IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF NORTH CAROLINA
CHARLOTTE DIVISION
No. 3:22-cv-191

KANAUTICA ZAYRE-BROWN, Plaintiff, v. NORTH CAROLINA DEPARTMENT OF ADULT CORRECTION, et al., Defendants.	**APPENDIX TO DEFENDANTS' RESPONSE TO PLAINTIFF'S MOTION FOR PARTIAL SUMMARY JUDGMENT** **(Hearing Requested)**

NOW COME Defendants to respectfully submit this Appendix with Exhibits to their Response to Plaintiff's Motion for Partial Summary Judgment.

Exhibit	Description
1	Expert Report of Sara E. Boyd, Ph.D., dated July 5, 2023
2	Medical Records (DAC 738-739, 741-742, 747-749, 753-755, 875)
3	Medical Records (DAC 724-725, 730-731, 734-736)
4	May 2021 Emails (DAC 4127-4130, 4447)
5	Excerpts of the deposition of Brian Sheitman, M.D., taken on May 17, 2023: Pages 27-29, 35, 44, 49-50, 56-65, 70-72, 84, 94-97, 109-111, 113-121, 131-132, 143-144
6	Excerpts of deposition transcript, Terri Catlett, taken on May 18, 2023: Pages 44-46, 61-64, 73-76
7	Excerpts of the deposition of Arthur Campbell, M.D., taken on April 18, 2023: Pages 79-82
8	Medical Records (DAC 2692-2696; PLAINTIFF0004)
9	Excerpts of the deposition of Gary Junker, PhD, taken on May 4,2023: Pages 224-228
10	Excerpts of deposition transcript, Joseph V. Penn, M.D., taken on August 8, 2023: Pages 55-56, 71-72, 84-87
11	Excerpts of the deposition of Lewis Peiper, Ph.D., taken on May 1, 2023: Pages 89-92
12	Excerpts of deposition transcript, Sara E. Boyd, Ph.D., taken on August 4, 2023: Pages 80-120, 156-170
13	Expert Report of Joseph V. Penn, M.D. dated July 5, 2023

14	Excerpts of the deposition of Marvella Bowman, Ph.D., taken on June 29, 2023: Page 119
15	Expert Report of Fan Li, Ph.D., dated June 17, 2023:
16	Excerpts of deposition transcript, Fan Li, Ph.D., taken on August 11, 2023: Pages 24-45, 51-70, 100-147, 150-160
17	Excerpts of 30(b)(6) deposition of Arthur Campbell, M.D., on behalf of the North Carolina Department of Adult Correction, taken on April 18, 2023: Pages16-35, 69-72

This the 19th day of October 2023.

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THE UNITED STATES DISTRICT COURT
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NO. 3:22-cv-191

KANAUTICA ZAYRE-BROWN, Plaintiff, v. NORTH CAROLINA DEPARTMENT OF PUBLIC SAFETY, et al., Defendant.	)	**EXPERT REPORT OF SARA E. BOYD, PH.D., ABPP**

I. Scope of Engagement

I have been engaged by attorneys from the North Carolina Department of Justice who are representing the defendants in the matter of *Kanautica Zayre-Brown v. North Carolina Department of Adult Correction, et al.*, Case No. 3:22-cv-191, which is currently pending in the United States District Court for the Western District of North Carolina. For my work on this case, I am charging $300.00 per hour for all in-office services that I render, $375.00 per hour for out-of-offices, and $450.00 per hour for preparing for and providing deposition or in-court testimony.

II. Summary Statement of Qualifications

I, Sara E. Boyd, am a licensed clinical psychologist with experience conducting forensic mental health assessments of transgender and gender diverse people in correctional settings. As a psychologist specializing in forensic mental health assessments, I have conducted more than 100 evaluations of incarcerated people housed in state and federal prisons and jails. In particular, I have conducted independent psychological evaluations related to gender-affirming care for incarcerated individuals. In that capacity, my role is to evaluate incarcerated individuals with respect to their capacity to provide informed consent to gender-affirming interventions, to describe the nature and

severity of their Gender Dysphoria (if present), to offer recommendations with respect to gender-affirming interventions or building capacity to provide informed consent, and identify any co-occurring psychological disorders that may require more active management or integration into treatment planning for gender-affirming interventions. As I am a psychologist and not a physician, I am not asked to and do not assess whether a particular intervention is medically necessary for a given patient.

Additionally, in a filing opposing a motion filed by defense counsel, Plaintiff's counsel incorrectly implied that my experience in conducting Gender Dysphoria evaluations has been limited to a one-year period. (*See* DE-39 at 14) The year long period, to which Mrs. Zayre-Brown's counsel refers, appears to be a reference to a specific post-doctoral fellowship that I completed at the University of Virginia. After completing that fellowship, I have continued to conduct Gender Dysphoria evaluations of individuals in the community and in carceral settings. These evaluations have included independent external evaluations of transgender individuals seeking gender-affirming interventions and accommodations in the Virginia Department of Corrections. I have also conducted presentence evaluations of transgender individuals, and when relevant, I identify recommendations for supportive treatment and protection of transgender individuals in prison settings.

I am also the co-author of a book chapter (in press) concerning psychological evaluation, management, and treatment of transgender and gender diverse people housed in correctional settings. Additionally, I am a diplomate of the American Board of Professional Psychology, for the Forensic Specialty. This board-certification requires credential review, a written exam, work sample review, and a three hour-duration oral defense of work samples.

For a more detailed statement of my education and experience, see the first three paragraphs of my earlier declaration. Additionally, see DE-18-6, and DE-18-7, which is my CV, both of which have been filed in this case, and which I incorporate herein by reference. Additionally, attached as Appendix A, is a list of the cases in which I have testified as an expert over the past four years.

III. Summary of Opinions

In this report I provide four primary opinions and conclusions. These opinions and conclusions are based on my education, training, and experience, and are stated to, at a minimum, a reasonable degree of psychological certainty.[1] First, the opinions and conclusions of Dr. Ettner are undermined by multiple deficiencies in Dr. Ettner's assessment, including the failure to apply an informed consent approach, the absence of a discussion of expectancies, and the lack of a robust discussion of Mrs. Zayre-Brown's mental state. Second, a clinical psychologist cannot reasonably predict with confidence that a particular intervention will be curative of a condition such as Gender Dysphoria which has a diverse manifestation and is inextricably bound up in aspects of a person's life and circumstances that go far beyond the physical appearance of their genitals. Thus, Dr. Ettner's opinion in this regard lacks sufficient basis and is misleading. Third, my evaluation of Mrs. Zayre-Brown did not reveal any significant findings in her mental state that would counsel in favor of the surgery as an immediate intervention, to be conducted in a prison setting, from a psychological standpoint. Fourth, the source of Mrs. Zayre-Brown's Gender Dysphoria appears

[1] A "reasonable degree of psychological certainty" is a somewhat controversial terminology within my field, with the primary critique being that the terminology is vague. My general practice, in response to the limitations of "reasonable degree of psychological certainty," is to be specific when there is doubt or other likely candidate explanations (or diagnoses) that could apply, and to note the limitations of any procedures and opinions (for example, if my opinion is only offered with confidence regarding a particular period of time).

multifaceted, with psychosocial, cultural, identity, environmental, and interpersonal factors, and the psychological benefits of gender-affirming interventions for Mrs. Zayre-Brown are significantly dependent on the setting where she is residing. In other words, the degree and timing of psychological symptom alleviation she is likely to experience is dependent in part on factors other than the surgery itself.

IV. Dr. Ettner's Opinions are Undermined by Significant Deficiencies in her Assessment

I have reviewed both of Dr. Ettner's declarations (DE-13-1 and 22-1) as well as her expert report dated on February 3, 2023. After review of these materials, I have multiple concerns regarding Dr. Ettner's conclusions and opinions. First, without presenting any medical credentials, Dr. Ettner offers opinions to a "reasonable degree of medical certainty." Furthermore, Dr. Ettner's assessment of Mrs. Zayre-Brown appears lacking in multiple ways.

A. Dr. Ettner's Opinions Exceed the Scope of Her Expertise

Dr. Ettner CV indicates that she is a clinical and forensic psychologist. Dr. Ettner's CV also lists her education, which includes a Bachelor of Arts degree, a Master of Arts degree, and Ph.D., in psychology. Dr. Ettner does not describe any medical education or training.[2] Nor does Dr. Ettner describe any professional medical experience. Additionally, Dr. Ettner does not list any medical certifications or licensures in her CV. Based on this, it is my understanding that Dr. Ettner is not a Medical Doctor, Doctor of Osteopathic Medicine, Nurse Practitioner, or Physician's Assistant.

[2] Dr. Ettner's CV does list "Medical staff; Department of Medicine: Weiss Memorial Hospital, Chicago, IL" among as one of the positions held. However, the CV offers no details as to what that position entailed. Based on the lack of any medical credentials, licenses, education, or training, being listed, I am assuming that this position was not held in the capacity of a physician or medical doctor.

Despite Dr. Ettner being a psychologist and not a medical provider, she states that "the opinions [she] hereafter render[s] are reliable and valid to a reasonable degree of medical certainty." DE-13-1 ¶ 82; Ettner Report ¶ 86. Additionally, throughout her declarations and in her report, Dr. Ettner repeatedly and consistently opines that surgical intervention is medically necessary in this case. These opinions appear to overstep the bounds of competence for a psychologist, to the extent that Dr. Ettner offers medical opinions without the requisite credentials.

