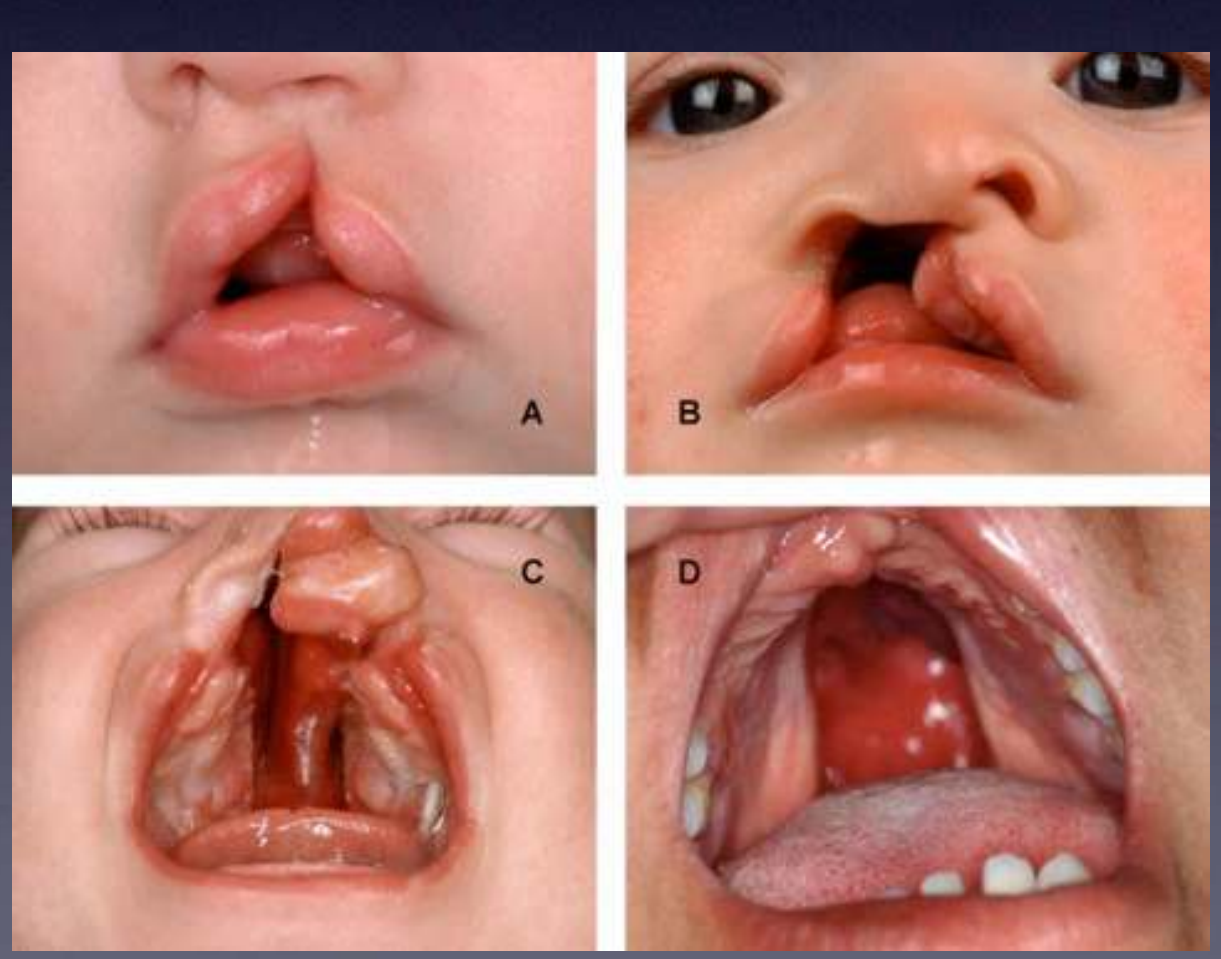


Restoration

- Degree of functional restoration is dictated by the intrinsic natural function of the lost part
  - Hand:
    - Grasping, pinching, stabilizing, pushing, dominant vs. helping.
- Goals are tailored to the life of the patient

Congenital Cleft Palate

- Congenital malformation of the face with varying degrees of palatal integrity
- Feeding difficulty
- Speech problems
- Hearing problems
- Dental problems



The Cost of Reconstruction

- What will be lost, or compromised in the course of reconstruction?
  - "Donor defect".
  - Risk vs. benefit

"Transitioning"
(Progressive Expression of Condition)

- Obsessive thoughts leading to compulsive behaviors.
- Interferes with living in the present moment.
- Managing anxiety by unhealthy means.
- Withdrawal, cross-sex dressing/ acting in secret.

Transitioning

- Secretive, dysfunctional life leads to conflicts with family, and peers. Causes "dysphoria".
- Psychological counseling: the broad and the narrow.
- APA: Presumes that "gender non-conforming" is the essential and true nature of the person, therefore health is to be found in giving full expression to the subjectively perceived persona.

Transitioning

- Psychological Testing of "maleness and femaleness" (objective standard).
- Cross-sex identity development: clothing, name, persona.
- Endocrine management
  - Puberty blocking in pre-pubertal children; cross-sex hormones.
- Voice training, hair management.

Children's Hospital of Philadelphia™

FIND A DOCTOR DEPARTMENTS CONDITIONS LOCATIONS YOUR VISIT Search...

Endocrinologist

Wilma C. Rossi, MD, MBE

Gender and Sexuality Development Clinic

CONTACT US

"Providers, patient and parents were ready to start hormone therapy with testosterone to help him align his body with who he had always known he was on the inside."

"While gender-related healthcare can be expensive in the short term, it is recognized to lead directly to improved health outcomes and long-term cost savings." ~CHOP

The Washington University

Transgender Center

at St. Louis Children's Hospital

E-m

314.454.KIDS (54

800.678.KIDS (

Resources About Us What to Expect

cs.wustl.edu/transgender-center/#

"Your first visit to the Washington University Transgender Center at St. Louis Children's Hospital will take about 60-90 minutes. You'll meet with one of our physicians for an informational discussion about age-appropriate therapies (depending on if the patient has started puberty.) You may be referred to a mental health provider for ongoing psychosocial support and assessment, if indicated.
Records from patient's primary care physicians should be sent prior to the first visit, so our doctors can review them for pre-existing conditions that may be affected by hormone therapy."

Karen Hamon, BSN, RN, CDE

Pronouns: She, Her, Hers

Karen is a Clinical Nurse Coordinator in outpatient care at Washington University School of Me
of Endocrinology and Diabetes. She received her Bachelor's of Science in Nursing from Goldfar
Science in Justice Systems with a minor in Sociology from Truman State University. Karen's prio
pediatric general medicine floor and as an inpatient diabetes educator at St. Louis Children's H
Diabetes in 2013 and has won two division awards since then. She is also currently a finalist fo
Karen is very passionate about social justice issues and jumped at the chance to be part of the

Casey E. Lofquest, MSN, RN, CPNP

Pronouns: She, Her, Hers

Casey is a Pediatric Nurse Practitioner (PNP) in outpatient care at Washington University Schoo
Division of Endocrinology and Diabetes. She received both her Bachelor's of Science in Nursing
specialty), from Saint Louis University. Casey's prior experience includes staff nursing care in p
intensive care nursing. She practiced as a PNP in primary care in Arnold, MO, prior to joining th

-Education regarding gender dysphoria and its possible treatments. Gender dysphoria refers to the distress that may accompany the incongruence between one's gender identity and one's assigned sex at birth.

-Administering pubertal blockers, which delay puberty and suppress unwanted and irreversible secondary sexual characteristics; for example, deepening of the voice and facial hair for transgender females and breast development for transgender males.

-Administering cross sex (gender-affirming) hormones that make a person's physical body match their gender identity. These may begin between the ages of 14 and 16 after patients meet readiness and eligibility criteria.

Puberty blocking drugs
Cross-sex hormones

Absence of medical evidence

Human experimentation

Irreversible effects on:

- Fertility
- Neuropsychiatric/ musculoskeletal development

Desistance data. 9% vs. 100%

Transitioning

- Surgery
  - Secondary surgeries: hair, forehead, nose, jaw, neck, breast. Euphemism: “Top Surgery”.
- Definitive and final: castration and vaginoplasty, or hysterectomy / oophorectomy and phalloplasty. “Bottom Surgery”.

PSEN University: Gender Affirming Surgeries 101 - Webinar (Includes Gender Affirming 101 Series)

Member Price **$250.00**

Non-Member Price **$325.00**

Members Save $75.00

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Product Description

Presented by: Loren Schechter, MD

About this Course :

This course is a live webinar CME course to be held on **April 18th 2018 at 7pm cst.** This course also includes the 2017 ***PSEN University: Gender Affirming 101 for Surgeons - Video Series*** which features ten webinar recordings from a

The Surgery

- Top surgery is largely reversible.
- Bottom surgery is irreversible. Fully functioning genital organs are mutilated in order to produce a counterfeit form.
  - Form has primacy
  - Function is destroyed (donor morbidity)

Grave Matter

- Willful sterilization destroys the procreative aspect.
- Simultaneous degradation of the unitive aspect.
  - major loss of sensory apparatus, and persistence of the native neural "map" in the brain.

Grave Matter

- "Banking" of ova and sperm for future in vitro and proxy pregnancies.
- Objectification of children; the "right to a child".
- Link between "reproductive technology", & "gender affirmation medicine".

Plea For Mercy

- Because self-identified transgender persons suffer greatly
  - High rate of substance abuse.
  - High rate of homelessness.
  - High rate of suicide attempt:
    - 18yo - 55yo steady at approx. 40% risk.

The Appeal From Sentiment

Compulsion To "Mercy"

- "Everything must be done to help these persons live their new identity"
  - Home, school, work
  - Names, pronouns, bathrooms, etc.
  - Health insurance directed toward transitioning, not treatment of OCD.
  - Attempts to diagnose and treat are labeled "hate speech".

So...it is working, right?

Evidence Based Medicine

- Over the years, many small retrospective studies.
- Inconsistent criteria for inclusion of patients and the selection of controls
- Much self-selection bias; high drop out rate.
- Small samples and short follow-up
- Varying degrees of “success”. Ranging from “improved in gender dysphoria” to continued elevated psychiatric hospitalization and suicide attempts and death.

The Swedish Study

- Population cohort study over 30 year period.
- Age and sex matched cohort.
- Data from consistent national database.
- Standardized reporting for identity change, hospitalization, psychiatric diagnosis and co-morbidities, and mortality.

The Swedish Study

Long-Term Follow-Up of Transsexual Persons Undergoing Sex Reassignment Surgery: Cohort Study in Sweden

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James Scott, Editor

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Abstract

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Context

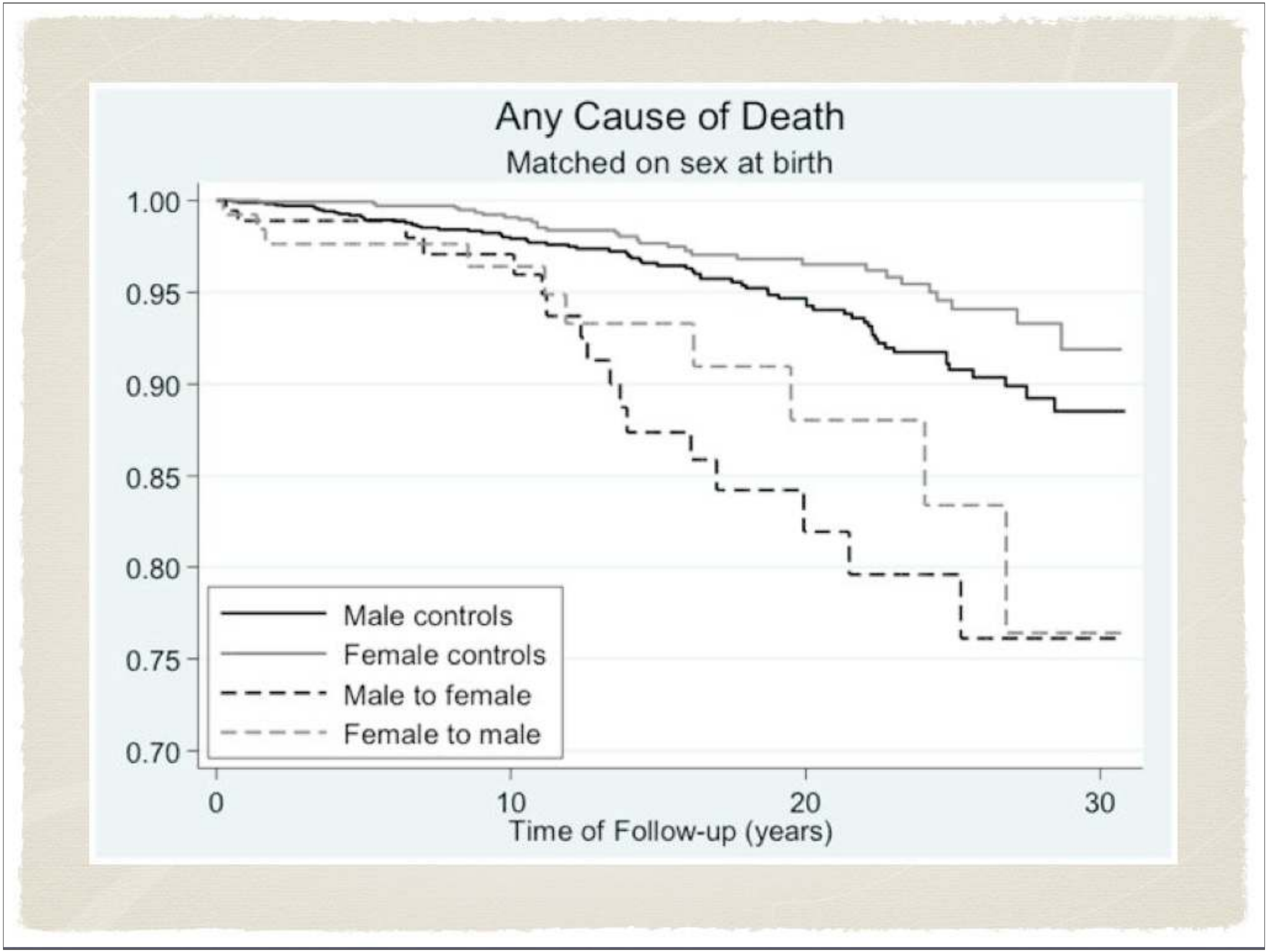
The treatment for transsexualism is sex reassignment, including hormonal treatment and surgery aimed at making the person's body as congruent with the opposite sex as possible. There is a dearth of long term, follow-up studies after sex reassignment.

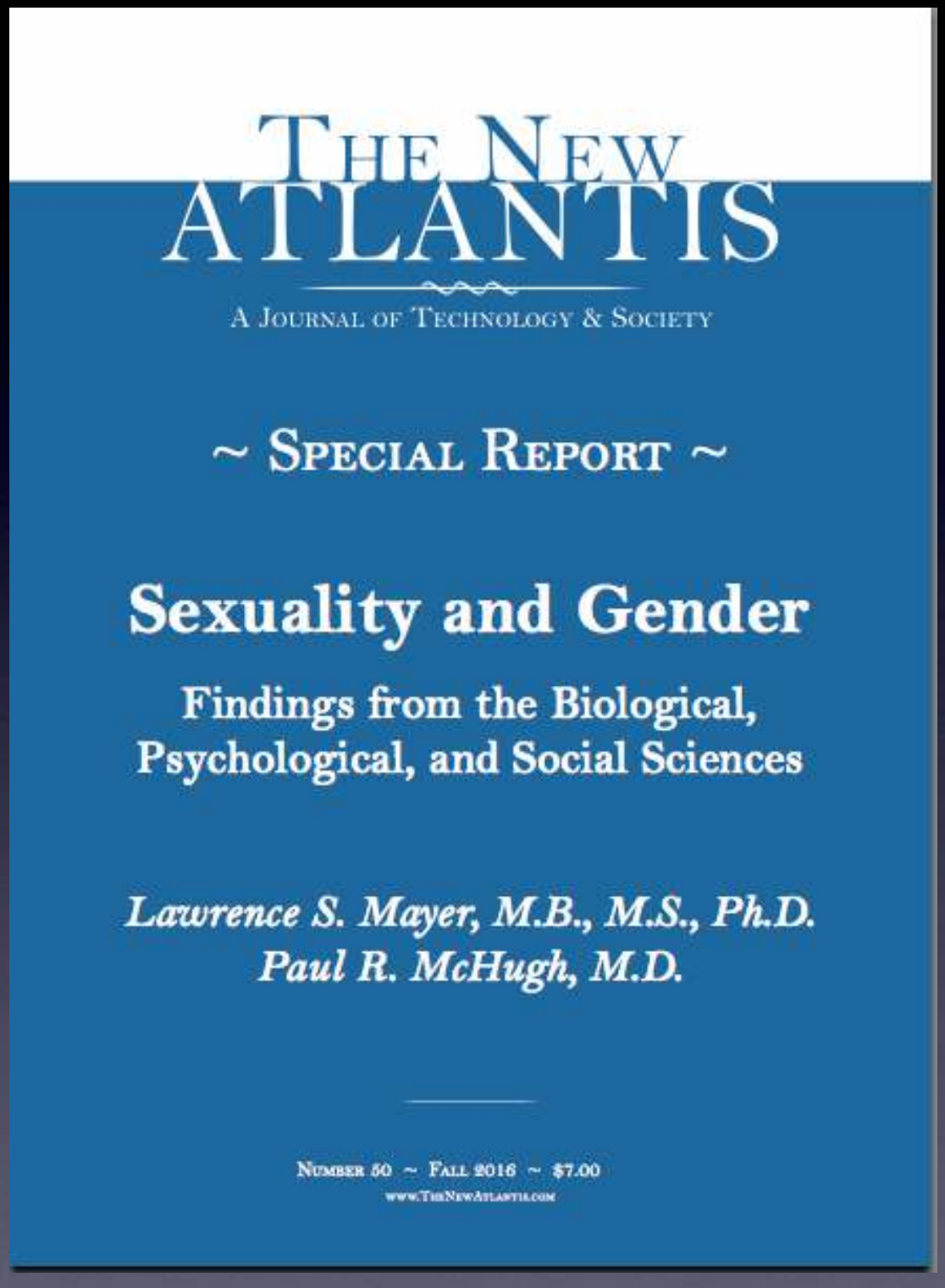
Swedish Study

Table S1. Risk of various outcomes in sex-reassigned subjects in Sweden compared to population controls matched for birth year and *birth sex*.

		Crude hazard ratio (95% CI)			Adjusted* hazard ratio (95% CI)		
Outcome	**No. of events (male-to-female/ female-to-male)**	**All sex-reassignment persons (N=324)**	**Male-to-female only (N=191)**	**Female-to-male only (N=133)**	**All sex-reassignment persons (N=324)**	**Male-to-female only (N=191)**	**Female-to-male only (N=133)**
Any death	27 (17/10)	2.9 (1.9-4.5)	2.6 (1.5-4.5)	3.7 (1.8-7.7)	2.8 (1.8-4.3)	2.4 (1.4-4.1)	3.8 (1.8-7.9)
Death by suicide	10 (6/4)	19.1 (6.5-55.9)	13.9 (3.9-49.6)	40.0 (4.5-357.9)	N/A	N/A	N/A
Death by cardiovascular disease	9 (6/3)	2.6 (1.2-5.4)	2.3 (0.9-5.7)	3.2 (0.9-11.9)	N/A	N/A	N/A
Death by neoplasm	8 (4/4)	2.1 (1.0-4.6)	1.7 (0.6-4.9)	2.8 (0.9-8.5)	N/A	N/A	N/A
Any psychiatric hospitalisation‡	64 (43/21)	4.2 (3.1-5.6)	4.7 (3.2-6.7)	3.4 (2.1-5.6)	2.8 (2.0-3.9)	3.2 (2.1-4.9)	2.2 (1.3-4.0)
Substance misuse	22 (14/8)	3.0 (1.9-4.9)	2.8 (1.6-5.1)	3.5 (1.6-7.8)	1.7 (1.0-3.1)	1.5 (0.7-3.1)	2.3 (0.9-5.8)
Suicide attempt	29 (22/7)	7.6 (4.7-12.4)	15.4 (7.9-30.2)	2.9 (1.3-6.8)	4.9 (2.9-8.5)	10.4 (4.9-22.1)	1.9 (0.7-4.8)
Any accident	32 (19/13)	1.6 (1.1-2.3)	1.4 (0.9-2.2)	1.9 (1.0-3.4)	1.4 (1.0-2.1)	1.2 (0.7-2.0)	1.8 (1.0-3.3)
Any crime	60 (33/27)	1.9 (1.4-2.5)	1.2 (0.8-1.7)	5.6 (3.5-9.1)	1.3 (1.0-1.8)	0.8 (0.5-1.2)	4.1 (2.5-6.9)
Violent crime	14 (8/6)	2.7 (1.5-4.9)	1.8 (0.8-3.7)	9.9 (3.2-30.7)	1.5 (0.8-3.0)	0.8 (0.3-2.1)	7.2 (2.1-24.4)

Notes: N/A Not applicable due to sparse data. *Adjusted for immigrant status and psychiatric morbidity up to baseline. ‡ Hospitalisations for gender identity disorder were excluded.


Any Cause of Death
Matched on sex at birth
1.00
0.95
0.90
0.85
0.80
0.75
0.70
Male controls
Female controls
Male to female
Female to male
0
10
20
30
Time of Follow-up (years)



A study of the studies.

-Examination of 500 papers in: epidemiology, genetics, endocrinology, psychiatry, neuro-science, embryology, and pediatrics

"The scientific definition of biological sex is, for almost all human beings, clear, binary, and stable, reflecting an underlying biological reality that is not contradicted by exceptions to sex-typical behavior, and cannot be altered by surgery or social conditioning."

~ Lawrence S. Mayer, M.B.,M.S., Ph.D.

"The notion that a two-year-old, having expressed thoughts or behaviors identified with the opposite sex, can be labeled for life as transgender has absolutely no support in science.

Indeed, it is iniquitous to believe that all children who have gender-atypical thoughts or behavior at some point in their development, particularly before puberty, should be encouraged to become transgender."

~Lawrence S. Mayer, M.B.,M.S., Ph.D.

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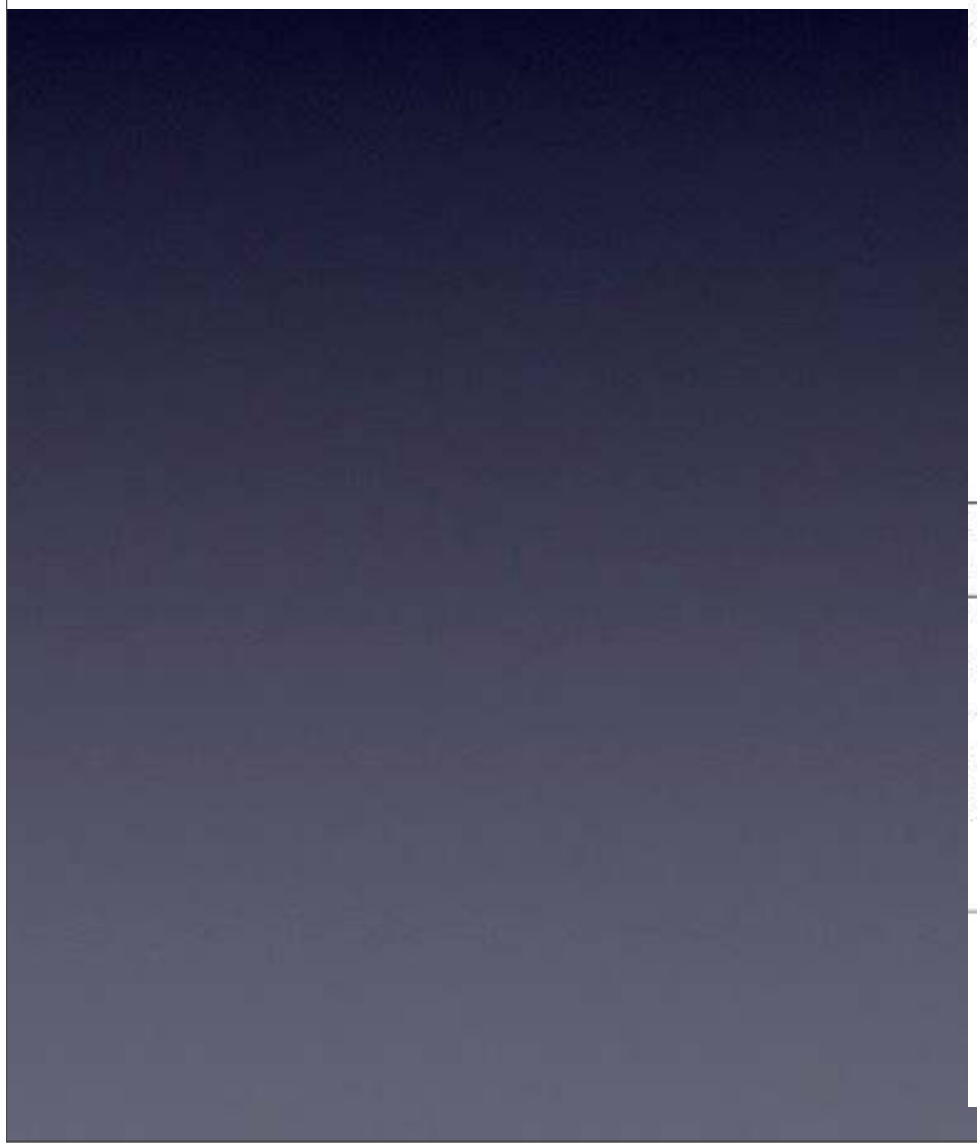
RESEARCH ARTICLE

Rapid-onset gender dysphoria in adolescents and young adults: A study of parental reports

Lisa Littman

Published: August 16, 2018 • https://doi.org/10.1371/journal.pone.0202330



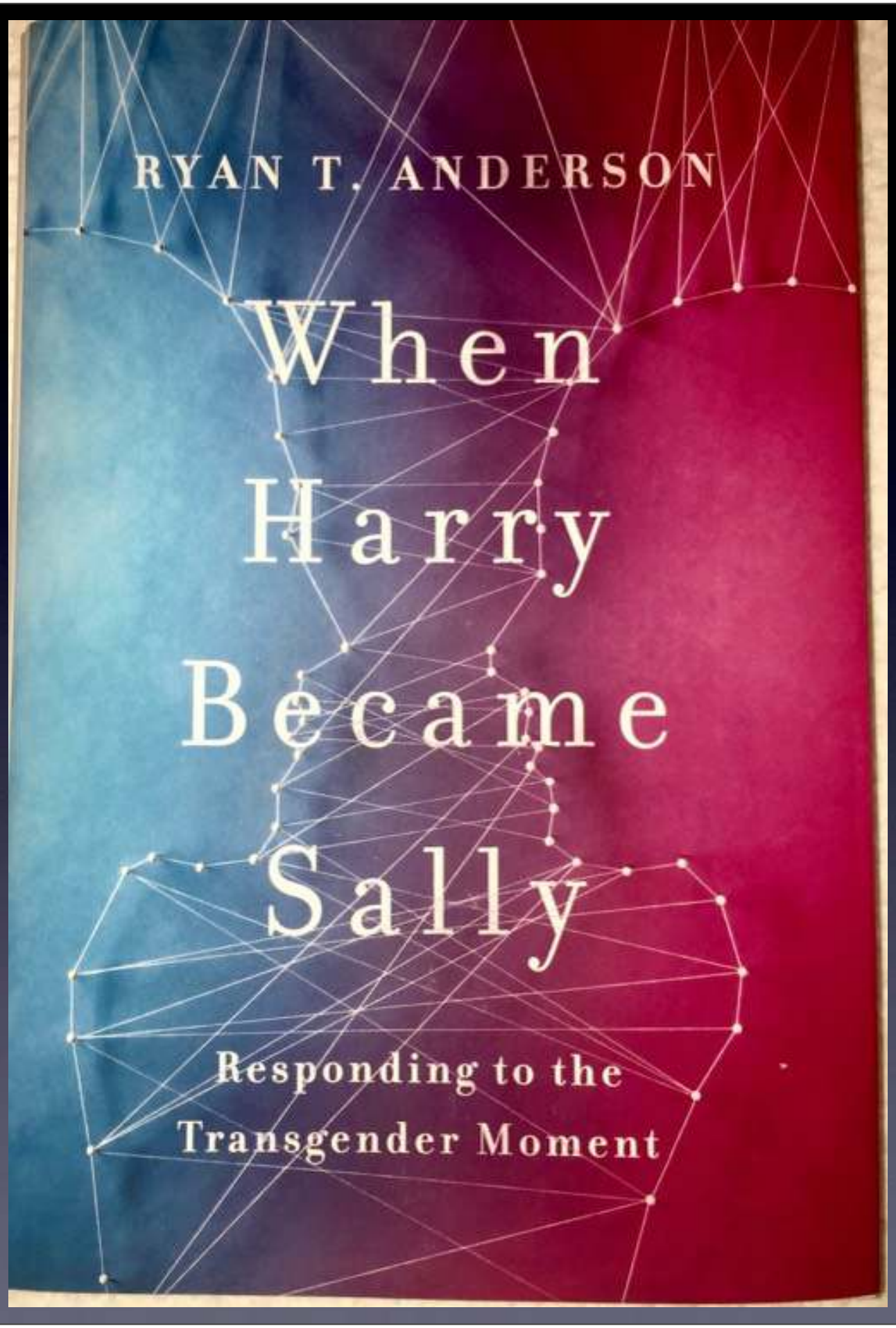
	Instructions on lying
	• "TL;DR find out what they want to hear if they're gonna give you T and then tell them just that. It's about getting treatment, not about being true to those around you. It's not their business and a lot of time doctors will screw stuff up for you."[a]
	• "…Get a story ready in your head, and as suggested keep the lie to a minimum. And only for stuff that can't be verified. Like how you were feeling, but was too afraid to tell anyone including your family."[b]
	• "I'd also look up the DSM for the diagnostic criteria for transgender and make sure your story fits it, assuming your psych follows it."[c]
Urgency to transition	• "…If you don't do it when you are young. You'll be miserable and unhappy with your body for the rest of your life."[d]
Vague and nonspecific symptoms called signs of GD	• "Signs of indirect gender dysphoria: 1. Continual difficulty with simply getting through the day. 2. A sense of misalignment, disconnect, or estrangement from your own emotions. 3. A feeling of just going through the motions in everyday life, as if you're always reading from a script. 4. A seeming pointlessness to your life, and no sense of any real meaning or ultimate purpose. 5. Knowing you're somehow different from everyone else, and wishing you could be normal like them…"[e]

a. https://www.reddit.com/r/asktransgender/comments/2nt8gi/having_a_psych_eval_soon/#bottom-comments
b. https://www.reddit.com/r/asktransgender/comments/4agf76/is_it_best_to_be_completely_honest_or_lie_a/
c. https://www.reddit.com/r/asktransgender/comments/4ihwar/what_things_should_i_never_tell_my_psychologist/
d. https://www.reddit.com/r/asktransgender/comments/3gpb94/at_the_final_stage_of_questioning_need_some/#bottom-comments
e. https://transgenderteensurvivalguide.tumblr.com/post/62036014416/that-was-dysphoria-8-signs-and-symptoms-of

JA2848

Britain's Youngest Patient

Although Ms Cooper underwent a thorough psychological assessment and counseling at Hull Royal Infirmary prior to starting her sex change therapy she has suffered such torment living as a woman that she has tried to commit suicide twice.


RYAN T. ANDERSON
When Harry Became Sally
Responding to the Transgender Moment

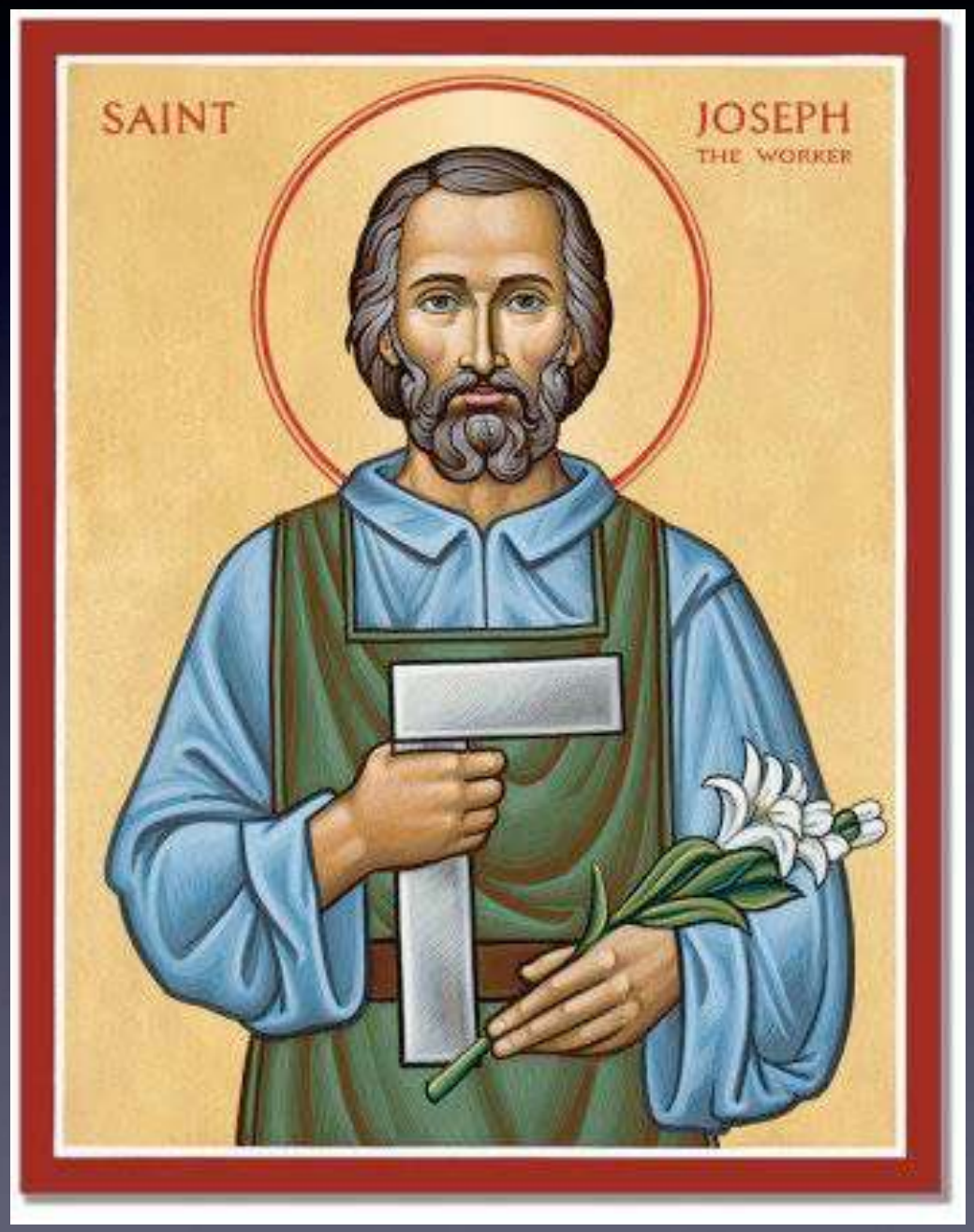
Summary

- Not a new condition. OCD w/ BDD.
- Psychological/ Spiritual wound.
- Ordinary childhood role playing being sexualized/treated with puberty blockers!
- In many cases, permanently mutilating surgeries.
- A huge engine of public opinion, policy, and enforcement aimed at the family, and the church.

- Transgender persons are at high risk for abuse and self harm.
- Care must be based in a true human anthropology.
- Missteps must be anticipated
- Protection from “blind guides”.
- Fluency in the language, and knowledge about the erroneous science will permit witnessing with patience and fraternal love.

Let Us Pray

God our Father,
creator and ruler of the universe, in every age you call man to develop and use his gifts for the good of others.
With Saint Joseph as our example and guide, help us to do the work you have asked and come to the rewards you have promised.
We ask this through our Lord Jesus Christ, your Son, who lives and reigns with you and the Holy Spirit, one God, for ever and ever.
Amen

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MARINES

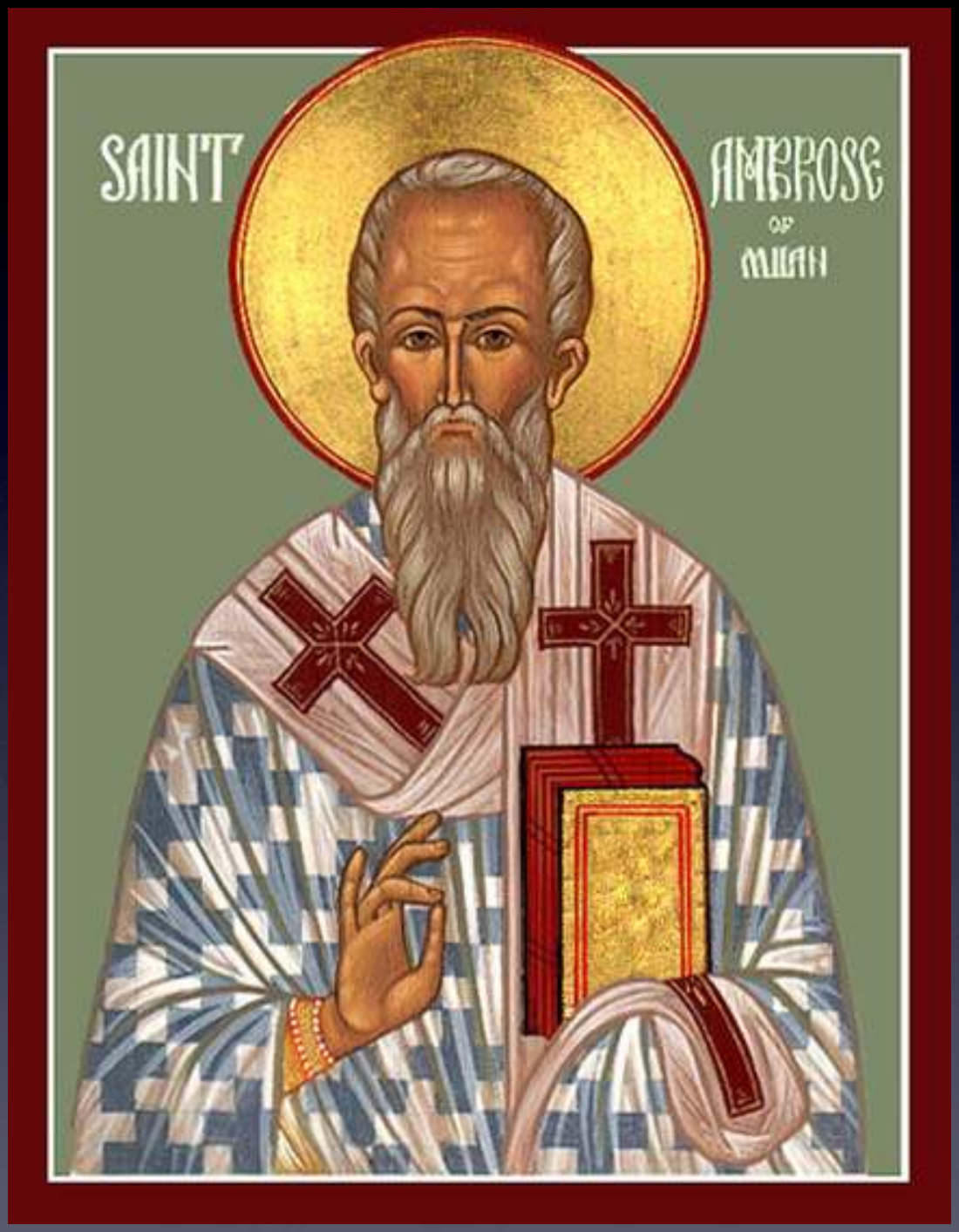
Let Us Pray

Oh glorious martyrs of Christ, Saints Cosmas and Damian, you gave your lives for the love of God, benefiting your fellow man, and crowning your martyrdom with an open and loyal profession of your faith. You taught us to love God above all things, and to love our fellow man as ourselves, professing always, and without fear, the religion of Jesus.Augmenting amongst the faithful populace many miracles, you are glorious indeed. Through your intercession, which brings about deliverance of these miracles, we pray to you for your aid in all things. May your patronage never be far from us in the illness of our body and soul.

Oh great protectors, Saints Cosmas and Damian, assist us with your love and free us from all evils. Amen

Let Us Pray

Lord,
you made Saint Ambrose an outstanding teacher of the Catholic faith and gave him the courage of an apostle.
Raise up in your Church more leaders after your own heart, to guide us with courage and wisdom.
We ask this through our Lord Jesus Christ, your Son, who lives nad reigns with you and the Holy Spirit, one God, for ever and ever.
Amen.



Let us Pray

Almighty God, whose deacon Vincent, upheld by you, was not terrified by threats nor overcome by torments: Strengthen us to endure all adversity with invincible and steadfast faith; through Jesus Christ our Lord, who lives and reigns with you and the Holy Spirit, one God, for ever and ever.

Amen

St. Vincent of Saragossa

Let Us Pray

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God our Father,
source of strength for all your saints; you led Paul Miki and his companions
through the suffering of the cross to the joy of eternal life.
May their prayers give us courage to be loyal until death in professing our faith.
Through Jesus Christ, your Son,who lives and reigns with you
in the unity of the Holy Spirit, one God, for ever and ever.
Amen.

Let Us Pray

O God, almighty Father, you have consecrated us to the work of bringing our brothers and sisters to the life of grace; there to grow in that perfection of our nature which leads to eternal life.
Grant unto us ,O Lord, an unswerving devotion to the service of those suffering from wounds that keep them from that fullness of life which you intend for all of us.
Do not allow us to be mislead by the deceptions of a world that has lost sight of you, and help us to follow in the obedience of your Son, Jesus Christ, who lives and reigns with you in the unity of the Holy Spirit, One God, for ever, and ever.
Amen


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In a first, the Pentagon plans to pay for a transgender soldier's gender transition surgery
transition surgery for first time

www.sexchangeregret.com

1947 From Male to Female and Back Again 2013

Sex Change REGRET

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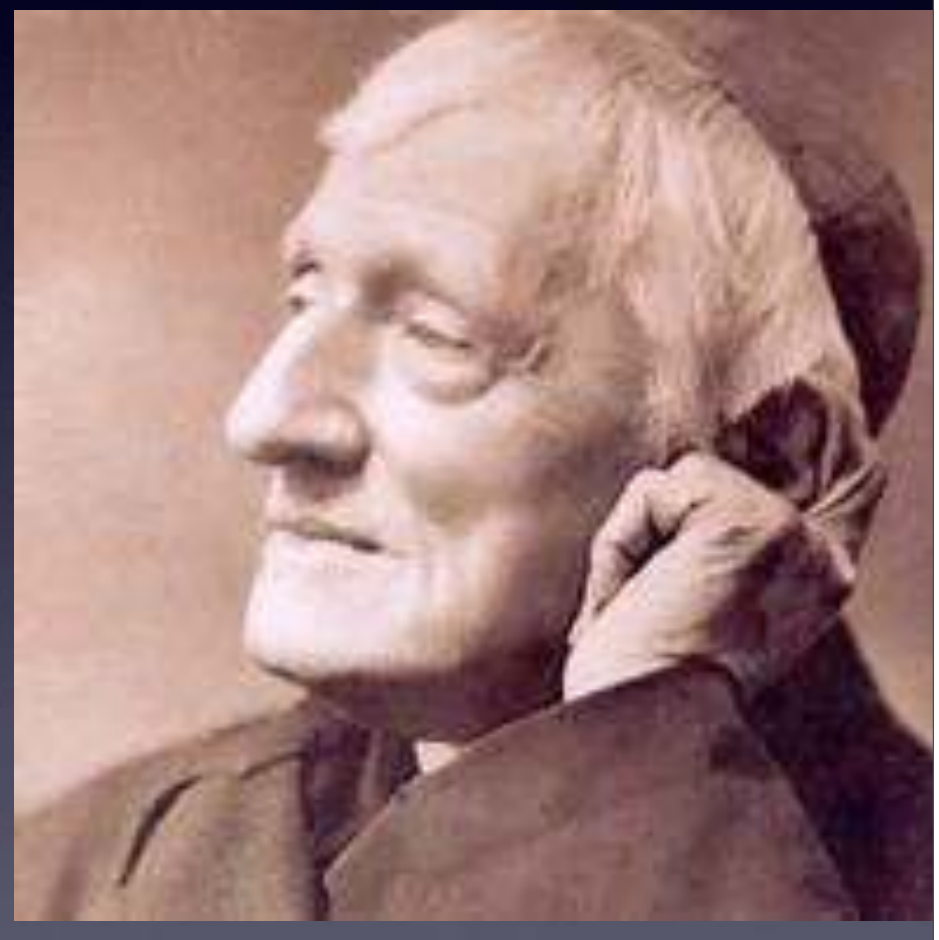
Reaching Out to Those with Sex Change Regret

This is the book you need in your hands

The Challenge

- Evangelizing people who are being relentlessly mislead concerning human sexuality.
- In need of catechesis at all levels.
- In need of pastoral sensitivity to particular wounds.
- In need of the sacraments.



Bl. John Henry Cardinal Newman

Plea For Mercy

- For The Children!
- To prevent suicide!

Let Us Pray

O Mary, Powerful Virgin; thou art the mighty and glorious protector of the Church; Thou art the marvelous **Help of Christians**; Thou art terrible as an army in battle array; Thou alone hast destroyed every heresy in the whole world. In the midst of our struggles, our anguish, and our distress, defend us from the power of the enemy, and at the hour of death, receive our souls into Paradise.
Amen

Transgender Surgery and Christian Anthropology

COURAGE
A Roman Catholic Apostolate

Deacon Patrick W. Lappert, MD
Birmingham in Alabama
256-303-8509

EXHIBIT 16

LIFESITE

NEWS

Plastic surgeon: Sex-change operation ‘utterly unacceptable’ and a form of ‘child abuse’

Dr. Patrick Lappert, a Catholic deacon in Alabama, says changing a person's sex is a lie and also a moral violation for a physician.

Exhibit
0034
9/30/2021
Dr. Lappert

Lisa Bourne

Mon Sep 9, 2019 - 6:42 pm EDT

EDITOR'S NOTE: This story contains explicit content.

September 9, 2019 (LifeSiteNews) – The idea that you can change someone's sex is a lie, an Alabama-based plastic surgeon said, and pursuing this avenue with children amounts to child abuse.

"It's a form of tyranny, exercising a form of tyranny over our own bodies," Dr. Patrick Lappert said. "And in the case of children, it's child abuse."

Appearing on a recent broadcast of Relevant Radio's Trending with Timmerie, Lappert said the view that the human body is something that someone owns, that they can do things in order to provoke happiness in themselves, is a self-reverential view divorced from the objective reality of the human person.

Lappert briefly touched on the negative physical effects of same-sex sexual activity, and he also explained in detail the disturbing reality of what happens when a person undergoes so-called sex-change surgery.

He called it "utterly unacceptable" on moral grounds for a plastic surgeon, because it disregards the surgeon's call to balance respect for both form and function of the body in his or her work.

Regarding children, Lappert said, sexualizing them at a young age with these ideas is grooming them for later abuse.

"It's atrocious," he said. "And no one even knows how that's going to play out. There's no body of scientific evidence to even support the safety of doing that to children. But it's being done."

"Children do not have the capacity to consent to those sorts of treatments," Lappert said of sex-change procedures. "You cannot tell a pre-adolescent child anything about their adult life and expect that they're going to understand what you're telling them."

"Their concept of themselves is in the formative years," he continued. "And to ask a child to think of their sexuality when they're pre-adolescent is utterly insane. And it's in fact another great evil that's being inflicted upon children because it's the sexualization of normal chaste friendships of childhood."

'They will never be the other sex'

Asked "What is a sex change?" Lappert responded, "Well, to begin with, the idea that you can change someone's sex is a lie."

"Many people have been led to believe by a lot of very clever programs and advertising from plastic surgeons and whatnot that you can actually change a man into a woman or a girl into a boy or anything like that," he said. "You cannot. Essentially all you can do is you can modify people's bodies both with medicines as well as with surgery to make them appear to be the other sex, but they will never be the other sex."

Lappert, a board certified general surgeon and plastic and reconstructive surgeon, is a Navy and Marine veteran, as well as a permanent deacon for the Diocese of Birmingham, Alabama. He is also chaplain for the Courage apostolate in the Birmingham diocese.

Experts have said for years that surgery or hormone treatment for gender-confused individuals, and certainly encouraging transgender ideas in children, is not the solution, and can result in exacerbating their condition.

Nonetheless, sex change surgeries have been on the rise, transgender ideology continues to be pushed in schools, civil government, and healthcare associations and institutions, while gender confused-individuals are also appearing more and more in pop culture, sports, media, and advertising.

The beginning stages

Lappert said gender confused individuals will typically begin by adopting a lifestyle and persona, change their name, hair and other aspects of their looks, and then move onto other identity components such as changing their driver's license and so on. Then hormonal medications are often introduced, and while sometimes these may initially make someone feel better about their gender confusion, this gives the false impression that surgical intervention will result in success, and taking hormones of the opposite sex over time can have a negative physical impact.

Irreversible

Most of the chemical interventions and cosmetic procedures done to alter a person's face or neck are to a degree reversible. However, Lappert warned, more invasive surgeries, such as mastectomy and procedures involving genitalia, are not.

A counterfeit vagina

In the case of men seeking to present as women, after they've had the other initial interventions performed, a definitive genital surgery includes castration, removal of the testicles, and the opening of the penis and removal of the erectile tissue, which is a procedure called penile inversion. This is where the penis is turned inside out and suspended up in the pelvis, turning it into "a receptive structure," Lappert explained.

The tissues of the scrotum are then turned into labia, meaning the external genitalia portions of the phallus itself are used to create the labia minora. In creating the receptive structure, the surgeon is trying to preserve the nerves, so that those parts of the genitalia that provoke erotic sensation can do so.

"Which is a very challenging thing to try to do when you're essentially mutilating the penis," he said, "to try to preserve the neurological support for it, so that the person can have erotic sensation from this counterfeit vagina that you've created."

"The problem is that this counterfeit vagina doesn't want to keep its dimensions," said Lappert. "And so you're constantly having to attend to the dilation of it to try to preserve its dimensions and so on. You also are taking the urethra that was in the penis and shortening it down so that it essentially is just an opening at the top of this counterfeit vaginal orifice that you've created."

This is the most commonly performed operation for males trying to present as female, he said.

A counterfeit penis

In the case of women trying to present as men, it begins with the removal of the ovaries and the uterus, removal of the vagina and the creation of a neo phallus, or a counterfeit penis.

This can be done a couple of different ways, he said, one being a high dose of testosterone, which will produce an enlargement of the clitoris, and then when you have exhausted those very high levels of testosterone, and they've had this effect on the clitoris, an operation is done to lengthen the urethra so that the urethra is extended along the underside of this enlarged clitoris, so that the urine empties at the tip of this structure.

That operation is called a metoidioplasty.

"And essentially what you get there is a small phallus," said Lappert, "and that's usually supplemented by creating a neo scrotum into which are placed two prosthetic testicles."

For women seeking a more developed physique, Lappert continued, a neo phallus is produced by what's called a flap operation.

This is where an area of tissue, typically from the leg, is raised up and surgically turned into a cylindrical structure inside of which is a urethral tube. That urethra tube is then connected to the native urethra, which appears at the base of the clitoris. The clitoris tissue itself is draped over the base of this neo phallus and then, again, a counterfeit scrotum with prosthetic testicles.

“And then in that whole apparatus you can also implant malleable or inflatable prosthetics that can produce the appearance of an erection,” explained Lappert. “So that's called a phalloplasty by flap operation.”

The most common flap operation done today is to harvest the skin for the neo phallus from the forearm, said Lappert.

“It's called a radial forearm flap and it's a tremendously disfiguring surgery on the forearm,” he said. “And so these women who are presenting as men will tattoo their forearms to conceal the disfigurement.”

“And then so (ultimately) what you wind up with is a counterfeit phallus or a counterfeit vagina,” stated Lappert.

Why are these counterfeit?

“Because they don't function the way those structures function,” said Lappert. “It’s obviously the case with the reproductive organ that what you're doing is you're robbing the person of an essential human capacity of the reproductive faculty. And that's not reversible or retrievable.”

“You cannot preserve the procreative function when you do these operations,” stated Lappert.

A sterile act

The doctor then touched on the spiritual component with these procedures.

“As Catholics, we recognize the human sexual embrace that's having two aspects, its unity and its procreative,” said Lappert. “It unites the two persons in an emotional-spiritual bond. But it's also a fruitful union.”

“Well, (with sex change procedures) you've robbed it of its fruitfulness,” he said. “It's now become a sterile act.”

The erotic sensation is never fully preserved

"The other thing that people don't understand is that because of the surgeries I've just described the desire to preserve erotic sensation from these structures that you're mutilating is never fully met," said Lappert.

In the nature of our nervous system there is a thing called neural mapping, he continued, meaning even though the physician works to preserve those nerves, the nerves continue to recognize sensations from their original form and function.

"The brain is still thinking that, even though you've turned your penis into a counterfeit vagina, whenever it is stimulated the brain is still thinking that there is a penis down there," said Lappert. "So here's a person trying to live as a woman hoping that they're going to be able to conduct their lives as women, who enters into a relationship with a man, and then in a sexual act is constantly being reminded by their own bodies that they are in fact still men, and that's a hard one to get over."

The malpractice of medicine

Lappert also warned that a whole generation of children is being raised whose psychosexual, physical, and neurological development are being stunted in hopes of supporting this cross-sex idea of themselves – pushed by the transgender industry.

He pointed out that if you took 100 children with cross-sex idea of themselves, 91 percent of them will desist.

"Ninety-one percent of them will stop thinking of themselves as the other sex," said Lappert. "But if you take the same hundred children to a transgender clinic at your local urban center, 100 percent of them will persist in it, which on the face of it tells you that this is this is the malpractice of medicine."

"If 91 percent of them would have gotten over the disease and 100 percent of them persistent and obviously you're doing something wrong here," he added. "But nonetheless that's how it's being presented."

"People are being led to believe that if you have the surgery your sorrows will go away," said Lappert. "But what's called gender dysphoria, this interior sense of sadness that the persons who suffer with transgender feel, they're being told that if they have all of this medical and surgical therapy, that those bad feelings will go away. And the best study looking into that tells us that that is not the case."

After a period of observation beyond some eight to 10 years, the suicide rate goes right back to where it was if nothing had been done for these people.

"If you didn't offer them any care at all, you'd have the same suicide rate that people have now after all of the surgical interventions," said Lappert. "And after the excitement dies down, and eight, 10 years later, they're right back to a 40 to 42 percent suicide rate. So that's a huge misrepresentation of benefit that is just not true."

Advocates for gender-confused individuals continually say these individuals need authentic psychological help that focuses upon the source of the confusion.

This kind of surgery is utterly unacceptable

Lappert called sex change surgery "an intentional destruction of a human faculty," and "so on moral grounds from the perspective of a plastic surgeon this kind of surgery is utterly unacceptable."

The language of slavery

Because these procedures result in sterilization, they are tied to assisted reproductive technology, Lappert explained, with patients asked how they want to "preserve their fertility," donating either sperm or ova, should they want children later.

"Those things will be put aside and for future assisted reproductive technology, essentially turning human persons into commodities," Lappert said.

A huge evil

"Because they will be told, you have a right to have a child even though you're having this transgender surgery," he said. "You have a right to have a child. So we're going to do these things for you. Well, that's the language of slavery, to speak of a person that's having a right to another person is the language of slavery."

"It's leading us to seeing the human person as a commodity that is regulated by the government, by government institutions, universities, and by laboratories," Lappert continued. "And that is a huge evil. It's a huge evil and never forget, that transgender surgery is right at the heart of that evil."

"First of all because it utterly perverts our sense of human sexuality," he said. "It internally divides the human person from their very own bodies. And now it's separating the human community from their reproductive faculties, in the era of assisted reproductive technology. So this is diabolical in every sense of the word. Diabolical."

Rejecting objective truth

Encouraging people to pursue sex-change surgery rejects understanding of who the human person is, said Lappert.

“One of the mistakes that people are making in contemporary life is viewing themselves as sort of a spirit creature and their bodies as something that they own or something that they possess,” he said. “They view their own bodies as something that they can do things to in order to provoke happiness in themselves. It's a very self-referential view of the human person and it has at its heart this division of the nature of the human person.”

Plastic surgery can never divorce itself from objective reality just as no form of medical care can separate itself from the objective truth of who the human person is, he said.

“So if I aim to be a good surgeon, then the very first thing I have to understand is the subject upon whom I am working,” Lappert stated. “If I have met grave misunderstandings about the objective reality of that of the person, I'm going to be making some serious mistakes when I embark on medical or surgical care.”

“To view the body as a thing, but somebody that a person owns, to view themselves, their personhood is something separate from their own bodies, is a very grave mistake,” he said. “And then to set about modifying the body in ways that you hope will bring about a lasting happiness can't possibly succeed, because it begins with a lie, it begins with an error about the objective truth of who the human person is.”

The full interview with Dr. Patrick Lappert is available HERE.

Two positive resources for gender-confused and same-sex attracted individuals featured in the discussion were the Roman Catholic Courage apostolate and Walt Heyer’s outreach titled Sex Change Regret. Heyer had transitioned to living as a woman and then returned to living as a man, and now performs outreach for gender-confused people.

Information on Courage is available HERE and HERE.

The Sex Change Regret website can be accessed HERE.

James Shupe, formerly Jamie Shupe, ex-transgender and former non-binary person, writes about his experience and chronicles transgender issues HERE.

The National Suicide Prevention Hotline provides free and confidential help and resources to individuals in distress 24/7. The number is 800-273-8255.

Additional resources are available here, here and here.

TOPICS

Gender

TAGGED AS

Gender Confused Hormone Treatment Patrick Lappert Penis Plastic Surgery Sex-change Surgery Transgenders Vagina

EXHIBIT 17

Reference Module in Neuroscience and Biobehavioral Psychology
Encyclopedia of Mental Health (Second Edition)
2016, Pages 183-186

Body Dysmorphic Disorder

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Abstract

Body dysmorphic disorder (BDD) is primarily characterized by an excessive preoccupation with a perceived defect or flaw in appearance that others would be unable to observe, or would consider slight in appearance. BDD is accompanied by repetitive behaviors intended to hide, fix or check on the perceived appearance flaw. This article provides an overview of the current understanding of the factors influencing the onset and maintenance of BDD symptoms, as well as prevalence rates. The assessment and treatment of this common and severe disorder are also discussed.

Keywords

Assessment; BDD; BDD by proxy; Body dysmorphic disorder; Body image; Clinical features; Epidemiology; Etiology; Muscle dysmorphia; Treatment

Recommended articles Citing articles (0)

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Dr. Wilhelm has been the principal investigator or site principal investigator of 7 NIMH-funded research grants. She is the vice chair of the Scientific Advisory Board of the International OCD Foundation, and she serves on the Scientific Council for the Anxiety and Depression Association of America as well as on the Tourette Syndrome Association Behavioral Science Consortium. Dr. Wilhelm serves on several editorial boards and is a Representative-at-Large for the Association for Behavioral and Cognitive Therapies (ABCT).

IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF NORTH CAROLINA

MAXWELL KADEL, *et al.*, *Plaintiffs*, v. DALE FOLWELL, in his official capacity as State Treasurer of North Carolina, *et al.*, *Defendants*.	Case No. 1:19-cv-00272-LCB-LPA

PLAINTIFFS' MOTION TO EXCLUDE
EXPERT TESTIMONY OF STEPHEN B. LEVINE, M.D.

Now come, Plaintiffs, by and through their counsel, and respectfully move this Court to exclude the expert report, opinions, and testimony of State Health Plan Defendants[1] proposed expert, Stephen B. Levine, M.D., pursuant to Federal Rules of Civil Procedure 26 and 37, and Federal Rules of Evidence 104, 403, and 702. Dr. Levine is not a qualified expert on gender dysphoria or its treatment, and his opinions and testimony are neither relevant nor reliable pursuant to the standards set forth in *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579 (1993), and its progeny. His opinions and testimony are likewise inadmissible because any probative value they may have is substantially outweighed by the danger of unfair prejudice, confusion of the issues, waste of time, undue delay, and needless presentation of cumulative evidence. *See* Fed. R. Evid. 403.

[1] The State Health Plan Defendants are the North Carolina State Health Plan for Teachers and State Employees ("NCSHP"); Dale Folwell, in his official capacity as State Treasurer; and Dee Jones, in her official capacity as Executive Administrator of the NCSHP.

A memorandum of law is filed contemporaneously herewith.

Dated this 2nd day of February, 2022.

Respectfully submitted,

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PLAINTIFFS' MEMORANDUM OF LAW IN SUPPORT OF MOTION TO EXCLUDE EXPERT TESTIMONY OF STEPHEN B. LEVINE, M.D.

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I. STATEMENT OF THE CASE AND FACTUAL BACKGROUND

Plaintiffs, all current or former employees, or dependents of current or former employees, of certain North Carolina public Universities ("NC Universities") or the North Carolina Department of Safety ("NCDPS") filed an Amended Complaint with this Court on March 12, 2021 challenging a discriminatory exclusion in the North Carolina State Health Plan for Teacher and State Employees ("State Health Plan").

Plaintiffs contend that the State Health Plan's exclusion of coverage for gender-confirming healthcare treatment violates their equal protection rights and discriminates against them based on their sex in violation of Title IX and the Affordable Care Act.

II. QUESTION PRESENTED

Whether the testimony of Stephen B. Levine, M.D.,[1] should be excluded because it is irrelevant and unreliable in accordance with *Daubert* v. *Merrell Dow Pharm. Inc.*, 509 U.S. 579 (1993) and the applicable Federal Rules of Evidence.

III. SUMMARY OF THE ARGUMENT

Dr. Levine's proffered opinions fall into three categories of exclusion. First, most of Dr. Levine's opinions are irrelevant because they are not in opposition to the relief Plaintiffs seek and instead align with Plaintiffs' experts. Second, Dr. Levine's opinions fail to create any material disputes of fact because the relevance of his opinions are outside the scope of the parties' dispute which is simply whether an insurance plan can exclude coverage for some people that it does not exclude for others. Further, his opinions cover

[1] Declaration of Stephen B. Levine, M.D., signed April 28, 2021, is attached as Exhibit A to the concurrently filed Declaration of Carl S. Charles ("Charles Decl.").

topics already addressed by Fourth Circuit precedent including the appeal in this case, *Kadel v. N. Carolina State Health Plan for Tchrs. & State Emps.*, 12 F.4th 422 (4th Cir. 2021) and *Grimm v. Gloucester Cnty. Sch. Bd.*, 972 F.3d 586 (4th Cir. 2020), as amended (Aug. 28, 2020), *cert. denied*, 141 S. Ct. 2878 (2021). Third, Dr. Levine's remaining opinions must be excluded because they are unreliable, not based on scientific methodology but rather untested hypotheses, pure speculation, and beliefs that lack any support besides Dr. Levine's own *ipse dixit*. As Dr. Levine's opinions should be excluded pursuant to *Daubert* standards, and – when viewed in the context of Federal Rule of Evidence 403, any probative value is substantially outweighed by the danger of unfair prejudice, confusion of issues confusion of the issues, waste of time, undue delay and needless presentation of cumulative evidence – this Court must exclude them.

Relevant to this Court's consideration is other federal courts' resounding dismissal of Dr. Levine's opinions about transgender people and the treatment of gender dysphoria. This began seven years ago with the holding in *Norsworthy v. Beard*, 87 F. Supp. 3d 1164, 1188–89 (N.D. Cal. 2015) that "the Court gives very little weight to the opinions of Levine, whose report misrepresents the Standards of Care; overwhelmingly relies on generalizations about gender dysphoric prisoners, rather than an individualized assessment of Norsworthy; contains illogical inferences; and admittedly includes references to a fabricated anecdote." This holding was echoed in *Edmo v. Idaho Dep't of Corr*. 358 F. Supp. 3d 1103, 1125-1126 (D. Idaho 2018) (vacated in part on other grounds in *Edmo v.*

Corizon, Inc., 935 F.3d 757 (9th Cir. 2019)) (holding that Dr. Levine "is an outlier in the field of gender dysphoria" and place[s] "virtually no weight" on his opinions.).

Dr. Levine's opinions were further diminished in *Hecox v. Little,* where the Court dismissed his opinion that "gender affirming policies are harmful to transgender individuals," and instead "accept[ed] Plaintiffs' evidence regarding the harm forcing transgender individuals to deny their gender identity can cause." 479 F. Supp. 3d 930, 977 n.33 (D. Idaho 2020). And in this year alone, two more federal courts strongly discounted his proffered testimony by granting preliminary injunction motions against laws banning gender-confirming medical care and participation in school athletics, respectively. *Brandt v. Rutledge*, No. 4:21CV00450 JM, 2021 WL 3292057 (E.D. Ark. Aug. 2, 2021); *B. P. J.* v. *W. Virginia State Bd. of Educ*., No. 2:21-CV-00316, 2021 WL 3081883 (S.D.W.Va. July 21, 2021).

IV. ARGUMENT

A. Legal Standard

Federal Rule of Evidence 702 places "a special gatekeeping obligation" on a trial court to ensure that an expert's testimony is "relevant to the task at hand" and "rests on a reliable foundation." *Daubert*, 509 U.S. at 597; *Sardis v. Overhead Door Corp.*, 10 F.4th 268, 281 (4th Cir. 2021); *see* Advisory Committee Note to 2000 Amendments to Rule 702 (amendment "affirms the trial court's role as gatekeeper," and that "all types of expert testimony present questions of admissibility for the trial court in deciding whether the evidence is reliable and helpful"). The party offering the expert carries the burden of

establishing the admissibility of testimony by a preponderance of the evidence. *Cooper v. Smith & Nephew, Inc.*, 259 F.3d 194, 199 (4th Cir. 2001).

The initial step is to determine whether the proposed expert is qualified to render the proffered opinion. In doing so, a trial court considers an expert's professional qualifications and "full range of experience and training." *Belk, Inc. v. Meyer Corp., U.S.,* 679 F.3d 146, 162 (4th Cir. 2012), *as amended* (May 9, 2012) (cleaned up). If the purported expert lacks the knowledge, skill, experience, training or education on the issue for which the opinion is proffered, the trial court must exclude the expert. *See, e.g., Thomas J. Kline, Inc. v. Lorillard, Inc.*, 878 F.2d 791, 799 (4th Cir. 1989); *Mod. Auto. Network, LLC v. E. All. Ins. Co.*, 416 F. Supp. 3d 529, 537 (M.D.N.C. 2019) (Biggs, J.), *aff'd*, 842 F. App'x 847 (4th Cir. 2021). Even if the expert is deemed qualified, the trial court must consider the relevancy of the expert's testimony as "a precondition to admissibility." *Sardis,* 10 F.4th at 282 (cleaned up). To be relevant, the testimony must have "a valid scientific connection to the pertinent inquiry." *Id*. at 281 ("Simply put, if an opinion is not relevant to a fact at issue, *Daubert* requires that it be excluded.").

Finally, if deemed relevant, the trial court will inquire if the opinion is based on a reliable foundation, which focuses on "the principles and methodology" employed by the expert to assess whether it is "based on scientific, technical, or other specialized *knowledge* and not on belief or speculation." *Id*. at 281, 290 (cleaned up). When evaluating whether an expert's methodology is reliable, a court considers, among other things:

> (1) whether the expert's theory can be and has been tested; (2) whether the theory has been subjected to peer review and publication; (3) the known or

> potential rate of error of the particular scientific technique; and (4) whether the technique is generally accepted in the scientific community.

Id.; *see also Kumho Tire Co., Ltd. v. Carmichael*, 526 U.S. 137, 149-150 (1999); *Daubert,* 509 U.S. at 593-94. While trial courts have "broad latitude" to determine reliability, they must engage in the gatekeeping process and not simply "delegate the issue to the jury." *Sardis*, 10 F.4th at 281.

In certain situations, when an expert relies upon his experience and training, and not a specific methodology, the application of *Daubert* is more limited. *See Freeman v. Case Corp.*, 118 F.3d 1011, 1016 n.6 (4th Cir. 1997). When addressing an expert whose methodology is grounded in experience, courts use three factors: "1) how the expert's experience leads to the conclusion reached; 2) why that experience is a sufficient basis for the opinion; and 3) how that experience is reliably applied to the facts of the case." *SAS Inst., Inc. v. World Programming Ltd*., 125 F. Supp. 3d 579, 589 (E.D.N.C. 2015); *see also Nat'l Ass'n for Rational Sexual Offense L. v. Stein*, No. 1:17-cv-53, 2021 WL 736375, at *3 (M.D.N.C. Feb. 25, 2021) (Biggs, J.).

Finally, because "expert evidence can be both powerful and misleading because of the difficulty in evaluating it," "the judge in weighing possible prejudice against probative force under Rule 403…exercises *more* control over experts than over lay witnesses." *Daubert,* 509 U.S. at 595 (cleaned up). As such, "the importance of [the] gatekeeping function cannot be overstated." *Sardis*, 10 F.4th at 283 (cleaned up).

B. Many of Dr. Levine's Opinions Have No Relevance To This Case Because They Are Consistent With Plaintiffs' Position.

Nearly all of Dr. Levine's opinions are not relevant and will not help the "trier of fact to understand the evidence or to determine a fact in issue," because, with very limited exception, he simply does not oppose the relief plaintiffs seek. *Nease*, 848 F.3d at 229. For that reason, Dr. Levine's opinions do not "fit" with the facts relevant to resolving Plaintiffs' claims. *Bourne v. E.I. DuPont de Nemours & Co.*, 85 F. App'x 964, 966 (4th Cir. 2004); *Viva Healthcare Packaging USA Inc. v. CTL Packaging USA Inc.*, 197 F. Supp. 3d 837, 846 (W.D.N.C. 2016) ("The test for relevance, or 'fit,' considers 'whether expert testimony proffered in the case is sufficiently tied to the facts of the case that it will aid the jury in resolving a factual dispute.'" (quoting Daubert, 509 U.S. at 591)).

Overwhelmingly, Dr. Levine's opinions align with the relief Plaintiffs seek in this case: that adolescents and adults with gender dysphoria receive and be able to access and afford individualized medical treatments. Charles Decl., Ex. B at 66:21-67:3; 69:18-70:2. For almost fifty years, Dr. Levine's clinical practice has notably adhered to the medical community's widely accepted and authoritative guidance for transgender care, the World Professional Association of Transgender Health ("WPATH") Standards of Care ("SOC"). Charles Decl., Ex. C at 1-100:15-22. As the WPATH's former Chairman of the SOC Committee, Dr. Levine helped to write Version 5 of the WPATH SOC, recognized his own writing in Version 7, and asked if he could help draft the forthcoming Version 8. Charles Decl., Ex. A at ¶3; Ex. D at 37:17-38:7; Ex. C at 1-90:10-20. In accordance with the SOC,

he provides individualized treatment including providing letters of recommendation for gender affirming surgeries and hormone therapy. Charles Decl., Ex. B at 55:13-17; 56:2-5; 112:16-21; 176:8-16. He does not provide such letters unless he has sufficiently informed patients and received a reasonable assurance that they understand. Charles Decl., Ex. B at 176: 8-16; 225:24-226:17. He testified repeatedly that he "is not advocating denying endocrine treatment or surgical treatment" to transgender people, a position he described as "draconian."[2]

Dr. Levine admitted at deposition that he is "not an expert in health insurance," nor an expert about what "health insurance should or should not cover." Charles Decl., Ex. B at 86:1-8. But he supported the idea that patients should be able to access and afford treatment for gender dysphoria.[3] *Id.* at 66:21-67:3. Dr. Levine also confirmed that he has not met with or interviewed any of the Plaintiffs and is not offering any opinions about them, including the veracity of their symptoms of gender dysphoria, the accuracy of their

[2] Charles Decl., Ex. B at 73:4-7 ("Q: Is the worrisomeness about a patient's future health, is that a reason to ban all medical care for gender dysphoria? A: Absolutely not."); 84:21-85:1 ("Q: Given all those concerns you have, is that a reason to deny all medical interventions to people with gender dysphoria? A: No …."); 85:4-11 ("Q: Are those concerns you raised justifications in your mind for denying medical interventions to people who have gender dysphoria? A: You know, I'm not advocating denying endocrine treatment or surgical treatment."); 152:1-6 ("Q: do you think because that study showed that some people committed suicide after gender affirming surgery that no patient should be able to access gender affirming surgery? A: That would be illogical"); 154:3-5 ("Q: But you're not recommending total bans on gender affirming surgery? A: I'm not recommending total bans."); 160:23-25 ("I did not say that gender affirming treatment in general should be stopped. I've never said that.").

[3] And testified at deposition only nine months earlier that treatment should be afforded through insurance coverage if necessary. Charles Decl., Ex. G at 156:10-157:17.

diagnoses, their mental health histories, or the effects of any treatment they have received. Charles Decl., Ex. A at ¶128; Ex. B at 91:5-92:5. None of these opinions are oppositional to relief Plaintiffs seek, and therefore are not relevant to the issues before this Court. Additionally, his uncertainty about the percentage of transgender people who experience gender dysphoria, ECF No. 137-8, 241:24-242:14, has no relevance to the transgender plaintiffs before the Court who *do* requirement treatment. And his speculation about people "who present themselves as cis gender" but may have cross-gender identification and "really dangerous degrees of substance abuse" is completely untethered to the claims here. ECF No. 137-8, 242:15-243:20.

C. Certain Opinions of Dr. Levine Have No Relevance To This Case Because They Address Issues Beyond The Scope Of The Dispute Or Have Already Been Decided By The Fourth Circuit.

Dr. Levine's opinions fail to create any material disputes of fact because the relevance of his opinions has been disclaimed by the binding admissions of Defendants' witnesses. For example, Dr. Levine proposes to offer the opinion that "sex as defined by biology and reproductive function cannot be changed." Charles Decl., Ex. A at ¶8(a), ¶12. But this is simply an insurance dispute asking whether a state health plan's categorical exclusion of care for transgender people that is covered for cisgender people discriminates based on sex and transgender status. The Court need not resolve questions about the etiology of sex or being transgender, whether "sex is permanently assigned at conception," or, frankly, whether it is okay for a person to be transgender. *Id*. at ¶9. The Court here need only decide whether this insurer can deny the same kinds of treatments to transgender

people that it affords to cisgender people. The Fed. R. Civ. P. 30(b)(6) witness for the health plan, Dee Jones, agrees. She testified that individuals enrolled in the State Health Plan can change their sex identification marker in the Plan's records by simply calling into the call center, talking to a representative, validating their identity and requesting the change. Charles Decl., Ex. E at 85:10-87:22. She further testified that to make such a change the Plan does not require proof of the enrollee's current physical anatomy, their DNA, or their chromosomal make up. *Id*. The Plan thus takes no position on the issues in Dr. Levine's report about the etiology of sex, and instead respects participants' self-reported gender identity as an accurate determinant of their sex designation. Facts provided by Defendants' own witnesses render Dr. Levine's proposed opinions about "immutable biology" irrelevant.

Dr. Levine's opinions do not help this Court because the Fourth Circuit's precedent informs review of the issues. Controlling precedent on these issues in the recently decided *Grimm v. Gloucester Cnty. Sch. Bd.* and the Fourth Circuit appeal in this case render Dr. Levine's opinions irrelevant. His attempts to disparage the credibility of the WPATH and diminish the SOC as ideological and unscientific fail and are ironically contrary to his testimony about treatment he provides transgender patients in private practice, which follows the SOC. Charles Decl., Ex. B at 55:13-17; 56:2-5; 112:16-21; 176:8-16; 225:24-226:17. Further, this "opinion" is directly contrary to the Fourth Circuit's holding in *Grimm*:

> Fortunately, we now have modern accepted treatment protocols for gender dysphoria. Developed by the World Professional Association for Transgender

> Health (WPATH), the Standards of Care for the Health of Transsexual, Transgender, and Gender Nonconforming People (7th Version 2012) (hereinafter "WPATH Standards of Care") represent the consensus approach of the medical and mental health community, Br. of Medical Amici 13, and have been recognized by various courts, including this one, as the authoritative standards of care, see *De'lonta v. Johnson*, 708 F.3d 520, 522–23 (4th Cir. 2013); see also *Edmo*, 935 F.3d at 769; *Keohane v. Jones*, 328 F. Supp. 3d 1288, 1294 (N.D. Fla. 2018), vacated sub nom. *Keohane v. Fla. Dep't of Corrs. Sec'y*, 952 F.3d 1257 (11th Cir. 2020). There are no other competing, evidence-based standards that are accepted by any nationally or internationally recognized medical professional groups." *Edmo*, 935 F.3d at 769 (quoting *Edmo v. Idaho Dep't of Corr.*, 358 F. Supp. 3d 1103, 1125 (D. Idaho 2018)).

Grimm, 972 F.3d at 595-596. Further irreconcilable with available data and the consensus of the medical community, Dr. Levine asserts that gender dysphoria is a psychiatric condition, and "educational failure, vocational inconstancy and social isolation" are "clinical errors" of gender confirming treatment. Charles Decl., Ex. A at ¶8(m), ¶23. The Fourth Circuit disagrees, holding that: "Being transgender is also not a psychiatric condition, and implies no impairment in judgment, stability, reliability, or general social or vocational capabilities." *Grimm*, 972 F.3d at 594 (quote marks omitted); *see also*, *Kadel*, 12 F.4th at 427. Dr. Levine espouses the belief that gender dysphoria, or being transgender, is a way of living that people commit to in youth and is a "product of other things," including possibly familial sexual abuse, distress over "their body changing," growing up in a single-parent home, or having an autism diagnosis. Charles Decl., Ex. B at 154:5-8; 235:23-25; 137:10-13; 235:20-22; 235:17-20. Here too, the Fourth Circuit has held conclusively that "[J]ust like being cisgender, being transgender is natural and is not a choice." (*Kadel*, 12 F.4th at 427 (quoting *Grimm*, 972 F.3d at 594)). Dr. Levine admits to

practicing and advocates for the use of "conversion therapy" with transgender youth,[4] but the Fourth Circuit has found that "mental health practitioners' attempts to convert transgender people's gender identity to conform with their sex assigned at birth did not alleviate dysphoria, but rather caused shame and psychological pain." (*Grimm*, 972 F.3d at 595). Fourth Circuit precedent renders much of Dr. Levine's testimony irrelevant.

D. Dr. Levine's Testimony Is Methodologically Unreliable and Unsupported by Science or Medicine.

Expert testimony should only be admitted if its methodology is sufficiently reliable. *Sardis*, 10 F.4th at 281. Dr. Levine's opinions fall far short of each prong of this reliability standard. Dr. Levine admitted at deposition that theories upon which he relies lack any scientific support and have not been tested or subjected to peer review or publication. Charles Decl., Ex. B at 109:20-25; 116:4-7; 122:8-124:22; 131:11-132:1; 200:11-201:25. As such, Dr. Levine cannot and does not offer the known or potential error rates, and perplexingly asserts without any evidence whatsoever that his views are accepted and shared by the amorphous and unspecific "scientific community." Charles Decl., Ex. A at ¶9, ¶10, ¶11, ¶12, ¶13, ¶23 ¶48, ¶121.

Even putting the *Daubert* factors aside, as Dr. Levine claims his "experience" is sufficient foundation for his opinions, he fails to address how this purported experience leads to his conclusions and how such experience is reliably applied to the facts here. *See*, *e.g.*, *Cooper,* 259 F.3d at 200 (affirming the exclusion of an expert because he "asserted

[4] Charles Decl., Ex. A at ¶31, ¶18, ¶119.

what amounted to a wholly conclusory finding based upon his subjective beliefs rather than any valid scientific method."); *SAS Inst.,* 125 F. Supp. 3d at 589; *see also Nat'l Ass'n. for Rational Sexual Offense L.* at *3 (excluding expert where offering party failed to establish how expert's "experience leads to his conclusions nor how those experiences have been reliably applied to the facts").

1. Dr. Levine's Assertion that There are Widely Varying Views about the Appropriate Treatment for Gender Dysphoria Is Simply Wrong.

Chief among Dr. Levine's many unreliable opinions is his assertion that wide disagreement exists about the appropriate treatment for gender dysphoria and that the SOC are not accepted by the scientific community. Charles Decl., Ex. A at ¶8(c). Contrary to Dr. Levine's personal feelings, there ***is broad consensus*** about the appropriate treatment for gender dysphoria. All major medical associations, the largest health systems in the United States (Department of Veterans Affairs, Kaiser-Permanente, the Federal Bureau of Prisons), and most major health insurers endorse and follow the treatment protocols established by the WPATH in the SOC Version 7. Charles Decl., Ex. F at ¶27. This factual reality, combined with Dr. Levine's *own admissions* about his use of the WPATH treatment protocols calls into serious question the reliability of this proffered opinion. Charles Decl., Ex. B at 55:13-17; 56:2-5; 112:16-21; 176:8-16; 225:24-226:17. Dr. Levine even admitted this in his most recent prior deposition in December 2020, acknowledging that he continues to utilize the WPATH SOC when writing letters to authorize hormones or surgery for someone with gender dysphoria. Charles Decl., Ex. G at 29:10-18; 37:2-13; 47:22-49:3;

103:11-19. At the *Claire* deposition, Dr. Levine confessed that he does not dispute that the WPATH SOC is widely accepted, but just maintains, without evidence, that they are "wrong," even though his clinical care continues to be consistent with these standards. Charles Decl., Ex. G at 145:16-24; Charles Decl., Ex. B at 55:13-17; 56:2-5; 112:16-21; 176:8-16; 225:24-226:17; Ex. G at 103:11-19. Dr. Levine fails to show how his experience leads to this conclusion, and when applied to the present facts, he cannot bridge the analytic gap.