I, just as Dr. Ettner, am a clinical and forensic psychologist. And, I, just as Dr. Ettner, perform evaluations of transgender individuals seeking gender-affirming interventions and accommodations. However, unlike Dr. Ettner, I do not offer medical conclusions or opinions. Thus, my role in such cases is not to make determinations regarding whether a person should or should not receive a given intervention. Nor is it my role in performing such evaluations to offer opinions as to the medical necessity of such interventions. Instead, I use an informed consent approach to evaluate: (i) a person's capacity to consent to a particular intervention; (ii) a person's fund of relevant knowledge; (iii) the presence and severity of symptoms which may be related to Gender Dysphoria; and (iv) any potential need for accommodations if a disability is present, or coordinated treatment or additional evaluation if other mental disorders (aside from Gender Dysphoria) are present. I know other psychologists, like Dr. Ettner and I, who also perform similar evaluations related to gender-affirming care for transgender and gender non-conforming individuals, and in my experience, it would not be typical for them offer medical opinions.

In short, based on my education, training, and experience, it is my conclusion that a psychologist who lacks formal medical education and training should not offer opinions regarding medical necessity or state that their opinions are reliable and valid to a reasonable degree of medical certainty.

B. Dr. Ettner Misunderstands and Failed to Apply the Informed Consent Model

I will first provide background regarding the informed consent model. Then, I will discuss Dr. Ettner's criticism of the model and why Dr. Ettner's failure to apply this model undermines her conclusions in the case.

1. The Informed Consent Model

The informed consent approach re-orients healthcare providers, including mental health care clinicians, from a gatekeeping-type role, which tends to focus on diagnostic criteria for Gender Dysphoria and an examination of the individual's general appropriateness for a given intervention, to a more collaborative and detailed examination of that individual's understanding of the anticipated benefits, risks of, and possible alternatives to a given treatment, as well as their capability for personal autonomy in choosing care options. If aspects of the informed consent are deficient, either because the individual has not been provided with sufficient information or because the person is experiencing some kind of barrier with respect to their capacity, professionals can take a problem-solving approach.

Under the informed consent approach, the discussion of the anticipated benefits and risks of a given treatment are tailored to the interventions that the evaluee is seeking or considering. The evaluator reviews the individual's understanding of their options, as well as associated risks, costs, and benefits, to ascertain the person's expectancies as well as their fund of knowledge about their options. It is important that the individual not only understand the generic risks, costs, and potential benefits, but also the likelihood that the specific interventions they are considering will be as effective as they expect, and not significantly more or less risky or costly than they anticipate.

Dr. Ettner takes specific exception to portions of my declaration where I discuss informed consent and more specifically the lack of a robust consideration of informed consent by Dr. Ettner.

Dr. Ettner discounted the need for a psychologist to assess informed consent by stating that it is unclear as to what detail should have been included in her assessment and that informed consent is typically obtained by the surgeon, as that is the provider performing the procedure for which consent is necessary. *See* DE-22-1 ¶53. Dr. Ettner is incorrect in this regard, and I detail why below.

2. Disconnect Regarding the Nature of the Phrase Informed Consent

Dr. Ettner asserts that that the informed consent process was undertaken and completed by Dr. Figler. (DE-22-1 ¶ 60) I have reviewed the surgical consult record prepared by Dr. Figler and while it does state that "extensive discussion of risks, benefits and alternatives" were discuss with Mrs. Zayre-Brown, there is little concrete information regarding the depth, scope, and details of the discussion. Given that Dr. Figler is a surgeon, I suspect the informed consent discussion focused on the risk, benefits, and alternatives relative to the surgery under consideration. In any event, it is not clear whether this informed consent discussion explored Mrs. Zayre-Brown's fund of knowledge as to the anticipated benefits or risks of the procedure, let alone her expectations with respect to outcomes. Because this information was not detailed in the records, it was necessary to explore this information through an interview with Mrs. Zayre-Brown. Furthermore, it is unreasonable to offer opinions regarding expectancies and efficacy without exploring these aspects of informed consent, as well as the person's response to prior gender affirming interventions (including nonsurgical interventions when relevant). Yet, Dr. Ettner does not document engaging in this process with Mrs. Zayre-Brown during their interviews.

This distinction is important because when I refer to anticipated benefits, risks, expectations, and outcomes, I am referring to how the patient's Gender Dysphoria may or may not be impacted by the procedure and not merely the physiological risk, benefits, and outcomes

associated with the surgery. Indeed, a discussion of the medical risks, benefits, and outcomes are certainly within the purview of the surgeon. However, Gender Dysphoria and the treatment of Gender Dysphoria necessarily requires consideration of more than medical outcomes, as it implicates psychosocial factors such as ability to engage in valued activities, relationship functioning, reproductive choices, and perceived social/gender role. Thus, a robust informed consent discussion that includes exploration of the anticipated benefits, expectations, and outcomes, and the bases of the patient's understanding is paramount. Furthermore, even when the individual appears to lack sufficient knowledge, have inaccurate expectancies, or exhibit co-occurring symptoms of other psychological conditions, an informed consent approach can take a problem-solving approach to resolving those obstacles without foreclosing the individual's opportunity to receive treatment.

3. Dr. Ettner Overlooks the Importance of a Robust Informed Consent Approach

Dr. Ettner's suggestion that mental health providers have no role to play in assessing informed consent is misguided. Such a suggestion overlooks the research literature related to informed consent assessments as a model for mental health provider engagement in gender-affirming interventions (*see* Cavanaugh, Hopwood, & Lambert, 2016, which describes the informed consent model as superior to the then existing *Standards of Care* published by the World Professional Association for Transgender Health ("WPATH") because the informed consent approach is "more patient-centered and respectful of the patient's sense of agency").

Also, to the extent that Dr. Ettner implies that informed consent is only necessary for surgical (or other medical) interventions, this would also be incorrect. All patients should be provided the opportunity to review relevant information for the purpose of informed consent for all medical and psychological interventions, including Dr. Ettner's psychological evaluation of

Mrs. Zayre-Brown. Psychologists are specifically exhorted by our American Psychological Association's Code of Ethics to seek informed consent for psychological interventions and evaluations (see APA Ethics Code 9.03 for assessments, and 10.01 for treatment). Furthermore, capacity to consent is not a static and generalizable characteristic of the individual, therefore a person may demonstrate the ability to provide informed consent for one type of intervention or activity but not another, or their ability to provide informed consent may change over time.

Furthermore, an evaluation of informed consent and capacity to provide consent are indeed standard components of an assessment of persons seeking gender affirming care. This much is illustrated in the Chapter 5 of the most recent version of the WPATH Standards of Care, which specifically "recommend[s] health care professionals assessing transgender and gender diverse adults for physical treatments […] [a]re able to assess capacity to consent for treatment." (WPATH 8 at S32) Indeed, WPATH's recommendations provide that among other things, "[t]he role of the assessor is to assess for the presence of gender incongruence and identify any co-existing mental health concerns," […] "to support the TGD person in considering the effects/risks of GAMSTs[3], and to assess if the TGD person has the capacity to understand the treatment being offered and if the treatment is likely to be of benefit." (WPATH 8 at S31)

Additionally, as WPATH also recognizes, in some situations a more comprehensive assessment by an interdisciplinary team may be necessary. (*See* WPATH 8 at S31) So any suggestion by Dr. Ettner that it would be unusual or unnecessary for her, as an evaluating psychologist to consider informed consent is inaccurate. Accordingly, psychologists play a part in

[3] This is an abbreviation used in the WPATH publication which stands for Gender Affirming Medical and/or Surgical Treatments.

the informed consent process, and in fact measures have been developed for formal assessment of various types of decisional capacity that are routinely used by psychologists.

4. Dr. Ettner Discounts the Importance of a Psychologist Role in Informed Consent

Based on my education, training, and experience, it is my opinion that an informed consent approach, as articulated above, is often a better method for evaluating transgender individuals seeking gender-affirming interventions and accommodations. This is because the informed consent approach allows the examiner to more fully explore that individual's understanding of the anticipated benefits and the potential risks more comprehensively, including the bases of that understanding. The informed consent approach shows respect for the individual's right to self-determination, and their role as an expert with respect to their history and identity. The informed consent approach also enables psychologist and other mental health care providers to sidestep the role of treatment gatekeeper. Avoiding a gatekeeping posture is key for psychologists to remain within the bounds of their competency, to establish and maintain rapport with the people they treat or evaluate, and to offer problem-solving and remediation options that do not foreclose the individual's opportunity to seek treatment and have their identity respected.

A prospective patient's understanding of the likely outcomes of a procedure, and the timing of these outcomes, is key to their ability to make decisions while also weighing the risks and costs. This need to balance the information provided to the individual, and recognizing that their decision-making process necessitates comparison of not just the possible outcomes but also the likelihood of potential outcomes, underscores the importance of providing accurate information about psychological outcomes. For example, a patient who believes an intervention will be curative may accept more serious or higher-probability risks compared to a patient who believes that an intervention will alleviate but not cure their symptoms. Communicating to a prospective patient

that a surgical procedure will be curative carries significant risk of misleading the individual, and influencing their decision-making with inaccurate information leading to exaggerated expectancies. Believing that one will be cured of a psychological condition secondary to a surgical procedure, then finding out that one was not cured, can be extraordinarily painful and discouraging, as well as psychologically destabilizing, to vulnerable individuals.

C. Dr. Ettner's Declarations and Report Lack Critical Elements

Dr. Ettner's assessment lacks documentation of evaluation or observations of Mrs. Zayre-Brown's history of psychological distress and overall psychological functioning over time, and basic information regarding Dr. Ettner's administration and interpretation of psychological tests.

1. The Absence of Discussion of Expectancies is Striking

Dr. Ettner makes bold assertions and states a very specific opinion in her declarations and report. Namely, Dr. Ettner states that the vulvoplasty which Mrs. Zayre-Brown has requested will "creat[e] typically appearing gender-congruent genitals, and remov[e] the source of her significant Gender Dysphoria and curing it." DE-22-1 ¶ 56.

I struggled to locate a reasonable basis in Dr. Ettner's two declarations and report for the opinion that a vulvoplasty would cure Mrs. Zayre-Brown's Gender Dysphoria. Nowhere in her materials does Dr. Ettner discuss Mrs. Zayre-Brown's historical understanding of her expectancies as to prior interventions and how those expectancies may have lined up with outcomes. Without that sort of undertaking, there is no reasonable basis upon which to assess her fund of knowledge as to the anticipated benefits of the procedure.

Rather than providing details of discussions that she had with Mrs. Zayre-Brown regarding her expectancies with respect to the vulvoplasty and why she believed earlier surgical interventions inadequately mitigated her Gender Dysphoria symptoms, Dr. Ettner makes a general comment

regarding nonspecific contents of Mrs. Zayre-Brown's records which reportedly detail Mrs. Zayre-Brown's prior expectations for earlier interventions. More specifically, Dr. Ettner writes: "Mrs. Zayre-Brown's records clearly identify her expectations regarding her previous gender-affirming surgery. Again, Mrs. Zayre-Brown's primary expectations were to alleviate gender-dysphoria by aligning her primary and secondary sexual characteristics with her gender identity." (DE-22-1 ¶ 58) And as to the lack of any discussion about Mrs. Zayre-Brown's sense of how the outcomes of prior interventions measured up to her expectations, Dr. Ettner simply notes that the WPATH publication provides that "gender-affirming care is patient-centric and the timing and number of gender-affirming interventions, including surgeries are different for each patient." (DE-22-1 ¶ 58)

Neither of these responses address my criticism. Simply referring to nonspecific records and asserting that they "clearly identify [Mrs. Zayre-Brown's] expectations" amounts to *ipse dixit*, as Dr. Ettner does not point to any particular record or the contents thereof to support Dr. Ettner's assertion. Moreover, nothing in this response actually disputes my specific critique, which was that Dr. Ettner did not reference any details regarding discussion of Mrs. Zayre-Brown's prior expectancies and how closely those expectancies matched the outcomes.

Identification of Mrs. Zayre-Brown's historical understanding and expectancies regarding prior interventions is relevant to ascertaining whether or not her expectancies have historically lined up with the results of interventions. Given that Dr. Ettner has essentially offered the

professional judgment[4] that vulvoplasty will be curative, the basis for such a prediction, and the likelihood that it will bear out is critical. Without some articulation of a discussion regarding her expectancies, it would be unreasonable for Dr. Ettner to offer an opinion regarding how future interventions including surgery would affect Mrs. Zayre-Brown.

2. Lack of Robust Discussion of Mrs. Zayre-Brown's Mental State

Dr. Ettner's expert report is more than 60 pages long, yet she spends only approximately 6 pages discussing Mrs. Zayre-Brown as an individual. And in those 6 pages, Dr. Ettner offers very little information, assessment, or discussion about Mrs. Zayre-Brown's mental and emotional state. What little discussion there is on this topic lacks depth and tends to be conclusory rather than descriptive. For example, Dr. Ettner writes:

> My examination of Mrs. Zayre-Brown and her medical history demonstrate that gender-affirming surgery actually is necessary to protect her life given the risks of suicide in failing to provide such surgery, to prevent the ongoing disability she is suffering from due to her extreme Gender Dysphoria, and to alleviate the psychological pain she has long experienced and continues to experience.

Ettner Report ¶ 105. Dr. Ettner does not articulate how her examination of Mrs. Zayre-Brown or her medical history demonstrate that she is at any particular risk of suicide, nor the factors that may have historically aggravated or attenuated Mrs. Zayre-Brown's suicidality. Dr. Ettner does not discuss any disability that Mrs. Zayre-Brown may have and how it would persist or worsen absent the surgical intervention she seeks. Additionally, Dr. Ettner does not provide any

[4] In addition to Dr. Ettner opining that the vulvoplasty would be curative (*see* DE-22-1 ¶ 56), Mrs. Zayre-Brown testified in her deposition that Dr. Ettner told her "how [vulvoplasty] will totally alleviate my Gender Dysphoria." Zayre-Brown Dep. 86: 9-22. For her part, based on the deposition transcript, Mrs. Zayre-Brown articulated the view that nothing could be curative with respect to her Gender Dysphoria (because Mrs. Zayre-Brown does not view Gender Dysphoria as a disease). Although Mrs. Zayre-Brown did not explicitly endorse the more extreme "curative" language used by Dr. Ettner, she did describe the expectation that vulvoplasty will "totally alleviate" her Gender Dysphoria.

methodical examination of Mrs. Zayre-Brown's psychological pain, including the scale, scope, and manifestations of Mrs. Zayre-Brown's psychological distress, and the relationships between stressors and mental health conditions (*e.g.,* Gender Dysphoria) that increase or decrease the risk of increased suicidal ideation and possible attempts.

Another example can be seen in paragraph 93 of Dr. Ettner's expert report, where Dr. Ettner writes: "[DAC][5] continues to ignore [Mrs. Zayre-Brown's] serious, urgent, and longstanding medical need for gender-affirming surgery." This pronouncement is not preceded nor followed by any discussion of specific medical or mental health records nor any discussion of Dr. Ettner's in-person assessment of Mrs. Zayre-Brown to support the assertions that treatment is urgent. Additionally, the history of DAC's interactions with Mrs. Zayre-Brown are not totally irrelevant, but are also not central with respect to the current question of what interventions Mrs. Zayre-Brown needs, when she needs them, and where/how those interventions ought to be delivered to achieve psychological benefit.

This absence of any robust discussion of Mrs. Zayre-Brown's records is notable because there are multiple incidents that are chronicled in her medical records which warrant an examination. For example, twice in 2019, Mrs. Zayre-Brown reportedly experienced a disturbance significant enough that she was sent to the local emergency room for evaluation. Yet Dr. Ettner does not report that Dr. Ettner explored these incidents with Mrs. Zayre-Brown.

In March 2019, Mrs. Zayre-Brown was transferred to the local emergency department evidently due to an altered mental status, crying, stating that she was dying, and staff's inability to

[5] At the time that this litigation was filed, North Carolina state prisons were operated by a division within the North Carolina Department of Public Safety. The state prisons are now operated by the North Carolina Department of Adult Correction (DAC) which has now been substituted into this litigation as a party.

take her vitals due to erratic movements. *See* DAC 1550-1553. The hospital records indicate that she was transferred to the emergency department for a mental health evaluation with a chief complaint of, "I want to die." DAC 2114. The record states that Mrs. Zayre-Brown refused a medical work up, expressed that she does not want to hurt herself and wanted to return to prison. DAC 2115. She then reportedly signed an "against medical advice" form and was discharged. DAC 2115, 2136. Prison records state that she acknowledged smoking something out of a pipe but would not state whether it was K2. Subsequently, Mrs. Zayre-Brown stated she had not been smoking anything, and she denied the specific allegation that she used K2. *See* Zayre-Brown Dep. 159: 7-16. Records noted that, upon her return from the hospital, Ms. Zayre-Brown also reported this episode was due to stress arising from being housed at a male facility. DAC 1548.

In August 2019, Mrs. Zayre-Brown was sent to the emergency room after vomiting and stating that her "mind is gone." DAC 1465. The hospital records note that she was brought to the emergency room after fainting. During the emergency room visit, Mrs. Zayre-Brown attributed her distress to her housing situation. DAC 1920. She was examined and released. DAC 1920-1924. Upon her return from the hospital, Mrs. Zayre-Brown was noted as stable but distraught about having to go into a restrictive housing setting. DAC 1463.

No matter the precise cause of these episodes, a thorough assessment of Mrs. Zayre-Brown's mental and emotional state, currently, and historically, should include some exploration of those events. Such an assessment could provide information relevant to Mrs. Zayre-Brown's level of impairment, distress, and dysfunction, factors that alleviate versus exacerbate her symptoms, and the possible presence of co-occurring mental health conditions that should be taken into account with respect to treatment and recovery planning. Dr. Ettner does not offer sufficient examination and interpretation of these events.

The same is true with respect to at least two other incidents. In December 2020, Mrs. Zayre-Brown was sent to an inpatient mental health unit after she reported thoughts of engaging in self-injurious behavior. While Dr. Ettner references this event in her report—she merely recounts what is evident from the medical record and does not write about her assessment of how this incident factors into any of her opinions or conclusions. She does not describe additional information from Mrs. Zayre-Brown that might contextualize the incidents or connect the events directly to Gender Dysphoria by describing the history in detail.

Likewise, Mrs. Zayre-Brown's records indicate that in April 2021 she reported to her psychologist that she had placed a band around her phallus[6] as a protest because she had not yet had her surgical consult with Dr. Figler. However, Dr. Ettner simply recounts what the records indicate and does not offer any description of the information Mrs. Zayre-Brown provided regarding the relationship between her distress on that day and her Gender Dysphoria. Dr. Ettner also does not examine the possibility that a person's frustration with the pace of treatment, assessment, and institutional decision-making—separately from any Gender Dysphoria that might be present—could cause an individual to engage in this type of self-injurious behavior.

Given the two incidents in 2019, the report of thoughts of self-harm in December 2020, and the reported attempt of self-harm in April of 2021, Dr. Ettner should have evaluated these incidents with Mrs. Zayre-Brown and articulated the same in her report, because these incidents raise concerns that Mrs. Zayre-Brown may have other mental health difficulties that should be addressed in addition to her Gender Dysphoria.