2. Dr. Levine's Opinion That Accessing Gender-Confirming Care Is Experimental and Unethical is Unfounded.

Dr. Levine alleges that because transgender adults face increased vulnerability to negative life outcomes, providing any "affirmation treatments," particularly to adolescents, is experimental and unethical. Charles Decl., Ex. A at ¶8(k), ¶81. This opinion cannot satisfy the reliability standard because Dr. Levine authorizes this care for his own patients and either ignores studies contrary to his belief or distorts them beyond the authors' explicit intentions or design. Significantly, he omits recent studies demonstrating that medical treatments for transgender adolescents and adults have favorable outcomes across many measures. Charles Decl., Ex. F at ¶79. A plethora of studies also show that trans people experience pervasive stigma and discrimination, resulting in health disparities. But Dr. Levine baselessly claims that receiving gender-confirming care *causes* those disparities and is therefore experimental, relying most heavily on two articles which do not support this assertion. Charles Decl., Ex. A at ¶74. First, he relies on a study by Cecilia Dhejne, a

scholar in the field who has publicly and specifically said Dr. Levine's assertion is a mischaracterization of her work. Charles Decl., Ex. H at 65. Her study also does not support his assertion because *the study itself* states it is not designed to "evaluate whether or not gender affirming care is beneficial." Charles Decl., Ex. I at 2. And when confronted at deposition, he admitted the study design created a serious limitation in drawing any conclusions about the efficacy of the care. Charles Decl., Ex. B at 156:7-11. The second study that Dr. Levine misrepresents to support his claim that gender confirming care is experimental reached a similar conclusion to Dhejne's. Despite this, Dr. Levine implies that the article demonstrates higher death rates among people who received gender-confirming surgery, but the article itself precisely states that "the present study design does not allow for determination of causal relations between HT (hormone therapy) and SRS (sex reassignment surgery) and somatic morbidity or mortality." Charles Decl., Ex. J at e65-e66.

Ultimately, Dr. Levine fails to cite any literature that supports this belief, and regardless, he confirmed that this should not prevent Plaintiffs from receiving the relief they seek. When asked if he believes that because a study showed that some people committed suicide *no patient* should be able to access gender affirming surgery, Dr. Levine responded, "that would be illogical." Charles Decl., Ex. B at 151:25-152:6. And when asked if all the concerns he has are justifications for denying medical interventions to all people with gender dysphoria, he responded "I'm not advocating denying endocrine treatment or surgical treatment." Charles Decl., Ex. B at 85:4-11.

3. Dr. Levine's Opinions About Gender Dysphoria in Transgender Children and Puberty-Delaying Treatment Are Not Based In Fact.

Another unreliable opinion presented by Dr. Levine is that "a majority" of pre-pubescent children diagnosed with gender dysphoria will cease to be transgender. Charles Decl., Ex. A at ¶8(d); Charles Decl., Ex. B at 178:17-24. This opinion is undermined by Dr. Levine's admission at deposition that some children are transgender and that as they progress into adolescence, they would need medical care that he has, and would, authorize. Charles Decl., Ex. B. at 173:7-15; 137:14-23; 173:22-174:5; 53:16-54:7. Dr. Levine glosses over the lack of peer-reviewed and scientific evidence to support his opinion by providing only vague references to "science articles," and "eleven studies," that support his belief. Charles Decl., Ex. B at 178:17-24. Upon closer inspection, this "evidence" falls apart. Dr. Levine could not name eleven studies, but rather only one article from 2019 which purportedly listed those studies. Charles Decl., Ex. B at 191:20-192:7. But all studies used to support this conclusion suffer from the same malady: they analyze data from children identified under the obsolete and overly broad diagnosis for "Gender Identity Disorder in Children" and not the current DSM-5 diagnostic criteria "Gender Dysphoria in Children." Dr. Levine then notes "the latest one" of the "eleven studies" was published in 2021 by Singh. *Id*. But not only does Singh's article suffer the same infirmity as the "eleven studies," but it also analyzes data initially collected *30 years ago*, with children diagnosed under criteria from the DSM III, which is now four versions old. Charles Decl., Ex. B at 192:5-14. Therefore, the "desistance" rates Dr. Levine discusses reflect children who might

have exhibited gender non-conforming behaviors but did not necessarily identify as transgender and *would not satisfy the current diagnostic criteria*. Charles Decl., Ex. K at ¶89. This illustrates Dr. Levine manipulating available research to assert his personal views as unreliable "opinions."

Dr. Levine's most strikingly unreliable opinion is his testimony at deposition that puberty blockers should not be available to any transgender adolescents.[5] Charles Decl., Ex. B at 184:14-18; 187:8-11. Dr. Levine's methodological and scientific support for this opinion is woefully insufficient. He states that in the cases he has seen, puberty blocking treatment was "like a treatment for the mother's pathology, not for the child." Charles Decl., Ex. B at 184:25-185:2. He asserts, without evidence, that the cause of gender dysphoria is related to "acting out the ambitions of the mother or father," and puberty "lead[s] to desistance in many, many children." Charles Decl., Ex. B at 185:7-16. If it were up to Dr. Levine, he would "consider banning puberty blocking hormones even for children who have been cross-gender identified for four years to give them a chance to desist." Charles Decl., Ex. B at 186:20-25. Taken together with Dr. Levine's view that parents

[5] It is contradictory and newly formed. Dr. Levine's report states, "it is not possible to make a single, categorical statement about the proper treatment of children presenting with gender dysphoria," and yet this new opinion does just that. Charles Decl., Ex. A at ¶43. And a mere nine months earlier, Dr. Levine sat for deposition and opined the exact opposite, i.e., puberty blockers should be available in limited cases "[w]here we had a healthy mother and father, an intact family who was psychologically informed and who has – where a child has come out of toddlerhood acting consistently in a gender atypical fashion, and where the parents are not homophobic people." Charles Decl., Ex. G at 158:6-16.

should be able to subject their children to conversion therapy "to assist their child to achieve comfort with the gender corresponding to his or her sex" assigned at birth, this makes clear that Dr. Levine's believes transgender people should not exist, an opinion he cannot connect to any meaningful data, and that is not reliably applied to the facts of this case. Charles Decl., Ex. A at ¶119. Even Dr. Levine admits the unscientific nature of this opinion, he does not know where it comes from or "to what extent it's from my politics, or from my being a parent or a doctor, I don't know." Charles Decl., Ex. B at 187:20-24.

4. Dr. Levine's Assertion that "Social Contagion," "Rapid Onset Gender Dysphoria," and "Involvement With the Internet," as Causes for Gender Dysphoria Justify Denying Treatment to Transgender People Is Not Supported By Scientific Evidence.

A stark example of Dr. Levine's opinions failing to meet methodological reliability is his assertion that the untested and scientifically unsupported hypotheses of "social contagion," "rapid onset gender dysphoria" and "involvement with the Internet," justifies denying treatment to transgender adolescents and adults. Charles Decl., Ex A at ¶15. "[W]hile hypothesis is essential in the scientific community because it leads to advances in science, speculation in the courtroom cannot aid the fact finder in making a determination … ." *Dunn v. Sandoz Pharms. Corp.*, 275 F. Supp. 2d 672, 684 (M.D.N.C. 2003). Dr. Levine conceded that "social contagion" has not even been tested, let alone proven and could not provide a single citation to a scientific source discussing the theory in any research study. Charles Decl., Ex. A at ¶122(f); Charles Decl., Ex. B at 114:8-11; 116:4-7. When confronted with a news article cited in his report to support the hypothesis,

Dr. Levine confessed he was not familiar with the article, its authors, or whether it was peer-reviewed. Charles Decl., Ex. B at 123:4-124:20. The only publication Dr. Levine *could* name in relation to these hypotheses was withdrawn and republished with a significant correction that Dr. Levine confessed he had not read. Charles Decl., Ex. B at 116:22-117:9. The correction admitted that: "rapid onset gender dysphoria is not a formal mental health diagnosis," "the report did not collect data from adolescents and young adults or clinicians and therefore does not validate the phenomenon," and "the use of the term, rapid onset gender dysphoria should be used cautiously by clinicians and parents to describe youth." Charles Decl., Ex. L at 1. Indeed, the only peer-reviewed study to interrogate this hypothesis using adolescent clinical data "did not support the ROGD hypothesis." Charles Decl., Ex. M at 1.

Finally, Dr. Levine uses "the Internet" as a sword to question the veracity of transgender adolescents' identities and deny them medically necessary care and a shield for his unsubstantiated beliefs about the prevalence of "detransition." Charles Decl., Ex. A at ¶14, ¶15, ¶99; *id.* at ¶35, ¶56, ¶98. Again, Dr. Levine admitted that his belief about transgender adolescents being "influenced by the internet" is a hypothesis lacking any support in studies, research, or peer-reviewed publications. Charles Decl., Ex. B at 115:24-116:7. While Dr. Levine even admits he has not performed any research or "scientifically acceptable" studies to support this hypothesis, he claims others have but provided not even a single study in his report or at deposition. Charles Decl., Ex. B at 115:13-19.

Similarly, when confronted about his report's assertion that "the internet housed some 60,000 reports of detransition," in a "subreddit called r/detransition," Dr. Levine admitted this was a substantial numerical error repeated throughout his report, and the figure should be *16,000*. Charles Decl., Ex. B at 196:3-7. Even still, he admitted he had no evidence that *even one* of the 16,000 members of the subreddit had actually "detransitioned." Charles Decl., Ex. B at 200:6-201:25. Given that these hypotheses about the influence of the internet and the evidence of these estimates about "detransition" are entirely unverified, Dr. Levine cannot claim that they are supported by the scientific community or have any known error rate. His reliance on his own *ipse dixit* fails to establish a reliable basis upon which to assert this opinion.

5. Dr. Levine's Assertion That The "Transgender Treatment Industry" Is An Entity That Exists And Is Monetarily And Politically Motivated To Push Medical Treatments On Transgender People Is A Political Not Scientific Opinion.

Ironically, while Dr. Levine invokes the mantra throughout his testimony that interventions should be "based on science and not politics," he brings politics into the discussion by claiming a cabal of medical professionals are part of a "Transgender Treatment Industry." He employs this novel term to malign, stereotype, and diminish the thousands of medical professionals working to provide competent and standards-based psychiatric and medical care to transgender people. Charles Decl., Ex. A at ¶8(l)(n), ¶15, ¶62, ¶65, ¶120, ¶125. As Dr. Levine has confessed with other asserted "opinions," there is no peer-reviewed study or published research that uses this term. Charles Decl., Ex. B at

131:18-24. When asked to describe the term's genesis, Dr. Levine said he long pondered this concept and yet "if it's not the first, it might be the second" time he used the phrase. Charles Decl., Ex. B at 128:9-19. Notably, this term appeared in another of Defendants' expert witness reports who, at deposition, claimed the term was his and admitted it does not appear in a peer-reviewed article or study and is not accepted or commonly used in the scientific or medical community. Charles Decl., Ex. N at 63:3-16. Again, Dr. Levine can point to no data or research to support his theory the "Transgender Treatment Industry" exists as a concept outside of his subjective beliefs, and therefore is not reliable or relevant in application to the facts of Plaintiffs' claims.

E. Dr. Levine Is Not Qualified To Offer Opinions About the Treatment of Pre-Pubescent Transgender Children In This Case.

To render expert testimony, the witness must possess the requisite "knowledge, skill, experience, training, or education" that would assist the trier of fact. *Kopf v. Skyrm*, 993 F.2d 374, 377 (4th Cir. 1993); *Wright v. United States*, 280 F. Supp. 2d 472, 478 (M.D.N.C. 2003) ("A witness may testify as to his specialized knowledge so long as he is qualified as an expert based on any combination of knowledge, skill, experience, training, or education."). If not qualified, the expert's testimony is unreliable. *Reliastar Life Ins. Co. v. Laschkewitsch*, No. 5:13-CV-210-BO, 2014 WL 1430729, at *1 (E.D.N.C. Apr. 14, 2014); *see, e.g., Mod. Auto. Network, LLC* at 537 (affirming the district court's exclusion of an expert because they lacked experience relevant to the matters at issue); *Lebron v. Sec. of Fla. Dept. of Children and Families*, 772 F.3d 1352, 1369 (11th Cir. 2014) (holding

expert witness was properly excluded who did not propose to testify about matters growing naturally and directly out of research he had conducted independent of the litigation).

Dr. Levine admitted at his deposition—as he must—that he has almost no experience researching and writing about or administering psychiatric treatment to transgender children. He confessed that none of the numerous external grants he has received for research and writing during his 48-year career were to study the treatment of transgender children or adolescents. Charles Decl., Ex. A at ¶1; Ex. B at 23:1-8. Indeed, in the voluminous list of articles he has authored or co-authored, only one even mentions transgender children ("Ethical Concerns"), and only to echo Dr. Levine's personal views on their care, not to report any study he has completed. Charles Decl., Ex. A at Exhibit A at 6-16.

Dr. Levine's report states that when he began practicing in 1974 that, "[a]n occasional child was seen during this era." Charles Decl., Ex. A at ¶3. When asked to clarify, he explained that "this era" meant the first twenty years of his practice and that "occasional" meant that "95 percent of the patients that we saw were 16, 17, 18 and up," and "in the first twenty years, transgender issues were primarily an older teenager and adult, mostly adult issues." Charles Decl., Ex. B at 47:5-6; 47:10-13. When asked about more recent experience treating children with gender dysphoria, Dr. Levine confessed that he had treated *no children* with gender dysphoria in the last year and had seen only *one child* under age 11 in the last five years. Charles Decl., Ex. B at 51:14-18; 52:14-22 (he

"personally [has] not delivered a psychotherapeutic care or evaluation directly of a child" in the last five years.).

Dr. Levine is not recognized as an expert in providing treatment to transgender children by his private employer, nor by the university where he is a clinical professor of psychiatry. He does not write or research about providing treatment to transgender children, nor does he deliver any psychiatric care to them in his day-to-day practice. Dr. Levine is not qualified under the *Daubert* standards to offer opinions on matters relating to the care of transgender children, and he cannot use his personal beliefs as evidence in this case.

F. Dr. Levine's Report, Opinions, And Testimony Lack Probative Value And Are Thus Inadmissible Under Federal Rule Of Evidence 403.

Finally, the Court should exclude evidence if its introduction will result in unfair prejudice, confusion of the issues, or result in misleading testimony. Fed. R. Evid. 403. As noted above, Dr. Levine offers no opinions on any factual dispute in this case, and, in any event, the opinions he offers are irrelevant and unreliable. Consideration of his testimony would waste time and create confusion. The testimony would also result in prejudice, as the testimony seeks to sow confusion about the veracity of Plaintiffs' gender identity, gender dysphoria diagnosis, and other experiences—issues unrelated to whether this insurer can deny coverage of the same kinds of treatments to transgender people that it provides cisgender people. Accordingly, Dr. Levine's testimony fails to satisfy the requirements of Federal Rule of Evidence 403 and should be excluded.

CONCLUSION

WHEREFORE, based on the foregoing, Plaintiffs respectfully request that this Court grant the instant motion and exclude all of Dr. Levine's purported expert testimony because it is not admissible under *Daubert* and the Federal Rules of Evidence.

Dated: February 2, 2022

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

I hereby certify that the foregoing brief is in compliance with Local Rule 7.3(d)(1) because the body of this brief, including headings and footnotes, does not exceed 6,250 words as indicated by Microsoft Word, the program used to prepare this document.

Dated: February 2, 2022

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CERTIFICATE OF SERVICE

I hereby certify that the foregoing document was filed electronically with the Clerk of Court using the CM/ECF system which will send notification of such filing to all registered users.

Dated: February 2, 2022

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IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF NORTH CAROLINA

MAXWELL KADEL, *et al.*, *Plaintiffs*, v. DALE FOLWELL, in his official capacity as State Treasurer of North Carolina, *et al.*, *Defendants*.	Case No. 1:19-cv-00272-LCB-LPA

DECLARATION OF CARL S. CHARLES

Pursuant to 28 U.S.C. § 1746, I, Carl S. Charles, do hereby declare as follows:

1. I am over 18 years of age.

2. I am a Staff Attorney at Lambda Legal Defense and Education Fund, Inc. and serve as counsel of record for the plaintiffs in the above-captioned matter.

3. I have personal knowledge of the facts stated herein, except those stated on information and belief, and if called upon, could and would testify competently to them.

4. I submit this declaration in support of Plaintiffs' Motion to Exclude Expert Testimony of Dr. Stephen B. Levine.

5. Attached as **Exhibit A** is a true and correct copy of excerpts from the expert witness declaration of Dr. Stephen B. Levine, M.D., (including Exhibit A, a copy of his curriculum vitae) in the above-captioned matter, which is dated April 28, 2021,

was served upon Plaintiffs on May 1, 2021, and was entered as Exhibit 1 to Dr. Levine's deposition in this matter on September 10, 2021.

6. Attached as **Exhibit B** is a true and correct copy of excerpts of the transcript of the deposition of Dr. Stephen B. Levine on September 10, 2021, taken in relation to the above-captioned matter.

7. Attached as **Exhibit C** is a true and correct copy of excerpts from the transcript of the bench trial in *Soneeya v. Turco*, No. 07-12325-DPW (D. Mass 2019) where Dr. Stephen B. Levine testified on April 4, 2019, and which was entered as Exhibit 6 to Dr. Levine's deposition in this matter on September 10, 2021.

8. Attached as **Exhibit D** is a true and correct copy of an excerpt of the transcript of the deposition of Dr. Stephen B. Levine taken on August 30, 2018, in relation to *Soneeya v. Turco*, No. 07-12325-DPW (D. Mass. 2019).

9. Attached as **Exhibit E** is a true and correct copy of an excerpt of the transcript of the deposition of Dee Jones on August 3, 2021, taken in relation to the above-captioned matter.

10. Attached as **Exhibit F** is a true and correct of an excerpt of the rebuttal report of Dr. George R. Brown, M.D., signed on June 10, 2021, and served on Defendants on June 11, 2021, in the above-captioned matter.

11. Attached as **Exhibit G** is a true and correct copy of excerpts of the zoomed deposition of Dr. Stephen B. Levine taken in related to *Claire v. Florida Dept. of*

Management Services, 504 F. Supp. 3d 1328 (N.D. Fla. 2020), and which was entered as Exhibit 2 to Dr. Levine's deposition in this matter on September 10, 2021.

12. Attached as **Exhibit H** is a true and correct copy of an excerpt from the published Ph.D. Thesis, "On Gender Dysphoria," written by Cecilia Dhejne in 2017 which was entered as Exhibit 13 to Dr. Levine's deposition in this matter on September 10, 2021.

13. Attached as **Exhibit I** is a true and correct copy of the article "Long-Term Follow-Up of Transsexual Persons Undergoing Sex Reassignment Surgery: Cohort Study in Sweden," published in February 2011, which was entered as Exhibit 12 to Dr. Levine's deposition in this matter on September 10, 2021.

14. Attached as **Exhibit J** is a true and correct copy of the article "Long Term Follow-Up of Individuals Undergoing Sex-Reassignment Surgery: Somatic Morbidity and Cause of Death," published in March 2016 which was entered as Exhibit 14 to Dr. Levine's deposition in this matter on September 10, 2021.

15. Attached as **Exhibit K** is a true and correct copy of an excerpt of the rebuttal report of Dr. Joanna Olson-Kennedy, signed on May 30, 2021, and served on Defendants June 1, 2021, in the above-captioned matter.

16. Attached as **Exhibit L** is a true and correct copy of the article "Correction: Parent reports of adolescents and young adults perceived to show signs of a rapid onset of gender dysphoria," published March 19, 2019, which was entered as Exhibit 7 to Dr. Levine's deposition in this matter on September 10, 2021.

17. Attached as **Exhibit M** is a true and correct copy of the article "Do Clinical Data From Transgender Adolescents Support the Phenomenon of 'Rapid-Onset Gender Dysphoria'?," accepted for publication in the scientific journal The Journal of Pediatrics on November 10, 2021, and published online on November 15, 2021.

18. Attached as **Exhibit N** is a true and correct copy of an excerpt from Day One of Remote Videotaped Deposition of Dr. Paul McHugh, M.D., from September 8, 2021, taken in relation to the above captioned matter.

I declare under the penalty of perjury that the foregoing is true and correct.

Dated this 2nd day of February, 2022.

/s/ Carl S. Charles
Carl S. Charles

Exhibit A

IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF NORTH CAROLINA
Case No.: 1:19-cv-272-LCB-LPA

MAXWELL KADEL, et al.,	)
	)
Plaintiffs;	)
v.	)
	)
DALE FOLWELL, in his official capacity as State Treasurer of North Carolina, et al,	)
	)
Defendants.	)

Declaration of
STEPHEN B. LEVINE, M.D.
Version of APRIL 28, 2021

SECTION I. CREDENTIALS - KNOWLEDGE, TRAINING, and EXPERIENCE:

1. Education - Academic Appointments - Research Grants: I am a Clinical Professor of Psychiatry at Case Western Reserve University School of Medicine, and also maintain an active private clinical practice. I received my MD from Case Western Reserve University in 1967, and completed a psychiatric residency at the University Hospitals of Cleveland in 1973. I became an Assistant Professor of Psychiatry at Case Western in 1973, and became a Full Professor in 1985. I have been the recipient of the following grants for scientific research and/or program development:

a. 23 separate pharmaceutical company grants to study various prosexual medications

b. U.S. National Institute of Health grant for the study of sexual consequences of Systemic Lupus Erythematosis. Co-principal investigator

3. Founder of the Case Western Gender Identity Clinic - former WPATH Chairman of the Standards of Care Committee: I first encountered a patient suffering what we would now call gender dysphoria in July 1973. In 1974, I founded the Case Western Reserve University Gender Identity Clinic, and have served as Co-Director of that clinic since that time. Across the years, our Clinic evaluated and treated hundreds of patients who were experiencing a transgender identity. An occasional child was seen during this era. I was the primary psychiatric caregiver for several dozen of our patients and supervisor of the work of other therapists. I was an early member of the Harry Benjamin International Gender Dysphoria Association (later known as WPATH) and served as the *Chairman of the WPATH Standards of Care Committee* that developed the 5th version of its Standards of Care. In 1993 the Case Western Reserve University Gender Identity Clinic was renamed, moved to a new location, and became independent of Case Western Reserve University. I continue to serve as Co-Director. In 2020, the clinic was renamed the Gender Diversity Clinic.

4. Court Appointed Expert: In 2006, Judge Mark Wolf of the Eastern District of Massachusetts asked me to serve as an independent, court-appointed expert in a litigation involving the treatment of a transgender inmate within the Massachusetts prison system. After providing a six-hour workshop to the mental health professionals in the system, I was retained by the Massachusetts Department of Corrections in 2007 as a consultant on the treatment of transgender inmates. I have been in that role continuously since.

5. Experience as an Expert Witness: I was qualified as an expert and testified concerning the diagnosis, understanding, developmental paths and outcomes, and therapeutic treatment, of transgenderism and gender dysphoria, particularly as it relates to children, in 2019 in the matter of *In the Interest of J.A.D.Y. and J.U.D.Y.*, Case No. DF-15-09887-S, 255th Judicial District,

youth and that for any 16 or 17 year old to obtain hormonal therapy for gender dysphoria they must have court approval for its administration.

k. London 2 : In the High Court of Justice Queen's Bench Division administrative court. The Queen (on the application of) L. and Hampshire County Council. (A matter of education about transgender identities in schools; not yet decided.)

l. Expert in this case Kadal v. Folwell: I have been retained by the defense in this case to serve as an expert witness. My compensation is $400 per hour and such payments are in advance of any written opinions to avoid conflicts of interest and independent judgment.

7. A more complete review of my professional experience, publications, and awards is provided in my curriculum vitae, a copy of which is attached hereto as Exhibit A.

8. Summary of Issues: In this declaration, I offer information and my expert opinions concerning a number of aspects of the phenomenon of Gender Dysphoria and transgender identity (i.e., Gender Discordance, Gender Incongruity), as well as a discussion of competing views among mental health and other professionals as to the appropriate assessment and therapeutic methods-practices for patients who experience gender dysphoria. At many points in this statement, I provide citations to published, peer-reviewed articles that provide foundational or additional supporting or relevant information. A summary of the key points I discuss in this statement includes:

a. Sex as defined by biology and reproductive function cannot be changed. While hormonal and surgical procedures may enable some individuals to "pass" as the opposite gender during some or all of their lives, such procedures carry with them physical, psychological, and social risks, and no procedures can enable an individual to perform the reproductive role of the opposite sex. (Section II.A.)

b. The diagnosis of "gender dysphoria" encompasses a diverse array of conditions, with widely differing pathways and characteristics depending on age of onset among other things. Data from one population (e.g. adults) cannot be assumed to be applicable to others (e.g. children). (Section II.B.)

c. Among psychiatrists and psychotherapists who practice in the area, there are currently widely varying views concerning both the causes of and appropriate therapeutic response to gender dysphoria. Existing studies do not provide a basis for a reliable scientific conclusion as to which therapeutic responses result in the best long-term outcomes for affected individuals — thus the field remains in an experimental stage. (Sections II.E, II.F.)

d. For example, a majority of children (in several studies, a large majority) who are diagnosed with gender dysphoria "desist"—that is, their gender dysphoria does not persist—by puberty or adulthood. It is not currently known how to distinguish children who will persist from those who will not — thus the majority of patients will do best with no "affirmation" treatments in childhood and we cannot reliably determine which patients would do better with "affirmation" treatments which can involve life-long damage to healthy organs and natural biological processes. (Section IV.) See consistent findings in detailed discussions of the new National Gender Dysphoria Review Guidelines from Sweden, Finland, England, the Cochrane Review, and sciencearticles below.

e. Some recent studies suggest that active affirmation of transgender identity in young children will substantially reduce the number of children naturally outgrowing or "desisting" from transgender identity. This raises ethical and public health concerns that "affirmation" treatments will increase the number of individuals who suffer the multiple long-term

physical, mental, and social limitations that are strongly associated with living life as a transgender person. (Section IV.)

f. Thus, social transition is itself an important intervention with profound implications for the long term mental and physical health of the child. When a mental health professional evaluates a child or adolescent and then recommends social transition, presumably that professional is available to help with interpersonal, familial, and psychological problems that may arise. However, many adolescents transition without mental health assessment and ongoing care, leaving themselves and their families on their own to deal with subsequent problems. (Section IV.)

g. In most cases, parental involvement is necessary for an accurate and thorough diagnosis of a child or adolescent presenting with gender dysphoria or a desire for a transgender identity, as well as for effective psychotherapeutic treatment and support of the young person. (Section V.)

h. The knowledge base concerning the cause and treatment of gender dysphoria available today has been repeatedly characterized in multiple reviews as of "low scientific quality". (Section VI.) (See detailed analysis below).

i. There are currently no studies that show that affirmation of transgender identity in young children reduces suicide, suicidal ideation, or improves long-term outcomes as compared to other therapeutic approaches. Meanwhile, multiple studies show that adult individuals living transgender lives suffer much *higher* rates of suicide and *negative* physical and mental health conditions than does the general population thus it remains unclear how much benefit, if any, is provided by the experimental treatments required for medical transitioning. (Section VI.)

j. In light of what is known and not known about the impact of affirmation on the incidence of suicide, suicidal ideation, and other indicators of mental and physical health, it is *scientifically baseless and unethical* to assert that a child or adolescent who expresses an interest in a transgender identity will kill him or herself — or is more likely to do so — unless adults and peers affirm that child in a transgender identity. (Section VI.)

k. Putting a child or adolescent on a pathway towards life as a transgender person puts that individual at risk of a wide range of long-term or even life-long harms, including: sterilization (whether chemical or surgical) and associated regret and sense of loss; inability to experience orgasm (for trans women); physical health risks associated with exposure to elevated levels of cross-sex hormones; surgical complications and life-long after-care; alienation of family relationships; inability to form healthy romantic relationships and attract a desirable mate; elevated mental health risks. (Section VII.) In my opinion, putting children through such risks who are very likely to naturally grow out of gender dysphoria into acceptance of their biological sex and gender is an experimental and unethical practice. This is especially true given the affirmation treatments have untested and unproven long-term outcomes.

l. Informed consent is ethically required for potentially life-altering psychological or medical procedures. However, the informed consent process in such complex cases is also complex. In some cases, it may not be possible to obtain meaningful informed consent to place a child on a psychological pathway that carries with it lifetime risks of the serious injuries, harms, and damages (including sterilization, limited sexual response, and social marginalization) that I detail in this report. A child is not competent, of course, to weigh how these potentially devastating life-long risks and issues will impact his or her lifetime happiness. At a minimum, informed consent of parents is essential, although it may not be sufficient. Withholding accurate information

— from patients or parents — on risks and benefits or misrepresenting the current state of research in this controversial field should be viewed as a serious ethics violation and reported to the proper licensing authorities. There is substantial evidence from science publications and also from journalist research that the "affirmation" treatment industry (i.e., often referred to as the Transgender Treatment Industry) is providing misleading information to the public and the legal system. For example, it is not the case that puberty halting hormone treatments are "easily reversed". (Section VIII.)

m. Research reviews support my opinion that gender affirmation treatments remain experimental and have never been accepted by the relevant scientific community and have no known nor published error rate — meaning the rates of clinical errors as manifested by desistance, increased mental suffering, educational failure, vocational inconstancy, or social isolation have not been established. See, e.g., Haupt, C., Henke, M. et. al., Cochrane Database of Systematic Reviews Review Intervention, Antiandrogen or estradiol treatment or both during hormone therapy in transitioning transgender women, 28 November 2020 ; See, e. g., Swedish Agency for Health Technology Assessment and Assessment of Social Services, SBU Policy Support no 307, 2019 www.sbu.se/en • registrator@sbu.se Contact SBU: Jan Adolfsson, Medical Advisor, Project Manager, jan.adolfsson@sbu.se, English Proofreading: Project group and Jan Adolfsson, SBU ["*No relevant randomized controlled (treatment outcome) trials in children and adolescents were found."]*

Within the last two years, detailed research reviews exposing multiple and serious methodological and ethical flaws in the research of Bränström, and Panchankis and Turban, and other "affirmation" supporters have pinpointed fundamental methodological errors in their papers which claim to support affirmation treatment. These reviews, also support my opinions that gender

affirmation treatments remain experimental and have never been accepted by the relevant scientific community and have no known nor published error rate. See, Kalin N. H. (2020). Reassessing Mental Health Treatment Utilization Reduction in Transgender Individuals After Gender-Affirming Surgeries: A Comment by the Editor on the Process. *The American journal of psychiatry*, *177*(8), 764. https://doi.org/10.1176/appi.ajp.2020.20060803; Biggs M. (2020). Puberty Blockers and Suicidality in Adolescents Suffering from Gender Dysphoria. *Archives of sexual behavior*, *49*(7), 2227–2229. https://doi.org/10.1007/s10508-020-01743-6; D'Angelo, R., Syrulnik, E., Ayad, S., Marchiano, L., Kenny, D. T., & Clarke, P. (2020). One Size Does Not Fit All: In Support of Psychotherapy for Gender Dysphoria. *Archives of sexual behavior*, 10.1007/s10508-020-01844-2. Advance online publication. https://doi.org/10.1007/s10508-020-01844-2;

n. Bases for Expert Opinions and Review-Opinions regarding the Expert Declarations in this case by Drs. Schechter and Brown. I have reviewed dozens of scientific articles, national science reviews and guidelines (England (NICE), Sweden, Finland, Cochrane Review, association positions, the Complaint and Answer in this case, the plaintiff's medical records, and all expert declarations in this case. I have formulated opinions regarding the reports by Drs. Schechter and Brown. In my opinion, Drs Schechter and Brown failed to properly disclose and discuss the ongoing international debates and controversies as to whether Transgender Treatment Industry methods and procedures are unproven, experimental, and potentially more harmful than helpful to vulnerable patients. Similarly, Drs Schechter and Brown failed to properly disclose and discuss the recent and very public exposes documenting significant methodological failures and flaws in trans treatment science. Finally, Drs Schechter and Brown failed to report or discuss the recently published national reviews and research documenting the "weak" and methodologically defective

research foundations of the Transgender Treatment Industry including recent reviews from Great Britain (NICE), Sweden, Finland, the Cochrane Review, the 2020 Carmichael report, the Griffin study, the Zucker study and other important work published within the last 24 months.. [See, e.g. Carmichael P, Butler G, Masic U, et al. Short-term outcomes of pubertal suppression in a selected cohort of 12 to 15 year old young people with persistent gender dysphoria in the UK. medRxiv 2020.12.01.20241653; doi:https://doi.org/10.1101/2020.12.01.20241653 https://www.medrxiv.org/content/10.1101/2020.12.01.20241653v1 BBC summary: https://www.bbc.com/news/uk-55282113journal.pone.0243894. pmid:33529227], and Devita Singh, Susan J. Bradley and Kenneth J. Zucker, Frontiers in Psychiatry, March 2021 | Volume 12 | Article 632784, www.frontiersin.org] and related research discussed in detail below.

SECTION II. BACKGROUND IN THIS FIELD

A. The biological base line of sex

9. Sex is permanently "assigned" at conception by DNA: The sex of a human individual at its core structures the individual's biological reproductive capabilities—to produce ova and bear children as a mother, or to produce semen and beget children as a father. Sex determination occurs at the instant of conception, depending on whether a sperm's X or Y chromosome fertilizes the egg. Medical technology can be used to determine a fetus's sex before birth. It is thus not scientifically correct to talk of doctors "assigning" the sex of a child at birth; almost anyone can accurately and reliably identify the sex of an infant by genital inspection. What the general public may not understand, however, is that every nucleated cell of an individual's body is chromosomally identifiably male or female—XY or XX. Claims that patients can obtain a "sex change" or a "gender transition" process are misleading and scientifically impossible. In reality, the typical "transgender" Gender Discordant patient has normal healthy sex organs but struggles

with Gender Discordant feelings and perceived identity. Such patients can receive cosmetic surgeries and hormone treatment — but such methods never actually "transition" a patient to "another sex." In my opinion, these views are generally accepted by the relevant scientific community in the fields of biology, zoology, neonatology, genetics, pediatrics, and psychiatry.

10. The self-reported gender of a child, in contrast, arises in part from how others label the infant: "I love you, son (daughter)." This designation occurs thousands of times in the first two years of life when a child begins to show awareness of the two possibilities. As acceptance of the designated gender corresponding to the child's sex is the natural outcome in >99% of children everywhere, anomalous gender discordant identity formation begs for understanding. Is it biologically shaped or influenced? Is it biologically determined? Is it the product of how the child was privately regarded and treated? Does it stem from trauma-based rejection of maleness or femaleness, and if so flowing from what trauma? Is it a symptom of another, as of yet unrevealed emotional disturbance? Is it the result of a social contagion process — such as anorexia or bulimia may be, or from Internet involvement with trans websites? The ongoing scientific, clinical, and societal debate over such issues awaits reliable answers; while some offer authoritative opinions on these questions, they are not scientifically proven. In my opinion, these views are generally accepted by the relevant scientific community.

11. Under the influence of hormones secreted by the testes or ovaries, numerous additional sex-specific differences between male and female bodies continuously develop postnatally, culminating in the dramatic maturation of the primary and secondary sex characteristics with puberty. These include differences in hormone levels, height, weight, bone mass, shape and development, musculature, body fat levels and distribution, and hair patterns, as well as physiological differences such as menstruation. These are genetically programmed biological

consequences of sex which also serve to influence the consolidation of gender identity during and after puberty. In my opinion, these views are generally accepted by the relevant scientific community.

12. Despite the increasing ability of hormones and various surgical procedures to reconfigure some male bodies to visually pass as female, or vice versa, the biology of the person remains as defined by his (XY) or her (XX) chromosomes, including cellular, anatomic, and physiologic characteristics and the particular disease vulnerabilities associated with that chromosomally-defined sex. For instance, the XX (genetically female) individual who takes testosterone to stimulate certain male secondary sex characteristics will nevertheless remain unable to produce sperm and father children. Contrary to assertions and hopes that medicine and society can fulfill the aspiration of the trans individual to become "a complete man" or "a complete woman," this is not biologically attainable. It is possible for some adolescents and adults to pass unnoticed as the opposite gender that they aspire to be—but with limitations, costs, and risks, as I detail later. See, S. Levine (2018), Informed Consent for Transgendered Patients, J. of Sex and Marital Therapy, at 6, DOI: 10.1080/0092623X.2018.1518885 ("Informed Consent"); S. Levine (2016), Reflections on the Legal Battles Over Prisoners with Gender Dysphoria, J. American Academy of Psychiatry and Law 44, 236 at 238 ("Reflections"). In my opinion, these views are generally accepted by the relevant scientific community.

B. Definition and diagnosis of gender dysphoria

13. Specialists have used a variety of terms over time, with somewhat shifting definitions, to identify and speak about a distressing incongruence between an individual's sex as determined by their chromosomes and their thousands of genes, and the gender with which they eventually subjectively identify or to which they aspire. Today's American Psychiatric

Association's *Diagnostic and Statistical Manual of Mental Disorders* (DSM-5) employs the term Gender Dysphoria and defines it with separate sets of criteria for adolescents and adults on the one hand, and children on the other. It is important to note that the DSM is not a reliable-valid scientific journal publication. The DSM began as an attempt to create a dictionary for psychiatry.The process by which DSM classifications are created involves voting by committee — this is nota reliable-valid scientific process. The committees' recommendations are approved or rejected by superordinate committees. DSM content is largely decided by consensus-seeking methodologies — such as "voting" by small committees of advocates and activist practitioners whose judgment may suffer from significant financial conflicts of interest — as appears to be the case with all three of the plaintiff's experts in this case. The limitations of the DSM methodology are well known in the relevant scientific community. See, e.g., Lee, C., *The NIMH Withdraws Support for DSM-5: The latest development is a humiliating blow to the APA*. Psychology Today News Blog at https://www.psychologytoday.com/us/blog/side-effects/201305/the-nimh-withdraws-support-dsm-5 ["Just two weeks before DSM-5 is due to appear, the National Institute of Mental Health, the world's largest funding agency for research into mental health, has indicated that it is withdrawing support for the APA's manual. In a humiliating blow to the American Psychiatric Association, Thomas R. Insel, M.D., Director of the NIMH, made clear the agency would no longer fund research projects that rely exclusively on DSM criteria. Henceforth, the NIMH, which had thrown its weight and funding behind earlier editions of the manual, would be "re-orienting its research away from DSM categories."] In my opinion, these views are generally accepted by the relevant scientific community.

14. There are at least five distinct pathways to gender dysphoria: early childhood onset; onset near or after puberty with no prior cross gender patterns; onset after homosexual lifestyle;

adult onset after years of heterosexual transvestism; and onset in later adulthood with few or no prior indications of cross-gender tendencies or identity. The early childhood onset pathway and the more recently observed onset around puberty pathway are relevant to this matter. Whereas, the onset of cross-gender identifications in the preschool years suggests temperamental and intrafamilial shaping forces, the post pubertal onset of what is now commonly referred to a rapid onset gender dysphoria seems to be heavily influenced by social forces. These derive primarily from the Internet and educational environments. The vulnerability to such social contagion may stem from conspicuous or subtle mental health problems or the child's misunderstanding of the normality of early pubertal discomfort with one's body, previous peer relationships, and despair about future gender-based social roles. The newly acquired trans identity is often passionately held as it explains away past and current unhappiness and emotional or behavioral problems.

Changing Complexities in Young Gender Dysphoric (GD) Patients

15. The Social Contagion Hypothesis. To avoid the methodological error of confirmation bias, clinicians and researchers generate and test alternative hypotheses. It is currently unclear how many new gender discordant patients have been influenced by social contagion processes. During the last 10-15 years, there have been multiple reports from multiple nations reporting a dramatic increase in the number of gender discordant patients as well as a dramatic change in the reported sex ratio of young patients presenting to clinics with trans gender identities. In the 20th century, the biologic male to biologic female ratio was consistently 3-4:1 in most North American and European clinics. Now some clinics are reporting a 7:1 ratio of girls to boys. Biological theories of gender dysphoria (e.g., "immutable", genetic, brain structures, etc.) appear unlikely to explain large, rapid demographic shifts in gender discordant patients. A social contagion - social influence theory has arisen in an attempt to help explain these dramatic demographic changes. In decades

past, gender discordant children and teens typically aspired to become a member of the opposite sex while more recently, patients are increasingly likely to define themselves as "non-binary persons" meaning that they have elements of both sex-genders within them or they have none of these elements. Such teens often report being influenced by trans websites and trans "influencers" on internet sources such as video blogs on YouTube. These onsite shows reportedly reach millions and teach adolescents to consider their problems, worries, discomforts, and anticipated social roles to be typical experiences of the unfolding of a biologically-determined trans self. In addition to YouTube and other internet sources, patients reportedly have been influenced by school trans awareness training programs teaching the normality of trans current and future lives — without an accurate discussion or depiction of the known risks and benefits.