[6] I use the term "phallus" as Mrs. Zayre-Brown indicated that this is the term she prefers.

3. Absence of Information Regarding the Psychometric Testing.

Dr. Ettner reports that she administered three psychometric tests to Mrs. Zayre-Brown during her in-person assessment. DE-13-1 ¶ 76; Ettner Report ¶ 80. Then, in two virtually identical sections from her first declaration and her expert report, both titled "Clinical and Psychometric Assessment," Dr. Ettner, offers a single paragraph on the topic. *See* DE-13-1 ¶ 82; Ettner Report ¶ 86.

> Mrs. Zayre-Brown was able to attend to the entire, lengthy interview without agitation or restlessness. She engaged with ease, maintained eye contact throughout, and her affect was appropriate to content. She has no disorders of thought, and thought processes are logical, goal directed, and without distortion. Memory and abstract reasoning are well within normal limits. Insight and judgment are good. Language is fluent, speech is natural, and intelligence is above average (by estimation).

DE13-1, ¶ 82. Because Dr. Ettner does not reference the nature of the testing, nor the results, this clinical assessment appears to be based exclusively on unstructured clinical judgment, which is significantly less accurate compared to more mechanical strategies such as the use of standardized and normed psychological testing. That the latter of these strategies is a superior method to the former, is a long-enduring finding. (*See* Dawes 1979, Grove et al, 2000, and Meehl 1954).

Additionally, that Dr. Ettner did not identify what tests she administered, let alone that she did not reference the results in any way in any of her declarations or her expert report is unusual.[7] In my experience, when clinical and/or forensic psychologist conducts psychometric testing as part of an evaluation, it is common practice to either summarize the results of that testing in the report or provide the results of the testing.

[7] I eventually received the results of the tests administered by Dr. Ettner, which were provided to me by counsel for Defendants, which they obtained in response to a specific discovery request. I will discuss those test results later in this report.

I have never encountered an expert report that did not include any names of the tests administered, so far as I can recall. This is particularly striking given that definitive nature of the statements of opinion that Dr. Ettner makes (*e.g.* "She has no disorders of thought, and thought processes are logical, goal-directed, and without distortion … abstract reasoning are well within normal limits."). Such statements should be supported by some reference to the psychometric tools or assessment techniques used to reach those conclusions, or at least framed as the evaluator's observations rather than statements of fact (*e.g.*, "Mrs. Zayre-Brown did not describe symptoms, and I did not observe signs, of significantly disorganized thinking," rather than, "[Mrs. Zayre-Brown] has no disorders of thought").

I ultimately received copies of the score reports and test protocols (in the case of the Beck instruments) administered by Dr. Ettner. Given that Dr. Ettner did not provide information or interpretation of the results, I will do so below.

a. Trauma Symptom Inventory, Second Edition (TSI-2)

This is a self-report measure intended to capture recent trauma-related psychological symptoms. The TSI-2 contains embedded validity scales that assess, broadly speaking, the person's level of willingness to disclose symptoms as well their endorsement of highly unusual symptoms (which may indicate malingering/feigning or a "cry for help" presentation). Mrs. Zayre-Brown's results on the TSI-2 validity scales were solidly within normal limits. The TSI-2 defines

clinical elevations as T score at or above 65.[8] Based on norms for adult women,[9] Mrs. Zayre-Brown produced only one clinical scale elevation, on the Defensive Avoidance scale (T = 66), and high scores on this scale are associated with a tendency to avoid remembering/thinking about traumatic events as well as avoiding reminders of traumatic events. Inspection of the TSI-2 factor scores, which are intended to capture broader domain-level trauma-related psychological constructs, showed that the Posttraumatic Stress factor was not (statistically, using T = 65) elevated but was high compared to the population (82nd percentile, meaning 82% of TSI-2 norming samples had lower scores on that factor). Suicidality was, like the Posttraumatic Stress factor, not statistically elevated (T = 58; about 78th percentile), but high compared to the average person. Inspection of the Suicidality subscales showed more suicidal ideation than suicidal behavior. Clinical elevations and high scores on these scales do not necessarily call Mrs. Zayre-Brown's ability to provide informed consent into account, however, the scores do suggest that she has some degree of trauma-related psychological symptomology which may have been below-threshold for formal diagnosis (e.g., Post-Traumatic Stress Disorder) at the time of Dr. Ettner's testing. Mrs. Zayre-Brown's TSI-2 results suggested that she had not made any suicide attempts or engaged in

[8] T scores enable us to compare scores within and across psychological tests. A T score of 50 is perfectly average, and most psychological tests define a clinically elevated score according to how statistically uncommonly high or low the score is, typically using a cutoff score of T = 65 or T = 70 to define a high score. A T score of 65 falls at roughly the 93rd percentile, meaning that if you obtain a T score of 65, your score is higher than about 93% of the other individuals in the samples used to norm the measure. A T score of 70 falls at roughly the 98th percentile.

[9] A significant limitation of most formal psychological assessments at this time is the absence of norms specific to transgender and gender nonconforming individuals, as well as a lack of specific examination of whether or not the existing norms can be generalized to transgender and gender nonconforming people. Therefore, all measures administered by Dr. Ettner and myself are described with the caveat that these tests' developments did not include validation studies using (known/identified) transgender individuals, and so we must be cautious about interpreting the results due to that limitation. Part of the reason that I chose the measures I did was based on the option of using non-gendered norms.

parasuicidal behavior in the six months prior to the TSI-2 administration, based on the raw score of 0 for the Suicidal Behavior subscale.

b. Beck Anxiety Inventory (BAI) and Beck Depression Inventory (BDI)

The Beck Anxiety Inventory and Beck Depression Inventory are both brief tests that were developed by Aaron Beck and colleagues. The measures were originally developed to assess separate constructs of depression and anxiety, but the tests are highly correlated as evidenced by the reliability and validity studies (*see* the Mental Measurements Yearbook entries for BAI and BDI). Mrs. Zayre-Brown obtained a score of 11 on the BAI, and 16 on the BDI, and these scores fall into the Mild range for anxiety and depression symptoms, respectively. On the BDI, Mrs. Zayre-Brown endorsed an item reflecting suicidal ideation without attempts, consistent with the TSI-2 findings.

Given these findings, it appears that trauma-related symptoms are a likely contributor to her suicidality. Thus, it cannot be stated with confidence that Mrs. Zayre-Brown's Gender Dysphoria alone is fully explanatory with regard to her psychological distress generally, and her suicidality specifically. Likewise, surgical intervention alone is not likely to be curative, and may not substantially ameliorate her suicidality.

D. Responses to Dr. Ettner's Criticisms of My Declaration

Dr. Ettner criticizes my reference to the fact that she did not conduct any collateral interviews. (*See* DE-22-1 ¶ 54). My observation and comment regarding collateral/third party interviews stems from the context in which Dr. Ettner provides her evaluation, which is litigation. Dr. Ettner and I are both offering forensic psychology opinions, and forensic psychological practice differs from non-forensic practice in a number of facets, including the need to rely on collateral sources. There are threats to validity, and a need for precision and thoroughness, that are

present in the forensic assessment context but typically may not present in community-based non-forensic evaluations.[10] As noted on page 52 of the Melton text referenced in footnote 5, "[f]orensic evaluators are more likely than therapists to seek and rely on third-party data for three reasons: a greater need for accuracy; differences between response style between persons in therapeutic and forensic evaluation contexts; and the greater scrutiny that evaluators' conclusions receive in the legal arena."

It was in this context that I pointed out the lack of any collateral or third-party interviews attempted/documented by Dr. Ettner. Thus, Dr. Ettner's summary dismissal of the notion of collateral interviews is misplaced. I would also note that Mrs. Zayre-Brown readily agreed to my inquiries regarding the possibility of conducting collateral interviews with correctional staff, treatment providers, other professional contacts, and her husband. Unfortunately, due to the timing of my interview relative to the deadline to submit this report, I was not able to conduct these interviews prior to submitting this report. The associated limitations with respect to my findings are described later in this report.

V. Dr. Ettner's Conclusion That Surgery Would "Cure" Mrs. Zayre-Brown's Gender Dysphoria Lacks a Reasonable Basis

As explained above, Dr. Ettner does not appear to have any medical education or training and yet offers opinions to a "reasonable degree of medical certainty." This in and of itself is concerning and for that reason alone, the opinion that Dr. Ettner asserts, that surgery would cure Mrs. Zayre-Brown's Gender Dysphoria lacks foundation. This is particularly true in light of the deficiencies in her assessment noted above.

[10] *See* chapter three of the text by Melton and colleagues, *Psychological Evaluations for the Courts: A Handbook for Mental Health Professionals and Lawyers, 2018*, which describes the differences between forensic and non-forensic psychological assessment.

Without ascertaining the person's expectancies regarding the likely efficacy of a given intervention and the basis for that belief, a clinical psychologist lacks any reasonable basis upon which to predict with confidence that a particular intervention will be curative. This is particularly true with respect to a condition such as Gender Dysphoria which has a diverse manifestation and is inextricably bound up in aspects of a person's life and circumstances (*e.g.*, their sense of validated identity, their family, their local community, their cultural context, etc.) that go far beyond the physical appearance of their genitals.

Furthermore, the absence of a discussion regarding Mrs. Zayre-Brown's prior expectancies and how they lined up with the outcomes is striking in light of the strong opinion that Dr. Ettner offered, *i.e.*, that surgery would be *curative* for Gender Dysphoria. Having reviewed Mrs. Zayre-Brown's deposition in January of 2023, the pronouncement that a surgical procedure would be curative seems particularly questionable in light of the very modest gains in psychological functioning that Mrs. Zayre-Brown described as occurring after prior interventions (*e.g.*, breast enhancement, orchiectomy).

The lack of an articulation by Dr. Ettner of an examination of Mrs. Zayre-Brown or her medical history, beyond cursory references to medical records, further erodes a reasonable basis upon which Dr. Ettner can assert that surgery would be curative. Simply put, Dr. Ettner does not document or otherwise describe methodical examination of Mrs. Zayre-Brown's psychological pain, including the scale, scope, and manifestations of Mrs. Zayre-Brown's psychological distress, and the relationships between stressors and mental health conditions. Therefore, it is difficult see the basis for her opinion that surgery would cure Mrs. Zayre-Brown's Gender Dysphoria. It is my opinion that it would be misleading to tell Mrs. Zayre-Brown that this particular gender-affirming surgery alone will be curative with respect to her Gender Dysphoria. My opinion with respect to

intervention and informed consent, which includes caveats and relevant conditions, are described below in the section detailing my procedures and findings.

VI. My Evaluation of Mrs. Zayre-Brown Did Not Reveal Any Specific Factors in her Mental State Counseling for or against Surgery, from a Psychological Perspective

In keeping with my typical practice, I administered broad measures of psychopathology, personality, interpersonal and identity functioning, and distress, when I met with Mrs. Zayre-Brown. She appeared capable of the reading level and comprehension required to complete these measures, and I provided an explanation of the purpose and demands of the testing before I asked Mrs. Zayre-Brown if she was willing to proceed. My evaluation of Mrs. Zayre-Brown did not reveal any significant findings in her mental state that would counsel in favor of the surgery as an immediate intervention, to be conducted in a prison setting, from a psychological standpoint. Nor were there any significant psychological contraindications to surgery revealed in my analysis. Overall, the assessment demonstrates that she has some issues of note but is relatively well adjusted, all things considered. Her results for each measure are discussed in turn below.

A. Minnesota Multiphasic Personality Inventory, Second Edition—Restructured Form (MMPI-2-RF)

This is a self-report inventory commonly used in forensic settings. Although the name of the measure refers to personality, the MMPI measures a broad range of psychopathology, including mood, anxiety, and perceptual disturbances, as well as self-concept and interpersonal functioning. The MMPI instruments contain embedded validity scales that are intended to measure how the person approached the test. Mrs. Zayre-Brown's validity scale results were within normal limits, and did not support the view that she exaggerated symptoms or distress, exhibited significant denial or "faking good," or answered items randomly. Of note, I entered Mrs. Zayre-Brown's gender as female, but the MMPI-2-RF does not use gendered norms.

With respect to the clinical results, Mrs. Zayre-Brown did not have many scale elevations (defined as a T score of 65 or greater). She produced clinical elevations on the following MMPI-2-RF scales: Behavioral/Externalizing Dysfunction (T = 78), Cynicism (T = 65), Antisocial Behavior (T = 71), Ideas of Persecution (T = 66), Aberrant Experiences (T = 66), and Hypomanic Activation (T = 72). Internalizing scales reflected suicidality (T = 66), high stress/worry (T = 65), and specific phobias/fears (T = 65). She did not produce elevations on scales related to substance abuse, aggression, social avoidance, family conflicts, or interpersonal passivity.

Integrating Mrs. Zayre-Brown's results, one concern is suicidality. She reported a history of suicidal ideation as well as attempts, and her responses indicated that she may have increased impulsivity when emotionally distressed. Mrs. Zayre-Brown appears to have a number of contributors to her suicide risk beyond Gender Dysphoria. Elevated suicidality in an individual with Gender Dysphoria does not necessarily mean that Gender Dysphoria is the primary or only cause of the elevated risk, nor does it mean that any particular affirming intervention would necessarily reduce or eliminate risk. Unfortunately, is not uncommon for incarcerated individuals to have elevated risk factors for suicidality. In other words, Gender Dysphoria is not necessarily the primary and direct cause of Mrs. Zayre-Brown's suicidality, and urgent surgical treatment for her Gender Dysphoria will not necessarily reduce or eliminate her risk of having suicidal ideation in the future.

Individuals who produce similar patterns of results on MMPI-2-RF typically describe frequent, intrusive, ruminative worry, vulnerability to stress, high suspiciousness/low trust, and some unusual thought processes and beliefs. Individuals with this pattern of results also often report a history of hypomania/elevated mood, which is characterized by dramatic shifts in energy levels and emotional status accompanied by impaired judgment and increased impulsivity. These

shifts are usually episodic and time-limited. In terms of objective indicators of elevated mood, these individuals may find that at times they have decreased need for sleep, increased physical activity and energy levels, and sometimes increased talkativeness/social drive as well.

Mrs. Zayre-Brown's endorsement of MMPI items reflective of persecutory ideation must be contextualized in terms of her current circumstances, which involve her feeling betrayed and abandoned by institutions and institutional actors. On balance, her psychological testing results are not supportive of the view that she has an active psychosis-spectrum illness.

Bipolar Disorder cannot be ruled out at this time, and should be considered as a potentially relevant diagnosis for overall future functioning. The significance of potential Bipolar Disorder with regard to informed consent decision-making is that Bipolar Disorder symptoms can fluctuate, and if severe could impair her decision-making capacities because of increased impulsivity and impaired judgment. So far as the relevant referral questions for this report are concerned, however, it does not appear that Mrs. Zayre-Brown's reasoning with regard to gender-affirming interventions has been substantially influenced by mood-related psychopathology, and she does not have severe active mood pathology that would be expected to interfere with her decision-making ability at present.

The elevation on the MMPI-2-RF scale measuring antisocial behavior is not particularly concerning, given that the elevation appeared to be caused by Mrs. Zayre-Brown forthrightly acknowledging a history of rule-breaking behavior, particularly as an adolescent. These elevations are also more common than not among incarcerated individuals.

B. The Personality Assessment Inventory (PAI)

The PAI is, similarly to the MMPI-2-RF, frequently used in the forensic context, with correctional norm comparison groups available. The PAI also measures a relatively broad

spectrum of personality and psychopathology-related symptoms and issues. As with the MMPI-2-RF, Mrs. Zayre-Brown's validity scale results appeared to show that she comprehended item content and answered consistently. The PAI scales related to positive impression management indicated that Mrs. Zayre-Brown's pattern of responses were consistent with an individual who may be attempting to portray herself as more problem-free and virtuous than is accurate, however this is also a pattern of validity scale results that are commonly seen in the forensic context, where most evaluees are attempting to put their best foot forward, so to speak. The positive impression management results were not supportive of the view that Mrs. Zayre-Brown's PAI results were invalid or uninterpretable. Negative impression management results could be interpreted as reflective of some degree of distortion with respect to Mrs. Zayre-Brown's symptom reports, but again these indicators were not so far out of range as to render the results invalid.

As with the MMPI-2-RF, Mrs. Zayre-Brown produced an elevation on a scale measuring mania/elevated mood (T = 76) The Mania scale was her only scale elevation on the primary clinical scales. Inspection of the PAI subscales showed that Mrs. Zayre-Brown endorsed significant health concerns (Somatic Health Concerns T = 76), and Antisocial Behaviors (T = 70). She did not produce an elevation on scales measuring self-harm (T = 57), aggression, identity problems, or psychotic experiences. The Anxiety-Related Disorders Obsessive Compulsive Scale was elevated (T = 70), but her overall levels of anxiety and depression were within normal limits. Of note, the PAI results reflected a lower level of suicidality than was indicated in the MMPI-2-RF results.

VII. The Degree of Psychological Benefit that Mrs. Zayre-Brown May Realize From Surgery Is Substantially Dependent on Her Setting

Gender Dysphoria has a variable presentation, with differing combinations of symptoms, aggravating/alleviating factors, and indicated treatment depending on the individual. Additionally, the drivers of the distress associated with Gender Dysphoria can vary and can be affected by an

individual's environment and their access to positive social and practical supports. This is true in Mrs. Zayre-Brown's case. The source of her Gender Dysphoria appears to be both a sense of incongruence between her identity and her physical body, as well as transphobia that she experiences when other individuals choose to misgender or harass her based on her gender minority status. Additionally, the psychological benefits that she may derive from gender-affirming interventions, including surgery, are significantly dependent on her setting, which in this case determine her options for treatment, aftercare, and support. For these reasons, there is no reliable way to assess the precise degree of psychological benefit that Mrs. Zayre-Brown may realize from undergoing the surgery, particularly in the carceral setting where I expect she would receive less psychological benefit and/or a delay in experiencing psychological benefit compared to the community. This conclusion is supported by my review of Mrs. Zayre-Brown's deposition and my own in-person assessment of her.

A. Overview of My In Person Assessment of Mrs. Zayre-Brown

I carefully reviewed the deposition of Mrs. Zayre-Brown on January 18, 2023. The deposition served as an additional collateral record, and review of the deposition enabled me to avoid significant redundancy in terms of my interview questions for Mrs. Zayre-Brown. During my interview with Mrs. Zayre-Brown on June 20, 2023, I was able to ask her some clarifying questions with regard to aspects of her deposition responses relevant to my evaluation and analysis.

My interview of Mrs. Zayre-Brown was focused on points of necessary clarification and elaboration, partly to ensure that she was not subjected to repetitive or redundant interviewing. Specifically, I asked Mrs. Zayre-Brown about her historical response to intervention, her experience transferring to the women's facility, her history of crisis events as reflected in the records, her self-concept with respect to her gender expression and associated goals for gender-

affirming intervention, her understanding of her options as well as risks/costs/benefits, her expectancies with respect to future surgical interventions, her experiences interacting with medical and mental health professionals in the context of gender-affirming assessment and treatment, sources of information and influence with regard to her mental health care decision-making, and her plans for re-entry as a returning citizen.