A multi-disciplinary analysis that includes developmental psychology and the history of psychiatry provides additional support for the socialization hypothesis. Mental health professionals have long experience with adolescent females experiencing social worries that help to create anorexia nervosa, bulimia, and self-harm through cutting, burning, and piercings. Prof. Amanda Rose at the University of Missouri has conducted research to understand why adolescent girls demonstrate heightened susceptibility to a social contagion of psychiatric symptoms. She reports that" teenage girls share symptoms via social contagions because their friendship processes involve "co-rumination"— that is, taking on the emotional pain and concerns of their friends. This is a potential — and as yet uninvestigated hypothesis — as to the reports of" clusters" and "friend groups" of teen girls who are adopting trans identity and "transitioning" together (See, L. Littman (2018), *Parent Reports of Adolescents & Young Adults Perceived to Show Signs of a Rapid Onset of Gender Dysphoria*, PLoS ONE 13(8): e0202330 at 13). Prof. Rose's investigations note that adolescent girls seem more willing to adopt a friend's pain and even suspend reality to "get on the

symptom team" of their friends. (See, R. Schwatz-Mette and A. Rose, Co-Rumination Mediates Contagion of Internalizing Symptoms Within Youths' Friendships, Developmental Psychology 48(5):1355-65, February 2012, DOI: 10.1037/a0027484 Further, reliable-valid scientific research is needed to address these complex issues. See also, McCall, B. andNainggolan, L., Medscape *Transgender Teens: Is the Tide Starting to Turn?* https://www.medscape.com/viewarticle/949842#vp_1 ["The vast majority of youth now presenting with gender dysphoria are adolescents who suddenly express revulsion with their sex from birth, and 70% of them were born female. Many of them have comorbidities such as anxiety, attention deficit hyperactivity disorder, autism spectrum traits, and depression, Malone explains, which need to be considered. This newer presentation — which has been termed late-, adolescent-, or rapid-onset gender dysphoria — has now been seen in every gender clinic in the western world, and there has been a huge surge in the number of cases. One recent US survey found a 4000% increase (over 40-fold) since 2006, and there have been similar large increases reported in Finland, Norway, the Netherlands, Canada, and Australia. The London GIDS clinic reported a 30-fold increase in referrals over the past decade – and again they were primarily adolescent girls who said they now identify as boys.

It should be noted that rapid, unpredicted changes in the demographics of trans patients (i.e., from chronically discordant, early onset males to rapid onset adolescent females) calls into question the usefulness and accuracy of predictions emanating from research conducted on previous, demographically and clinically different patient groups. This again highlights the complex, little known, and experimental nature of trans phenomenon as well as the experimental treatment methods of the current Transgender Treatment Industry. See, rapid and unpredicted demographic changes: [A US survey found a 4000% increase (over 40-fold) since 2006]

”National College Health Assessment: ACHA-NCHA s://www.acha.org/NCHA/ACHA-NCHA_Data/Publications_and_Reports/NCHA/Data/Publications_and_Reports.aspx?hkey=d5fb767c-d15d-4efc-8c41-3546d92032c5 ; similar large increases have been reported in Finland: Kaltiala-Heino, Riittakerttu, Hannah Bergman, Marja Työläjärvi, and Louise Frisen. "Gender Dysphoria in Adolescence: Current Perspectives." *Adolescent Health, Medicine and Therapeutics* Volume 9 (March 2018): 31–41. https://doi.org/10.2147/AHMT.S135432 ; and in Norway ; and in the Netherlands: de Vries, Annelou L.C. de. "Challenges in Timing Puberty Suppression for Gender-Nonconforming Adolescents." *Pediatrics* 146, no. 4 (October 2020): e2020010611. https://doi.org/10.1542/peds.2020-010611. ; and in Canada: Zucker, Kenneth J. "Adolescents with Gender Dysphoria: Reflections on Some Contemporary Clinical and Research Issues." *Archives of Sexual Behavior* 48, no. 7 (October 2019): 1983–92. https://doi.org/10.1007/s10508-019-01518-8, and others.

16. Gender dysphoria has very different characteristics depending on age and sex at onset. Young children who are living a transgender identity commonly suffer materially fewer symptoms of concurrent mental distress than do older patients. (See, K. Zucker (2018), The Myth of Persistence: Response to “A Critical Commentary on Follow-Up Studies & ‘Desistance ’Theories about Transgender & Gender Non-Conforming Children” by Temple Newhook et al., Int’l J. of Transgenderism at 10, DOI: 10.1080/15532739.2018.1468293 (“Myth of Persistence”). The developmental and mental health patterns for each of these groups are sufficiently different that data developed in connection with one of these populations cannot be assumed to be applicable to another.

17. The criteria used in DSM-5 to identify Gender Dysphoria (“Gender Incongruence” is another term used) include a number of signs of discomfort with one’s natal sex and vary

somewhat depending on the age of the patient, but in all cases require "clinically significant distress or impairment in important areas of functioning" such as social, school, or occupational settings. When these criteria in children, (or adolescents, or adults) are not met, two other diagnoses may be given. These are: Other Specified Gender Dysphoria and Unspecified Gender Dysphoria. Specialists sometimes refer to children who do not meet criteria as being "subthreshold."

18. In a complex, experimental, and little understood field such as transgender medicine, generating and exploring alternative hypotheses is essential to our efforts to help alleviate the tragic suffering of our patients. One such alternative is to teach coping and resilience skills to gender discordant children. Such training could include a realization that a wide range of behaviorsare available within their biologically concordant gender roles. Acquiring a broader perspective on the patient's natal sex roles might be a better solution for some than permanent damage to healthy sex organs via hormone and surgical "transitioning" procedures. Children who conclude that they are transgender are often unaware of a vast array of adaptive possibilities for how to livelife as a man or a woman—possibilities that become increasingly apparent over time to both malesand females. A boy or a girl who claims or expresses interest in pursuing a transgender identity often does so based on stereotypical notions of femaleness and maleness that are based on constrictive notions of what men and women can be. See, S. Levine (2017), Ethical Concerns About Emerging Treatment Paradigms for Gender Dysphoria, J. of Sex & Marital Therapy at 7, DOI: 10.1080/0092623X.2017.1309482 ("Ethical Concerns"). A young child's, even an adolescent's, understanding of this topic is quite limited. Nor do they have the perspective that discomfort with the body and perceived social role is not new to civilization; what is new is the option to become a trans person.

With most complex behavioral problems of child and adolescents, patients and families receive psychiatric attention that includes a thorough developmental history from parents, prolonged interviews with the patient, and a therapeutic approach which involves to some extent the parents, the patient, and the three together with or without medication assistance. Tragically, in too many gender clinics, young patients are not treated with the standard of care, complex, multi-disciplinary, evidence-based approach. Children are too often quickly referred to gender "specialists" — which generally means therapists who deeply believe (based on clinical-political ideology and not the relevant science) that every young person who is questioning his or her gender identity or declaring a trans identity should be quickly affirmed and supported in their atypical identity. Moreover, the ideological fashions of these therapists and the organizations that support them have effectively convinced many — contrary to the relevant science — that any other approach to these youth is dangerous, harmful, and might even lead to suicide. Other evidence-based, more methodologically sound approaches such as the generation and testing of alternative hypotheses as required by proper health care standards — are denigrated and ideologically labeled "conversion therapy."

The ideologically based indoctrination efforts to ban evidence based alternative treatments as "conversion therapy" can have harmful effects on our vulnerable patients. For example, many traditional therapists claim to not know how to take care of these gender discordant patients, as though they are not children who are suffering. This rationalization may only be a reflection of the fear of being attacked for performing dreaded, and now in some locations, illegal, "conversion therapy". In this way, qualified mental health professionals have failed to develop a robust experience with alternative ways of investigating patients 'and their families 'lives as they do with all other child and adolescent psychiatric problems. [The recently released National Guidelines

for Gender Dysphoria patients from Sweden and Finland do appear to be moving towards a much greater emphasis on alternative methods including psychosocial support, therapy, and long-term psycho-social evaluations — perhaps for years — prior to engaging in any "affirmation" medical interventions (hormones or surgery) See, e.g. "Finland Issues Strict Guidelines for Treating Gender Dysphoria" at https://genderreport.ca/finland-strict-guidelines-for-treating-gender-dysphoria/ ["Western countries around the world are *grappling with how to treat the exponentially growing number of children and adolescents being referred to gender clinics* for puberty blockers, cross-sex hormones and gender-affirming surgery. Finland recently issued very strict clinical guidelines for the treatment of children with gender dysphoria including: … clear differentiation in treatment guidelines between early-onset childhood gender dysphoria and adolescent-onset gender dysphoria…the guidelines acknowledge and recognize that identity exploration is a natural phase of adolescence and *restrict medical interventions* until "identity and personality development appear to be stable"….There is a *prioritization of psychotherapeutic non-invasive interventions* as the first course of action "due to variations in gender identity in minors"…. A *requirement* that there be *"no contraindications" prior to initiation of puberty blocker or cross-sex hormone interventions*… [such contraindications should include the presence of psychiatric illnesses such as depression, anxiety, or autistic conditions. Such disorders are reportedly present in over 50% of all gender discordant patients]…. and no surgical interventions are allowed for children underthe age of 18." ; See also, a Swedish National Investigative Report regarding cases of gender incongruence in children and young people, Article number 2021-3-7302 Published www.socialstyrelsen.se, March 2021. [Since our initial investigative report was published in 2015, the number of young people referred for investigation has *increased sharply, both in Sweden and internationally*. … *The reasons for the increase are not yet clear.*]

Such external pressures on providers should not be underestimated. Leaders in the field of gender dysphoria have been attacked, dissenters have been fired, and reputations have been sullied by activists who believe they know best how other people's children should be treated. The fact that science has not yet established the ideal treatment approaches to the diversity of situations does not seem to matter to these passionate persons.

19. Confirmation bias is a hazardous cognitive error that occurs throughout all of medicine and science. Confirmation bias is the methodologically defective tendency to process information by only looking for, and interpreting, evidence consistent with existing beliefs, favorite theories, and pre-conceived notions. This bias is a serious and potentially dangerous methodological error that leads a person or a field to ignore information that is contrary to what is common, fashionable, or has been taught to be the popular or "politically correct" theory of the day. It is often associated with a weak understanding of how science establishes the legitimacy of a therapy. Confirmation bias is often associated with the belief that because a therapeutic approach has been long employed or supported by powerful forces, adequate reliable-valid science must have previously established the popular approach. Both of the essential concepts of "gender affirmative treatment" and "conversion therapy" are based on such a misunderstanding.

20. The expected initial evaluation of a trans person typically begins with the patient who tells the evaluator, " "I am trans." The patient relates his or her symptoms of discomfort which may or may not fulfill DSM-5 criteria for Gender Dysphoria. Ideally a developmental history is taken from the parents and the patient to consider what is known as a differential diagnostic process to determine what other conditions may underlie these symptoms. The extent to which this latter process is undertaken depends upon the therapists *beliefs* about the origin of trans identities and the long term effectiveness of affirmative responses. To the extent that life-changing affirmative

distinctions. I attempt to summarize these three as though they are equally valid. I do not actually consider this to be true.

23. Gender dysphoria is conceptualized and described by some professionals and laypersons as though it were a serious, physical medical illness that causes suffering, comparable, for example, to prostate cancer, a disease that is curable before it spreads. Within this paradigm, whatever is causing distress associated with gender dysphoria—whether secondary sex characteristics such as facial hair, nose and jaw shape, presence or absence of breasts, or the primary anatomical sex organs of testes, ovaries, penis, or vagina—should be removed to alleviatethe illness. The promise of these interventions is the cure of the gender dysphoria. The underlyingassumption is that all types of gender dysphoria have their ultimate origin in "brain structures", often determined embryonically. Although numerous studies have been undertaken to attempt todemonstrate a distinctive physical "brain structure" associated with transgender identity, as of yetthere is no credible, reliable-valid scientific evidence that these patients have any defining abnormality in brain structure that precedes the onset of gender dysphoria. See, Mueller, De Cuypere & T'Sjoen. Transgender research in the 21st century: A selective critical review from a neurocognitive perspective. American Journal of Psychiatry 174: 12, 2017.

It should be noted that gender dysphoria is *a psychiatric rather than a medical diagnosis*. Since its inception in DSM-III, it has always and only been specified in the psychiatric DSM manuals. Notably, *gender dysphoria is the only psychiatric condition to be treated by surgery*, even though no endocrine or surgical intervention package corrects any identified biological abnormality (cf body integrity identity disorder (BIID) (See, Levine, *Reflections*, at 240.) In my opinion, the "affirmation" treatment protocols using endocrine and surgical "treatments" to change a psychiatric condition are not accepted by the relevant scientific community, are supported by

only "weak evidence" from methodologically defective research studies, and have no known, nor published error rates. Actual attempts at publishing error rates has come under the concept of "regrets" focused only only on patient injuries and misery following genital re-assignment surgery. There is much more to the human experience of trans patients regrets over time than the questionable, methodologically defective claims quoted by some of 2%. For example, in the Bränström., et.al., study, an enormous part of the sample was "lost" and never followed up. The authors failed to explore available data to see how many of these patients have de-transitioned, died via suicide, etc. One has to wonder why the suicide rate is reportedly so very high for patients who received trans genital surgery. In sum, these "treatments" remain experimental and poorly studied and we'll need much more and much higher quality scientific research before we will know if such "treatments" are actually helping or injuring patients. Is is essential to note that hormonal and surgical treatments for gender discordant patients have been increasingly done over a 50 year period and yet no reliable-valid protocols for evaluation or treatment have been properly researched, nor generally accepted by the relevant scientific community, nor published with methodologically sound error rates**.** For decades, vulnerable patients struggling with gender identity issues have deserved better, more effective, less experimental, less hazardous, less ideologically tainted, and properly researched treatments — they are still waiting.

24. Gender dysphoria can be effectively and alternatively conceptualized in developmental terms, as an adaptation to a psychological problem that was first manifested as a failure to establish a comfortable conventional sense of self in early childhood. This paradigm starts from the premise that all human lives are influenced by past processes and events. Trans lives are not exceptions to this axiom. (Levine, *Reflections*, at 238.) MHPs who think of gender dysphoria through this paradigm may work both to identify and address causes of the basic problem of the deeply

29. When a pre-adolescent child presents with gender dysphoria, a "watchful waiting" approach avoids hormonal treatments to allow for the developmental nature of gender identity in children to naturally resolve —that is, take its course from forces within and surrounding the child. Watchful waiting has two versions:

a. (Model 1 of watchful waiting) Treating any other psychological co-morbidities—that is, other mental illnesses as defined by the DSM-5—that the child may exhibit (separation anxiety, be bedwetting, attention deficit disorder, obsessive-compulsive disorder, depression) without a focus on gender

b. (Model 2 of watchful waiting) No treatment at all for anything, but a regular follow-up appointment. This might be labeled a "hands off" approach

The psychotherapy model: Alleviate distress by identifying and addressing causes

30. One of the foundational principles of psychotherapy has long been to work with a patient to identify the causes of observed psychological distress and then to address those causes as a means of alleviating the distress. The National Institute of Mental Health has promulgated the idea that 75% of adult psychopathology has its origins in childhood experience.

31. Many experienced practitioners in the field of gender dysphoria, including myself, have believed that it makes sense to employ these long-standing tools of psychotherapy for patients suffering gender dysphoria, asking the question as to what factors in the patient's life are the determinants of the patient's repudiation of his or her natal sex. (Levine, *Ethical Concerns*, at 8.) I and others have reported success in alleviating distress in this way for at least some patients, whether or not the patient's sense of discomfort or incongruence with his or her natal sex entirely disappeared. Relieving accompanying psychological co-morbidities leaves the patient freer to consider the pros and cons of transition as he or she matures.

is no sharp line between "watchful waiting" and the psychotherapy model in the case of prepubescent children.

35. To my knowledge, there is no credible, reliable-valid scientific evidence beyond anecdotal reports that psychotherapy can enable a return to male identification for genetically male boys, adolescents, and men, or return to female identification for genetically female girls, adolescents and women. *Controlled studies have never been attempted*. On the other hand, anecdotal case report evidence of such outcomes does exist; I and other clinicians have witnessed reinvestment in the patient's biological sex in some individual patients who are undergoing psychotherapy. The Internet contains many such reports, and I published a paper recently on a patient who sought my therapeutic assistance to reclaim his male gender identity after 30 years living as a woman and is in fact living as a man today. (Levine, *Transitioning*, at 1.) I have seen children desist even before puberty in response to thoughtful parental interactions and a few meetings of the child with a therapist. Recently, a paper reviewing the phenomenon of de-transition has been published in which the authors claims to have identified *60,000 case reports world wide* on the Internet. See Expósito-Campos P. A Typology of Gender Detransition and Its Implications for Healthcare Providers. J Sex Marital Ther. 2021;47(3):270-280. doi: 10.1080/0092623X.2020.1869126. Epub 2021 Jan 10. PMID: 33427094.

The affirmation therapy model

36. While it is widely agreed that the therapist should not directly challenge a claimed transgender identity in a child, some advocates and practitioners go much further, and promote and recommend that any expression of transgender identity should be immediately accepted as decisive, and thoroughly affirmed by means of consistent use of clothing, toys, pronouns, etc. associated with transgender identity. These advocates treat any question about the causes of the

a precondition for a diagnosis of gender dysphoria, precisely because of the risk of "transitory" symptoms and "hasty" diagnosis that might lead to "inappropriate" treatments. See, K. Zucker (2015), *The DSM-5 Diagnostic Criteria for Gender Dysphoria*, in C. Trombetta et al. (eds.), Management of Gender Dysphoria: Multidisciplinary Approach, DOI 10.1007/978-88-470-5696-1_4 (Springer-Verlag Italia 2015).

41. I do not know what proportion of practitioners are using which model. However, in my opinion, in the case of young children, prompt and thorough affirmation of a transgender identity disregards the principles of child development and family dynamics, and is not supported by credible, reliable-valid scientific evidence**.** Rather, the MHP must focus attention on the child's underlying internal and familial issues. Ongoing relationships between the MHP and the parents and the MHP and the child are vital to help the parents, child, other family members, and the MHP to understand over time the issues that need to be dealt with over time by each of them.

42. Likewise, since the child's sense of gender develops in interaction with his parents and their own gender roles and relationships, the responsible MHP will almost certainly need to delve into family and marital dynamics.

F. Patients Differ Widely and Must Be Considered Individually.

43. In my opinion, it is not possible to make a single, categorical statement about the proper treatment of children presenting with gender dysphoria or other gender-related issues. There is no single pathway of development and outcomes governing transgender identity, nor one that predominates over the large majority of cases. Instead, as individuals grow up and age, depending on their differing psychological, social, familial, and life experiences, their outcomes differ widely. I can, however, categorically opine that unproven, experimental affirmation "treatments"should not be used on uninformed or misinformed patients and families.

45. In almost any discussion of the diagnosis and care of patients suffering gender dysphoria or exhibiting transgender characteristics, the World Professional Association for Transgender Health (WPATH) and its Standards of Care will be mentioned. Accordingly, I provide some context concerning that private, activist, non-science, organization.

46. I was a member of the Harry Benjamin International Gender Dysphoria Association from 1974 until 2001. From 1997 through 1998, I served as the Chairman of the eight-person International Standards of Care Committee that issued the fifth version of the Standards of Care. I resigned my membership in 2002 due to my regretful conclusion that the organization and its recommendations had become dominated by politics and ideology, rather than by proper, reliable scientific methodologies, as was its mission years earlier. In approximately 2007, the Henry Benjamin International Gender Dysphoria Association changed its name to the World Professional Association for Transgender Health.

47. WPATH is a voluntary membership, activist advocacy organization. Since at least 2002, attendance at its biennial meetings has been open to trans individuals who are *not licensed professionals*. While this ensures taking patients 'perceived needs, values, and sensibilities into consideration, it limits the ability for honest, methodologically competent scientific debate. It also means that WPATH can no longer be considered a purely professional or scientific organization.

48. WPATH takes a very narrow and politically-ideologically driven view on increasingly controversial issues as to which there is a wide range of opinion among professionals. WPATH explicitly views itself as not merely a scientific organization, but also as an advocacy organization. *These are, obviously, conflicted, incompatible, and contradictory goals*. (Levine, *Reflections*, at 240.) WPATH is supportive to those who want Sex Reassignment Surgery ("SRS") even though such surgery is *not supported by credible, reliable-valid scientific research*, not accepted by the

relevant scientific community, and has no known error rates, and no careful systematic follow-up using agreed upon criteria to even assess multifaceted failure rates. Skepticism as to the benefits of SRS to patients, and strong alternate views, are not well tolerated in discussions within the organization. Such views have been literally shouted down and effectively silenced by the large numbers of nonprofessional adults who attend the organization's biennial meetings. Such "mob rule" is quite incompatible with appropriate, competent methodological discussions.

49. The Standards of Care ("SOC") is the product of an enormous effort, but it is not a politically neutral document. WPATH aspires to be both a scientific organization and an advocacy group for the transgendered. These aspirations are clearly in sharp conflict. The most serious limitations and defects of the Standards of Care, however, are not primarily political. They are caused by the decades-long and continuing lack of credible, rigorous research in the field, which allows room for passionate convictions and ongoing controversies on how to care for the transgendered. See, e.g. Vrouenraets et al, *Early Medical Treatment of Children and Adolescents With Gender Dysphoria: An Empirical Ethical Study*, Journal of Adolescent Health 57 (2015) 367e373. [The Endocrine Society and the World Professional Association for Transgender Health published guidelines for the treatment of adolescents with gender dysphoria (GD). The guidelines recommend the use of gonadotropin-releasing hormone agonists in adolescence to suppress puberty. However, in actual practice, *no consensus exists whether to use these early medical interventions* … Conclusions: As long as *debate* remains on these seven themes and *onlylimited long-term data are available*, *there will be no consensus on treatment*. Therefore, more systematic interdisciplinary and (worldwide) multi-center research is required.]

50. In recent years, WPATH has fully adopted — in the absence of reliable-valid scientific research — some mix of the medical and civil rights paradigms. It has downgraded the role of

"the cross gender wishes usually fade over time and do not persist into adulthood, with only 2.2% to 11.9% continuing to experience gender discordance." A third summarized the existing data as showing that "Symptoms of GID at prepubertal ages decrease or disappear in a considerable percentage of children (estimates range from 80-95%)." A 2021 publication found that 12% of previously evaluated grade school aged children persisted in their trans identities many years later. (Singh, Bradley, and Zucker, Frontiers of Psychiatry. See, P. T. Cohen-Kettenis, H. A. Delemarre-van de Waal et al. (2008), *The Treatment of Adolescent Transsexuals: Changing Insights*, J. Sexual Medicine 5(8) 1892 at 1895.

55. It is not yet known how to distinguish those children who will desist from that small minority whose trans identity will persist. (Zucker, Gender Dysphoria in Children and Adolescents, in Principles and Practices of Sex Therapy 6th edition, Guilford Press, 2020; Levine, *Ethical Concerns*, at 9.) Even severity of gender dysphoria is not a strong predictor of persistence. It is also apparent in the adolescent phenomenon of rapid onset of gender dysphoria following a gender normative childhood that childhood gender identity is not inherently stable. Some of these individuals desist and others evolve dramatically to become more non-binary and accepting of their complex male and female identifications.

56. Desistance (a patients' willing reacceptance of their biological sex through normal developmental processes) within a relatively short period may also be a common outcome for post-pubertal youths who exhibit recently described "rapid onset gender disorder." I observe an increasingly vocal online community of young women who have reclaimed a female identity after claiming a male gender identity at some point during their teen years. However, reliable-valid scientific data on outcomes for this age group with and without therapeutic interventions is not yet available. A recent review of de-transitioning claimed to have identified 60,000 case histories in

a search of proliferating websites devoted to this topic (Pablo Exposito-Campos. A typology of gender detransition and its implications for health care providers J Sex & Marital Therapy 2020 https:..doi.org/101080/0092623x.2020.1869126). In the past WPATH has simply declined to discuss this vital topic, another example of WPATH's political consensus-seeking, *increasingly anti-science methodology*.

57. In contrast, there is now data that suggests that a therapy that encourages social transition dramatically changes outcomes and often "locks in" a patient's journey into a life course of dependence on experimental hormone "treatments". A prominent group of authors has written that "The gender identity affirmed during puberty appears to predict the gender identity that will persist into adulthood." Similarly, a comparison of recent and older studies suggests that when an "affirming" methodology is used with young children, a substantial proportion of children who would otherwise have desisted by adolescence—that is, achieved comfort identifying with their natal sex—instead persist in a transgender identity. (Zucker, *Myth of Persistence*, at 7.)18

58. Indeed, a review of multiple studies of boys treated for gender dysphoria across the last three decades found that early social transition to living as the opposite sex severely reduces the likelihood that the child will revert to identifying with the child's natal sex, Studies that began before the widespread use of social transition for young children reported desistance rates in the range of 80-98%. A more recent study reported that fewer than 20% of boys who engaged in a partial or complete transition prior to puberty desisted when surveyed at age 15. See (T.D. Steensma, J.K. McGuire et al. (2013), *Factors Associated with Desistance & Persistence of Childhood Gender Dysphoria: A Qualitative Follow-up Study*, J. of the Am. Academy of Child and Adolescent Psychiatry. 52, 582. ; See, C. Guss et al. (2015), Transgender and Gender

population, or to the notably worse outcomes exhibited by the transgender population generally. *See, e.g.,* B. Ehrensaft (2015), *Listening and Learning from Gender-Nonconforming Children,* The Psychoanalytic Study of the Child 68(1) 28 at 34: "In my own clinical practice . . . of those children who are carefully assessed as transgender and who are allowed to transition to their affirmed gender, we have no documentation of a child who has 'desisted 'and asked to returnto his or her assigned gender."

61. However, I agree with Zucker who has written, "…we cannot rule out the possibility that early successful treatment of childhood GID [Gender Identity Disorder] will diminish the role of a continuation of GID into adulthood. If so, successful treatment would also reduce the need for the long and difficult process of sex reassignment which includes hormonal and surgical procedures with substantial medical risks and complications." See, Zucker, *Myth of Persistence,*at 8 (citing H. Meyer-Bahlburg (2002), *Gender Identity Disorder in Young Boys: A Parent- & Peer-Based Treatment Protocol,* Clinical Child Psychology & Psychiatry 7, 360 at 362.).

By the same token, a therapeutic methodology for children that *increases* the likelihood that the child will continue to identify as the opposite gender into adulthood will *increase* the need for the long and potentially problematic processes of hormonal and genital and cosmetic surgical procedures.

62. Given these facts, *encouraging social transition in children remains controversial*. Supporters of such transition acknowledge that "Controversies among providers in the mental health and medical fields are abundant . . . These include differing assumptions regarding . . . the age at which children . . . should be encouraged or permitted to socially transition These are complex and providers in the field continue to be at odds in their efforts to work in the best interests of the youth they serve." See, A. Tishelman et al. (2015), *Serving Transgender Youth: Challenges,*

Dilemmas and Clinical Examples, Prof. Psychol. Res. PR. at 11, DOI: 10.1037/a0037490 ("*Serving TG Youth*") Transition then, should be undertaken only subject to standards, protocols, and reviews appropriate to actual clincial experiments [Clincial experiments involve time-honored careful processes with Institutional Review Board — human subjects protections — approval required, a predetermined method of evaluation, primary and secondary endpoints and safeguards to protect the rights of patients to truly informed consent. These protections are not present in the Transgender Treatment Industry when vulnerable patients are receving "treatments" that lack sufficient proof of efficacy and safety.]

63. In sum, therapy for young children that encourages transition cannot be considered to be neutral, but instead *is an experimental procedure* that has a high likelihood of changing the life path of the child, with highly unpredictable effects on mental and physical health, suicidality, and life expectancy. Claims that a civil right is at stake do not change the fact that what is proposed is a social and medical experiment on vulnerable patients. (Levine, *Reflections,* at 241.)

IV. THE AVAILABLE DATA DOES NOT SUPPORT THE CONTENTION THAT "AFFIRMATION" OF TRANSGENDER IDENTITY REDUCES SUICIDE OR RESULTS IN BETTER PHYSICAL OR MENTAL HEALTH OUTCOMES GENERALLY.

64. I am aware that organizations including The Academy of Pediatrics and Parents, Families and Friends of Lesbians and Gays (PFLAG)) have published statements that suggest that all children who express a desire for a transgender identity should be promptly supported in that claimed identity. This position appears to rest on the belief —which is widely promulgated by certain advocacy organizations—that science has already established that prompt "affirmance" is best for all patients, including all children, who present indicia of transgender identity. As I discuss later below, this belief is scientifically incorrect, and ignores both what is known and what is unknown.

65. It is instructive to consider how policies are constructed by professional and lay organizations. Professional association vote on policies that are formulated in small committees. Such consensus processes are not a reliable valid scientific methodology. These professional, political, or community support groups do not rely upon scientifically tested methodologies, although they claim to have done so. All methodologically informed workers, even among those who work in this arena, have in the past and continue to conclude that there is low level science underlying treatment patterns and the policies that encourage them. A "low" level is defined by specific criteria of validity or trustworthiness.

Professional associations have a tainted history of supporting unproven, controversial notions that were later shown to be improper, unreliable, and/or unethical. For example, the American Medical Association supported eugenic proposals to "improve the quality of the human stock" by coercive sterilization of "defective and undesirable Americans" and selective breeding. During the 1890s the renowned surgeon Albert Ochsner was invited to speak about his vasectomy procedure to the meeting of the American Medical Association. He recommended vasectomies to prevent the reproduction of "criminals, chronic inebriates, imbeciles, perverts, and paupers." (See, Oshsner, AJ, Surgical treatment of habitual criminals. JAMA, 1899:32:867-868). The AMA's support was a political not a scientific process.

Similarly, the American Breeders Association founded a Eugenics Record Office with an advisory board that included a Harvard physiologist, a Princeton psychiatrist, a University of Chicago economist, and a Rockefeller Institute for Medical Research recipient of the Nobel Prize in Medicine. This movement was focused on "terminating the bloodlines" of the "submerged lower ten percent of the population with 'defective germ-plasm'". (See, Black, E. War Against the Weak, New York, NY, 2003).

such multi-disciplinary research, analysis, and treatment is now being blocked and threatened as "conversion therapy" by political advocates. [See, Olson-Kennedy, J, Cohen-Kettenis, P., et al., Research priorities for gender nonconforming/transgender youth gender identity development and biopsychosocial outcomes, Current Opinion in Endocrinology & Diabetes and Obesity: April 2016 - Volume 23 - Issue 2 - p 172-179, doi: 10.1097/MED.0000000000000236]

Suicide, suicidal ideation, suicide attempts, suicidal manipulations

74. With respect to suicide risks, individuals with gender dysphoria are well known to have a higher risk of committing suicide or otherwise suffering increased mortality before and after not only social transition, but also before and after SRS. (Levine, *Reflections,* at 242.) For example, in the United States, the death rates of trans veterans are *comparable to those with schizophrenia and bipolar diagnoses but 20 years earlier* than expected. These crude death rates include significantly elevated suicide rates. (Levine, *Ethical Concerns,* at 10.) Similarly, researchers in Sweden and Denmark have reported on almost all individuals who underwent sex-reassignment surgery over a 30-year period. The Swedish follow-up study found a suicide rate in the post-Sex Reassignment Surgery (SRS) population *19.1 times greater than that of the controls after affirmation treatment*; both studies demonstrated elevated mortality rates from *medical and psychiatric conditions*. (Levine, *Ethical Concerns,* at 10.) See, C. Dhejne et al. (2011), Long-Term Follow-Up of Transsexual Persons Undergoing Sex Reassignment Surgery: Cohort Study in Sweden, PLOS ONE 6(2) e16885 ("Long Term"); R. K. Simonsen et al. (2016), Long-Term Follow-Up of Individuals Undergoing Sex Reassignment Surgery: Psychiatric Morbidity & Mortality, Nordic J. of Psychiatry 70(4).

75. Advocates of immediate and unquestioning affirmation of social transition in children who indicate a desire for a transgender identity sometimes assert that any other course will result

79. Thus, given the lack of credible science evidence for suicide reduction, transition of any sort must be justified, if at all, as a life-*enhancing* measure, not a lifesaving measure — although there is no credible to support either hypothesis. (Levine, *Reflections*, at 242.) In my opinion, this is an important fact that patients, parents, and even many MHPs fail to understand. They also often do not understand that the current gender affirmation "treatment" datafor life saving or enhancement are so weak, sparse, and poorly gathered that they do not permit usto know if gender affirmation interventions will increase or decrease a patient's risk of suicide orreduced depression ***or even an improved life.*** How many years will go by before such research is competently completed? See, C. Dragon, P. Guerino, et al. (2017), *Transgender Medicare Beneficiaries & Chronic Conditions: Exploring Fee-for-Service Claims Data*, LGBT Health 4(6) 404, DOI: 10.1089/lgbt.2016.0208.

V. KNOWN, LIKELY, OR POSSIBLE DOWNSIDE RISKS ATTENDANT ON MOVING QUICKLY TO "AFFIRM" TRANSGENDER IDENTITY IN CHILDREN.

80. As some research has already demonstrated, enabling and affirming social transition in a prepubescent child appears to be highly likely to increase the odds that the child will in time pursue pubertal suppression and persist in a transgender identity into adulthood. I consider the ethical implications of this intervention in the next section. Here, I emphasize that the Mental Health Professional (MHP), pediatrician, and parent must consider long-term as well as short - term implications of life as a transgender individual when deciding whether to permit or encourage a child to socially transition.

81. The multiple studies from different nations that have documented ***the increased vulnerability of the adult transgender population to substance abuse, mood and anxiety disorders, suicidal ideation, and other health problems stand as a warning***: Given these well-documented data, ***assisting a child down the road to becoming a transgender adult is an ominous***

decision. Data about trans adults remind all concerned that a casual assumption that transition will improve the child's life is ***not*** justified beyond his or her short term happiness about gender expression. The possibility that steps along this pathway, while lessening the relatively minor pain of gender dysphoria, *could lead to additional future sources of crippling emotional and psychological pain,* are too often not properly considered by advocates of social transition and not considered at all by the trans child. (Levine, *Reflections,* at 243.). The informed consent process for parents considering this option ethically should spell out short-term gains and long-term risks (beginning at early puberty risks). What follows is a discussion of the medical, social, and psychological risks of affirmation interventions ("transition").

A. Physical risks associated with transition

82. Sterilization. Sex Reassignment Surgery (SRS) that removes testes, ovaries, or the uterus is ***inevitably sterilizing and irreversible***. While by no means all transgender adults elect SRS, many patients do ultimately feel compelled to take this serious step in their effort to "live fully as the opposite sex". More immediately, practitioners recognize that the administration of cross-sex hormones, which is often viewed as a less radical measure, and is now increasingly done to minors, creates a risk of irreversible sterility. These risks have never been properly studied nor quantified in a systematic manner. As a result, even when treating a child, the MHP, patient, and parents must consider ***permanent loss of reproductive capacity (sterilization)*** *to be one of the major risks of starting down the road*. The risk that supporting social transition may put the child on a pathway that leads to intentional or unintentional permanent sterilization is particularly concerning given ***the disproportionate representation of minority and other vulnerable groups*** among children reporting a transgender or gender-nonconforming identity. *See* C. Guss etal., *TGN Adolescent Care* at 4 ("a side effect [of cross-sex hormones] may be infertility") and 5

98. I noted above an increasingly visible online community of young women who have desisted after claiming a male gender identity at some point during their teen years. Given the rapid increase in the number of girls presenting to gender clinics within the last few years, the phenomena of regret and desistance by young women deserves careful attention and study by MHPs. As reported by one author in 2021, *60,000 testimonies of personal de-transition can be found on the Internet*. See, Pablo Exposito-Campos. A typology of gender detransition and its implications for health care providers J Sex & Marital Therapy 2020 https:..doi.org/101080/0092623x.2020.1869126).

99. Thus, misleading reports of clinical experience, publications that misreport evidence, and the unregulated content of the Internet - many falsely claiming transitions are "easily reversible" — prevent the sobering acceptance of what has previously been asserted for decades — for most all such patients "once a transgendered person, always a transgendered person", whether referring to a child, adolescent, or adult, male or female.

VI. MEDICAL ETHICS & INFORMED CONSENT

A. The obligation of the mental health professional to enable and obtain informed consent

100. I have reviewed above the knowledge and experience that, in my view, a mental health professional should have before undertaking the responsibility to counsel or treat a child who is experiencing gender dysphoria or transgender identification. The MHP who undertakes this type of responsibility must also be guided by the ethical principles that apply to all health care professionals. One of the oldest and most fundamental principles guiding medical and psychological care—part of the Hippocratic Oath—is that the physician must "do no harm." This states an ethical responsibility that cannot be delegated to the patient. Physicians themselves must

119. In light of the profound uncertainties in the field, and the many highly predictable or probable lifetime costs to the child if he or she persists in a transgender identity into adulthood, in my opinion it is not consistent with principles of medical ethics for physicians or other MHPs to suggest that parents should not or have no right to explore possible therapeutic options to assist their child to achieve comfort with the gender corresponding to his or her sex. The use of the label "reparative therapy" or "conversion therapy" by some advocates to lump all such possible therapies together and disparage them does not change this equation. (Levine, *Informed Consent*, at 7.)

120. The transgender clinical arena is growing increasingly uncertain as more attention has been paid to the lack of fundamental studies to support the current widespread fashions of professional recommendations and confirmation bias has been identified in recent highly acclaimed but deeply flawed work. While the general public is now accustomed to reading about trans culture wars, my opinion is that of a clinician who respects scientific methods of ascertaining best treatments. More caution is indicated when the consequences are greater. It has been repeatedly demonstrated in medicine that one size does not fit all. One must reject the idea that if a young person is trans, nothing else matters—the treatment should be immediate affirmation and endocrine support. All must realize that 50 years after trans treatment began to spread across the world, despite more than 10,000 publications, it is not known whether the burgeoning Transgender Treatment Industry is helping or damaging most GD patients.

121. It is my opinion that the scientific community finds the following matters to be uncertain, controversial, or incorrect.

— Gender dysphoria is a serious, physical brain based medical illness that causes suffering that must be treated by hormones and surgery if patients seek such treatments.

— All patients who label themselves as transgendered, regardless of the >120 sub-labels that may be invoked, gender all should be offered the same physical body-changing treatments, if they so desire.

— Hormones and surgery improve the lives of the transgendered in the long run.

— "Above all do no harm" principle can be sidestepped when administering hormones and removing healthy breast and genital tissues in the case of trans persons because it is "medically necessary" –that is, these patients represent a special exception to 2500 years of medical ethics.

-The uncertain long-term adjustments of trans adults, the rates of detransition, disappointment, and chronic depressive, anxiety, and substance abuse disorders do not need to be calculated nor should what is known about high psychiatric morbidity following hormonal and/or surgical treatment should not slow the affirmative treatment policy of trans youth.

--Civil rights considerations are more important than unanswered relevant scientific questions.

XX. SUMMARY OPINIONS:

122. There are no long-term, peer-reviewed published, credible, reliable and valid, research studies documenting or establishing:

a. The percentage of patients receiving gender transition procedures who are helped by such procedures according to well known criteria.

b. The percentage of patients receiving gender transition procedures who are harmed by such procedures according to well known criteria.

c. The reliability and validity of assessing gender identity by relying solely upon the expressed desires of a patient.

d. The mental health outcomes of trans behaving children who are either affirmed or not affirmed in childhood.

e. The percentage of various types of childhood functional challenges and psychiatric diagnoses of trans identified children

f. The percentage of patients whose new trans identity has been created by involvement in social media.

123. The above list of six issues can stimulate new research whose results may shape future trans care. In the meantime, those with gender dysphoria or a trans identity have a right to be more fully informed about what is known as do their physicians. Physicians, psychologists, parents, and patients have a right to be ***protected*** from these current experimental, politically tainted, fashionable "treatments".

124. Informed consent is designed to protect the rights of patients and families, the cognitive and ethical processes of physicians, and the ethical and legal duties of health care institutions. The need for credible, reliable-valid science is also essential to protect each of these entities. The informed consent document for affirmative treatments of youth should specify that up to 88% of children without affirmation will desist (heal naturally without treatment) from their childhood- onset trans preoccupations. Physicians always need to know the patient's original sex because while gender identity can dramatically change, biological sex and its unique susceptibilities to disease does not.

125. The Transgender Treatment Industry's policies and advocacies are a niche group of well meaning mental health professionals, endocrinologists, plastic and urological surgeons, and transgendered individuals. Many in their individual professions have differing opinions. They should not be viewed as speaking for all of medicine on these highly controversial issues.

126. Science not politics needs to drive trans care. The medical professions has many tragic examples of when political sensibilities drive medical treatments. When policy is made by voting in the face of low quality science, claims that treatments are evidence-based should be considered misleading and deceptive.

127. No medical, surgical, or psychiatric treatment is invariably successful in producing an agreed upon outcome. In other branches of medicine and psychiatry risks and benefits, outcomes and error rates are better known, far less controversial, and much better proven by credible, reliable-valid scientific research. Error rates for gender affirmation diagnoses, errors rates for predictions of effective vs. harmful affirmation treatments, error rates for increases or decreases in suicidal risk following affirmation treatments, remain unknown. In the field of gender affirmation intervention there has been a rush to treat and a remarkable absence of ethical concern based on obvious scientific limitations as outlined in this report.

128. **Expert Witness Report Methodological Limitations**: My opinions and hypotheses in this matter are — as in all expert witness reports — subject to the limitations of documentary and related evidence, the impossibility of absolute predictions, as well as the limitations of social, biological, and medical science. I have not met with, nor personally interviewed, anyone in this case. As always, I have no expert opinions regarding the veracity of witnesses in this case. I have not yet reviewed all of the evidence in this case and my opinions are subject to change at any time as new information becomes available to me. Only the trier of fact can determine the credibility of witnesses and how scientific research may or may not be related to the specific facts of any particular case. In my opinion, a key role of an expert witness is to help the court, lawyers, parties, and the public understand and apply reliable scientific, technical, and investigative principles, hypotheses, methods, and information. I have transmitted this confidential expert report directly

S1 Biopharma - a phase 1-B non-blinded study of safety, tolerability and efficacy of Lorexys in premenopausal women with HSDD

HRA - qualitative and cognitive interview study for men experiencing PE

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A) Books

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6) Editor, (Candace Risen and Stanley Althof, associate editors) Handbook of Clinical Sexuality for Mental Health Professionals. Routledge, New York, 2003
   (a) 2006 SSTAR Book Award: Exceptional Merit
7) Demystifying Love: Plain Talk For The Mental Health Professional. Routledge, New York, 2006
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B) Research and Invited Papers

(When his name is not listed in a citation, Dr. Levine is either the solo or the senior author)

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11) Articles in Medical Aspects of Human Sexuality

    (a) Treating the single impotent male. 1976; 10:123, 137

    (b) Do men enjoy being caressed during foreplay as much as women do? 1977; 11:9

    (c) Do men like women to be sexually assertive? 1977;11:44

    (d) Absence of sexual desire in women: Do some women never experience sexual desire? Is this possibility genetically determined? 1977; 11:31

    (e) Barriers to the attainment of ejaculatory control. 1979; 13:32-56.

    (f) Commentary on sexual revenge.1979;13:19-21

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Exhibit B

Deposition of:

Stephen B. Levine , MD

September 10, 2021

In the Matter of:

Kadel, et al vs. Folwell

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IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF NORTH CAROLINA

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MAXWELL KADEL, et al.,

Plaintiffs,

vs. Case No. 1:19-cv-272-LCB-LPA

DALE FOLWELL, in his official capacity as State Treasurer of North Carolina, et al.,