B. Mental Status & Behavioral Observations During the Assessment

Mrs. Zayre-Brown was on time for our meeting and was dressed in the facility uniform. She appeared clean and well-groomed. Her movements and energy levels appeared to be within normal limits, without psychomotor abnormalities such as stereotypical rocking or excessive fidgeting. Eye contact and other aspects of social communication were normal. Interpersonally, she was cooperative but assertive, and she was polite throughout the evaluation process. At the outset, I explained how I would be making a video record of our meeting, and she asked two questions about the evaluation process. She demonstrated understanding of the context for the evaluation, her right to stop the evaluation or choose not to answer questions, and my role as a psychologist retained by Defense counsel in this case. She agreed to proceed with the evaluation, including creating a video record of our meeting.

Mrs. Zayre-Brown's thought content, as evidenced by her statements, was generally logical and reality-based. She did not make statements, and I did not observe signs, that were suggestive of a loss of contact with reality or active substantial perceptual distortions. Her overall demeanor was serious, and the emotions she expressed matched the content of her statements. Her speech showed a very subtle articulation abnormality (as evidenced by some difficulty pronouncing some phonemes), but she was understandable and her speech was normal in terms of pace and volume. Her mood appeared neutral initially, and brighter toward the end of the meeting. Intelligence was

estimated as average to somewhat above average, based on her vocabulary and verbal reasoning ability. Regarding her overall mental health functioning, Mrs. Zayre-Brown appeared to be coping with the stress of confinement as well as could be expected, using coping skills and relying on professional and social supports by her account.

C. Specific Instances of Acute Distress in 2019

During the interview, when asked about two instances in 2019 reflecting acute distress, one of which included the suspect use of K2, Mrs. Zayre-Brown stated that she had not consumed synthetic cannabis at the times of the crisis events reflected in her records. Instead, she said that she intentionally consumed an over-the-counter medication overdose in the context of a suicide attempt.

Additionally, she clarified that, at the time of her more acute crises, her distress was usually directly related to having been given bad news about her options for gender-affirming treatment. She stated that, after receiving somewhat blunt descriptions of administrative decision-making that did not result in favorable results, she was typically left to her own devices in terms of coping with her frustration, disappointment, and feelings of abandonment and being viewed as unworthy of care. In other words, Mrs. Zayre-Brown's acute mental health crises in recent years were indirectly rather than directly related to her Gender Dysphoria. Additionally, by her account, significant contributions to her distress were associated with administrative processes and delays related to her treatment.

D. Discussion Regarding Mrs. Zayre-Brown's Expectancies

Mrs. Zayre-Brown provided further elaboration regarding her expectancies for vulvoplasty (which would also apply to vaginoplasty). She stated that her aim was to continue to transition to a binary femme physical presentation that would essentially render her indistinguishable from a

cisgender woman—she remarked that her ultimate goal is to be "stealth." In other words, Mrs. Zayre-Brown identified her gender identity within a binary gender framework, and expressed a desire to modify her appearance, in part to minimize the likelihood that she would be read as a transgender woman in the community. This is partly because Mrs. Zayre-Brown's gender identity is woman, and she indicated that she would prefer to blend in socially as much as possible in terms of her appearance. She observed that this effort to blend in as a woman outside of the prison could be significantly hampered by the media coverage and information on the internet associating her name with her civil case, and she expressed some sadness and concern about this but also appeared to accept the nature of her circumstances.

While Mrs. Zayre-Brown did not make statements that were indicative of markedly unrealistic expectancies regarding surgical outcomes specifically, she did note that she expected her Gender Dysphoria to resolve after the surgery because she expected to be essentially indistinguishable from a cisgender woman. Such statements support the assertion that her Gender Dysphoria is the product of both a sense of incongruence between her identity and her physical body and the transphobia that she experiences as a transgender woman when she is read and/or known as such.

I asked Mrs. Zayre-Brown questions regarding her preference for vulvoplasty over vaginoplasty. She was able to articulate the pros and cons of each procedure, including considerations related to her options for an additional surgery later should she opt for vulvoplasty now. We discussed personal and sexual functioning considerations, and it appeared that she had a general understanding of her options and the associated risks and potential benefits. She did not report distorted expectancies regarding surgical outcomes, and she also had a fairly balanced view

of the surgery's effects on both her self-concept as well are how she is likely to be perceived and treated in her close relationships.

Mrs. Zayre-Brown's expectancies for the surgical aftercare that would be available to her in prison were less realistic, in light of the history. She reported that she essentially hoped that she would receive much more intensive and responsive aftercare for vulvoplasty than she recounted receiving when she initially came into custody while actively recovering from a very recent orchiectomy and had already experienced complications. Also, her reasoning for seeking vulvoplasty over vaginoplasty was strongly influenced by the constraints of the carceral setting, and her stated belief that it simply was far less likely that a vaginoplasty would be approved by DAC due to the preparatory requirements and aftercare elements. This characterization was consistent with her statements during her deposition as well as her records.

It appeared, based on Mrs. Zayre-Brown's statements, that her view of an ideal surgery context would include the following: (a) receiving medical care in the community, including aftercare and wound care management; (b) the opportunity to receive care and support from her husband, friends, and family; (c) and participating in meaningful personal and professional development opportunities while she is preparing for surgery and recovering from surgery.

E. Primary Findings From My Assessment of Mrs. Zayre-Brown

Based on the information I reviewed, Mrs. Zayre-Brown's Gender Dysphoria is a product of both a sense of incongruence between her identity and her physical body, as well as transphobia that she experiences when other individuals identify her as a transgender woman and react with mistreatment. Thus, one factor in the success of her surgical interventions, from her perspective, would be her ability to avoid being identified as a transgender person. In the carceral setting, even with the surgery she would still be known as a transgender woman because of the nature of the

insulated community at the prison, and the coverage of her case in the media. Additionally, whatever the benefit she would derive from the surgery will be less noticeable in a carceral setting than a community setting, because the community setting offers more opportunity to blend in, as Mrs. Zayre-Brown has indicated she wishes to do. Furthermore, a community setting has more opportunities to engage in the types of behaviors that have reportedly caused Mrs. Zayre-Brown a greater degree of self-consciousness and dysphoria, such as dancing, swimming, and other physical activities. So, in the community, she will likely experience a greater sense of expansion in terms of her ability to comfortably participate in valued activities.

The psychological benefits of surgery would be significantly dependent on the setting where Mrs. Zayre-Brown is residing and her options for treatment, aftercare, and support. Mrs. Zayre-Brown acknowledged that her decision-making regarding treatment in prison was predicated in part on her receiving a level of care that is significantly higher than what she has reported historically receiving in prison environments. She also anticipates significant support and possibly medical advocacy from her husband and the ACLU to assist her in the post operative phase.

For these reasons, it is my opinion the degree to which she would derive significant psychology benefit from the surgery is difficult to ascertain. However, I do believe that she would not derive the greatest psychological benefit from delivering the surgical intervention in the carceral setting. Not only would this be less comfortable and supportive for Mrs. Zayre-Brown, but it would also actually reduce, or at least at a minimum delay, the psychological benefits (specifically, alleviation of Gender Dysphoria symptoms) that Mrs. Zayre-Brown may achieve in response to treatment, due to the restrictive nature of the environment. It is possible (and in my view, likely) that Mrs. Zayre-Brown might experience better psychological health if her concerns

and experiences of frustration with treatment were validated, but this is a separate issue from her need for this particular gender-affirming procedure (*i.e.*, vulvoplasty), in this setting, at this point in time.

I noted in the foregoing that, although Mrs. Zayre-Brown readily provided permission, I was not able to conduct a collateral interview with her husband, or others, prior to the due date for my report. So far as resultant limitations are concerned, these interviews could have been informative with regard to Mrs. Zayre-Brown's husband's self-reported capacities and plans to provide her with emotional and practical support during her recovery from surgery in the community versus the carceral setting. Also, other interviews, such as that of any individuals involved in re-entry planning, may have provided additional information regarding the details of Mrs. Zayre-Brown's access to medical care and mental health supports as part of any re-entry planning. Because I was unable to conduct these interviews prior to the deadline for my report, I must rely solely on Mrs. Zayre-Brown's self-reported account of her husband's ability and willingness to provide support, and her access to resources with a re-entry program in the community.

CONCLUSION

In this report I provided the following primary opinions and conclusions:

(1) Dr. Ettner's opinions and conclusions are undermined by multiple deficiencies in her assessment.

   a. A psychologist who lacks formal medical education and training should not offer medical opinions (*e.g.*, medical necessity) or state that their opinions are reliable and valid to a reasonable degree of medical certainty.

b. Dr. Ettner's assessment does not reflect the use of, or awareness of, an informed consent approach, despite such an approach often being a better method for evaluating transgender individuals seeking gender-affirming interventions and accommodations.

c. Dr. Ettner's report lacks meaningful discussion of Mrs. Zayre-Brown's historical and current expectancies, which is striking considering the assertion that the intervention would be curative.

d. Similarly, Dr. Ettner's report lacks any thorough discussion of Mrs. Zayre-Brown's mental state.

(2) A clinical psychologist cannot reasonably predict with confidence that a particular intervention will be curative of a condition such as Gender Dysphoria which has a diverse manifestation and is inextricably bound up in aspects of a person's life and circumstances that go far beyond the physical appearance of their genitals.