Defendants.

~~~~~~~~~~~~~~~~~~~~

Video Deposition of
STEPHEN B. LEVINE, M.D.

September 10, 2021
9:05 a.m.

Taken at:
Veritext Legal Solutions
1100 Superior Avenue
Cleveland, Ohio

Tracy Morse, RPR

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ALSO PRESENT:

Joseph Vandetta, Videographer

TRANSCRIPT INDEX

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INDEX OF EXHIBITS (Continued)

Q. Okay. And so then were there any external grants to research and publish about the treatment of children or adolescents --

A. No.

Q. -- with gender dysphoria?

Okay. Is that a, "No," when I included the, "Gender dysphoria," as well?

A. That is a, no.

Q. Okay. Thank you. Okay. So on page 3 of your report -- actually, I'm sorry. It's going to be the bottom of page 4 and to the top of page 5. Your report lists your experience as an expert witness, which we talked about a little bit earlier. I just -- I'm wondering if you would confirm this is not an exhaustive list of your experience as an expert witness either via deposition or report.

A. I wouldn't want to testify that this is absolutely complete, given the fact that I don't keep a list compiled. This is kind of compiled retrospectively from memory and documents. And so this is the best I could have done on April of 2021 --

Q. Understood. Thank you. So --

A. -- you might find something else.

Q. Was it --

A. -- in a commercial building where our clinic was. It was just, you know, a conference room in our clinic.

Q. And that was within -- was that within a business --

A. It was --

Q. -- a psychiatric practice?

A. I'm sorry. I interrupted you.

It was within The Center For Marital Health, which was a business that I and two other people started and owned and ran. And in that business, we continued the same kind of work we did with the University minus the large number of trainees.

Q. You mentioned that after '93, you were not being paid by the University. Were you providing your clinical psychiatric professorship gratuitously?

A. Meaning without pay? Yes.

Q. Okay. Do you know if, after you moved the clinic away from Case Western Reserve, if Case Western Reserve University Medical School created a separate gender identity clinic?

A. Years later they did --
Q. Oh, sorry.
A. -- I would say, they created a separate clinic perhaps in 2017, 2016.
Q. Do you know the name of that clinic?
A. I don't think it's in the department of psychiatry. I think it's in the department of pediatrics. And the answer to your question is, no.
Q. Does The LGBTQ and Gender Care Program sound familiar?
A. No.
Q. But have you -- sorry. Have you evaluated any patients through that separate clinic that Case Western Reserve has?
A. No. Much to my dismay, that clinic was formed and maintained without any input from me, who I thought was one of the experts in the field.
Q. Do you know if they have psychiatrists, within that clinic?
A. I -- I'm not knowledgeable about the composition of that clinic. There is a very strong liaison between our department of

What do you mean by, "This era"?

A. Before 1993.

Q. Okay. And what do you mean by, "Occasional"?

A. I would say that 95 percent of the patients that we saw were 16 and 17, 18 and up. We could debate what the word, "Child," means, but to me an 11-year-old is a child, even a 13-year-old is a child, especially when my children were 13. And so we -- in the first twenty years, transgender issues were primarily an older teenager and adult, mostly adult issues. In recent years, I would say, 12, 15 years, the number of adolescents appearing in gender clinics at our place and everywhere as far as I can see has increased exponentially, especially the number of teenage girls who are declaring themselves trans boys.

Q. So how many -- sorry. So the first twenty or so years, you said approximately 5 percent of all patients were children.

A. Were younger -- on the younger end of the spectrum --

Q. Right.

A. -- yes.

it, you see? But at this moment -- this week, I have one patient that I see weekly, who is a transgender teen. My staff -- if I can be presumptuous to call them, "My staff" -- our staff sees more.

Q. And thinking about the last year, approximately how many adult patients did you see -- and let's use your framing of, "Regular." So that could be one, for one followup visit or that could be for more -- how many adult patients did you see for treatment of gender dysphoria?

A. Approximately six.

Q. And using that same framing of, "Regular," how many children, so under age 11?

A. In the last year?

Q. Yes, yes. In the last year.

A. Zero.

Q. How many adolescents in regular treatment for gender dysphoria would you approximate you've seen in the last five years individually, exclusive of your supervision of other clinicians?

A. If you ask me the question in the last year, I would have told you five or six,

but since you ask it as a five-year period, I'm at a loss to tell you whether it's twelve or fifteen. I --

Q. An approximate is fine. Thank you.

A. -- let's just say a dozen with an asterisk, very approximate.

Q. And jumping a little bit more in terms of time. How about the last ten years?

A. Again, using the same asterisk, I would say, double it.

Q. Okay. And you said zero people under age 11, so children this last year. What about in the last five years?

A. Oh, two years ago, we had this charming little 6-year-old. One of my colleagues specializes in children and I get to hear about these cases. Occasionally I get to meet the parents, but I personally have not delivered a psychotherapeutic care or evaluation directly of a child with the exception of this one person that I was involved with.

Q. And that was this last year, you said?

A. That was -- I think it was probably

two, two and a half years ago.

Q. Oh, okay. And what kind of treatment -- I should say, have you referred any of those adolescent patients for additional treatment, besides psychotherapy, for the treatment of gender dysphoria?

A. Yes.

Q. And what kinds of treatment have you referred them for?

A. For endocrine treatment.

Q. Okay. And approximately what percentage of those adolescent patients have you referred for endocrine treatment?

A. Give me the timeframe of that question, please.

Q. Sure. So you said a few moments ago, in the last five years, you saw maybe, asterisk, 12 to 15 adolescent individually yourself. Of those 12 to 15, what would be the approximate percentage you referred for endocrine treatment?

A. I'm hesitating to answer the question, because some of those children have been taking testosterone or estrogen surreptitiously from their parents. And while

I didn't refer them for the treatment, I was seeing them while they were taking the treatment. So if we're only talking about adolescent -- referrals of adolescents for hormones, I would say a very small percentage of those, say, I guess you would say 10 percent.

Q. Fair enough. Have you had yourself individually as a clinician, have you had any non-transgender children who you have made a referral for endocrine treatments related to other conditions?

A. No.

Q. Okay. So then zooming out 30,000 foot view of your 48-year career now, would you say overall, you have provided treatment -- that is, psychiatric treatment -- to mostly adults experiencing gender dysphoria, gender identity issues?

MR. KNEPPER: Objection, form.

A. I would say that throughout my career, we should divide my career into the first twenty years where mostly adults were seen by our team and myself. And then we ought to talk about the last ten or fifteen years

where the number of adults has diminished and the number of adolescents has increased dramatically.

Q. Okay. Thank you. So as a part of your private practice, do you write letters of authorization for endocrine treatments?

A. Yes.

Q. And do you write letters of authorization for gender affirming surgeries?

A. I have. I have not recently, because most of my patients are 13 or 15 or 16, you know.

Q. Okay. And I'm sorry. Just by, "Recent," when was the last time you wrote a letter of authorization for a gender affirming surgery for an adult?

A. Probably twelve months ago.

Q. Okay. And over the course of your career focusing on your treatment of adults experiencing gender identity issues, for what percentage of those patients would you estimate you wrote a letter of authorization for gender affirming surgery for?

MR. KNEPPER: Objection, form.

A. Again, I would like to put an

asterisk to whatever I answer this question as. I have not kept track of those figures. I have written -- I've written or cosigned letters for hormone treatments and for gender confirming surgeries for many people. There were more people in the '70s and '80s than in recent decades. In part as a reflection of my own evolution of understanding of these problems and in part it's a reflection of the demography of patients who are coming to see me. I really would not like to answer that question, only because I don't know if the word, "Fifteen," or the word, "Twenty-five," or the word, "Thirty-five," is more accurate --

Q. Understood.

A. -- but I can tell you, I have written letters, especially in the early years, for the things that you're making reference to.

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(Thereupon, Deposition Exhibit 2, 12/21/2020 Zoom Deposition of Stephen B. Levine, M.D., was marked for purposes of identification.)

- - - - -

Q. Okay. For the record, I'm showing

Q. Do you think as a general matter that it's good for patients who come to DELR for services related to gender dysphoria to be able to have insurance coverage of that care?

MR. KNEPPER: Objection, form. Beyond the scope.

A. Well, the people who come to DELR are generally coming for evaluation and psychotherapy services. And I believe it's very important that people have access to mental health care and that mental health care for many of our patients are not wealthy, affluent people. And the fees that even masters prepared people charge can become prohibitive. And so I think it's a very nice idea, the psychiatric services, mental health services evaluation and ongoing treatments, with or without medication, it would be nice to be able to cover those things, yes. I think that's a long answer, yes.

Q. Understood. And thinking about the treatment that you refer patients out for, the endocrine treatments in particular, do you think it is generally good if you provide authorization for that treatment that the

patient be able to afford it?

MR. KNEPPER: Objection, form.

A. May I say, of course?

Q. You may. You may say anything you would like.

A. Of course.

Q. Thank you. Well, anything you would like within reason.

If you make a letter of authorization for a patient for the treatment of gender dysphoria specifically related to a surgical treatment, do you think it is good that they be able to access that treatment that you've authorized?

MR. KNEPPER: Objection, form.

A. Not to be cagey, I want to talk about one word you just used in that sentence. I need you to understand that historically in our clinic for those 47 years, our clinics for 47 years, we are not in the business and we have never been in the business of recommending surgery or recommending hormones. We recommend a continued evaluation so that we -- the person can make up their mind how to proceed.

It is not our knowledge base to know who's going to do better and who's going to do

worse and who is not going to have any difference at all with hormones or with surgery. So what we do is we say, we will write a letter of support for endocrine treatment or for hormones if this is what you want. And we say what our concerns are. We tell the endocrinologist and we tell the surgeon what our concerns are and that we see -- we have reservations about this, and these are our reservations, but the patient has decided this is what he or she wants to do.

And so we write a letter of support, but I don't -- every time you use the word, "Recommendation," there's part of me that wants to say, no, we do not recommend. We have never recommended. We have not had the knowledge base. We have not had the clinical experience and the knowledge base to say, I'm a doctor. I know this field. This is what I recommend to make you better. We do not talk that way. We do not think that way. And so I may want to always put an asterisk to any sentence that you use the word, "Recommend." I need you to understand that that's where I'm coming from.

MR. CHARLES: Thank you,

Dr. Levine.

Excuse me just a moment. Can you read back my question. I don't recall if I used, "Recommend." I thought I used, "Authorization." I just want to make sure.

(Record was read.)

MR. CHARLES: If we could just go off the record for a second.

VIDEOGRAPHER: Off the record 10:52.

(Discussion held off the record.)

VIDEOGRAPHER: On the record 10:53.

BY MR. CHARLES:

Q. Okay. Thank you for that clarification, Dr. Levine. I'll be more careful about using terminology more close to, "Authorization," rather than, "Recommendation," and I understand your distinction in your practice. So do you, though, think it's good, if you are authorizing a treatment, a patient has said, This is the treatment I would like, and you have done an evaluation and determined that you will write, as you said, a letter of support, do you then, as a practitioner, think it's good that they can access it, that they can afford it?

concept of agency and being a doctor, I think is different than the implication of your question.

Q. Is the worrisomeness for a patient's future health, is that a reason to deny all medical care for gender dysphoria?

A. Absolutely not.

Q. Dr. Levine, I'd like to return back to, I believe it's Exhibit 2, the Claire deposition. And please, if you would turn to page 156.

A. I'm sorry. 150 what?

Q. Page 156. And beginning at line 10 on page 156, Dr. Levine, I'll read it, if you'll just follow along, please.

Question: "Are you aware that this case concerns an insurance exclusion that is categorical at preventing" --

Skipping to line 15.

"-- hormones and surgery as a treatment for gender dysphoria?"

Answer: "I am aware that your plaintiffs are suing to get coverage for -- that is not provided by their particular insurance. I am aware of that."

demonstrate their efficacy. This is the problem.

This is the essence of the problem. This is, I think the essence of my testimony with you today. It's not whether I personally as a doctor would like this patient to have insurance to cover their hormones. It's about, is this the right thing to do for this person and can I help the person see clearly what the dangers are and what the benefits are. That's the issue for a doctor, for Stephen Levine as a doctor. I hope that's a cogent answer --

Q. It is --

A. -- to your question.

Q. -- it is cogent. Thank you.

Given all of that, is that -- so you just explained, testified that there are complications, some lack of -- and I'm summarizing here, so I will confirm that this is an accurate summary of what you just shared, but I can't possibly repeat all of that. Given all of those concerns that you have, is that a reason to deny all medical interventions to people with gender dysphoria?

MR. KNEPPER: Objection, form.

A. No, but that's not -- that's a separate question about insurance.

Q. Yes, it is a separate question. So now I'm asking: Are those concerns you raised justifications in your mind for denying medical interventions to all people with gender dysphoria?

MR. KNEPPER: Objection, form.

A. You know, I'm not advocating denying endocrine treatment or surgical treatment. I'm just saying that we as a medical profession need to walk the walk that we talk. We say as a principle of ethics that our interventions should be based upon the best current knowledge, it should be based on science. It should not be based on politics. It should not be based on fashion. It should not be based on civil rights considerations. They should be based on the kinds of studies that I just described to you with predetermined outcome majors that are agreed upon --

Q. Sorry?

A. -- period.

Q. I was --

A. I forgot to put the period.

Q. That's okay. Did you just say, Dr. Levine, you're not an expert in health insurance?

A. I am not an expert in health insurance.

Q. Okay. Or what insurance should or should not cover?

A. Yes.

Q. Do you recall what the insurance billing code typically is for psychotherapy for gender dysphoria? I know it's been a long time since you've accepted commercial insurance, so I'm not sure if the billing codes are the same, but do you recall --

A. The billing code is 90837.

Q. Okay. Is there a code that you're familiar with that is F64.0?

A. That's not a billing -- that's diagnostic code --

Q. Thank you.

A. -- there's a separate code for diagnosis and a separate code for procedure.

Q. I see. So F64.0 is a diagnostic code?

A. Yes.

VIDEOGRAPHER: Off the record 11:26.

(Recess taken.)

VIDEOGRAPHER: On the record 11:31.

BY MR. CHARLES:

Q. Okay. Dr. Levine, in your report, you stated that you had not met with any of the plaintiffs in this case, correct?

A. Yes.

Q. Okay. And you have not interviewed any of the plaintiffs in this case, correct?

A. Correct.

Q. And so you are not offering any opinions about the plaintiffs in this case, correct?

A. Correct.

Q. Okay. And that would include the veracity of their experiences of gender dysphoria, correct?

A. Yes, correct.

Q. And that would not include the accuracy of their gender dysphoria diagnoses, correct?

A. Correct.

Q. Okay. You're not offering any opinions about their mental health histories?

A. Correct.

Q. Nor any of the affects of the gender affirming treatment they may have received?

A. Correct.

Q. Okay. Thank you. Let's return to your report. I don't know if you have that --

A. My report?

Q. Yes. You can put away that document in your hand.

So if you would, please, turn to page 6 of your report.

Okay. So on page 6, paragraph a. at the bottom of the page there, Dr. Levine. The report states that this is one of the opinions you're offering, which is, "Sex as defined by biology and reproductive function cannot be changed. While hormonal and surgical procedures may enable some individuals to 'pass' as the opposite gender during some or all of their lives, such procedures carry with them physical, psychological, and social risks, and no procedures can enable an individual to perform the reproductive role of the opposite sex." Did I read that correctly?

methodology and are capable of critically reviewing the literature. So your statement is true on the most superficial level, but is totally incorrect when it comes to scientific standards of care for issuing guidelines for the medical profession. So I don't know how to answer the question. On the surface, the answer is, yes. And underneath the surface, the answer is, no.

Q. So the International Journal For Transgender Health is still a peer-reviewed source, though, right?

A. It's peer reviewed by people who make their living supporting transgender care.

Q. But it's still peer reviewed, right?

A. It's peer reviewed --

Q. And as for your --

A. -- I think it's peer reviewed.

Q. Okay. Understood. And as for your more conservative approach, can you cite to any studies or research that resulted in better outcomes than people who adhere strictly to the WPATH standards of care version 7?

A. No. This is part of the problem in

evaluation leading to a therapeutic process, it seems prudent, given the fact that we are changing people's bodies, especially teenagers' bodies, and they are not of developmental sophistication yet that court systems or at least one court system thinks they're certainly too young to make these life-altering decisions. So people in SEGM are biased in the direction of being conservative and providing psychotherapeutic evaluations of the child, of the teenager and of their parents, of their family systems to see if we can find a way to help them be informed about what is going -- what they think they want to do in their future.

Q. And so when you provide letters of authorization for hormones or for surgery, do you do so in accordance with the WPATH standards of care?

A. Yes. That is the standard, to provide a letter of recommendation.

Q. Okay. So turning back to your report, Dr. Levine. You can go ahead and put away the trial transcript there.

A. I'm sorry. Did you say, "Turning

Q. Okay. So is a, "Hypothesis," an idea about why something happens, but doesn't provide evidence for why something is happening?

MR. KNEPPER: Objection, form.

A. A, "Hypothesis," generates the pursuit of evidence.

Q. Has social contagion as an explanation for increased cases of gender dysphoria been scientifically proven yet?

A. No. But when you seek -- when you see -- actually see patients and talk to them about their friends and hear about the influence of the Internet and the gurus on the Internet who tell 13 and 12-year-old children who are concerned about menses or concerned about breast development or concerned about their bodies changing and then they're told that they're transsexual by somebody that they've never met that they talked to on the Internet, that would be social contagion or social education.

Or when you hear about a friend who declares themselves trans and then your patient six months later declares themselves trans, you

wonder about the -- the interpersonal, psychological link between best friends in young puberty, young years of puberty and how one can identify with one's friends and that would be a social contagion. Those are 3the kinds of ideas that people like me get when we sit with people week after week talking about their lives. You see, that's not science.

But that is clinician and this is the kind of thing that leads to intuition, clinical intuition and that's the source of the generation of the hypothesis. But we think as clinicians, when we hear -- I mean, I don't think I've ever seen a teenager trans person who hasn't been heavily involved and influenced by the Internet, for example, but I have not done studies to document that in a way that would be scientifically acceptable. There are other people who have.

And I doubt very much if you'll ever find a clinician on any side of this issue, you see, who would say, oh, no most of my patients have never talked to anyone on the Internet about transgender. The Internet is just part of life today and -- but transgender teenagers spend

hours and hours of their time getting counseled or participating with the virtual trans community. That's a hypothesis.

Q. So no scientific citation?

A. When we use the word, "Scientific," in the best sense, yes, the answer to your question is, no scientific.

Q. Okay. No studies of citations you can point to today to support that hypothesis?

A. Oh, I think Lisa Littman's studies are in the literature and/or in press that documents this.

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(Thereupon, Deposition Exhibit 7, "Correction: Parent reports of adolescents and young adults perceived to show signs of a rapid onset of gender dysphoria," Article, was marked for purposes of identification.)

- - - - -

Q. Okay. For the record, please note I'm showing to Dr. Levine what has been marked as Exhibit 7. "Correction: Parent reports of adolescents and young adults perceived to show

signs of a rapid onset of gender dysphoria," by Lisa Littman published March 19, 2019. Have you seen this material before, Dr. Levine?

A. I've seen of it. I don't think I've read it.

Q. Okay. Were you aware that the Lisa Littman article had to be withdrawn, corrected and republished?

A. Yes.

Q. Okay. And were you aware that the initial article was based on a survey of parents --

A. Yes.

Q. -- of purportedly transgender children and the parents were recorded -- I'm sorry. Let me start over. Were you aware that the Littman article was based on a survey of parents who were recruited through some parent groups?

MR. KNEPPER: Objection, form.

A. I knew it was a survey of parents.

Q. Okay. And did you know there were no report-outs from the young adults of those parents in the article?

A. It was a report of parents'

transitioning. However, it is...important to note that there are other survey items where the parent would have direct access to information about their child and that those answers reflect items that can be directly observed." Did I read that correctly?

A. Yes, you did.

Q. All right. Your report also cites as support for the social contagion hypothesis to an article from Medscape.com written by Becky Mccall and Lisa Nainggolan as support for the social contagion theory. Is that correct? I'm sorry. It's not going to be on this article, Doctor.

A. I don't know that article.

Q. Okay.

A. You haven't asked me a question about this. Did I misunderstand something?

Q. No, no. Sorry. We're just --

A. You haven't asked my opinions about that, yeah.

- - - - -

(Thereupon, Deposition Exhibit 8, "Transgender Teens: Is the Tide Starting To Turn?" Article, was

marked for purposes of identification.)

- - - - -

Q. Yeah. So, for the record, I'm showing Dr. Levine what has been marked as Exhibit 8. "Transgender Teens: Is the Tide Starting To Turn?" by Becky McCall and Lisa Nainggolan, April 26, 2021. Dr. Levine, you said you have not reviewed this article before?

A. Which one are you referring to?

Q. I'm sorry. That one to your left.

A. This?

Q. Yes. Take your time.

A. Have I reviewed it, no. You know, I've seen the picture of Keira Bell. I've seen news reports of this in the past, but they were just news reports, yeah.

Q. Do you know if either of the authors of this article is a scientist?

A. I have no idea.

Q. Okay. Or a psychiatrist?

A. (Indicating.)

Q. I'm sorry. Could you make your responses verbal? I'm forgetting.

A. I have no idea.

Q. Okay. Thank you. Have either of them ever treated transgender children or adolescents?

A. I would have no idea.

Q. Okay. To your knowledge, is the information provided on Medscape.CA subject to peer review?

A. I don't know how Medscape works. I've heard there have been retractions, but I don't know how their peer reviewed is made. Perhaps people write in that, This is ridiculous what you've been teaching or what you've been saying, but whether they're peer reviewed or not, I have no idea.

Q. So you probably -- I'm sorry. So do you know if this article has been published in a peer-reviewed journal to your knowledge?

A. "Transgender teens: Is the Tides" -- that article?

Q. Yes.

A. I don't know. I don't know this article. I don't know where it's from.

Q. Okay. So your report includes a quotation from this article. "The vast majority of youth now presenting with gender

multi-continental set of observations from Europe, from Australia, from North America --

Q. Okay.

A. -- it almost doesn't even need citations it's so clinically apparent.

Q. Okay. But there's no citation in your report?

A. In my report, yes.

Q. Okay. So on page 18, going back to your report, at the bottom of page 18, you use a term, "Transgender Treatment Industry." Is this the first time you have used this term?

A. In this report?

Q. No.

A. You mean, did I ever use it in another report?

Q. Yeah, yeah.

A. I'm not sure. If this is -- if it's not the first, it might be the second.

Q. And where did the term originate?

A. I think it -- the term originated from Dwight Eisenhower at the end of his -- when he was leaving the presidency in 1952, he warned the people about the military industrial complex and that there was a very comfortable

the methods we made reference to before, the efficacy of the treatment and the downsides of the treatment. But because WPATH is an advocacy organization and the scientific establishment of the efficacy of their treatments are not important to them, what they are doing is teaching young mental health professionals and medical professionals as a whole what their ideology is. They say it's scientifically established.

I'm here to tell you to the extent that I understand science, it is not scientifically established. In a sense, there is an industry that has different elements that feed each other; that's the transgender treatment industry. I think if we put our heads together, we could find another term.

Q. So did you coin that phrase then?

A. No --

Q. Okay.

A. -- no.

Q. Have you seen it used before in any peer-reviewed articles?

A. Not in a peer-reviewed article. I've seen it used in these kind of expert

opinion -- (Indicating.)

Q. Okay.

A. -- I would -- you know, if I had time and I had a committee of people, I -- I would probably find a different term for it. But I don't mean it in a disparaging way. I mean that this is a group of compassionate people trying to help other people who actually believe that the science has established the best practices when in fact they're not well informed.

Q. Do you need a sip of water after that?

A. No. I'm just a long-winded guy.

I want to add, if I may, that we should make a distinction between education and indoctrination. Education can be based on science. Indoctrination is based on preferred beliefs that, if you allow me to use this term again. The transgender treatment industry is heavy on indoctrination and has declared, if you look at the standards of care, if you don't believe these systems, you're not a competent -- you're not competent to take care of people. That of course is the height of

A. No. Their gender dysphoria may be a product, you see, of these other things. For example, if you have someone who has been sexually abused by her stepfather and becomes a trans person in adolescents, we want to talk about the sexual abuse and the process between that person and what fears for the present and the future that has caused the child. And we're not attacking their trans identity. We're trying to help them understand where they came from and what they're coping with and why they're so fearful or so distressed by their body changing.

Q. And their gender dysphoria could be separate and apart from that traumatic experience?

A. Theoretically it could be, yes.

Q. And if it persisted sufficiently enough, you would consider a letter of authorization for --

A. Yes.

Q. -- hormones?

A. Yes.

MR. KNEPPER: Objection, form.

Q. Okay. If you would, please, turn

A. That is correct. And may I add that it's very, very difficult to understand. The natural question would be, how do you compare the general population with the trans people who did not have surgery with the trans people who did have surgery.

Q. Thank you, Dr. Levine. That's not my question, though. I just wanted to confirm that was not the control group. You mentioned this study later in your report, page 66 beginning at paragraph 74. Do you see that?

A. Um-hum.

Q. Okay. And basically that -- well, here, let me point you exactly. The sentence starts with, "Similarly," about halfway down the page, third sentence of that paragraph.

A. Um-hum.

Q. And, as you mentioned, you cite the Dhejne study and I believe -- or I should ask: Is the Denmark study you're referencing the study directly after it --

A. The Simonsen study.

Q. -- the Simonsen study?

A. Yes.

Q. Okay. So beginning with the Dhejne

study, do you think because that study showed that some people committed suicide after gender affirming surgery that no patient should be able to access gender affirming surgery?

MR. KNEPPER: Objection, form.

A. That would be illogical.

Q. Okay. Dr. Levine, I understand you said that would be illogical, but just to be clear. You're not recommending -- sorry. I'm not using that word. You're not saying that the fact that some people commit suicide following gender affirming surgery means that there should be a ban on access to that surgery. Is that right?

A. Not for that reason, no.

MR. KNEPPER: Objection, form.

Q. Not for that reason. Okay. Are you recommending that there would be bans on gender affirming surgery for any reason?

A. I think there are -- you know, I think most prudent people in this field, just to use the example of what you read out loud about the Finland study, a case-by-case basis. That's how doctor need to decide things, but there are many, many reasons to be cautious

fashion and to be very hesitant about going forward.

Q. But you're not recommending total bans on gender affirming surgery?

A. I'm not recommending total bans. I'm aware of the individual circumstances of individual people's lives and their commitment to transgender living. And I don't want to be draconian about this. I want to be compassionate about this.

Q. I understand. I appreciate that. I just want to make sure I'm understanding you correctly.

- - - - -

(Thereupon, Deposition Exhibit 12, "Long-Term Follow-Up of Transsexual Persons Undergoing Sex Reassignment Surgery: Cohort Study in Sweden," Article, was marked for purposes of identification.)

- - - - -

Q. So for the record, I'm presenting to Dr. Levine what has been marked as Exhibit 12. "Long-Term Follow-Up of Transsexual Persons Undergoing Sex Reassignment

For the 22nd time today, did I read that correctly?

A. It's the 23rd time.

Q. Oh, okay.

A. Yes.

Q. I was hoping you weren't counting, but, okay. Did you testify earlier today that the limitation of the Dhejne study is that the controls were not transgender persons who had not undergone gender affirming surgery?

A. Yes.

MR. KNEPPER: Objection, form.

Q. Okay. You can set that aside, Dr. Levine.

- - - - -

(Thereupon, Deposition Exhibit 13, 2017 "On Gender Dysphoria," Booklet From Department of Clinical Neuroscience, Karolinska Institutet, Stockholm, Sweden, was marked for purposes of identification.)

- - - - -

Q. For the record, Dr. Levine has an exhibit that has been marked as Exhibit 13. "On Gender Dysphoria," by Cecilia Dhejne from

ideation in transgender people.

A. Well, you know about the Branstrom-Pachankis study and the criticism of the study --

Q. But I'm not talking about the study.

A. -- and part of the study demonstrated that it increased suicidal ideation and attempts in the first two and a half years after surgery, especially in the first year --

Q. Right. Is your testimony --

A. -- so I'm not testifying that. I thought you were asking me about this, which I need to comment on, because this is not an accurate depiction of my statement in the reference. (Indicating.)

Q. Well, that's not what I'm asking about, Dr. Levine.

A. Well, you're reading this and I'm misquoted here. So I don't want you to imply that she is accurately representing my views, because I did not say that gender affirming treatment in general should be stopped. I've never said that. This is an article about

at different times have reported that in the large majority of patients, absent a substantial intervention such as social transition and/or hormone therapy, gender dysphoria does not," continue, "through puberty."

So there are some children who persist in their asserted gender identity through puberty, correct?

MR. KNEPPER: Objection, form.

A. Correct.

Q. And some who persist in wanting to transition via medical treatments?

MR. KNEPPER: Objection, form.

A. Yes. Some of the children have learned about medical treatments somewhere along the line and they feel instantly that this is for them.

Q. And then looking at paragraph 56, which is on page 41, so just the very next page on the bottom, the second sentence in that paragraph. "I observe an increasingly vocal online community of young women who have reclaimed a female identity after claiming a male...identity at some point during their teen

transgender people is individual based, right?

A. Well, it's both --

MR. KNEPPER: Objection, form.

A. -- yes, that's partially true. And ideally that's true, but it's obviously not entirely true. It's why we're here, is it's categorically based.

Q. Let me rephrase that. You design treatment for your patients based on what that patient in front of you, what they need, what they want, what you determine -- sorry. Not what you determine, but what you might authorize?

MR. KNEPPER: Objection, form.

A. What the patient and I discern together.

Q. Thank you. Okay. Let's jump to, again, still in your report, page 68.

A. We've left 40 and 41? 68.

Q. Okay. Looking at the bottom of page 68, Dr. Levine, paragraph 78. It states, "Similarly, the American Psychological Association has stated because approach" --

A. Sorry.

Q. I apologize.

Gender Nonconforming People (2015)."

So is that lack of consensus that you discuss a justification to categorically ban social transition for children as a treatment for gender dysphoria?

MR. KNEPPER: Objection, form.

A. By, "Children," you mean 6 and 7 year olds?

Q. Those for whom medical intervention is not indicated.

A. Is that a reason to ban it?

Q. Correct, social transition.

MR. KNEPPER: Objection, form.

A. The reason to -- so let me qualify that. There's a, yes, answer, there's a reason to ban it. And the reason to ban it is both a developmental and an ethical reason. There have been eleven studies of these cross-gender identity children who are not socially transitioned and the vast majority of them de-transition by the time they're mid adolescents or older adolescents. They become homosexual individuals usually or bisexual individuals, but they are cis gender.

So if we take a 6-year-old child and

A. -- nor you didn't ask me to comment on that.

Q. It was related to what you had said before. So this is related but not related to what we just read. So you can put that aside.

A. Okay. But your next question was about puberty blocking hormones, which are not being used for 6-year-old's and 7-year-old's --

Q. Correct, yes, a separate group of people.

A. -- so we're on a different category.

Q. Yes.

A. Okay. So you asked me if I think puberty blocking hormones should be used on a case-by-case basis?

Q. Correct, yes.

A. I don't think so.

Q. So that is to say, there are no circumstances you would advocate for a total ban on that intervention?

MR. KNEPPER: Objection, form.

A. Number one, I've never seen a child where that has come up where I thought it was a good idea. In the cases I've seen, it was like

a treatment for the mother's pathology, not for the child. And it's like a warning sign, boy, be careful. You see, if you see one case like that, you wonder -- and it's so conspicuous, you wonder in the next case, if the same thing is going on in a more subtle way.

Is the child acting out the ambitions of the mother or the father? I just think prudence -- I think considering the child has not gone through puberty or has not gone far into puberty and puberty brings all kind of psychological, physical and social changes to a child and those changes lead to desistance in many, many children, to put them into a state where all their peers are developing physically and they're going to be poirot (phonetic).

And then most of those children have social anxiety problems and they avoid -- they don't have friends, right. And this is going to make them even more different than their peers and it's gone to deprive them of the sexualization of their mind and the discovery of masturbation and the discovery of sexual desire for partners, you see. This is only going to increase the child's difference from

her peers or his peers and I don't think this is a prudent idea.

And if you wanted me to suggest a ban on anything, it would be a ban on using puberty blocking hormones, especially when the evaluation of those children are focused on the gender dysphoria of the child and not on the background of the child and not on what's going on. So I think that's an answer to your question.

If we're going to use these drugs, if we're going to use social transformation of children, if we're going to use puberty blocking hormones, it should only be used in a carefully designed protocol. And follow up has to be guaranteed so in one year and in two years and in three years and before we start giving cross-gender hormones we have data --

Q. Sorry.

A. -- so the answer to your question is, I would consider banning puberty blocking hormones even for children who have been cross-gender identified for four years to give them a chance to desist, which is exactly what the Dutch protocol did, by the way.

Q. Sorry. So you just said you would ban -- you would recommend a ban on --

A. If --

MR. KNEPPER: Objection, form.

A. -- look, I'm a doctor. I'm not a policy maker --

Q. I understand, yes.

A. -- if you ask me my political opinion about, should we ban this, is that a reasonable thing, I think there's a very strong argument for banning puberty blocking hormones.

Q. Okay. And, right. So you're here as an expert offering an expert opinion. So are you separating that from -- like are you saying your political views that you would advocate for bans or are you saying your expert opinion you're offering in this case is you would recommend ban?

MR. KNEPPER: Objection, form.

A. I would recommend ban. To what extent it's from my politics or from my being a parent or from my being a doctor, I don't know. I would recommend we not use puberty blocking hormones.

Q. In Claire, in this case that we

Answer: "Where we had a healthy mother and father, an intact family who was psychologically informed and who has -- where a child has come out of toddlerhood acting consistently in a gender atypical fashion, and where the parents are not homophobic..."

Question: "The parents are not what kind of people?"

Answer: "Homophobic."

For the 27th time, did I read that correctly? Did I read that correctly?

A. Yes.

MR. CHARLES: Okay. All right. Let's go ahead and take a break for a few minutes.

VIDEOGRAPHER: Off the record 3:20.

(Recess taken.)

VIDEOGRAPHER: On the record 3:38.

BY MR. CHARLES:

Q. So, Dr. Levine, before the break, you were talking about 6 and 7 year olds and you mentioned there were eleven studies. Can you identify which eleven studies from your report you're referring to?

A. Cantor, the reference Cantor lists

the eleven studies and these eleven studies have been done over probably thirty years.

Q. Okay. So Cantor was one review of eleven studies?

A. Cantor was a review of the eleven studies. I can't list to you the eleven individual studies. The latest one is written by Singh, S-i-n-g-h. It was published in April of 2021, in the Frontiers of Psychiatry. And that perhaps is the most comprehensive of them. And that's the one that confirms -- that's a study of boys and it confirmed that 12.2, I think percentage of them persisted over a thirteen-year period.

Q. So that was one -- that was the Singh study that came out. Is that same study mentioned in the Cantor review?

A. (Nodding.)

Q. Okay. And you said that established that 12.2 percent of prepubertal boys persisted into adolescents? Okay.

A. Yes. This harkens back to the ethical issue that I talked about before. You know, if you know that 88 percent of them are going to persist -- desist, why in the world

identified 60,000 case reports world wide on the Internet. See Exposito-Campos..." --

A. That is an error, by the way.

Q. Sorry. Which part of that is an error?

A. That, "60,000," is my error. It should say, "16,000."

- - - - -

(Thereupon, Deposition Exhibit 17, "A Typology of Gender Detransition and Its Implications for Healthcare Providers," Article, was marked for purposes of identification.)

- - - - -

Q. Okay. So for the record, I'm showing Dr. Levine what has been marked as Exhibit 17. "A Typology of Gender Detransition and Its Implications for Healthcare Providers," Pablo Exposito-Campos, 2021. Okay. Have you seen this study before, Dr. Levine?

A. Yes.

Q. Okay. So on page 1 of this report, about halfway through the very first paragraph in the introduction beginning with, "As a consequence." Do you see that there?

important to note that this typology does not suggest two clear-cut categories, for a secondary detransition can lead to a primary detransition" -- oh, sorry. Let me start over. Sorry.

Okay. Let me start from a different place, Dr. Levine. The second sentence. "In r/detrans" --

And there's an HTTP address --

A. Okay.

Q. Okay. You see that.

-- "a subreddit for detransitioners to share their experiences with more than 16,000 members, one can find several stories of people who call their transgender status into question after stopping transitioning due to medical complications or feeling dissatisfied with their treatment results"?

Do you know what a, "Subreddit," is, Dr. Levine?

A. I believe it's just a division of a larger website where people, you know, with similar interests.

Q. Okay. Do you understand this sentence to be suggesting that all 16,000 of

those members have offered a story of detransition?

MR. KNEPPER: Objection, form.

A. I think -- I think it may be true that either they have offered a personal story or they're fascinated because of their own considerations of that story. They're thinking about it themselves, which would be in keeping with the idea that even people who have transitioned begin to doubt whether they made a wise decision and they're considering detransition. I'm not so sure it means that all 16,000. I would have no way of ascertaining that. You know, in my worry, I would lean towards most of them are seriously considering or have detransitioned. And in my skepticism, I would say I'm not sure whether it's 15,000 or 12,000 or 8,000.

Q. But you have no way to confirm that --

A. I have no way.

Q. -- if it's all of them or a few of them or three of them?

A. You're absolutely right. I have no way of confirming that.

where hormones are safe and surgery is a good thing to do. If a person said that, you know, skeptically, I think that would disappoint certain patients, but how it was said and when it was said in response to what would either determine whether the person is engaged with the mental health professional or leaves the mental health professional. You know, all mental health professionals are not created equal.

Q. So it sounds like you're saying it could do harm to that patient?

MR. KNEPPER: Objection, form.

A. No, I'm not saying that. I'm saying it could be disappointing to that person. What that person did with the disappointment may prove harmful just because of that person or it may prove in fact beneficial.

Q. Are you satisfied -- let's orient this question around the patients you've seen in the last 12 months. Are you satisfied that those patients -- actually, sorry. Let me start over. Are you satisfied that the patients you have seen historically for whom

you provide letters of authorization for hormones give sufficiently informed consent?

MR. KNEPPER: Objection, form.

A. From my point of view, I did what I could to reach the standard of having the person internalize and think about, digest, dream about and come back and talk to me about it. That's all I can do. I can't guarantee that if I do what I do that it's going to change your mind or help you steer your ship in a slightly different angle --

Q. So --

A. -- so I would not write a letter of recommendation if I didn't feel like I did my part. And if the person indicated that they couldn't pay attention to me, I wouldn't write the letter.

MR. CHARLES: Understood.

Okay. John, finished.

MR. KNEPPER: You're finished?

MR. CHARLES: I mean, barring --

MR. KNEPPER: Barring --

MR. CHARLES: We can't tell the future.

MR. KNEPPER: I wasn't ready for

history and current psychiatric diagnosis, it's more complicated than just the internet.

But we need to understand who these children are and how they're different from their peers and what we could possibly do to help them to have a better life. I know some of the conversation today was, we'll help them have a better life by giving them puberty blocking hormones, but that doesn't address -- I think it has a risk of harming them further. And it doesn't address the comorbid developmental challenges that these children face.

And I'm afraid -- and it's controversial, because I don't have the answer. I'm afraid there's a possibility we're making these children have a worse outcome. And until you can demonstrate to me in a very careful controlled study that separates the autistic from the non-autistic, you see? That separates the kids who come from a family that's intact from a family where there's a single parent. Where you can separate the kids who were sexually abused from the kids who were not sexually abused. I'm not sure puberty blocking

Exhibit C

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

_____

KATHEENA SONEEYA,

Plaintiff,

V.

THOMAS A. TURCO III, in his official capacity as Commissioner of the Massachusetts Department of Correction,

Defendant.

_____

Civil Action
No. 07-12325-DPW

April 8, 2019

10:23 a.m.

TRANSCRIPT OF BENCH TRIAL DAY 1

BEFORE THE HONORABLE DOUGLAS P. WOODLOCK

UNITED STATES DISTRICT COURT

JOHN J. MOAKLEY U.S. COURTHOUSE

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BOSTON, MA 02210

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witness, ask me.

MS. HANCOCK: Okay. Apologies, your Honor.

BY MS. HANCOCK:

Q. So two versions were released since 1999, correct?

A. Correct.

Q. And one in 2001, as you just testified, right?

A. Right.

Q. And another one in 2011; is that right?

A. Yes.

Q. And as you understand it, there's going to be an eighth version coming out soon, correct?

A. Yes.

Q. And you're not involved in drafting that version, correct?

A. I am not.

Q. And you requested to participate in drafting that version, correct?

A. I'm not sure that's correct.

Q. You did not ask to be involved in drafting that version?

A. I think -- I think I actually might have, now that you bring it up, but I was told I had to be a member of WPATH.

Q. Now, you've worked as a consultant for the DOC since around 2007 or 2008. Does that sound right?

A. That sounds right.

Q. And you're not technically engaged by the DOC, though, right?

Exhibit D

STEPHEN B. LEVINE, M.D.

IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF MASSACHUSETTS

Civil Action No. 07-12325-DPW

----------x

KATHEENA NEVIA SONEEYA,
f/k/a Kenneth Hunt,
Plaintiff,

V.

THOMAS A. TURCO III,
in his official capacity as
Commissioner of the Massachusetts
Department of Corrections,
Defendant.

----------x

DEPOSITION OF STEPHEN B. LEVINE, M.D.

Thursday, August 30th, 2018, 9:42 a.m.

Regus

2000 Auburn Drive, Beachwood, OH 44122

Reported by:
Jill A. Kulewsky, RPR
JOB NO. 146861

answer to it. I think the verbiage of the criteria may have changed in very subtle ways, but practically speaking, it did not.

The name change came about, in part, because one can be gender dysphoric without having a disorder. So there are many people who objected to the D in GID. The assumption that this variation in identity was a disorder was politically objectionable to many people in the trans community and those people who advocate for those -- for those what used to be patients.

So this is probably going to change again, and if we had this deposition in two years, we would probably call this not gender dysphoria but gender incongruence.

Q. Could you tell me a little bit more about that, why you think it's changing, what's changing about it?

A. This is fraught -- this is a political subject. The psychiatric

conditions, what constitutes a disorder changes with the time, and afterall, the DSM changes every 10, 12 years.

We in psychiatry and mental health, we reconfigure our concepts about every decade about what is a disorder and how to name them, and both scientific data, clinical experience and politics all influence the DSM.

And the DSM is in controversy with the World Health Organization that produces the ICD, the International Classification of Diseases. So the proposed ICD-11 is to stop calling this a disorder, stop implying by nosology that there is anything wrong with these people, and that this is just going to be considered a phenomenon that affects one's mental health.

So that's why there are people who are advocating to get rid of gender dysphoria and just call it gender incongruence because some people have gender incongruence who are not

dysphoric, they just accept the fact that they have the body of one -- an anatomic body and mental identity that is somewhat different from their body, and at various times in their life they struggle with that incongruence, but they're not mentally distressed, and therefore, they don't have a disorder or they're not dysphoric.

So when you see in the development of one's gender sense, for in the population there are enormous variations in the degree to which one is consonant or happy with or feels masculine in a male body, where to draw a line between disorder, disease, mental condition, emotional distress and just ordinary human diversity is unclear.

And the changes in nosology are reflecting the increased awareness over time, both within the trans community and the mental health community, of great diversity and the lack of invariability of distress over

STEPHEN B. LEVINE, M.D.

the diversity or over the incongruence. So you and I are caught up at a certain point in time where our concepts are rapidly changing, and none of us are very sure what's going on.

It's not like schizophrenia. It's not like somebody who's tried to jump off a bridge six times in his or her life.

Q. So would you --

A. Okay.

Q. Is GD a medical or psychiatric condition, in your opinion?

A. In my opinion, it is definitely a psychiatric condition.

Q. Are you familiar with WPATH?

A. Oh, yes.

Q. What is it?

A. Well, it used to be the Harry Benjamin International Gender Dysphoria Association. I, in fact, was the chairman in writing the standards of care for the 19 -- the 5th version. It was published in 1999. Most of the

STEPHEN B. LEVINE, M.D.

language -- as I read the seventh version, much of the language I actually wrote.

And the seventh version is just lifted from the fifth version, so I'm sort of familiar with it.

Q. We'll get to the standards in just a second. What's your understanding of what that organization does?

A. That organization initially arose to study the phenomenon of men who wanted to live as women and women who wanted to live as men. It was -- it began in the '70s -- in the '60s, actually, late '60s, I think, and it was funded by somebody who himself was a transgendered person, and we began developing -- I joined it in the '70s, and we began to articulate the standards of care for how these people ought to be handled by psychiatry, by endocrinology and by surgery.

So it began as a bunch of academics interested in this subject, and

STEPHEN B. LEVINE, M.D.

it became over the years not just an academic institution, but it became -- well, an organization that invited the trans people themselves to be part of it.

By doing that, the organization became an advocate of trans people, and it always claims to be a scientific organization, but in fact, there is a great distinction between science and behavior that science dictates for professionals and advocacy, which leads to entirely different things far beyond science.

So what kind of organization is this today, I think you're asking me? Well, it's a mixture -- it's a minority rights organization that feels very strongly that there's nothing inherently wrong with anybody who has an incongruence in their gender identity, and it's not a symptom of anything, it's just the way people are, and that these people are marginalized and discriminated against just like homosexual people used

to be by psychiatry in the mid '70s, and that anyone who is interested in trans people needed to be their strong advocate at all times.

So that became a standard of -- I would say if you're a credentialed person, if you know about this, you must be an advocate. If you're a cynic, if you're a scientific, if you have skepticism, well, you may be the enemy.

So what has happened is that over the years, WPATH has become an advocacy organization that lawyers or the legal profession, in trying to understand how medicine operates, relies very heavily on the collective wisdom of organizations.

So WPATH has great respect in the courtroom and great respect as the international standard for how people ought to be treated, even though there are parts of WPATH that say these are case-by-case decisions, and that patients

elect surgeries, doctors don't recommend surgeries.

It seems that the WPATH standards have stimulated a social phenomenon in this society, and not just in America but elsewhere, where if a person wants something, the doctors should be providing them. If a doctor is skeptical about providing what this teenager or 70-year-old person wants, then the doctor is obviously not competent.

As a result of that, there are many people who just abandon interest in these patients because they just feel like WPATH is much more political than it is scientific, and the doctors need to be skeptical and need to be humble, and there's too much certainty embodied in the behavior that, I would say, rests upon the standards of care.

The standards of care are actually more conservative sounding than the people who quote them are, and so

Exhibit E

Deposition of:

Dee Jones

August 3, 2021

In the Matter of:

Kadel, et al vs. Folwell

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IN THE UNITED STATES DISTRICT COURT FOR
THE MIDDLE DISTRICT OF NORTH CAROLINA

MAXWELL KADEL, et al.,
Plaintiffs,
V.
DALE FOLWELL, et al.,
Defendants.

No. 1:19-cv-272-LCB-LPA

DEPOSITION
OF
DEE JONES

IN HER INDIVIDUAL CAPACITY
and
30(b)(6) DESIGNEE FOR NC STATE HEALTH PLAN

AUGUST 3, 2021

THIS TRANSCRIPT IS NOT COMPLETE
PORTIONS OF THIS TRANSCRIPT AND/OR EXHIBITS
MAY BE DESIGNATED CONFIDENTIAL/ATTORNEYS EYES ONLY
AFTER REVIEW OF TRANSCRIPT BY ATTORNEYS WITHIN 30
DAYS OF DATE OF DEPOSITION PER PROTECTIVE ORDER

PNC PLAZA DOWNTOWN
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Raleigh, North Carolina

Reported by: Michelle Maar, RDR, RMR, FCRR

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Zpadget@ncdoj.gov

A. Yes.

Q. So looking at all enrollees in the Plan, 15 percent of those enrollees account for 85 percent of the cost of treatment?

A. Correct.

Q. Can an individual enrolled in the State Health Plan request that the State Health Plan change the pronoun associated with that enrollee?

A. Please rephrase.

Q. Can an individual that's enrolled in the State Health Plan request that the Plan change in its records the pronoun that's associated with that individual?

A. The member can change his or her own pronoun.

Q. How does that process occur?

A. The member logs in to eBenefits or calls into the call center, benefit-focused call center, and either changes it him or herself, or requests that it be changed.

Q. Okay.

A. It's not validated.

Q. What does that mean for it not to be validated?

A. You could put in whatever you want. There's two options, male or female.

And if I were female and put in female, I could do that. Or if I wanted to put in male, I can do that. If I make an error, I can do that too.

Q. And you said an individual can either log in and change that themselves or they can make a request that the Plan make that change?

A. No. They call into the call center, talk to a call center rep who will record the call. And then they can be requested to make that change.

Q. To whom is that request made?

A. The call center rep.

Q. If a call center rep gets that kind of request, what happens next?

A. They comply with the request.

Q. And how does that process occur?

A. They go into the system and check yes or no or male or female or exactly -- I guess it's male or female.

Q. And prior to going into the system, is any validation requested?

A. Absolutely. Whatever -- like the member would call in, and there would be validation questions from the call center rep back to the member to confirm any number of demographic statistics.

Q. What are those validation questions?

A. I don't know them specifically. But it's something that would be similar to what we all do, which is your address, your full name, possibly your Social Security number, you know, phone numbers, whatever, to try to --

they're a vendor. I don't tell them how to do their job. I just tell them they have to validate it. It's not my obligation how to exactly do it.

Q. So is it fair to say that validation is with respect to making sure that the person calling in and making this request is who they say they are?

A. Yes.

Q. Does the Plan require proof of any enrollee's chromosomes before it goes into the system and complies with that question?

A. No.

Q. Does it require proof of an enrollee's anatomy?

A. No.

Q. And does it require proof of an enrollee's DNA?

A. No.

Q. Everything we just talked about with regard to changing the pronoun in the system, does that also apply to a request to change an individual enrollee's gender marker in the system?

A. We don't track gender markers in the system other than male or female. We only have but two options right now.

Q. Is participation in the Plan required for state agency employees?

A. No. They have a choice. I mean the benefit

Exhibit F

IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF NORTH CAROLINA

MAXWELL KADEL, *et al.*, *Plaintiffs*, v. DALE FOLWELL, *et al.*, *Defendants*.	No. 1:19-cv-00272-LCB-LPA

EXPERT REBUTTAL DISCLOSURE REPORT OF
GEORGE RICHARD BROWN, M.D., DFAPA

I, George R. Brown, declare as follows:

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

2. I have actual knowledge of the matters stated and would so testify if called as a witness. I reserve the right to supplement or amend this report based on any future information that is provided to me, including but not limited to information produced by Defendants in discovery or in response to Defendants' expert disclosures.

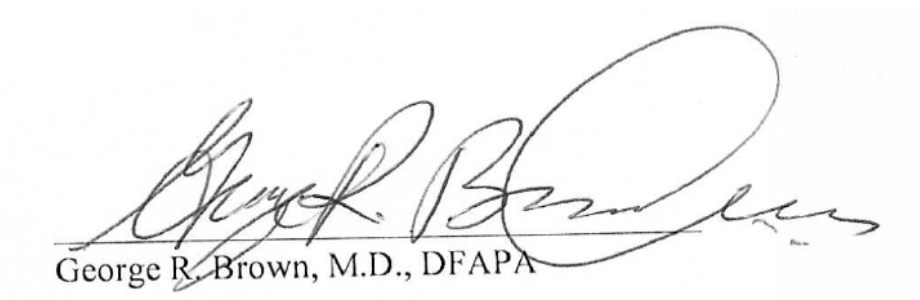
3. I previously submitted an expert report that was served on March 1, 2021 setting forth my opinions on: (1) the medical condition known as Gender Dysphoria; (2) the prevailing treatment protocols for a diagnosis of Gender Dysphoria, their efficacy, and the cost-effectiveness of this care; (3) whether there is a legitimate medical basis for the exclusions in the health plans offered by the North Carolina State Health Plan for Teachers

following the WPATH Standards of Care (SOC). This is likely because, in my understanding and experience, no such scientifically-reliable literature has been published in at least the last 15 years.

27. Defendants' experts also erroneously generalize about the appropriate course of treatment for Gender Dysphoria in adults or adolescents based on data about pre-pubertal children. This is inappropriate. The Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition ("DSM-5") recognizes separate criteria for diagnosing Gender Dysphoria in children, on the one hand, and adults and adolescents on the other. The WPATH Standards of Care (SOC) have distinct standards of care for pre-pubertal children, adolescents and adults. As noted in my original report, the WPATH SOC, version 7 (Coleman, et al, 2011), are the nationally and internationally accepted standards of care for the evaluation and treatment of a diagnosis of Gender Dysphoria in adolescents and adults. These standards of care are also specifically followed by the largest healthcare systems in the United States (Department of Veterans Affairs, Kaiser-Permanente) as well as most major insurers of healthcare in the United States, including the corporate policy for Blue Cross and Blue Shield which specifically references these WPATH standards. *See* Blue Cross Blue Shield of North Carolina, Corporate Medical Policy, *Gender Affirmation Surgery and Hormone Therapy* (2021). They are also utilized as standards of care by many Departments of Corrections, the Federal Bureau of Prisons, the National Health Service of the UK, and many other countries as well. Coverage for transgender health care has been considered medically necessary for appropriately diagnosed individuals suffering from

to transition to the male gender role. This is a misinterpretation of that statement, and is an example of Dr. Lappert engaging in the "confirmation bias" that he claims to be present in all of the clinicians' records and in my evaluations of the Plaintiffs. Had Dr. Lappert interviewed C.B., as I did, he would have learned that that comment meant that C.B. was tired of the lengthy process of "being trans" and wanted to get to the point where "trans" no longer identified him and he could just be identified as a "man" and not as a "transgender man." It should also be noted that no fewer than seven clinicians have diagnosed C.B. as having the diagnosis of Gender Dysphoria.

I declare under penalty of perjury that the foregoing is true and correct. Executed this 10th day of June, 2021.



George R. Brown, M.D., DFAPA

CERTIFICATE OF SERVICE

I hereby certify that on June 11, 2021, I caused a copy of the foregoing document and all attachments to be served upon the following parties via email:

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Dated: June 11, 2021

/s/ Amy E. Richardson

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Exhibit G

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

CASE NO. 4:20-cv-00020-MW/MAF

JAMI CLAIRE, KATHRYN LANE and AHMIR MURPHY,

Plaintiffs,

vs.

FLORIDA DEPARTMENT OF MANAGEMENT SERVICES, et al,

Defendants.

ZOOMED DEPOSITION OF STEPHEN B. LEVINE, M.D.

Monday, December 21, 2020

9:30 a.m. - 2:51 p.m.

Via Zoom

Tallahassee, Florida 32308

STENOGRAPHICALLY REPORTED BY:

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I N D E X

(STENOGRAPHER'S NOTE: Exhibits were received premarked electronically; only Exhibits 1, 2, 3, 7, 10, 11 and 13 were referred to in deposition.)

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right?

A No, that is. I think -- we'll quibble over the word only. If you use the word predominantly, I would say they are predominantly taking care of. They are a specialty clinic for the transgender.

Q So predominantly treating transgender people, but not 100 percent?

A That's my guess.

Q Okay. What sorts of treatments do you provide for your patients with gender dysphoria?

A Psychiatric evaluation of the patient and the family, the parents and the other siblings; psychotherapy to further the process of understanding this whole phenomenon; recommendations for hormones and occasionally recommendations for -- depending on the biologic sex of the patient, for genital or breast surgery.

Q How many patients have you recommended hormone therapy for?

A You mean over 47 years?

Q Let's start with the 47 years, yeah.

A I don't know. Can I give you a gross estimate?

Q Sure.

to be directed to the surgeon.

Q Okay. If a surgeon told you I require a letter for this facial feminization surgery, are there circumstances under which you could see yourself providing a letter, not of recommendation but of authorization, for a person to receive this surgery from the surgeon?

A I could see myself under certain circumstances, if I understood the patient's motives and had a lot of time to discover and discuss this, the history and alternative approaches and wondering about the psychology of wanting this, I could see theoretically.

That's what I do, you know, as a psychiatrist; I am trying to investigate the meaning of the wish and the solution that the patient is hoping for, the problem the patient is hoping this would be a solution for.

And so I want to be able to consider this and have a respectful, mutual, slow dialogue that is slow, meaning multiple sessions, to consider the nuances of this because, you know, all of us have a self-concept of how handsome we are or pretty we are, and most everyone wants to get a little more handsome and a little more pretty and we are -- we

Q Okay.

A I believe that if a surgeon is going to do this, he ought to know what I think -- what I know about the person's history and the person's intellectual capacities and the prices they paid for their gender dysphoria already.

For example, the loss of a family and no relations to children, or the inability to have a relationship, an intimate relationship with other people. I believe the surgeon needs to have an understanding of the person.

I don't have an understanding whatsoever of the techniques of surgery. You see? I am just a psychiatrist. And the psychiatrist -- and the surgeon has very little understanding of how a person got to be in his office. And I believe that the letters of recommendation should capture the humanness of this person and the desperation of this person and the justification that the person uses and the hopes they have for this surgery. But that's Levine, you know.

Q I want to show you the WPATH Centers of Care section that discusses letters. This is Exhibit 7 which we are going to put on the screen.

(Exhibit 7 was marked for identification.)

BY MR. TILLEY:

Q Let's go to page 27. It looks like the document page 27, it's .pdf page 33, Bates stamp PL 0450524.

You see, Dr. Levine --

MS. COLES: Can you read that, Dr. Levine? It looks a little small on my computer.

THE WITNESS: I can read it. It says referral for surgery.

MS. COLES: Okay. Just making sure.

BY MR. TILLEY:

Q At the bottom, I am going to start there and then we'll go on to the following page. At the bottom it says, The recommended content of the referral letters for surgery is as follows: 1, the client's general identifying characteristics -- now we are continuing on to the next page -- number 2, results of the client's psychosocial assessment, including any diagnoses.

And then it goes on to 3, 4, 5, and 6.

Dr. Levine, can you just review those if you can read it and then let me know if you agree with those statements.

(Short pause.)

A I don't disagree with the statements, but each of those statements, of course, need to be operationalized by the letter writer. For example, the first one, identifying characteristics, oftentimes identifying characteristics would be like this is a 63-year-old Caucasian veterinarian. But there are many other identifying characteristics that might be included.

So you can interpret these things with terse statements or elaborate statements. I favor elaborate statements. For example, I would like to say a divorced father of four, or a roller derby official. I would like to identify him as much as a person as possible. But in the history of medicine, race, age, and nourishment passes for identifying information.

So the results of the psychosocial assessment, including any diagnosis. Psychosocial assessment would be the processes in his life history, including any current or past diagnoses, you see. So substance abuse might be a very important part of number 2.; and the duration. So if I am writing a letter, if I am one of two people who have been hired to write a letter for genital surgery, and I might have had three visits with the

not inquiring about your medical history and your psychiatric history. But it may be psychologically beneficial to you and an M.D. may recommend that you do that. And that recommendation would be based on his or her knowledge that you are likely to suffer from seasonal affective disorder, and the treatment is bright lights and sunshine. And sunshine would be far superior because of its luminescence, the number of lumens exposed, than bright lights.

BY MR. TILLEY:

Q Let's go back just briefly to WPATH. And I know you mentioned you have a more conservative approach. So let me ask you this.

Is it fair to say that if you personally believed that you would authorize hormones or surgery for someone with gender dysphoria, someone following the WPATH Standards of Care would also believe that?

A Yes.

Q Okay. Let's talk about insurance for a little bit. If you recommended that -- if you authorized some form of treatment for gender dysphoria, whether it be hormones or some form of surgery, would you expect that that treatment would be covered by your patient's insurance?

offering an opinion on transgender people accessing sex-specific public places; is that right?

A No.

Q It's correct that that's not right?

A You mean like bathrooms, and so forth?

Q Right. You are not making an expert opinion in this case concerning sex-specific spaces; is that correct?

A That's right.

Q Okay. Let's go to page 13. You say that plaintiffs assert that the WPATH Standards of Care are widely accepted. Do you see that statement?

A Please tell me what paragraph it's in.

Q Under heading number 4.

A Yes. Okay.

Q Do you disagree that the WPATH Standards of Care are widely accepted by the major medical and mental health associations?

A No.

Q Okay. You just think that they are wrong; is that correct?

A Yes, and widely accepted doesn't tell you 60 percent or 40 percent. It just says widely accepted.

Q Okay. Is it -- how would -- how would you

You see?

So I am saying, please, let me talk to you about human beings here and how important having ongoing lifelong relations with one's children are and being a grandfather or grandmother, and being connected to a family of origin. I am not talking about categorical bans. I am talking about being smart.

BY MR. TILLEY:

Q Are you aware that this case concerns an insurance exclusion that is categorical at preventing --

MS. COLES: Form.

BY MR. TILLEY:

Q -- hormones and surgery as a treatment for gender dysphoria?

MS. COLES: Form.

A I am aware that your plaintiffs are suing to get coverage for -- that is not provided by their particular insurance. I am aware of that.

BY MR. TILLEY:

Q Do you think that exclusion is appropriate?

MS. COLES: Form.

A I've already answered that question, I

believe.
BY MR. TILLEY:
Q What is the answer?
A That it's a political decision that varies from state to state, and it belongs to the process of political science and the courts and not doctors.
Q And if you yourself were treating them and determined that they understood the risks and you thought the treatment would be psychologically beneficial and provided letters of authorization to them, you would want that treatment to be covered by insurance; is that correct?
MS. COLES: Form.
A I am an agent of the patient, I want what's best for the patient, and especially if the patient couldn't otherwise afford it, I would wish for my patient to have it, yes.
BY MR. TILLEY:
Q I know you said you are not about categorical bans, but let me ask you about minors again.
Would you support a categorical ban on access to puberty blockers to treat gender dysphoria?
MS. COLES: Form.

Exhibit H

From DEPARTMENT OF CLINICAL NEUROSCIENCE
Karolinska Institutet, Stockholm, Sweden

ON GENDER DYSPHORIA

Cecilia Dhejne

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On Gender Dysphoria

THESIS FOR DOCTORAL DEGREE (Ph.D.)

at Karolinska Institutet, to be publicly defended in lecture hall Nanna Svartz, Karolinska University Hospital Solna.

Friday, March 31, 2017 at 9:00 a.m.

By

Cecilia Dhejne

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6 ON THE IMPACT OF RESEARCH FINDINGS

Researchers are happy if their findings are recognized and have an impact. However, once published, the researcher loses control of how results are used. Study III is the first long-term cohort study of mortality and psychiatric inpatient care following gender transition (Dhejne et al., 2011). This paper has also had an impact outside the scientific world. Our findings have been used to argue that gender-affirming treatment should be stopped since it could be dangerous (Levine, 2016). But the results have also been used to show the vulnerability of the group and that better transgender health care is needed (Arcelus & Bouman, 2015; Zeluf et al., 2016). Despite the paper clearly stating that the study is not designed to evaluate whether or not gender-affirming is beneficial, it has been interpreted as such. But we do not know what would have happened without gender-affirming treatment; the situation may have been even worse. As an analogy, similar studies have found increased somatic morbidity, suicide rates, and overall mortality for patients treated for depression and bipolar disorder (Ösby, Brandt, Correia, Ekbom, & Sparen, 2001). This is important information, but it does not follow that antidepressant or mood stabilizing treatment cause the mortality. Most of the articles that use the study to argue against gender-affirming health care are published in non-peer reviewed papers and the public media in general. These non-scientific publications are difficult to keep track of. I am grateful to friends, colleagues, patients, LGBT organizations, and journalists who have alerted me when the results of the study have been misinterpreted, giving me a possibility to respond to the authors. One could argue that the results should never have been published due to the hurt caused to transgender persons. However, not publishing the results would also hurt the transgender group and take away an opportunity to receive better health care.

Exhibit I

OPEN ACCESS Freely available online PLoS one

Long-Term Follow-Up of Transsexual Persons Undergoing Sex Reassignment Surgery: Cohort Study in Sweden

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Abstract

Context: The treatment for transsexualism is sex reassignment, including hormonal treatment and surgery aimed at making the person's body as congruent with the opposite sex as possible. There is a dearth of long term, follow-up studies after sex reassignment.

Objective: To estimate mortality, morbidity, and criminal rate after surgical sex reassignment of transsexual persons.

Design: A population-based matched cohort study.

Setting: Sweden, 1973-2003.

Participants: All 324 sex-reassigned persons (191 male-to-females, 133 female-to-males) in Sweden, 1973–2003. Random population controls (10:1) were matched by birth year and birth sex or reassigned (final) sex, respectively.

Main Outcome Measures: Hazard ratios (HR) with 95% confidence intervals (CI) for mortality and psychiatric morbidity were obtained with Cox regression models, which were adjusted for immigrant status and psychiatric morbidity prior to sex reassignment (adjusted HR [aHR]).

Results: The overall mortality for sex-reassigned persons was higher during follow-up (aHR 2.8; 95% CI 1.8–4.3) than for controls of the same birth sex, particularly death from suicide (aHR 19.1; 95% CI 5.8–62.9). Sex-reassigned persons also had an increased risk for suicide attempts (aHR 4.9; 95% CI 2.9–8.5) and psychiatric inpatient care (aHR 2.8; 95% CI 2.0–3.9). Comparisons with controls matched on reassigned sex yielded similar results. Female-to-males, but not male-to-females, had a higher risk for criminal convictions than their respective birth sex controls.

Conclusions: Persons with transsexualism, after sex reassignment, have considerably higher risks for mortality, suicidal behaviour, and psychiatric morbidity than the general population. Our findings suggest that sex reassignment, although alleviating gender dysphoria, may not suffice as treatment for transsexualism, and should inspire improved psychiatric and somatic care after sex reassignment for this patient group.

Citation: Dhejne C, Lichtenstein P, Boman M, Johansson ALV, Långström N, et al. (2011) Long-Term Follow-Up of Transsexual Persons Undergoing Sex Reassignment Surgery: Cohort Study in Sweden. PLoS ONE 6(2): e16885. doi:10.1371/journal.pone.0016885

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Competing Interests: The authors have declared that no competing interests exist.

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Introduction

Transsexualism (ICD-10),[1] or gender identity disorder (DSM-IV),[2] is a condition in which a person's gender identity - the sense of being a man or a woman - contradicts his or her bodily sex characteristics. The individual experiences gender dysphoria and desires to live and be accepted as a member of the opposite sex.

The treatment for transsexualism includes removal of body hair, vocal training, and cross-sex hormonal treatment aimed at making the person's body as congruent with the opposite sex as possible to alleviate the gender dysphoria. Sex reassignment also involves the surgical removal of body parts to make external sexual characteristics resemble those of the opposite sex, so called sex reassignment/confirmation surgery (SRS). This is a unique

intervention not only in psychiatry but in all of medicine. The present form of sex reassignment has been practised for more than half a century and is the internationally recognized treatment to ease gender dysphoria in transsexual persons.[3,4]

Despite the long history of this treatment, however, outcome data regarding mortality and psychiatric morbidity are scant. With respect to suicide and deaths from other causes after sex reassignment, an early Swedish study followed 24 transsexual persons for an average of six years and reported one suicide.[5] A subsequent Swedish study recorded three suicides after sex reassignment surgery of 175 patients.[6] A recent Swedish follow-up study reported no suicides in 60 transsexual patients, but one death due to complications after the sex reassignment surgery.[7] A Danish study reported death by suicide in 3 out of 29 operated male-to-female transsexual persons followed for an average of six years.[8] By contrast, a Belgian study of 107 transsexual persons followed for 4–6 years found no suicides or deaths from other causes.[9] A large Dutch single-centre study (N = 1,109), focusing on adverse events following hormonal treatment, compared the outcome after cross-sex hormone treatment with national Dutch standardized mortality and morbidity rates and found no increased mortality, with the exception of death from suicide and AIDS in male-to-females 25–39 years of age.[10] The same research group concluded in a recent report that treatment with cross-sex hormones seems acceptably safe, but with the reservation that solid clinical data are missing.[11] A limitation with respect to the Dutch cohort is that the proportion of patients treated with cross-sex hormones who also had surgical sex-reassignment is not accounted for.[10]

Data is inconsistent with respect to psychiatric morbidity post sex reassignment. Although many studies have reported psychiatric and psychological improvement after hormonal and/or surgical treatment,[7,12,13,14,15,16] other have reported on regrets,[17] psychiatric morbidity, and suicide attempts after SRS.[9,18] A recent systematic review and meta-analysis concluded that approximately 80% reported subjective improvement in terms of gender dysphoria, quality of life, and psychological symptoms, but also that there are studies reporting high psychiatric morbidity and suicide rates after sex reassignment.[19] The authors concluded though that the evidence base for sex reassignment "is of very low quality due to the serious methodological limitations of included studies."

The methodological shortcomings have many reasons. First, the nature of sex reassignment precludes double blind randomized controlled studies of the result. Second, transsexualism is rare [20] and many follow-ups are hampered by small numbers of subjects.[5,8,21,22,23,24,25,26,27,28] Third, many sex reassigned persons decline to participate in follow-up studies, or relocate after surgery, resulting in high drop-out rates and consequent selection bias.[6,9,12,21,24,28,29,30] Forth, several follow-up studies are hampered by limited follow-up periods.[7,9,21,22,26,30] Taken together, these limitations preclude solid and generalisable conclusions. A long-term population-based controlled study is one way to address these methodological shortcomings.

Here, we assessed mortality, psychiatric morbidity, and psychosocial integration expressed in criminal behaviour after sex reassignment in transsexual persons, in a total population cohort study with long-term follow-up information obtained from Swedish registers. The cohort was compared with randomly selected population controls matched for age and gender. We adjusted for premorbid differences regarding psychiatric morbidity and immigrant status. This study design sheds new light on transsexual persons' health after sex reassignment. It does not, however, address whether sex reassignment is an effective treatment or not.

Methods

National registers

The study population was identified by the linkage of several Swedish national registers, which contained a total of 13.8 million unique individuals. The Hospital Discharge Register (HDR, held by the National Board of Health and Welfare) contains discharge diagnoses, up to seven contributory diagnoses, external causes of morbidity or mortality, surgical procedure codes, and discharge date. Discharge diagnoses are coded according to the 8th (1969-1986), 9th (1987–1996), and 10th editions (1997-) of the International Classification of Diseases (ICD). The register covers virtually all psychiatric inpatient episodes in Sweden since 1973. Discharges that occurred up to 31 December 2003 were included. Surgical procedure codes could not be used for this study due to the lack of a specific code for sex reassignment surgery. The Total Population Register (TPR, held by Statistics Sweden) is comprised of data about the entire Swedish population. Through linkage with the Total Population Register it was possible to identify birth date and birth gender for all study subjects. The register is updated every year and gender information was available up to 2004/2005. The Medical Birth Register (MBR) was established in 1973 and contains birth data, including gender of the child at birth. National censuses based on mandatory self-report questionnaires completed by all adult citizens in 1960, 1970, 1980, and 1990 provided information on individuals, households, and dwellings, including gender, living area, and highest educational level. Complete migration data, including country of birth for immigrants for 1969–2003, were obtained from the TPR. In addition to educational information from the censuses, we also obtained highest educational level data for 1990 and 2000 from the Register of Education. The Cause of Death Register (CDR, Statistics Sweden) records all deaths in Sweden since 1952 and provided information on date of death and causes of death. Death events occurring up to 31 December 2003 are included in the study. The Crime Register (held by the National Council of Crime Prevention) provided information regarding crime type and date on all criminal convictions in Sweden during the period 1973–2004. Attempted and aggravated forms of all offences were also included. All crimes in Sweden are registered regardless of insanity at the time of perpetration; for example, for individuals who suffered from psychosis at the time of the offence. Moreover, conviction data include individuals who received custodial or non-custodial sentences and cases where the prosecutor decided to caution or fine without court proceedings. Finally, Sweden does not differ considerably from other members of the European Union regarding rates of violent crime and their resolution.[31]

Study population, identification of sex-reassigned persons (exposure assessment)

The study was designed as a population-based matched cohort study. We used the individual national registration number, assigned to all Swedish residents, including immigrants on arrival, as the primary key through all linkages. The registration number consists of 10 digits; the first six provide information of the birth date, whereas the ninth digit indicates the gender. In Sweden, a person presenting with gender dysphoria is referred to one of six specialised gender teams that evaluate and treat patients principally according to international consensus guidelines: Standards of Care.[3] With a medical certificate, the person applies to the National Board of Health and Welfare to receive permission for sex reassignment surgery and a change of legal sex status. A new national registration number signifying the new gender is assigned after sex reassignment surgery. The National

Board of Health and Welfare maintains a link between old and new national registration numbers, making it possible to follow individuals undergoing sex reassignment across registers and over time. Hence, sex reassignment surgery in Sweden requires (i) a transsexualism diagnosis and (ii) permission from the National Board of Health and Welfare.

A person was defined as exposed to sex reassignment surgery if two criteria were met: (i) at least one inpatient diagnosis of gender identity disorder diagnosis without concomitant psychiatric diagnoses in the Hospital Discharge Register, and (ii) at least one discrepancy between gender variables in the Medical Birth Register (from 1973 and onwards) or the National Censuses from 1960, 1970, 1980, or 1990 and the latest gender designation in the Total Population Register. The first criterion was employed to capture the hospitalization for sex reassignment surgery that serves to secure the diagnosis and provide a time point for sex reassignment surgery; the plastic surgeons namely record the reason for sex reassignment surgery, i.e., transsexualism, but not any co-occurring psychiatric morbidity. The second criterion was used to ensure that the person went through all steps in sex-reassignment and also changed sex legally.

The date of sex reassignment (start of follow-up) was defined as the first occurrence of a gender identity disorder diagnosis, without any other concomitant psychiatric disorder, in the Hospital Discharge Register after the patient changed sex status (any discordance in sex designation across the Censuses, Medical Birth, and Total Population registers). If this information was missing, we used instead the closest date in the Hospital Discharge Register on which the patient was diagnosed with gender identity disorder without concomitant psychiatric disorder prior to change in sex status. The reason for prioritizing the use of a gender identity disorder diagnosis *after* changed sex status over *before* was to avoid overestimating person-years at risk of sex-reassigned person.

Using these criteria, a total of 804 patients with gender identity disorder were identified, whereof 324 displayed a shift in the gender variable during the period 1973–2003. The 480 persons that did not shift gender variable comprise persons who either did not apply, or were not approved, for sex reassignment surgery. Moreover, the ICD 9 code 302 is a non specific code for sexual disorders. Hence, this group might also comprise persons that were hospitalized for sexual disorders other than transsexualism. Therefore, they were omitted from further analyses. Of the remaining 324 persons, 288 were identified with the gender identity diagnosis *after* and 36 *before* change of sex status. Out of the 288 persons identified *after* changed sex status, 185 could also be identified *before* change in sex status. The median time lag between the hospitalization *before* and *after* sex change for these 185 persons was 0.96 years (mean 2.2 years, SD 3.3).

Gender identity disorder was coded according to ICD-8: 302.3 (transsexualism) and 302.9 (sexual deviation NOS); ICD-9: 302 (overall code for sexual deviations and disorders, more specific codes were not available in ICD-9); and ICD-10: F64.0 (transsexualism), F64.1 (dual-role transvestism), F64.8 (other gender identity disorder), and F64.9 (gender identity disorder NOS). Other psychiatric disorders were coded as ICD-8: 290-301 and 303-315; ICD-9: 290-301 and 303-319; and ICD-10: F00-F63 as well as F65-F99.

Identification of population-based controls (unexposed group)

For each exposed person (N = 324), we randomly selected 10 unexposed controls. A person was defined as unexposed if there were no discrepancies in sex designation across the Censuses, Medical Birth, and Total Population registers *and* no gender identity disorder diagnosis according to the Hospital Discharge Register. Control persons were matched by sex and birth year and had to be alive and residing in Sweden at the estimated sex reassignment date of the case person. To study possible gender-specific effects on outcomes of interest, we used two different control groups: one with the same sex as the case individual at birth (birth sex matching) and the other with the sex that the case individual had been reassigned to (final sex matching).

Outcome measures

We studied mortality, psychiatric morbidity, accidents, and crime following sex reassignment. More specifically, we investigated: (1) all-cause mortality, (2) death by definite/uncertain suicide, (3) death by cardiovascular disease, and (4) death by tumour. Morbidity included (5) any psychiatric disorder (gender identity disorders excluded), (6) alcohol/drug misuse and dependence, (7) definite/uncertain suicide attempt, and (8) accidents. Finally, we addressed court convictions for (9) any criminal offence and (10) any violent offence. Each individual could contribute with several outcomes, but only one event per outcome. Causes of death (Cause of Death Registry from 1952 and onwards) were defined according to ICD as suicide (ICD-8 and ICD-9 codes E950-E959 and E980-E989, ICD-10 codes X60-X84 and Y10-Y34); cardiovascular disease (ICD-8 codes 390-458, ICD-9 codes 390-459, ICD-10 codes I00-I99); neoplasms (ICD-8 and ICD-9 codes 140-239, ICD-10 codes C00-D48), any psychiatric disorder (gender identity disorders excluded); (ICD-8 codes 290-301 and 303-315, ICD-9 codes 290-301 and 303-319, ICD-10 codes F00-F63 and F65-F99); alcohol/drug abuse and dependence (ICD-8 codes 303-304, ICD-9 codes 303-305 (tobacco use disorder excluded), ICD-10 codes F10-F16 and F18-F19 (x5 excluded); and accidents (ICD-8 and ICD-9 codes E800-E929, ICD-10 codes V01-X59).

Any criminal conviction during follow-up was counted; specifically, violent crime was defined as homicide and attempted homicide, aggravated assault and assault, robbery, threatening behaviour, harassment, arson, or any sexual offense.[32]

Covariates

Severe psychiatric morbidity was defined as inpatient care according to ICD-8 codes 291, 295-301, 303-304, and 307; ICD-9 codes 291-292, 295-298, 300-301, 303-305 (tobacco use disorder excluded), 307.1, 307.5, 308-309, and 311; ICD-10 codes F10-F16, F18-F25, F28-F45, F48, F50, and F60-F62. Immigrant status, defined as individuals born abroad, was obtained from the Total Population Register. All outcome/covariate variables were dichotomized (i.e., affected or unaffected) and without missing values.

Statistical analyses

Each individual contributed person-time from study entry (for exposed: date of sex reassignment; for unexposed: date of sex reassignment of matched case) until date of outcome event, death, emigration, or end of study period (31 December 2003), whichever came first. The association between exposure (sex reassignment) and outcome (mortality, morbidity, crime) was measured by hazard ratios (HR) with 95% CIs, taking follow-up time into account. HRs were estimated from Cox proportional hazard regression models, stratified on matched sets (1:10) to account for the matching by sex, age, and calendar time (birth year). We present crude HRs (though adjusted for sex and age through matching) and confounder-adjusted HRs [aHRs] for all outcomes. The two potential confounders, immigrant status (yes/no) and history of severe psychiatric morbidity (yes/no) prior to sex

reassignment, were chosen based on previous research[18,33] and different prevalence across cases and controls (Table 1).

Gender-separated analyses were performed and a Kaplan-Meier survival plot graphically illustrates the survival of the sex reassigned cohort and matched controls (all-cause mortality) over time. The significance level was set at 0.05 (all tests were two-sided). All outcome/covariate variables were without missing values, since they are generated from register data, which are either present (affected) or missing (unaffected). The data were analysed using SAS version 9.1 (SAS Institute Inc., Cary, NC, USA).

Ethics

The data linking of national registers required for this study was approved by the IRB at Karolinska Institutet, Stockholm. All data were analyzed anonymously; therefore, informed consent for each individual was neither necessary nor possible.

Results

We identified 324 transsexual persons (exposed cohort) who underwent sex reassignment surgery and were assigned a new legal sex between 1973 and 2003. These constituted the sex-reassigned (exposed) group. Fifty-nine percent (N = 191) of sex-reassigned persons were male-to-females and 41% (N = 133) female-to-males, yielding a sex ratio of 1.4:1 (Table 1).

The average follow-up time for all-cause mortality was 11.4 (median 9.1) years. The average follow-up time for the risk of being hospitalized for any psychiatric disorder was 10.4 (median 8.1).

Characteristics prior to sex reassignment

Table 1 displays demographic characteristics of sex-reassigned and control persons prior to study entry (sex reassignment). There were no substantial differences between female-to-males and male-to-females regarding measured baseline characteristics. Immigrant status was twice as common among transsexual individuals compared to controls, living in an urban area somewhat more common, and higher education about equally prevalent. Transsexual individuals had been hospitalized for psychiatric morbidity other than gender identity disorder prior to sex reassignment about four times more often than controls. To adjust for these baseline discrepancies, hazard ratios adjusted for immigrant status and psychiatric morbidity prior to baseline are presented for all outcomes [aHRs].

Mortality

Table 2 describes the risks for selected outcomes during follow-up among sex-reassigned persons, compared to same-age controls of the same birth sex. Sex-reassigned transsexual persons of both genders had approximately a three times higher risk of all-cause mortality than controls, also after adjustment for covariates. Table 2

Table 1. Baseline characteristics among sex-reassigned subjects in Sweden (N = 324) and population controls matched for birth year and sex.

Characteristic at baseline	Sex-reassigned subjects (N = 324)	Birth-sex matched controls (N = 3,240)	Final-sex matched controls (N = 3,240)
Gender			
Female at birth, male after sex change	133 (41%)	1,330 (41%)	1,330 (41%)
Male at birth, female after sex change	191 (59%)	1,910 (59%)	1,910 (59%)
Average age at study entry [years] (SD, min-max)			
Female at birth, male after sex change	33.3 (8.7, 20–62)	33.3 (8.7, 20–62)	33.3 (8.7, 20–62)
Male at birth, female after sex change	36.3 (10.1, 21–69)	36.3 (10.1, 21–69)	36.3 (10.1, 21–69)
Both genders	35.1 (9.7, 20–69)	35.1 (9.7, 20–69)	35.1 (9.7, 20–69)
Immigrant status			
Female at birth, male after sex change	28 (21%)	118 (9%)	100 (8%)
Male at birth, female after sex change	42 (22%)	176 (9%)	164 (9%)
Both genders	70 (22%)	294 (9%)	264 (8%)
Less than 10 years of schooling prior to entry vs. 10 years or more			
Females at birth, males after sex change	49 (44%); 62 (56%)	414 (37%); 714 (63%)	407 (36%); 713 (64%)
Males at birth, females after sex change	61 (41%); 89 (59%)	665 (40%); 1,011 (60%)	595 (35%); 1,091 (65%)
All individuals with data	110 (42%); 151 (58%)	1,079 (38%); 1,725 (62%)	1,002 (36%); 1,804 (64%)
Psychiatric morbidity* prior to study entry			
Female at birth, male after sex change	22 (17%)	47 (4%)	42 (3%)
Male at birth, female after sex change	36 (19%)	76 (4%)	72 (4%)
Both genders	58 (18%)	123 (4%)	114 (4%)
Rural [vs. urban] living area prior to entry			
Female at birth, male after sex change	13 (10%)	180 (14%)	195 (15%)
Male at birth, female after sex change	20 (10%)	319 (17%)	272 (14%)
Both genders	33 (10%)	499 (15%)	467 (14%)

Note:
*Hospitalizations for gender identity disorder were not included.
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Table 2. Risk of various outcomes among sex-reassigned subjects in Sweden (N = 324) compared to population controls matched for birth year and birth sex.

	Number of events cases/ controls 1973–2003	Outcome incidence rate per 1000 person-years 1973–2003 (95% CI)		Crude hazard ratio (95% CI) 1973–2003	Adjusted* hazard ratio (95% CI) 1973–2003	Adjusted* hazard ratio (95% CI) 1973–1988	Adjusted* hazard ratio (95% CI) 1989–2003
		Cases	Controls				
Any death	27/99	7.3 (5.0–10.6)	2.5 (2.0–3.0)	2.9 (1.9–4.5)	2.8 (1.8–4.3)	3.1 (1.9–5.0)	1.9 (0.7–5.0)
Death by suicide	10/5	2.7 (1.5–5.0)	0.1 (0.1–0.3)	19.1 (6.5–55.9)	19.1 (5.8–62.9)	N/A	N/A
Death by cardiovascular disease	9/42	2.4 (1.3–4.7)	1.1 (0.8–1.4)	2.6 (1.2–5.4)	2.5 (1.2–5.3)	N/A	N/A
Death by neoplasm	8/38	2.2 (1.1–4.3)	1.0 (0.7–1.3)	2.1 (1.0–4.6)	2.1 (1.0–4.6)	N/A	N/A
Any psychiatric hospitalisation‡	64/173	19.0 (14.8–24.2)	4.2 (3.6–4.9)	4.2 (3.1–5.6)	2.8 (2.0–3.9)	3.0 (1.9–4.6)	2.5 (1.4–4.2)
Substance misuse	22/78	5.9 (3.9–8.9)	1.8 (1.5–2.3)	3.0 (1.9–4.9)	1.7 (1.0–3.1)	N/A	N/A
Suicide attempt	29/44	7.9 (5.5–11.4)	1.0 (0.8–1.4)	7.6 (4.7–12.4)	4.9 (2.9–8.5)	7.9 (4.1–15.3)	2.0 (0.7–5.3)
Any accident	32/233	9.0 (6.3–12.7)	5.7 (5.0–6.5)	1.6 (1.1–2.3)	1.4 (1.0–2.1)	1.6 (1.0–2.5)	1.1 (0.5–2.2)
Any crime	60/350	18.5 (14.3–23.8)	9.0 (8.1–10.0)	1.9 (1.4–2.5)	1.3 (1.0–1.8)	1.6 (1.1–2.4)	0.9 (0.6–1.5)
Violent crime	14/61	3.6 (2.1–6.1)	1.4 (1.1–1.8)	2.7 (1.5–4.9)	1.5 (0.8–3.0)	N/A	N/A

Notes:
*Adjusted for psychiatric morbidity prior to baseline and immigrant status.
‡Hospitalisations for gender identity disorder were excluded.
N/A Not applicable due to sparse data.
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separately lists the outcomes depending on when sex reassignment was performed: during the period 1973-1988 or 1989–2003. Even though the overall mortality was increased across both time periods, it did not reach statistical significance for the period 1989–2003. The Kaplan-Meier curve (Figure 1) suggests that survival of transsexual persons started to diverge from that of matched controls after about 10 years of follow-up. The cause-specific mortality from suicide was much higher in sex-reassigned persons, compared to matched controls. Mortality due to cardiovascular disease was moderately increased among the sex-reassigned, whereas the numerically increased risk for malignancies was borderline statistically significant. The malignancies were lung cancer (N = 3), tongue cancer (N = 1), pharyngeal cancer (N = 1), pancreas cancer (N = 1), liver cancer (N = 1), and unknown origin (N = 1).

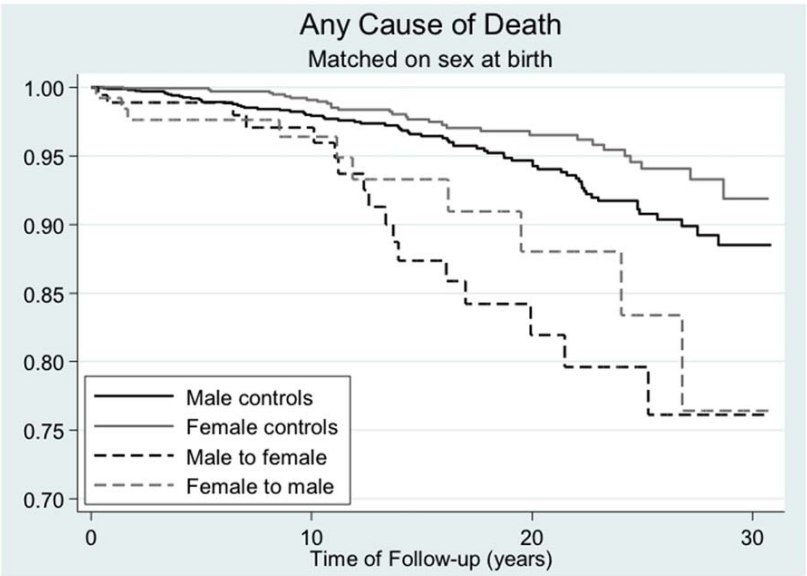

Figure 1. Death from any cause as a function of time after sex reassignment among 324 transsexual persons in Sweden (male-to-female: N = 191, female-to-male: N = 133), and population controls matched on birth year.
doi:10.1371/journal.pone.0016885.g001

Psychiatric morbidity, substance misuse, and accidents

Sex-reassigned persons had a higher risk of inpatient care for a psychiatric disorder other than gender identity disorder than controls matched on birth year and birth sex (Table 2). This held after adjustment for prior psychiatric morbidity, and was true regardless of whether sex reassignment occurred before or after 1989. In line with the increased mortality from suicide, sex-reassigned individuals were also at a higher risk for suicide attempts, though this was not statistically significant for the time period 1989–2003. The risks of being hospitalised for substance misuse or accidents were not significantly increased after adjusting for covariates (Table 2).

Crime rate

Transsexual individuals were at increased risk of being convicted for any crime or violent crime after sex reassignment (Table 2); this was, however, only significant in the group who underwent sex reassignment before 1989.

Gender differences

Comparisons of female-to-males and male-to-females, although hampered by low statistical power and associated wide confidence intervals, suggested mostly similar risks for adverse outcomes (Tables S1 and S2). However, violence against self (suicidal behaviour) and others ([violent] crime) constituted important exceptions. First, male-to-females had significantly increased risks for suicide attempts compared to both female (aHR 9.3; 95% CI 4.4–19.9) and male (aHR 10.4; 95% CI 4.9–22.1) controls. By contrast, female-to-males had significantly increased risk of suicide attempts only compared to male controls (aHR 6.8; 95% CI 2.1–21.6) but not compared to female controls (aHR 1.9; 95% CI 0.7–4.8). This suggests that male-to-females are at higher risk for suicide attempts after sex reassignment, whereas female-to-males maintain a female pattern of suicide attempts after sex reassignment (Tables S1 and S2).

Second, regarding any crime, male-to-females had a significantly increased risk for crime compared to female controls (aHR 6.6; 95% CI 4.1–10.8) but not compared to males (aHR 0.8; 95% CI 0.5–1.2). This indicates that they retained a male pattern regarding criminality. The same was true regarding violent crime. By contrast, female-to-males had higher crime rates than female controls (aHR 4.1; 95% CI 2.5–6.9) but did not differ from male controls. This indicates a shift to a male pattern regarding criminality and that sex reassignment is coupled to increased crime rate in female-to-males. The same was true regarding violent crime.

Discussion

Principal findings and comparison with previous research

We report on the first nationwide population-based, long-term follow-up of sex-reassigned transsexual persons. We compared our cohort with randomly selected population controls matched for age and gender. The most striking result was the high mortality rate in both male-to-females and female-to males, compared to the general population. This contrasts with previous reports (with one exception[8]) that did not find an increased mortality rate after sex reassignment, or only noted an increased risk in certain subgroups.[7,9,10,11] Previous clinical studies might have been biased since people who regard their sex reassignment as a failure are more likely to be lost to follow-up. Likewise, it is cumbersome to track deceased persons in clinical follow-up studies. Hence, population-based register studies like the present are needed to improve representativity.[19,34]

The poorer outcome in the present study might also be explained by longer follow-up period (median >10 years) compared to previous studies. In support of this notion, the survival curve (Figure 1) suggests increased mortality from ten years after sex reassignment and onwards. In accordance, the overall mortality rate was only significantly increased for the group operated before 1989. However, the latter might also be explained by improved health care for transsexual persons during 1990s, along with altered societal attitudes towards persons with different gender expressions.[35]

Mortality due to cardiovascular disease was significantly increased among sex reassigned individuals, albeit these results should be interpreted with caution due to the low number of events. This contrasts, however, a Dutch follow-up study that reported no increased risk for cardiovascular events.[10,11] A recent meta-analysis concluded, however, that data on cardiovascular outcome after cross-sex steroid use are sparse, inconclusive, and of very low quality.[34]

With respect to neoplasms, prolonged hormonal treatment might increase the risk for malignancies,[36] but no previous study has tested this possibility. Our data suggested that the cause-specific risk of death from neoplasms was increased about twice (borderline statistical significance). These malignancies (see Results), however, are unlikely to be related to cross-hormonal treatment.

There might be other explanations to increased cardiovascular death and malignancies. Smoking was in one study reported in almost 50% by the male-to females and almost 20% by female-to-males.[9] It is also possible that transsexual persons avoid the health care system due to a presumed risk of being discriminated.

Mortality from suicide was strikingly high among sex-reassigned persons, also after adjustment for prior psychiatric morbidity. In line with this, sex-reassigned persons were at increased risk for suicide attempts. Previous reports [6,8,10,11] suggest that transsexualism is a strong risk factor for suicide, also after sex reassignment, and our long-term findings support the need for continued psychiatric follow-up for persons at risk to prevent this.

Inpatient care for psychiatric disorders was significantly more common among sex-reassigned persons than among matched controls, both before and after sex reassignment. It is generally accepted that transsexuals have more psychiatric ill-health than the general population prior to the sex reassignment.[18,21,22,33] It should therefore come as no surprise that studies have found high rates of depression,[9] and low quality of life[16,25] also after sex reassignment. Notably, however, in this study the increased risk for psychiatric hospitalisation persisted even after adjusting for psychiatric hospitalisation prior to sex reassignment. This suggests that even though sex reassignment alleviates gender dysphoria, there is a need to identify and treat co-occurring psychiatric morbidity in transsexual persons not only before but also after sex reassignment.

Criminal activity, particularly violent crime, is much more common among men than women in the general population. A previous study of all applications for sex reassignment in Sweden up to 1992 found that 9.7% of male-to-female and 6.1% of female-to-male applicants had been prosecuted for a crime.[33] Crime after sex reassignment, however, has not previously been studied. In this study, male-to-female individuals had a higher risk for criminal convictions compared to female controls but not compared to male controls. This suggests that the sex reassignment procedure neither increased nor decreased the risk for criminal offending in male-to-females. By contrast, female-to-males were at a higher risk for criminal convictions compared to female controls and did not differ from male controls, which suggests increased crime proneness in female-to-males after sex reassignment.

Strengths and limitations of the study

Strengths of this study include nationwide representativity over more than 30 years, extensive follow-up time, and minimal loss to follow-up. Many previous studies suffer from low outcome ascertainment,[6,9,21,29] whereas this study has captured almost the entire population of sex-reassigned transsexual individuals in Sweden from 1973–2003. Moreover, previous outcome studies have mixed pre-operative and post-operative transsexual persons,[22,37] while we included only post-operative transsexual persons that also legally changed sex. Finally, whereas previous studies either lack a control group or use standardised mortality rates or standardised incidence rates as comparisons,[9,10,11] we selected random population controls matched by birth year, and either birth or final sex.

Given the nature of sex reassignment, a double blind randomized controlled study of the result after sex reassignment is not feasible. We therefore have to rely on other study designs. For the purpose of evaluating whether sex reassignment is an effective treatment for gender dysphoria, it is reasonable to compare reported gender dysphoria pre and post treatment. Such studies have been conducted either prospectively[7,12] or retrospectively,[5,6,9,22,25,26,29,38] and suggest that sex reassignment of transsexual persons improves quality of life and gender dysphoria. The limitation is of course that the treatment has not been assigned randomly and has not been carried out blindly.

For the purpose of evaluating the safety of sex reassignment in terms of morbidity and mortality, however, it is reasonable to compare sex reassigned persons with matched population controls. The caveat with this design is that transsexual persons before sex reassignment might differ from healthy controls (although this bias can be statistically corrected for by adjusting for baseline differences). It is therefore important to note that the current study is only informative with respect to transsexuals persons health after sex reassignment; no inferences can be drawn as to the effectiveness of sex reassignment as a treatment for transsexualism. In other words, the results should not be interpreted such as sex reassignment *per se* increases morbidity and mortality. Things might have been even worse without sex reassignment. As an analogy, similar studies have found increased somatic morbidity, suicide rate, and overall mortality for patients treated for bipolar disorder and schizophrenia.[39,40] This is important information, but it does not follow that mood stabilizing treatment or antipsychotic treatment is the culprit.

Other facets to consider are first that this study reflects the outcome of psychiatric and somatic treatment for transsexualism provided in Sweden during the 1970s and 1980s. Since then, treatment has evolved with improved sex reassignment surgery, refined hormonal treatment,[11,41] and more attention to psychosocial care that might have improved the outcome. Second, transsexualism is a rare condition and Sweden is a small country (9.2 million inhabitants in 2008). Hence, despite being based on a comparatively large national cohort and long-term follow-up, the statistical power was limited. Third, regarding psychiatric morbidity after sex reassignment, we assessed inpatient psychiatric care. Since most psychiatric care is provided in outpatient settings (for which no reliable data were available), underestimation of the *absolute* prevalences was inevitable. However, there is no reason to believe that this would change the *relative risks* for psychiatric morbidity unless sex-reassigned transsexual individuals were more likely than matched controls to be admitted to hospital for any given psychiatric condition.

Finally, to estimate start of follow-up, we prioritized using the date of a gender identity disorder diagnosis *after* changed sex status over *before* changed sex status, in order to avoid overestimating person-years at risk after sex-reassignment. This means that adverse outcomes might have been underestimated. However, given that the median time lag between the hospitalization before and after change of sex status was less than a year (see Methods), this maneuver is unlikely to have influenced the results significantly. Moreover, all deaths will be recorded regardless of this exercise and mortality hence correctly estimated.

Conclusion

This study found substantially higher rates of overall mortality, death from cardiovascular disease and suicide, suicide attempts, and psychiatric hospitalisations in sex-reassigned transsexual individuals compared to a healthy control population. This highlights that post surgical transsexuals are a risk group that need long-term psychiatric and somatic follow-up. Even though surgery and hormonal therapy alleviates gender dysphoria, it is apparently not sufficient to remedy the high rates of morbidity and mortality found among transsexual persons. Improved care for the transsexual group after the sex reassignment should therefore be considered.

Supporting Information

Table S1 Risk of various outcomes in sex-reassigned persons in Sweden compared to population controls matched for birth year and *birth sex*.
(DOCX)

Table S2 Risk of various outcomes in sex-reassigned persons in Sweden compared to controls matched for birth year and *final sex*.
(DOCX)

Author Contributions

Conceived and designed the experiments: CD PL AJ NL ML. Performed the experiments: MB AJ. Analyzed the data: CD PL MB AJ NL ML. Contributed reagents/materials/analysis tools: PL NL AJ. Wrote the paper: CD PL MB AJ NL ML.

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Exhibit J

Long-Term Follow-Up of Individuals Undergoing Sex-Reassignment Surgery: Somatic Morbidity and Cause of Death

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Long-Term Follow-Up of Individuals Undergoing Sex-Reassignment Surgery: Somatic Morbidity and Cause of Death

Rikke Kildevæld Simonsen, MA,[1] Gert Martin Hald, PhD,[2] Ellids Kristensen, MD, FECSM,[3] and Annamaria Giraldi, PhD, MD, FECSM[3]

ABSTRACT

Introduction: Studies of mortality and somatic well-being after sex-reassignment surgery (SRS) of transsexual individuals are equivocal. Accordingly, the present study investigated mortality and somatic morbidity using a sample of transsexual individuals who comprised 98% (n = 104) of all surgically reassigned transsexual individuals in Denmark.

Aims: To investigate somatic morbidity before and after SRS and cause of death and its relation to somatic morbidity after SRS in Danish individuals who underwent SRS from 1978 through 2010.

Methods: Somatic morbidity and mortality in 104 sex-reassigned individuals were identified retrospectively by data from the Danish National Health Register and the Cause of Death Register.

Main Outcome Measures: Somatic morbidity and cause of death.

Results: Overall, 19.2% of the sample were registered with somatic morbidity before SRS and 23.1% after SRS (P = not significant). In total, 8.6% had somatic morbidity before and after SRS. The most common diagnostic category was cardiovascular disease, affecting 18 individuals, 9 before and 14 after SRS, and 5 of those 14 who were affected after SRS had cardiovascular disease before and after SRS. Ten individuals died after SRS at an average age of 53.5 ± 7.9 years (male to female) and 53.5 ± 7.3 years (female to male).

Conclusion: Of 98% of all Danish transsexuals who officially underwent SRS from 1978 through 2010, one in three had somatic morbidity and approximately 1 in 10 had died. No significant differences in somatic morbidity or mortality were found between male-to-female and female-to-male individuals. Despite the young average age at death and the relatively larger number of individuals with somatic morbidity, the present study design does not allow for determination of casual relations between, for example, specific types of hormonal or surgical treatment received and somatic morbidity and mortality.

Key Words: Follow-Up; Gender Identity Disorder; Somatic Morbidity; Sex-Reassignment Surgery; Transsexualism

INTRODUCTION

Transsexualism refers to a condition in which the core characteristic is an individual's experience of profound incongruence between assigned sex at birth and the experienced gender.[1] According to the *International Statistical Classification of Diseases and Related Health Problems, 10th Edition* (*ICD-10*),[2] the diagnostic criteria of transsexualism are (i) the desire to live and be accepted as the opposite sex, (ii) usually a sense of discomfort with or inappropriateness of one's anatomic sex, and (iii) a wish to have surgery and/or hormonal treatment (HT) to make the body as congruent as possible with the preferred sex. To develop characteristics of the opposite sex, treatment with cross-sex hormones (HT), castration, and genital reconstructive surgery (sex-reassignment surgery [SRS]) might be conducted.

The parent category of transsexualism in the *ICD-10* is gender identity disorder (GID).[2] In Denmark, individuals with GID are referred to the Gender Identity Unit, University of Copenhagen (GIUUC) under *ICD-8*[3] code 302.39 and 1993 *ICD-10*[2] codes DF64.0 to DF64.9 by a general practitioner or psychiatrist. Assessment, in accordance with Danish Health Authority

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guidelines,[4] includes blood sample analyses for chromosomal and hormonal abnormalities, screening for psychiatric and somatic morbidities, psychological testing, and sessions with a psychologist or psychiatrist.

If SRS is desired by the individual diagnosed with transsexualism, an observational period of at least 1 year 6 months (in the study period, 2 years), including 1 year of HT and living in the gender role as the opposite sex, is obligatory before applying for SRS to the Danish Health Authority. The Danish legal criteria for SRS and castration are an *ICD-10* diagnosis of transsexualism (F64.0), persistent wish for and understanding of the consequences of castration, and a minimum age of 18 years (during the study period, ie,1978–2010, the minimum age was 21 years).[5] All treatment is paid for by the public Danish medical system. Treatment with cross-sex hormones and genital reconstructive surgery has existed for more than 60 years, but findings on mortality and somatic well-being after SRS in long-term follow-up studies are equivocal.[6] For possible somatic consequences of HT, the following outcomes have been studied the most: cardiovascular disease (CVD), bone growth, and hormone-sensitive cancer malignancies.

A review and meta-analysis of 16 studies, including 1,471 male-to-female (MtF) and 651 female-to-male (FtM) individuals, found no overall significant effect of HT on CVD.[7] However, the type of HT (ethinyl estradiol) and the manner in which HT (oral estrogens) was administered in MtF patients were significantly associated with CVD.[8,9] Further, in a Swedish study, increased CVD mortality in FtM and MtF individuals at least 10 years after HT was found,[6] indicating a possible delay of adverse somatic consequences from HT on cardiovascular pathology.[10]

Studies of muscle and musculoskeletal diseases, bone growth, and bone deficiencies overall did not show an increased risk of osteoporosis in FtM individuals.[11–16] However, in MtF individuals, lower bone mass density, possibly from androgen deprivation, was found after treatment compared with before treatment with HT.[17–19] However, because of increased bone density before treatment and no loss of bone density from menopause, MtF individuals maintain a lower risk of osteoporosis than assigned women.[20]

In cancer studies involving transsexuals receptive of SRS and/or HT, the focus has been on breast cancer, although the overall number of studies in relation to this issue is limited. The conclusions emerging from these studies suggest that for MtF individuals[20–23] the risk of breast cancer is lower than the expected risk of breast cancer in assigned women but similar to that expected in assigned men. For FtM individuals, male sex hormones might have an antiproliferative effect on breast cancer cell lines.[24,25] Thus, few cases of breast cancer in FtM individuals have been reported,[26,27] indicating FtM individuals have similar risk as expected for male breast cancer.

Concerning cancer malignancies, a Belgian study, in which the average time of HT was 6 years (FtM) or 7 years (MtF), found no increase in cancer malignancies among included transsexuals compared with controls randomly selected from the population.[28] In contrast, a Swedish study found borderline significant risk of death from neoplasms compared with controls.[6] Lifestyle habits such as smoking and avoidance of the health care system were suggested as possible mediating mechanisms.

When studying increased and decreased risks of cancer in transsexuals receiving HT, it is important to note that HT has been used for 60 years in some transsexual individuals. Accordingly, the duration of exposure to HT might not be long enough for tumors to manifest and the number of individuals exposed is small.[29] Further, it has been suggested that inconsistency in reporting cancer incidents among transsexuals might lead to an underreporting of cancer in this cohort,[21,30] likely affecting prevalence and incidence rates.

Studies of mortality in transsexuals have suggested an increased mortality risk compared with controls.[6,10] For example, a Swedish study of 324 MtF and FtM individuals after SRS (follow-up = 11.4 years) found that the all-cause mortality rate was three times higher in this cohort compared with controls.[6] Similarly, in a Dutch long-term follow-up study of 966 MtF and 365 FtM individuals (follow-up = 18.5 years), a 51% higher mortality rate was found in MtF subjects compared with the general population.[10] For FtM subjects, no increased mortality was found compared with the general population. A Dutch study of 1,109 individuals receiving HT found no increased mortality overall, but in MtF subjects 25 to 39 years old, mortality was significantly increased because of suicide, acquired immune deficiency syndrome, CVD, drug abuse, and unknown causes.[31] The only Danish study on transsexualism conducted thus far, which included 37 individuals, reported three deaths of 29 reassigned MtF individuals and no deaths of 8 FtM individuals studied from 1956 through 1978.[32]