(3) My evaluation of Mrs. Zayre-Brown did not reveal any significant findings in her mental state that would counsel in favor of the surgery as an immediate intervention, to be conducted in a prison setting, from a psychological standpoint.

(4) The source of Mrs. Zayre-Brown's Gender Dysphoria appears multifaceted, with psychosocial, cultural, identity, environmental, and interpersonal factors, and the psychological benefits of gender-affirming interventions for Mrs. Zayre-Brown are significantly dependent on the setting where she is residing.

I, Sara E. Boyd, Ph.D., ABPP, pursuant to 28 U.S.C. § 1746, declare that the foregoing report is true and correct.

This the 5rd day of July, 2023.

Sara E. Boyd, Ph.D., ABPP

EXPERT TESTIMONY 2019 – July 2023

2019 23rd Judicial Circuit Court; *West Virginia v. Devin Michael Collin*, 16-M19F-00361

2019 23rd Judicial Circuit Court; *West Virginia v. Molly Jo Delgado*, CC-0202017-F-149

2019 23rd Judicial Circuit Court; *West Virginia v. Seth Beathard*, CC-33-2019-F-3

2019 Escambia County Circuit Court; *Timothy Lee Hurst v. State of Florida*, 1998-CF-001795

2019 Fairfax County Circuit Court; *Normand v. Brown*, CL2018-07653

2019 Prince William County Circuit Court; *Commonwealth of Virginia v. Robert Campbell*, CR17004221-00

2019 THE UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF VIRGINIA; *Doe v. Fairfax County School Board*, 1:18-cv-00614-LO-MSN

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2019 Shelby County Circuit Court; *Fortner v. Runyon,* CT-001847-11

2020 Superior Court of the District of Columbia; *United States v. Smith, Preston G JAS*, 1991 FEL 010665

2020 THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF COLUMBIA; *USA v. Boutros*, 1:20-cr-00082-APM

2020 THE UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF VIRGINIA; *USA v. Johnson et al*., 1:19-cr-00351-RDA-1

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2021 Arlington Circuit Court; *Commonwealth of Virginia v. Rodolfo Rivera-Valencia*, CR19000179-00

2021 Fayette County Circuit Court; *Commonwealth v. Rodriguez, Tammy Marie*, 19-CR-01493

2021 Logan County Circuit Court; *Commonwealth v. Roberson, Demetrius*, 17-CR-00220

2021 Prince William County Circuit Court; Commonwealth of Virginia v. John Pleasant Johnson Jr., CR20000938-00

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2021 Superior Court of the District of Columbia; *United States v. Byrd, Brandon A MJD*, 2016 CF1 012762

2021 Superior Court of the District of Columbia; *United States v. Winston, Marcus K MO*, 1997 FEL 004943

2021 THE UNITED STATES DISTRICT COURT DISTRICT OF MARYLAND; *Dinardo v. It's My Amphitheater, Inc.*, 8:19-cv-01841-CBD

2021 THE UNITED STATES DISTRICT COURT FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA; (Child plaintiffs not identified by name) v. The Board of Education of the County of Kanawha, and Ron Duerring, Superintendent; 2:20-cv-00057

2021 Frederick County Circuit Court; *Commonwealth of Virginia v. Anthony Natale*; CR20000190-00

2021 THE UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF VIRGINIA; *USA v.Viscomi*; 2:12-CR-00134

2021 Rockbridge County Circuit Court; *Commonwealth of Virginia v. Joseph Shaner Carlock*; CR20000371-00

2021 Superior Court of the District of Columbia; *United States v. Raphael Parker*; 1993 FEL 006266

2021 Rockingham County Circuit Court; *Commonwealth of Virginia v. Daniel Farrell*; CR200000017-00, -18-00, -19-00

2021 Berkeley County Circuit Court; *West Virginia v. Evan Ottey*, CC-02-2019-F-247

2021 THE UNITED STATES DISTRICT COURT FOR THE SOUTHERN DISTRICT OF NEW YORK; *Watson v. NY Doe 1, et al.*; 1:19-cv-522

2022 THE UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF WEST VIRGINIA; *USA v. Brandon Sabol*; 3:21-cr-00020

2022 THE UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF VIRGINIA; *USA v. Otis Goodman*; 3:20-cr-00134-001

2022 THE UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF PENNSYLVANIA; *Doe v. Manor College*; 2:19-cv-05309

2022 County of Arlington Circuit Court; *David Matias v. Commonwealth*; CL21-3182

2022 County of Arlington Circuit Court; *Commonwealth of Virginia v. Roscoe Shaw*; CR21000393-00

2022 THE UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF ALABAMA; *USA v. Hooks*, 2:18-cr-00249 (resentencing)

2022 THE UNITED STATES DISTRICT COURT FOR THE SOUTHERN DISTRICT OF INDIANA; *USA v. Max B. Schafer*, 1:21-cr-00071

2022 Fairfax County Circuit Court; *Commonwealth of Virginia v. Vincent Wesley*; FE-2021-0000028

2022 302nd District Court of Dallas County; *In the Interest of E.C.B. and L.S.B. children*; DF-21-20175

2022 Superior Court of the District of Columbia; *United States of America v. Kenneth Carter*; 1995 FEL 005021

2022 Rockingham County Circuit Court; *Commonwealth of Virginia v. Daniel Schoenhardt*; CR21000331-00, 332-00, 333-00, 334-00, 335-00, 336-00, 337-00, 338-00, 339-00, 340-00

2022 Stafford County Circuit Court; *Commonwealth of Virginia v. George Ronnie Batts, Jr.*; CR22000071-00

2022 Superior Court of the District of Columbia; *United States of America v. James Bassil*; F10472-95B,C; F10105-95E

2022 Superior Court of the District of Columbia; *United States of America v. John Dewitt Blunt, III*; F-3065-92C, D, E, G, H, O

2023 Bedford County Circuit Court; *Commonwealth of Virginia v. Matthew James Perretta*; CR21000279-00 through -07

2023 Rockingham County Circuit Court; *Commonwealth of Virginia v. Jonathan Eli Ringle*; CR14R01806-01, CR14R01807-01, CR14R01808-01

2023 THE UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF VIRGINIA; *USA v. Jordan Willoughby*; 2:21-mj-00330

2023 Fayette County Circuit Court; *Commonwealth of Kentucky v. Andrew Buster, Jr.*; 20-CR-344

2023 Rockingham County Circuit Court*; Commonwealth of Virginia v. Jacob Tyler Leonard;* CR22000999-00, CR22001000-00, CR22001001-00, CR22001002-00, CR22001003-00, CR22001004-00, CR22001005-00, CR22001006-00, CR22001007-00, CR22001008-00, CR22001009-00, & CR22001010-00

2023 Fairfax County Circuit Court; *Commonwealth of Virginia v. Brendan Gilroy Lynch*; FE-2022-277.

2023 Fairfax County Circuit Court; *Commonwealth of Kentucky v. Alvin Brooks*, 21-CR-40

2023 Rockingham County Circuit Court; *Commonwealth of Virginia v. Christopher Allen Nesselrodt*; CR22001431, CR23000001

2023 Fairfax County Circuit Court; *Commonwealth of Virginia v. Yohannes Nessibu*; FE-2017-317

Juvenile Court Cases Sealed – Not Publicly Available

2019 Charleston West Virginia Special Education Due Process No. 19-020

2021 District of Columbia Juvenile Court (In re. D.M.)

2021 District of Columbia Juvenile Special Ed. Due Process (In re. E.J.)

2021 Superior Court of the District of Columbia Juvenile Court (In re. W.B.)

North Carolina Department of Public Safety
Psychology Services
Restrictive Housing Review

Offender Name:	[redacted], [redacted]			**Off #:**	0618705
Date of Birth:	[redacted]	**Sex:**	F	**Facility:**	ANSO
Date:	01/11/2021 13:20	**Provider:**	Lutz, Shannon C M.A. Psych.		

		Type:	SHU
Status:	In Restrictive Housing	**Threat to Self:**	None Indicated
Basis of Review:	Inmate was interviewed	**Adjustment:**	Appears to be Adjusting Well
Mental Status:	No significant mental health issues.	**Threat to Others:**	None indicated

Comment

Offender [redacted] was seen at the door of her cell on the RHU for both a door check and in response to a request form from her regarding interest in TDU program that this writer received this morning. Ms. [redacted] reported that she was fine and had no mental health concerns at present. In regards to the request form, Ms. [redacted] seemed baffled that it had been submitted, stating, "What is that? I didn't write that. I wonder who wrote that cause I didn't." This writer explained that the form was in her mail box upon return to facility today but encouraged her not to stress out about it or who may have written it. Ms. [redacted] indicated that the TDU program coordinator at NCCIW, as well as her psychologist Dr. Hahn and the psychiatrist Dr. Mann had all spoken with her about TDU while she was at NCCIW recently as "they thought it would be good for me." She indicated that she would have participated if accepted but the coordinator was not starting any new cohorts at present due to COVID. She asked this writer "to put me down for the program here please." This writer advised that she would add her to the list of those offenders who have expressed interest in participating when the program is officially started here. She thanked this writer for speaking with her. Contact ended. No evidence of acute clinical distress noted/observed/endorsed during the door check/contact.

Completed by Lutz, Shannon C M.A. Psych. Serv. Coord. on 01/11/2021 14:12

North Carolina Department of Public Safety
Mental Health Progress Note

Offender Name: [redacted], [redacted] Off #: 0618705
Date of Birth: [redacted] Sex: F Facility: ANSO
Date: 01/12/2021 13:50 Provider: Lynch, Lekeshia M MSW

Treatment Setting

Outpatient Program at Anson CI.