Somatic morbidity after alcohol abuse has not been investigated previously, although studies of substance abuse in individuals with transsexualism have been conducted. A Belgian study (N = 35) conducted at the University Hospital of Gent found alcohol and drug abuse in 50% of MtF and 61.5% of FtM individuals.[33] A Spanish study (N = 230) of individuals with complaints of GID seen at the Hospital Clinic (Barcelona, Spain) found current alcohol- and substance-related disorders in 11% MtF and 1.4% of FtM subjects.[34] A Swiss study found that 45% of 31 GID individuals diagnosed by the *Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition, Text Revision*[35] had lifetime substance abuse (MtF = 50%, FtM = 36.4%).[36] A Swedish study of 233 individuals found substance abuse in 18.2% of FtM and 11.9% MtF individuals.[37] However, in a different Swedish study of 324 MtF and FtM transsexual individuals, no significant risk of being hospitalized for substance abuse was found compared with the general Swedish population.[6] Lung diseases related to or caused by smoking have not been investigated previously in persons with transsexualism, although lesbian, gay, bisexual, and transgender persons have a higher incidence of smoking.[38,39] Accordingly, this was included as an outcome in the present study.

For many of the studies that have focused on somatic morbidity and mortality, including those reviewed earlier, the following methodologic shortcomings apply: small sample, recruitment and diagnostic biases and inconsistencies (eg, place of participant recruitment and differences in diagnostic criteria), heterogeneity of treatment regimens, and varied duration of follow-up periods.[6]

The aim of the present study was to (re)investigate somatic morbidity and mortality using registry data in a cohort including 98% of all Danish individuals referred to a public GID clinic in Denmark who underwent SRS from 1978 through 2010 after a diagnosis of transsexualism.

AIMS

The specific aims of the study were to investigate (i) somatic morbidity before and after SRS and (ii) cause of death and its relation to somatic morbidity.

METHODS

Procedure

The study was approved by the Danish Data Protection Agency and the Danish Health Authority. Permission was obtained from the Civil Law Board to identify names and social security numbers of individuals who underwent SRS from 1978 through 2010 and who were treated at the GIUUC.

National Registers

The Danish National Health Register (LPR) was used to draw data on somatic morbidity. The LPR contains diagnoses and dates of onset and end of treatment of all somatic episodes at hospitals from 1977 (inpatients) and from 1995 (outpatients). In the LPR, diagnoses are coded according to the *ICD-8* (1969−1993) or *ICD-10* (1994−).[2,3] Data from the LPR from 1977 to January 2013 were included in the study.

The Cause of Death Register has recorded all deaths and causes of death in Denmark since 1970. Death events occurring up to April 2014 were included in the study.

Study Population

Included in the study were 104 individuals (56 MtF and 48 FtM) diagnosed with transsexualism according to the *ICD-8*[3] or *ICD-10*[2] at the GIUUC. All participants underwent castration with permission from the Danish Health Authority from 1978 through 2010. Verification that an individual had undergone SRS was accomplished using social security numbers (ie, Danish Cause of Death Register numbers); numbers ending in even numbers indicate female-assigned sex and those ending with odd numbers indicate male-assigned sex. Accordingly, changes in this number from even to odd or vice versa indicate the official change of assigned sex (ie, successful completion of SRS). Baseline data (Table 1) were obtained from medical records.

Table 1. Baseline Data

Variables	Male to female (n = 56)	Female to male (n = 48)
Mean age at referral (y), mean (SD)	30.3 (9.8)	27.0 (8.7)
Mean age at permission for SRS (y), mean (SD)	37.1 (9.7)	32.6 (8.0)
Mean age at initiating cross-sex hormones (y), mean (SD)	32.0 (9.9)	29.8 (8.4)
Mean length of follow-up (y), mean (SD)	16.38 (7.1)	10.21 (6.1)

SRS = sex-reassignment surgery.

Sociodemographic data (Table 2) were obtained from medical records and are further described by Simonsen et al.[40]

Because of the lack of a specific code for SRS, the date of start of follow-up was defined as the date of permission to undergo SRS.

Measures

Baseline data (Table 1) were obtained from medical records based on interviews performed by specialized psychiatrists, psychologists, and medical doctors at the GIUUC during the treatment period.

Using the LPR and death registers, we obtained information pertaining to somatic morbidity before and after permission to undergo SRS and time and cause of death after obtaining this permission. More specifically, somatic diagnoses given to the patient from 1977 to January 2013 were investigated. Accordingly, each individual could present with different diagnoses, but multiple contacts with the somatic care system with the same diagnosis only had one outcome before SRS and one outcome after SRS. In addition, data on time and cause of death after permission to undergo SRS were drawn from the death registers until April 2014.

For each diagnosis, specifically chronic heart disease (*ICD-10* diagnoses F400−490), chronic lung disease (*ICD-10* diagnoses J40−47, *ICD-8* diagnoses 490−493), cancer (*ICD-10* diagnoses C00−C97.9, D00−D10.9, *ICD-8* diagnoses 140−209), alcohol-related liver morbidity (*ICD-10* K70−77, *ICD-8* 303−304), or muscle and musculoskeletal diseases (*ICD-10* M80−85, *ICD-8* 720−729), individuals were stratified by diagnostic group membership (ie, had received the diagnosis or had not received the diagnosis) and assigned sex (ie, MtF or FtM).

Mortality was determined by the cause-of-death certificate. Hence, each individual was dead or alive. For death, data related to cause of death were drawn from the death certificate.

Statistics

Statistical analyses were conducted in SPSS 19.0 (SPSS, Inc, Chicago, IL, USA). Clinical variables were analyzed using descriptive statistics. Means and SDs were calculated for

Table 2. Sociodemographics by Male to Female and Female to Male*

	Male to female (n = 58)	Female to male (n = 50)
Primary and secondary education (y), n (%)		
≤11	40 (69.0)	38 (76.0)
12–13 (completion of high school)	16 (27.6)	12 (24.0)
Missing information	2 (3.4)	0
Education beyond primary and secondary school at time of referral, n (%)		
None	29 (50.0)	30 (60.0)
≤3 y or apprenticeship	21 (36.2)	8 (16.0)
≥4 y	5 (8.6)	10 (20.0)
Unknown	3 (5.2)	2 (4.0)
Education beyond primary and secondary school when permission for SRS was granted, n (%)		
None	25 (43.1)	25 (50.0)
≤3 y or apprenticeship	21 (36.2)	13 (26.0)
≥4 y	8 (13.8)	10 (20.0)
Unknown	4 (6.9)	2 (4.0)
Employment at time of referral, n (%)		
Employed	36 (62.1)	31 (62.0)
Unemployed		
Sickness or unemployment benefits	12 (20.7)	7 (14.0)
Social welfare or pension	10 (17.3)	12 (24.0)
Employment when permission for SRS was granted, n (%)		
Employed	32 (55.2)	27 (54.0)
Unemployed		
Sickness or unemployment benefits	5 (8.6)	11 (22.0)
Social welfare or pension	20 (34.5)	11 (22.0)
Unknown	1 (1.7)	1 (2.0)

From Simonsen et al.[40]
SRS = sex-reassignment surgery.
*The χ^2 and Fisher exact tests were conducted but showed no significance ($P < 0.05$).

continuous variables. Frequencies and percentages were generated for nominal and categorical variables. Between-group differences were analyzed using χ^2 test, t-test, and Fisher exact test.

No missing values were found for somatic outcome variables because they were obtained from the register data, where values are present (affected) or absent (unaffected).

RESULTS

Baseline data related to age at referral, permission for SRS, cross-sex hormonal initiation, and years of follow-up after SRS are presented in Table 1.

To investigate the first study aim concerning somatic morbidity before and after SRS, the total number of included individuals who received a somatic diagnosis was identified (Table 3). As presented in Table 3, 20 FtM and MtF individuals (19.2%) before SRS and 24 FtM and MtF individuals (23.1%) after SRS had somatic morbidity, with no significant difference. Nine individuals (eight MtF and one FtM) had somatic morbidity before and after SRS, resulting in 35 individuals (33.7%) overall who had somatic morbidity. Table 4 lists the specific diagnoses of somatic morbidity.

As presented in Table 4, 25 somatic diagnoses were reported before SRS and 27 diagnoses after SRS from a total of 20 individuals before SRS and 24 individuals after SRS. Nine of the 24 individuals had somatic morbidity before and after SRS. The most common diagnostic category was CVD, affecting a total of 18 individuals, 9 before and 14 after (23 diagnoses) SRS, and 5 of the 14 individuals had CVD before and after SRS. The second most common diagnostic category was muscle and musculoskeletal diseases, with 12 diagnoses, six before and six after SRS, affecting a total of 11 individuals, with only one individual having muscle and musculoskeletal disease before and after SRS.

To investigate differences in somatic morbidity between MtF and FtM individuals, χ^2 test, Fisher exact, and t-test were used. Across diagnostic categories, no significant differences in somatic morbidity between MtF and FtM individuals were found. When comparing somatic diagnoses using χ^2 test, no significant differences between the number of somatic diagnoses given before and after SRS were found.

Concerning the second study aim, cause of death and its relation to somatic morbidity was investigated from after SRS until April 2014. Ten individuals (9.6%; six MtF [10.7%] and four FtM [8.3%]) died from after SRS to April 2014. Mean age at death was 53.5 ± 7.9 years (median = 55.5) for MtF individuals and 53.5 ± 7.3 years (median = 52.5) for FtM individuals ($P > .05$ by t-test). Somatic morbidity (ie, official cause of death) included two suicides (19 and 26 years after SRS, respectively), heart disease (n = 2), cancer (n = 1), ulcer (n = 1), and smoking- and alcohol-related diseases (n = 4).

Because the results might be influenced by changes in clinical procedures and guidelines over time and the cultural acceptance of transsexualism, data were checked for systematic differences in permission to undergo SRS from the first 16 years (1978–1994) to the next 16 years (1994–2010). Significantly ($P < .05$) more individuals with transsexualism received permission to undergo SRS from 1995 through 2010 (28 individuals in 1978–1994 and 76 individuals in 1995–2010).

DISCUSSION

We report the first nationwide register-based SRS follow-up study in Denmark of 98% of individuals who officially underwent SRS from 1978 through 2010.

For the first study aim (ie, investigation of somatic morbidity before and after SRS), we found that 19.2% of the cohort had a somatic diagnosis before and 23.1% after SRS. This difference

Table 3. Individuals with Somatic Morbidity Before and After SRS*

	Before SRS		After SRS		Before and after SRS	
Diagnosis, n (%)	Male to female (n = 56)	Female to male (n = 48)	Male to female (n = 56)	Female to male (n = 48)	Male to female (n = 56)	Female to male (n = 48)
Cancer	0	3	2	1	0	1
CVD	5	4	6	8	5	0
Musculoskeletal	3	3	3	3	1	0
Lung	2	1	3	1	2	0
Alcoholic liver	1	3	0	0	0	0
Individuals with somatic diagnosis						
Yes	8 (14.3)	12 (25.0)	12 (21.4)	12 (25.0)	8 (14.3)	1 (2.1)
No	48 (85.7)	36 (75.0)	44 (78.6)	36 (75.0)	48 (85.7)	47 (97.9)

CVD = cardiovascular disease; SRS = sex-reassignment surgery.
*The χ^2 and Fisher exact tests were conducted but showed no significance ($P < 0.05$).

was found not to be statically significant. Further, no significant difference in somatic morbidity between FtM and MtF cohorts was found. For the second study aim (ie, investigation of mortality), no significant difference in mortality between MtF and FtM cohorts was found. Average age at death was 53.5 years, and 10 individuals died after SRS.

For somatic morbidity, CVD was found in 6 MtF individuals (10.7%) and 12 FtM individuals (25.0%). In comparison, 4.4% of assigned men and 3.6% of assigned women older than 35 years in the general Danish population were found to have CVD.[41] In the present study, CVD might have been due to long-term follow-up after HT (16.3 years for MtF cohort, 10.8 years for FtM cohort) as reported by other studies,[6,10] or the observed prevalence of CVD might be explained by a correlation between depression and anxiety and CVD as suggested by previous research.[42,43] Socioeconomic status and CVD are related,[44,45] and the present study group was characterized not only by anxiety and depression[46] but also by social marginalization[47] and difficulties in school, education, and employment.[40] Hence, these factors could be important underlying mediating and/or moderating mechanisms driving or affecting prevalence rates of CVD in transsexuals, although the design of this study did not enable us to explore this further.

Muscle and musculoskeletal morbidity was found in 11 individuals (10.5%). From 1997 through 2002, 13.9% of the general Danish population was diagnosed with muscle and

Table 4. Number of Somatic Diagnoses*

	Before SRS		After SRS	
Diagnosis, n (%)	Male to female (n = 56)	Female to male (n = 48)	Male to female (n = 56)	Female to male (n = 48)
Alcohol related				
Yes	1 (1.8)	3 (6.2)	0	0
No	55 (98.2)	45 (93.8)	56 (100.0)	48 (100.0)
Cancer				
Yes	0	3 (6.3)	2 (3.8)	1 (2.0)
No	56 (100.0)	45 (93.8)	55 (98.2)	47 (97.9)
Heart				
Yes	5 (8.9)	4 (8.3)	6 (10.7)	8 (16.7)
No	51 (91.1)	44 (91.7)	50 (89.3)	40 (83.3)
Lung				
Yes	2 (1.8)	1 (2.1)	3 (5.4)	1 (2.1)
No	54 (96.4)	47 (97.9)	53 (94.6)	47 (97.9)
Musculoskeletal				
Yes	3 (5.4)	3 (6.3)	3 (5.4)	3 (6.3)
No	53 (94.6)	45 (93.8)	53 (94.6)	45 (93.7)
Positive somatic diagnosis	11	14	14	13

SRS = sex-reassignment surgery.
*The χ^2 and Fisher exact tests were conducted but showed no significance ($P < 0.05$).

musculoskeletal disease by hospital care.[48] Smoking and excessive alcohol consumption have been linked to low bone mass and increased fracture risk in MtF and FtM individuals,[49,50] and such lifestyle issues might characterize the present cohort.[6,46,51,52] However, given the limited number of individuals presenting with skeletal morbidity in this study, more comparable studies are needed to confirm the possible increased risk of skeletal morbidity in this cohort.

Concerning cancer malignancies, five individuals (6.2% of FtM and 3.6% of MtF) were found to have a diagnosis of cancer compared with 2.4% of assigned women and 1.56% of assigned men older than 15 years in the Danish general population.[53] Previous studies involving transsexual individuals have found hormone-sensitive tumors.[16,20,54] Further, in the present study, two deaths were caused by cancer and by leukemia and lung cancer, respectively. However, as in the present study, small samples and the sample design preclude causal inferences regarding relations between treatment of SRS individuals and cancer or cancer-related deaths.

In Denmark, alcohol-related diseases cause 5% of the total number of deaths,[55] with more alcohol and substance abuse in sexual minority groups.[51,52,56–58] Four individuals had a diagnosis of alcohol-related diseases before SRS with none after SRS. Further, in the present cohort, two individuals died of the effects of alcohol abuse after SRS. In a previous study on psychiatric morbidity of the present cohort, four diagnoses indicative of alcohol abuse after SRS were found.[46] Alcohol-related diseases are often the consequence of long-lasting alcohol abuse. Therefore, the actual number of individuals in the present cohort with alcohol abuse could be larger.

Four individuals had a diagnosis indicative of chronic lung disease (3.8%). In comparison, 1.3% of individuals older than 35 years in the in the general Danish population had a diagnosis of severe chronic lung disease.[59] Lung diseases have, to our knowledge, not been investigated previously in individuals with transsexualism, and therefore we lack and call for comparable studies in which to situate our findings.

Somatic morbidity in the present study group could be due to long-term HT and/or, as suggested by numerous previous studies, influenced by poor mental health, low economic status, social exclusion,[60] harassment, negative experiences with school[61] and the employment system,[34,37,62] and discrimination in the health care system.[46,63,64] Thus, previous studies of the present group have found that 50% of the cohort did not complete further education beyond primary and secondary school. Also, at the time of SRS, only 55% were employed[40] and 25% presented with psychiatric morbidity before and after SRS.[46]

For the second study aim (ie, cause of death and its relation to somatic morbidity), the study found that 9.6% of the cohort had died at an average age of 53.5 years, with the main cause of death related to smoking and alcohol abuse. The life expectancy of assigned women and men in Denmark is 81.9 and 78.0 years, respectively. Previous studies of mortality in transsexual individuals in countries comparable to Denmark[6,10] have found an increased risk of death in transsexual individuals. The present study had a lack of statistical power, and further long-term studies are needed to draw firm conclusions about transsexualism and increased risk of death.

Two individuals in the study group committed suicide 19 and 26 years after SRS, respectively. A Swedish study of SRS individuals (N = 324) found significantly increased mortality from suicide and significantly higher risk for suicide attempts compared with the general Swedish population.[6] A Dutch study (N = 1,109) of SRS and non-SRS individuals found a high incidence of attempted suicide and completed suicide in the study cohort compared with the general Dutch population.[31] An Italian study of 163 SRS MtF individuals found that four had attempted suicide before SRS and one had attempted suicide 12 to 18 months after SRS.[65] A Danish study reported death from suicide in 3 of 29 SRS MtF individuals (follow-up = 6 years).[32] Many explanations can be considered for suicide and attempted suicide. One might be regret for undergoing SRS,[32] but in the present study suicide occurred more than 19 years after SRS and therefore does not seem to be an immediate consequence of SRS. Because reasons for suicide attempts and manifest suicide often are multifactorial and because of the low incidence in the present study, further research is needed to contextualize these results further.

Limitations

The strength of this study is the unique cohort studied. Thus, on a national basis and over a 30-year period, 98% of all SRS individuals were included. This provides a unique opportunity to assess differences between MtF and FtM individuals on variables for somatic morbidity and mortality. The cohort included only individuals who received permission to undergo SRS during a period with strict criteria for obtaining permission to undergo SRS. Accordingly, the group is highly selected and might not reflect transsexuals per se in Denmark. Although we had a very large cohort for this type of study, some of our statistics had small cell sizes, limited numbers, and thus low statistical power, increasing the chances for type II errors. Because most somatic care in Denmark is provided by general practitioners, an underestimation of the prevalence of somatic morbidity in the study is plausible. Thus, somatic morbidity as presented in this study might be substantially higher.

CONCLUSION

Using a sample comprised of 98% of all individuals who underwent SRS in Denmark from 1978 through 2010, this study found somatic morbidity in 19.1% of the study group before and 23.2% after SRS. Mortality rates were 9.6%, with an average age at death of 53.5 years. No significant differences in somatic morbidity or mortality were found between MtF and FtM individuals. No firm conclusions can be drawn from the

present study, because the present study design does not allow for determination of causal relations between HT or SRS and somatic morbidity or mortality. One can speculate as to whether the increased risk of psychiatric problems and lifestyle issues in sexual minority groups influenced the risk of mortality and CVD in the present study. The findings underline the importance of supporting individuals with transsexualism to contact and be treated in the public health care system and to pay more attention to lifestyle issues in general.

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Exhibit K

IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF NORTH CAROLINA

MAXWELL KADEL, *et al.*, *Plaintiffs*, v. DALE FOLWELL, *et al.*, *Defendants*.	No. 1:19-cv-00272-LCB-LPA

EXPERT REBUTTAL REPORT OF DR. JOHANNA OLSON-KENNEDY, M.D., M.S.

1. My name is Johanna Olson-Kennedy. I have been retained by counsel for plaintiffs Maxwell Kadel, Jason Fleck, Connor Thonen-Fleck, Julia Mckeown, Michael D. Bunting, Jr., C.B., Sam Silvaine, and Dana Caraway (collectively, "Plaintiffs") as an expert in connection with the above-captioned litigation.

2. I have been asked by Plaintiffs' counsel to provide my expert opinion on gender identity, the treatment and diagnosis of gender dysphoria, particularly as it pertains to children and adolescents, and to respond to, rebut, and provide my expert opinion regarding the reports by Dr. Stephen R. Levine, Dr. Paul R. McHugh, Dr. Paul W. Hruz, and Dr. Patrick W. Lappert in this case.

3. I have actual knowledge of the matters stated herein. If called to testify in this matter, I would testify truthfully and based on my expert opinion.

I. BACKGROUND AND QUALIFICATIONS

4. I received my Doctor of Medicine (M.D.) degree from the Chicago Medical School in 1997. In 2000, I completed my residency in pediatrics at the Children's Hospital of Orange

align with one's gender, as well as later medical interventions after the onset of puberty, such as puberty blockers, hormones, or surgery. Because care is individualized, it also may not.

89. Dr. Levine asserts that there is a growing body of evidence that suggests that affirmation of gender diverse children results in a higher likelihood of persistence of gender incongruence. He cites an article entitled "The myth of persistence: Response to 'A critical commentary on follow-up studies and 'desistance' theories about transgender and gender non-conforming children'" by Temple Newhook et al. (2018) written by Ken Zucker. This is not a research article. It simply provides a rebuttal by Dr. Zucker to a previous manuscript. In it Dr. Zucker reviews some of the existing literature about persistence and desistance of gender incongruence among children over time. As previously noted, though, the studies upon which Dr. Zucker relies were based on the now obsolete and overly broad categorizations contained in the diagnosis for "Gender Identity Disorder in Children." None of the studies use the current DSM-5 "Gender Dysphoria in Children" diagnosis. Thus, the desistance rates of which Dr. Levine speaks include children who did not identify as transgender to begin with or would be considered "sub-threshold" for a Gender Dysphoria diagnosis. In addition, research shows that children who identify as transgender into adolescence, which is when any medical treatment begins, persist in their transgender identity. (de Vries, et al., 2011).

90. Dr. Levine attempts to create a causal relationship by asserting that gender affirmation (social transition specifically) in childhood *causes* children to continue to assert a gender incongruent with the sex they assigned at birth and that they would not have done so had they not undergone social transition. There is a failure to consider the clinical observation that children who end up socially transitioning are often experiencing the greatest distress about their gender incongruence, a discussed predictor of persistence. He presents an argument against

carrying out necessary investigations. The denial of much needed care only serves to harm transgender people.

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

Executed this 30th day of May, 2021.

Johanna Olson-Kennedy, M.D., M.S.

CERTIFICATE OF SERVICE

I hereby certify that on June 1, 2021, I caused a copy of the foregoing document and all attachments to be served upon the following parties via email:

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Exhibit L

Correction: Parent reports of adolescents and young adults perceived to show signs of a rapid onset of gender dysphoria

Lisa Littman

Published: March 19, 2019 • https://doi.org/10.1371/journal.pone.0214157

Notice of republication

After publication of this article [1], questions were raised that prompted the journal to conduct a post-publication reassessment of the article, involving senior members of the journal's editorial team, two Academic Editors, a statistics reviewer, and an external expert reviewer. The post-publication review identified issues that needed to be addressed to ensure the article meets *PLOS ONE*'s publication criteria. Given the nature of the issues in this case, the *PLOS ONE* Editors decided to republish the article, replacing the original version of record with a revised version in which the author has updated the Title, Abstract, Introduction, Discussion, and Conclusion sections, to address the concerns raised in the editorial reassessment. The Materials and methods section was updated to include new information and more detailed descriptions about recruitment sites and to remove two figures due to copyright restrictions. Other than the addition of a few missing values in Table 13, the Results section is unchanged in the updated version of the article. The Competing Interests statement and the Data Availability statement have also been updated in the revised version. The original version of the published article is appended to this Correction as S1 File.

This Correction Notice serves to provide additional clarifications and context for the article in response to questions raised during the post-publication review of this work.

Emphasis that this is a study of parental observations which serves to develop hypotheses

This study of parent observations and interpretations serves to develop the hypotheses that rapid-onset gender dysphoria is a phenomenon and that social influences, parent-child conflict, and maladaptive coping mechanisms may be contributing factors for some individuals. Rapid-onset gender dysphoria (ROGD) is not a formal mental health diagnosis at this time. This report did not collect data from the adolescents and young adults (AYAs) or clinicians and therefore does not validate the phenomenon. Additional research that includes AYAs, along with consensus among experts in the field, will be needed to determine if what is described here as rapid-onset gender dysphoria (ROGD) will become a formal diagnosis. Furthermore, the use of the term, rapid-onset gender dysphoria should be used cautiously by clinicians and parents to describe youth who appear to fall into this category. The term should not be used in a way to imply that it explains the experiences of all gender dysphoric youth nor should it be used to stigmatize vulnerable individuals. This article has been revised to better reflect that these parent reports provide information that can be used to develop hypotheses about factors that may contribute to the onset and/or expression of gender dysphoria among this demographic group.

Because this is a study of parent reports, there is some information about the AYAs that the parents would not have access to and the answers might reflect parent perspectives. Examples where parent answers reflect their perspective of the AYA include answers concerning the child's mental well-being, the parent-child relationship, and whether the child has high expectations about transitioning. However, it is also important to note that there are other survey items where the parent would have direct access to information about their child and that those answers reflect items that can be directly observed. Examples of this type include age, natal sex, diagnoses given by medical providers in the presence of the parent, directly observed behaviors of the child and the child's friend group, school performance, whether the child has dropped out or required a leave of absence from school, has been unable to hold a job, whether the child went to a clinic, or received treatment. Readers are reminded to keep in mind that this is a study of parent report and consideration of what information parents may or may not have access to is an important element of the findings.

Questions on whether the article describes adolescent-onset gender dysphoria or if it describes something new

There is some controversy over whether what is described as rapid onset of gender dysphoria, particularly in natal females, falls under the existing definition of late-onset or adolescent-onset gender dysphoria or whether it represents a new kind of development or presentation. This controversy might be a false dichotomy because both might be true. Although recent observations of adolescents and young adults who are predominantly natal female having a sudden onset of gender dysphoria symptoms beginning during or after puberty might technically fall under the existing definitions and criteria for adolescent and adult gender dysphoria [2], the substantial change in the demographics of patients presenting for care, the inversion of the sex ratio with disproportionate increase in adolescent natal females [3–5], and the new phenomenon of natal females exhibiting adolescent-onset and late-onset gender dysphoria [6–8] signal that something new may be happening as well. These changes may indicate that there are new etiologies leading to gender dysphoria and it is unclear, particularly without research about these new populations, whether gender dysphoria in this context has the same outcomes, desistence and persistence rates, and response to treatment as the gender dysphorias that have been previously studied.

Expanded discussion of qualitative analyses

Because this is a descriptive, exploratory study into a new topic with very little existing data, the addition of the qualitative analysis of two questions in addition to the quantitative analysis allowed for a greater depth of information to be used in the development of hypotheses. A grounded theory approach was selected as the strategy of choice for handling the qualitative data. There were two reviewers consisting of a professor with a PhD degree and expertise in qualitative methods (MM) [9] and the author (LL) who holds an MD and MPH degree, and has published both qualitative and quantitative research papers [10–11]. Each reviewer independently read and re-read the open-text responses in an iterative process to identify major themes arising from the data. Once each reviewer independently listed major themes and coded the open-text responses according to those themes, both reviewers compared notes to collaboratively revise and refine the major themes identified. Once an agreed-upon final list of themes was developed, attention was turned back to the data to code the open-text response with the final list of themes. After this task was completed, LL selected salient quotes to reflect each major theme, shared the quotes with MM, and both discussed collaboratively until agreement for the final list of major themes and associated quotes was reached. The incorporation of both the qualitative and quantitative analysis allowed for a more vivid picture of parent perspectives about the friendship group dynamics and behaviors and clinician interactions than could have been obtained from just one type of analysis.

Clarification of study design, methods, and related limitations

As mentioned in the article, the study design of this research falls under descriptive research: as such, it did not assign an exposure, there were no comparison groups, and the study's output was hypothesis-generating rather than hypothesis-testing [12]. Descriptive studies often represent a first inquiry into an area of research and the findings of descriptive studies are used to generate new hypotheses that can be tested in subsequent research [12–13]. Because of the known limitations of descriptive studies, claims about causal associations cannot be made [12], and there were none made in the article. The conclusions of the current study are that the findings raise certain hypotheses and that more research is needed. Simple descriptive metrics to describe the quantitative characteristics of a sample in a descriptive study are the appropriate measures to use in this study. Additionally, because the data were collected at one point in time, no claims of cause and effect can be made.

All research methods have advantages and limitations. Obtaining information from parents (and guardians) about the health and well-being of children and adolescents is an established method of research [14]. Parental report, used elsewhere and in this study, offers the advantages of collecting data from adults who are knowledgeable about the child, who are able and willing to complete research activities such as detailed surveys, and who can provide details that are not available by other methods. Limitations of parental report include information that parents may not be aware of and parental biases. Anonymous surveys, used elsewhere and in this study, are advantageous for topics that might be stigmatized and can allow participants to be more honest in their responses but introduce the limitation that the researcher cannot verify the identity and experiences of the participants. The use of targeted recruitment and convenience samples, used elsewhere and in this study, offers the benefit of connecting with hard-to-reach populations but introduces limitations associated with selection bias that can subsequently be addressed by further studies. For the current study, selection bias may have resulted in findings that are more positive or more negative than would be found in a larger and less self-selected population. Subsequent studies should address these issues.

Updated Information about recruitment

Concerns were raised that this study only posted links to the recruitment information on selected sites that are viewed as being unsupportive of transition. However, announcements about the study included requests to distribute the recruitment information and link, and because information about where the participants encountered the announcement was not collected, it is not known which populations were ultimately reached. It has come to light that a link to the recruitment information and research survey was posted on a private Facebook group perceived to have a pro-gender-affirming perspective during the first week of the recruitment period (via snowball sampling). This private Facebook group is called "Parents of Transgender Children" and has more than 8,000 members. This means that parents participating in this research may have viewed the recruitment information from one of at least four sites with varied perspectives. Specifically, three of the sites that posted recruitment information expressed cautious or negative views about medical and surgical interventions for gender dysphoric adolescents and young adults and cautious or negative views about categorizing gender dysphoric youth as transgender. And, one of the sites that posted recruitment information is perceived to be pro-gender-affirming. The rest of the Correction notice will refer to recruitment from the four sites that are known to have posted the survey in the first week of recruitment: 4thwavenow, transgendertrend, Youth Trans Critical Professionals, and Parents of Transgender Children.

Parental approaches to gender dysphoria and views on medical interventions

To oversimplify parental approaches as simply "accepting" or "rejecting" misrepresents the range of responses and complexity of approaches that parents take when addressing the needs of their gender dysphoric children. Parental approaches are complex and cover many variables. For example, one parental approach might be to affirm the child as a person, support gender nonconformity, support gender exploration, support mental health evaluation and treatment as needed, support the exploration of potential underlying causes for the dysphoria while expressing caution about medical interventions. Another approach might be to affirm the child's newly declared gender identity, support gender nonconformity, support a liberal approach to medical intervention while expressing caution about mental health evaluation and caution about the exploration of potential underlying causes for the dysphoria. To categorize the former as "rejecting" and the latter as "accepting" would be inaccurate.

This study recruited participants based on whether participants thought their child exhibited a sudden or rapid onset of gender dysphoria beginning during or after puberty and did not recruit based on parental beliefs about what types of approaches toward gender dysphoric AYAs are best. Although one of the sites posting recruitment information might be considered to hold a pro-gender affirming perspective and three sites might be considered to hold a cautious or even negative perspective about medical or surgical interventions, the site where a participant first heard about the study may not be an accurate reflection of their beliefs and whether they endorse or disagree with the content of the websites. Data about where participants first heard about this study were not collected. Future studies should seek a wider array of websites to post recruitment information, recruit from clinicians with varied approaches to gender dysphoria, and ask specific questions about parental beliefs regarding their approach to their child's gender dysphoria, including: whether parents support or don't support gender exploration, gender nonconformity, mental health

evaluation and treatment, exploration of potential underlying causes for dysphoria, non-heterosexual sexual identity, and whether they hold a liberal, cautious or negative view about the use of medical and surgical interventions for gender dysphoric youth. Exploration about what types of affirmation are endorsed by parents including affirmation of the child as a person and affirmation of the child's gender identity would also be valuable.

Expanded discussion about limitations and biases

Regarding the reporting of gender dysphoria, an absence of childhood gender dysphoria and whether the AYA was gender dysphoric at the time of survey completion were based on parent report of whether certain indicators of gender dysphoria were observed prior to puberty or at the time of the survey. These determinations were not diagnoses made by clinicians. Three of the indicators listed in the DSM-5 include information that a parent might not have access to (unless the child told them directly) [2], and therefore answers based on parent perceptions may not accurately reflect the experiences or traits of the AYAs themselves. However, the other five indicators include readily observable behaviors and preferences that would seem difficult for a parent not to notice such as: strong preference or strong resistance to wearing certain kinds of clothing; strong preference or strong rejection of specific toys, games and activities; and strong preference for playmates of the other gender [2]. It is possible that a parent could have ignored some of these indicators, though other people in the child's life may have observed them. To improve the reliability of this measure, future studies should include evaluation from clinicians with input from parents, AYAs and from third party informants such as teachers, pediatricians, mental health professionals, babysitters, and other family members who knew the youth during childhood to verify the whether the readily observable behaviors and preferences were present or absent during childhood.

For a clinician to make a diagnosis of gender dysphoria in childhood, a child would need to exhibit at least six of the eight indicators. Given that 97.6% of the participants reported 2 or fewer readily observable indicators, even if hypothetically all participants incorrectly under-reported all three of the subtler indicators, 97.6% would still have fewer than six indicators. So, although no clinical evaluation was performed and a clear presence or absence of a diagnosis cannot be verified, given the reports of the easily observed behaviors and preferences, it can be said that it would be very unlikely for these AYAs to have met criteria for childhood gender dysphoria if they had seen a clinician for an evaluation.

There is expected variation in how objective parents can be about their own children. Some individual biases may limit the objectivity of parents. This descriptive study was not designed to explore or measure the objectivity of participants. Participants may have first learned about this study from one of four (or more) sites described previously where recruitment information was posted. It is possible that exposure to websites that take a cautious or negative approach to transition during adolescence and young adulthood and exposure to websites that take a pro-gender-affirming approach might influence how parents report about their children's experiences. There have not been any studies to determine if parents who seek information from online sites in general, don't seek information from online sites, or seek information from specific online sites, including the four sites noted for this study, differ in their ability to provide objective assessments of their children. However, if there were an excess of participants who, compared to other parents who take surveys reporting on their children, were less able to be objective about their children, it could limit some of the findings of the study, particularly for findings that are more interpretive rather than the findings that are more concrete.

The research survey did not specifically ask whether parents supported their AYAs' exploration of gender identity, so whether and what numbers of participants supported their child's exploration of gender identity is unknown. However, if there were an excess of parents who did not support the exploration of gender identity, it could potentially result in higher reports of declining mental health. The parents' perception that their child's mental health and the parent-child relationship were worse after the child announced a transgender-identification could be due to several variables such as conflict between parent and child, maladaptive coping mechanisms, or worsening psychiatric issues unrelated to gender. The trajectories for adolescent-onset gender dysphoria are not well understood and additional research is desperately needed.

There are many ways that parents can provide support for their child which include: affirming them as a unique and valuable person and as a loved member of the family; supporting their emotional and financial needs; supporting them in pursuing their interests; supporting them to develop the skills needed for self-sufficiency; supporting their choices of gender nonconforming clothing and interests; supporting their exploration of their identity; and supporting them in their critical thinking skills. Parental support is multifaceted and should not be oversimplified into a binary of whether a parent agrees or disagrees with a specific medical course. This study was not designed to measure different types of support provided by parents or levels of support. If there were an excess of parents who were unsupportive of their children, it might affect some of these initial findings. The nature and extent of parental support—including the many different ways that parents can support their children in becoming healthy, self-sufficient adults—is well worth further study.

Clarification of Fig 1

The purpose of Fig 1 was to provide the reader with a quick sense of what kinds of advice can be found and shared on Reddit and Tumblr. One example includes an excerpt from a publicly available Tumblr blog that posted a list of purported indirect signs of gender dysphoria. This excerpt is indeed an example of advice that can be found on Tumblr. Note, however, that the excerpted Tumblr post itself does not reflect the full content of the original blog it refers to, nor does the excerpt in Fig 1. The original blog is titled, "'That was dysphoria?' 8 signs and symptoms of indirect gender dysphoria" [15].

Discussion of the ICD-11 change from "gender dysphoria" to "gender incongruence"

The ICD-11 will go into effect in January 2022, and, with this change, the new diagnosis of "gender incongruence" will replace "gender dysphoria." Because the current descriptive, exploratory study raises hypotheses about factors that may contribute to the onset and/or expression of gender dysphoria and concludes that more research is needed, it is unlikely that the change in diagnostic criteria will appreciably change the conclusion of the study, although the terminology may become outdated.

Supporting information

S1 File. PDF of the original article version that was published on August 16, 2018 (two figures removed due to copyright restrictions).
https://doi.org/10.1371/journal.pone.0214157.s001
(PDF)

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Exhibit M

Journal Pre-proof

Do Clinical Data From Transgender Adolescents Support the Phenomenon of "Rapid-Onset Gender Dysphoria"?

Greta R. Bauer, PhD, MPH, Margaret L. Lawson, MD, MSc, FRCPC, Daniel L. Metzger, MD, FAAP, FRCPC, for the Trans Youth CAN! Research Team

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Title: **Do Clinical Data From Transgender Adolescents Support the Phenomenon of "Rapid-Onset Gender Dysphoria"?**

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Abbreviations: ; OASIS = Overall Anxiety Severity and Impairment Scale; MDS = Modified Depression Scale; K6 = Kessler-6 Scale; TYC-GDS = Trans Youth CAN! Gender Distress Scale

Although emergence of gender dysphoria at puberty is long established, a distinct pathway of "rapid onset gender dysphoria" (ROGD) was recently hypothesized based on parental data. Using adolescent clinical data, we tested a series of associations that would be consistent with this pathway, however our results did not support the ROGD hypothesis.

Puberty has long been understood as one period when gender dysphoria often first emerges.(1) Although most transgender (trans) older adolescents and adults report needing gender-affirming medical care (hormones and/or surgeries), and also report having been aware of their gender at young ages,(2) only a small proportion receive gender-affirming care as adolescents. Use of hormonal suppression with a gonadotropic-releasing hormone agonist (GnRHa), and hormones such as estrogen and testosterone therapies in trans and gender-diverse adolescents is supported by the American Academy of Pediatrics, the Pediatric Endocrine Society, the Endocrine Society, and the World Professional Association for Transgender Health.(1,3–5) Referrals to adolescent gender clinics have increased internationally, particularly among those assigned female at birth.(6–9)

In 2018, a phenomenon of "rapid onset gender dysphoria" or "ROGD" was hypothesized as a distinct pathway involving social contagion among youth vulnerable due to mental or neurodevelopmental disorders,(10–12) raising public concerns regarding potential for later regret following gender-affirming medical care. This discussion has occurred primarily in the context of data from a single online parental survey.(10,11) Although this parental study has generated controversy,(13) methodological and social critique,(12,14,15) and calls for additional research,(16,17) its hypotheses have not yet been tested on data from youth themselves. Specifically, ROGD is hypothesized as a phenomenon in youth with gender dysphoria emerging

at or after puberty, socially influenced through peer contagion, and with contributing factors including poor mental health, neurodevelopmental disabilities, parent-child conflict, and maladaptive coping strategies.(10,11)

If the "ROGD" hypothesis indeed characterizes a distinct clinical phenomenon, and these youth access referrals for hormone suppression or gender-affirming hormones, then we would expect to see differentiation within clinical samples between those with more-recent (ie, "rapid-onset") vs. more-remote knowledge regarding their gender. Based on the published hypothesis,(10) we would expect more recent gender knowledge to be associated with self-reported mental health measures, mental health and neurodevelopmental disability diagnoses, behaviors consistent with maladaptive coping (e.g. self-harm), support from online and/or transgender friends but not parents, and lesser gender dysphoria. We aim to test these hypotheses.

Methods

Baseline data (2017–2019) from the Trans Youth CAN! Cohort included pubertal/postpubertal adolescents aged <16 attending a first referral visit for hormone suppression or gender-affirming hormones at 10 Canadian medical clinics that provide specialized gender-affirming care to adolescents through a range of different care models. Ethics approval was received from all study sites. Years gender was known was missing for one participant (excluded), for a final sample of n=173. Methods and measures are described in detail elsewhere.(18)

Self-reported measures were obtained from baseline interviewer-administered adolescent surveys,(19) and diagnoses from baseline clinical records.(20) *Recent gender knowledge* was

coded by subtracting age in years from age adolescents self-reported they "realized your gender was different from what other people called you". As ages were whole numbers, a difference of 1 could indicate <1 year to just under 2 years. Values ≤1 were coded as recent gender knowledge, with an alternate definition (values ≤2) for sensitivity analysis. *Mental health symptoms* were assessed with the Overall Anxiety Severity and Impairment Scale (OASIS),(21) the Modified Depression Scale (MDS),(22) and the Kessler-6 (K6) scale for psychological distress.(23) *Mental health diagnoses* extracted from chart included anxiety, depression, personality disorder, eating disorder, and *neurodevelopmental disorder diagnoses* included autism, obsessive compulsive disorder, or attention deficit hyperactivity disorder. *Gender dysphoria symptoms* were assessed using the Trans Youth CAN! Gender Distress Scale (TYC-GDS).(24) Self-reported *mental health behaviors* included self-harm, substance use, and suicidal behavior. Three measures captured *social connections* to online and trans communities: having gender-supportive online friends was coded if adolescents reported online friends who knew their gender and were "very supportive", and having online or trans friends as general sources of support was indicated in checklist items. *Parental support* was coded if youth indicated all biological/step/foster parents were "very supportive" of their gender identity or expression.

Statistical analyses were conducted using SAS version 9.4.1, weighted to account for clinics' different recruitment periods due to staggered start dates, to improve generalizability.(18) For analyses of associations between recency of gender knowledge and hypothesized correlates, a series of multiple regressions was conducted, with recency as the independent variable of interest, controlling for age and sex assigned at birth. Linear regressions were used for continuous dependent variables (e.g., psychometric scales). For dichotomous dependent variables, modified Poisson regression with robust variance estimation was used.(25)

As "rapid-onset" has not been precisely defined, we conducted a sensitivity analysis repeating these analyses using the alternate (value ≤2) definition of recent gender knowledge.

Results

Recency of gender knowledge is presented in the Figure, results of hypothesized associations (recency value ≤1) in Table I, and variable means and frequencies in Table II (available at www.jpeds.com). Controlling for age and sex assigned at birth, recent gender knowledge was not significantly associated with depressive symptoms, psychological distress, past diagnoses with mental health issues or neurodevelopmental disorders, gender dysphoria symptoms, self-harm, past-year suicide attempt, having gender-supportive online friends, general support from online friends or transgender friends, or gender support from parents. Recent gender knowledge was associated with lower scores on anxiety severity/impairment (b= −3.272; 95% CI: −5.172, −1.373), and lower prevalence of marijuana use (PR=0.11; 95% CI: 0.02, 0.82), counter to hypothesized directions of effect. For sensitivity analysis using the alternate (value ≤2) definition of recent gender knowledge, we found all results substantively the same in statistical significance and direction of effect, except past-year marijuana use, which now only approached statistical significance (p=0.0677).

Discussion

We did not find support within a clinical population for a new etiologic phenomenon of "ROGD" during adolescence. Among adolescents under age 16 seen in specialized gender clinics, associations between more recent gender knowledge and factors hypothesized to be involved in ROGD were either not statistically significant, or were in the opposite direction to

what would be hypothesized. This putative phenomenon was posited based on survey data from a convenience sample of parents recruited from websites,(10) and may represent the perceptions or experiences of those parents, rather than of adolescents, particularly those who may enter into clinical care. Similar analyses should be replicated using additional clinical and community data sources. Our finding of lower anxiety severity/impairment scores in adolescents with more recent gender knowledge suggests the potential for longstanding experiences of gender dysphoria (or their social complications) playing a role in development of anxiety, which could also be explored in future research.

Acknowledgment: The Trans Youth CAN! Study Team thank the trans youth and their families who have generously shared their time and experience with us. We acknowledge the contributions of the local site teams to participant recruitment, in particular the team of research assistants involved in data collection.

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Figure 1. Recency of gender knowledge among adolescents age <16 referred to Canadian clinics for hormone suppression or gender-affirming hormones (n=173). Age at which knew gender was different was subtracted from current age in years; thus, “2 years” could range from more than 1 year to less than 3 years. Lighter gray represents recent gender knowledge in this analysis, with a sensitivity analysis also including the patterned bar.

Table 1. Associations between short-term awareness of gender and variables hypothesized to be associated with "rapid-onset gender dysphoria," controlling for age and sex assigned at birth

Dependent variable	B [a]	SE	p	PR [a]	95% CI [b]
Mental health scales					
Anxiety severity/impairment (OASIS)	-3.272	0.961	0.0008		(-5.172 -1.373)
Depressive symptoms (MDS)	-1.276	0.845	0.1328		(-2.944, 0.392)
Psychological distress (K6)	-1.156	1.060	0.2771		(-3.248, 0.936)
Record of diagnosis with mental health disorder [c]	-0.509	0.315	0.1059	0.60	(0.32, 1.11)
Record of diagnosis with neurodevelopmental disorder [d]	0.066	0.362	0.8563	1.07	(0.52, 2.17)
Gender dysphoria/distress (TYC-GDS)	-0.193	0.122	0.1139		(-0.434, 0.047)
Mental health related behaviors					
Self harm, past year	-0.052	0.191	0.7833	0.95	(0.65, 1.38)
Marijuana use, past year	-2.178	1.010	0.0310	0.11	(0.02, 0.82)
Past-year suicide attempt	-0.592	0.785	0.4505	0.55	(0.12, 2.58)
Social connection indicators [e]					
Reports having online friends supportive of gender	-0.050	0.157	0.7505	0.95	(0.70, 1.29)

Indicates online friends as source of general support	-0.223	0.286	0.4366	0.80	(0.46, 1.40)
Indicates trans friends as source of general support	-0.049	0.298	0.1016	0.61	(0.34, 1.10)
All parents supportive of gender identity/expression	-0.004	0.202	0.9836	1.00	(0.67, 1.48)

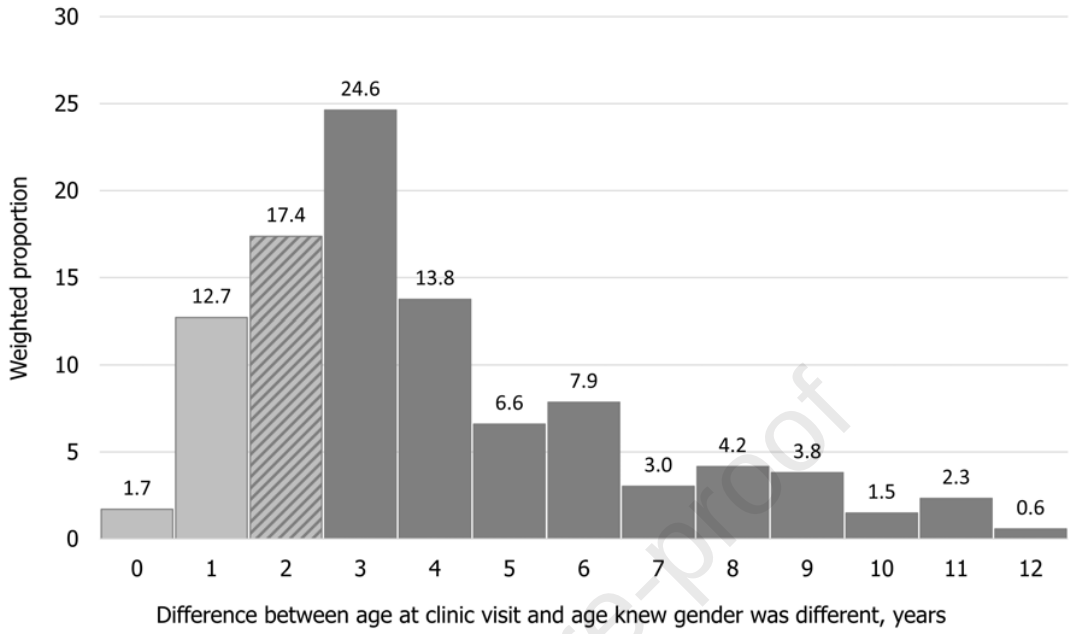
a. Estimates adjusted for age in years and sex assigned at birth. B = beta, regression parameter estimate; PR = prevalence ratio.

b. 95% confidence intervals for betas (for linear regressions) or PRRs (for modified Poisson regressions)

c. Extracted from medical record: any diagnosis from clinic or referrer of anxiety, depression, personality disorder, eating disorder. Personality disorder diagnoses were uncommon (n=2) and no youth had a record of eating disorder diagnosis.

d. Extracted from medical record: any diagnosis from clinic or referrer of attention deficit hyperactivity disorder (ADHD), obsessive compulsive disorder (OCD), or autism.

e. Hypothesized by other authors based on a survey of parents recruited from websites generally unsupportive of gender-affirming care.(10)



Appendix

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Online content to accompany the following Brief Report:

Bauer GR, Lawson ML, Metzger DL, for the Trans Youth CAN! Research Team. Do clinical data from transgender adolescents support the phenomenon of "rapid-onset gender dysphoria"? *Journal of Pediatrics*, 2021.

Online Table 2.
Weighted frequencies or means for sociodemographic and study variables (n=173)

Variable	Value
Age, n (%$_w$)	
10–11 years	17 (8.5)
12-13 years	37 (22.6)
14–15 years	119 (68.9)
Ethnoracial background,[a] , n (%$_w$)	
Indigenous	33 (18.4)
Non-Indigenous visible minority [b]	10 (6.6)
Non-Indigenous white	128 (75.0)
Immigration background, n (%$_w$)	
1 or more immigrant parent	126 (28.7)
No immigrant parents	44 (71.3)
Living environment, n (%$_w$)	
City	87 (55.2)
Suburb	59 (33.9)
Rural	27 (10.9)
Gender identity, n (%$_w$)	
Male or primarily a boy	125 (75.7)
Female or primarily a girl	32 (15.9)
Non-binary [c]	14 (8.3)
Mental health scales, mean$_w$ (SD)	
Anxiety severity/impairment (OASIS)	8.842 (4.548)
Depressive symptoms (MDS)	15.077 (4.030)
Psychological distress (K6)	10.746 (5.100)
Record of diagnosis with mental health disorder,[d] n (%$_w$)	92 (51.6)
Record of diagnosis with neurodevelopmental disorder,[e] , n (%$_w$)	44 (25.9)
Gender dysphoria/distress (TYC-GDS), mean$_w$ (SD)	4.048 (0.557)
Mental health related behaviors, n (%$_w$)	
Self harm, past year	110 (67.9)
Marijuana use, past year	29 (20.0)
Past-year suicide attempt	24 (16.9)
Social connection indicators,[f] n (%$_w$)	
Reports having online friends supportive of gender	109 (69.9)
Indicates online friends as source of general support	79 (49.3)
Indicates trans friends as source of general support	92 (55.8)
All parents supportive of gender identity/expression	109 (61.8)

a. Coded to match Statistics Canada categories of Indigenous, visible minority, and white. Non-white, Non-Indigenous ethnoracial backgrounds were indicated by the following numbers of participants: 6 Black Canadian or African-American, 2 Black African, 4 Latin American, 4 East Asian, 1 Indo-Caribbean, 3 Black Caribbean, 1 Middle Eastern, and 1 Southeast Asian (participants could indicate more than one).
b. The Canadian government defines visible minorities as "persons, other than Aboriginal peoples, who are non-Caucasian in race or non-white in colour".(1)
c. Response option was "non-binary or something other than male or female".
d. Extracted from medical record: any diagnosis from clinic or referrer of anxiety, depression, personality disorder, eating disorder. Personality disorder diagnoses were uncommon (n=2) and no youth had a record of eating disorder diagnosis.
e. Extracted from medical record: any diagnosis from clinic or referrer of attention deficit hyperactivity disorder (ADHD), obsessive compulsive disorder (OCD), or autism.
f. Hypothesized by other authors based on a survey of parents.(2)

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Exhibit N

Deposition of:

Dr. Paul McHugh

September 8, 2021

In the Matter of:

Kadel, et al vs. Folwell

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IN THE UNITED STATES DISTRICT COURT FOR
THE MIDDLE DISTRICT OF NORTH CAROLINA

* * * * *

MAXWELL KADEL, et. al., *
Plaintiffs * Case No.:
vs. * 1:19-CV-00272-LCB-LPA
DALE FOLWELL, et.al., *
Defendants *

* * * * *

Remote videotaped deposition of PAUL McHUGH, M.D., was taken on Wednesday, September 8, 2021, commencing at 9:40 a.m., before Allison L. Shearer, RPR, a Notary Public.

Reported By: Allison L. Shearer, RPR

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A. Well, I don't think so. It might have been something that I thought.

Q. Okay. Is it a term -- is the term Transgender Treatment Industries a term that is commonly used and accepted within the scientific community?

A. I don't think so. As I say, it's probably just mine.

Q. Is the term Transgender Treatment Industry a term that is commonly used and accepted within the medical community?

A. No, I -- I don't suppose so.

Q. Is there a peer-reviewed article or study you can point me to that utilizes the term Transgender Treatment Industry?

A. No, I -- I couldn't do that for you. No.

Q. I'll be honest. I never encountered this term until I saw your report and that of your colleagues in this case. So...

A. It -- it's okay.

Q. So I have questions because I, myself --