Reason for Services

Routine Follow-Up Session

Violence Alerts

There are no elevated risk factors presently noted for inmate [redacted].

Escape Alerts

There are no elevated risk factors presently noted for inmate [redacted].

Self-Injury Alerts

There are no elevated risk factors presently noted for inmate [redacted].

MSE/Behavioral Observations

Offender [redacted] AKA BROWN was seen on MP on the HOKE unit by cell door while on post transfer from inpatient treatment. This writer received the referral 1.11.2021 requesting I provide a follow-up contact with Brown. This writer spoke with BROWN briefly and provided a correspondence packet for her to complete to capture her current mental status. Offender BROWN appeared very agitated and expressed feeling unsafe and retaliation was the reason she was transferred back to Anson.

Offender was appropriately dressed in typical prison garb and demonstrated adequate hygiene and grooming. Offender was fully oriented x's 4. Her memory, attention and concentration were unimpaired. She spoke in a clear manner with speech of normal rate, tone and volume. Affect was mood congruent as she presented in a agitated state and is requesting to return back to Raleigh and shared "I feel that DPS has failed me and no one here is competent to address my concerns nor understands me. I feel more safe in a cell because I have had to suffer from abuse the last four years while in prison; its not easy for me because no one understands my Dysphoria." She presented with no overt evidence of psychosis or mania. Her thoughts were logical and goal oriented. She denied any current destructive, homicidal, or suicidal ideation but does report hopelessness. Offender does not report any concerns with her sleep, appetite or energy level. Insight and judgment are adequate.

Progress Towards Goal(s)

No progress was made this session as this writer met with offender by cell door in quarantine to assess her current mental status post inpatient treatment. No new presenting concerns were present.

Plan/Diagnostic Changes

There was no diagnostic change. Patient will continue to be followed by Outpatient Mental Health.

She verbally communicated her understanding of the emergency and non emergency mental health referral protocol and has agreed to utilize this process should the need arise.

Follow-up/Next Appointment

Offender [redacted] AKA BROWN will be seen by her schedule therapist for follow-up.

Diagnosis:

Gender Dysphoria in Adolescents and Adults, 302.85 - Current, Chronic, See Note

Unspecified Anxiety Disorder, 300.00 - Current, Temporary/Acute, See Note

Co-Pay Required: No **Cosign Required:** No

Telephone/Verbal Order: No

Standing Order: No

Offender Name:	[redacted], [redacted]			Off #:	0618705
Date of Birth:	[redacted]	Sex:	F	Facility:	ANSO
Date:	01/12/2021 13:50	Provider:	Lynch, Lekeshia M MSW		

Completed by Lynch, Lekeshia M MSW Clinical Social Worker on 01/12/2021 17:35

North Carolina Department of Public Safety
Psychology Services
Restrictive Housing Review

Offender Name:	[redacted], [redacted]			**Off #:**	0618705
Date of Birth:	[redacted]	**Sex:**	F	**Facility:**	ANSO
Date:	01/21/2021 08:24	**Provider:**	Dula, Jennifer L LCSW Clinical		

		Type:	SHU
Status:	In Restrictive Housing	**Threat to Self:**	None Indicated
Basis of Review:	Inmate was interviewed	**Adjustment:**	Appears to be Adjusting Well
Mental Status:	No significant mental health issues.	**Threat to Others:**	None indicated

Comment

Offender was seen at the door of her cell in restrictive housing. She denied having significant mental health concerns at present. Clinician informed offender that her assigned clinician was planning to see her early next week. Offender voiced understanding and understand how to submit referrals if in crisis.
No evidence of acute distress noted/observed/endorsed.

Completed by Dula, Jennifer L LCSW Clinical Social Worker on 01/21/2021 08:27

North Carolina Department of Public Safety
Mental Health Progress Note

Offender Name: [redacted], [redacted] Off #: 0618705
Date of Birth: [redacted] Sex: F Facility: ANSO
Date: 01/25/2021 10:30 Provider: Hahn, Patricia M Ph.D Asst. Dir.

Treatment Setting

Outpatient Program at Anson CI.

Reason for Services

Routine Follow-Up Session

Violence Alerts

Ms. [redacted] denied any current thoughts of wanting to harm others.

Escape Alerts

None currently noted.

Self-Injury Alerts

Ms. [redacted] denied any current thoughts of wanting to harm herself.

MSE/Behavioral Observations

Ms. [redacted] presented as a polite 39 year old Black-American female who appeared approximately her stated age. She was pleasant and cooperative during the therapy session. She displayed good eye contact and had no significant psychomotor agitation or retardation, although she did fidget with her mask frequently. Her speech was of normal rate, rhythm and volume. She was oriented to person, place, and time. Her attention and immediate memory appeared within normal limits. Her affect was basically euthymic and calm. She described her mood as mediocre." She denied current suicidal or homicidal ideation. She did not currently show active symptoms of psychosis or a thought disorder. Her judgment and insight were good.

Progress Towards Goal(s)

In December, Ms. [redacted] was sent to the inpatient unit at NCCIW due to thoughts of wanting to harm herself. She indicated she returned to Anson on 1/5/21, although she does not want to be at Anson because she does not think it is a good fit for her given her transgender status. She said she told clinicians at NCCIW that "Anson was a death sentence" for her, and that she would "make sure I would hurt myself to get back." She reported she also pointed out the high completed suicide rate for black transgender women and explained "we don't create mental health issues. We [just] kill ourselves."

Despite her reluctance to return, Ms. [redacted] has coped relatively well and did not try to obtain an emergency transfer back to NCCIW. She indicated the ACLU has sent a "demand letter" to Mr. Ishee asking that she be removed from Anson and that a private law firm may sue because she was kept in restrictive housing for 46 days instead of 30. She also explained that Zoloft has improved her mood considerably and stated "it makes me not care. It makes me really happy. I'm never late for it!" She did express some concern about using such a medication, and her reluctance was discussed. In addition, she reported she was moved to the geriatric pod, which she does currently like.

Ms. [redacted] was also happy about losing 20 pounds, but unfortunately she has at times used vomiting and laxatives to obtain this result. She described feeling "bad" about eating food and will make herself vomit, even though the food was a healthy food (like once it was an apple). Healthy weight loss and the dangers associated with purging were discussed, but will need to be addressed further if her purging continues.

Ms. [redacted] continued to express concern about a particular custody officer whom she believes is against her because she is transgender, and she stated the women in the clothes house did things to her clothes because they were friends of the offender with whom she had the altercation. She is also concerned about the scheduling of her appointment with Dr. Figlar, the urologist. Ms. [redacted] said she asked nursing for some information about vaginoplasty but was told mental health needed to print it for her.

Plan/Diagnostic Changes

Ms. [redacted] appeared closer to her stable baseline than she has been since August, despite being returned to Anson. Today, the undersigned worked with Ms. [redacted] about the idea of more actively addressing problems and decreasing her sense of shame about not yet having completed her surgery (as opposed to the goal of having her body be consistent with her gender). The undersigned also raised the idea of perhaps she and Ms. [redacted] meeting with the

Offender Name: [redacted], [redacted] Off #: 0618705
Date of Birth: [redacted] Sex: F Facility: ANSO
Date: 01/25/2021 10:30 Provider: Hahn, Patricia M Ph.D Asst. Dir.

woman she had the altercation with (perhaps with another individual the woman feels comfortable with) to try to work things out. Ms. [redacted] welcomed the idea and stated "I owe her an apology and would love to get her take on things." The undersigned may see if this could be done unless the other woman presses street charges, in which case it would not be advisable.

Follow-up/Next Appointment

Ms. [redacted] will be seen for her next appointment within 30 to 45 days. She knows to submit a referral if she needs to be seen prior to her appointment.

Co-Pay Required: No **Cosign Required:** No

Telephone/Verbal Order: No

Standing Order: No

Completed by Hahn, Patricia M Ph.D Asst. Dir. of Beh. Health on 01/26/2021 15:09

NORTH CAROLINA DEPARTMENT OF PUBLIC SAFETY
MENTAL HEALTH SERVICES REFERRAL

RECEIVED FEB 12 2021

Offender's Name: Kanautica Zayre-Brown OPUS Number: 0618705 RT

Facility at the time of Referral: Anson C.I. - Female

____ **Staff Referral** – Directions: Complete section below providing the reason for referral and description of behavior. Sign and date your request and return to Sick Call box or give to Medical or Behavioral Health Staff.

✓ **Offender Request** – Directions: Complete section below providing the reason for request and description of problem. Sign and date your request and return to Sick Call box or give to Medical or Behavioral Health Staff.

Reason for referral/request and description of behavior/problem:

I have submitted ~~numerous~~ request, letters, N sick calls in reference to getting information, updates, and/or important needed documented contact correspondence w/ UNC Urology, Dr. B. Fogler in accordance to my Approved UR for surgical consult for vaginoplasty.

my gender dysphoria needs ~~ACUTE~~ medical treatment and its causing depletion of my mental health. I have been patt having unlimited amounts of patience with DIS & Anson medical staff with providing me with the necessary medical treatment to allievate my diagnosis.

D. TARC N Dr. JACKSON approved the consult request in August 2020 and I have yet to be seen by urology.

I have utilized every available tool in my toolbox and now I am at a breaking point. Please assist. I have concluded that everyone is taking my diagnosis as a joke. Transferales has a suicide rate of 83%. and I am trying not to be part of that number.

Signature and Title of Staff Member Making Referral	*Print Staff Member Name*	*Date*
Kan P. Zay Brown	KANAUTICA P. ZAYRE-BROWN	11 Feb. 2021
Signature of Offender	*Print Offender Name*	*Date*

Scan: To the Electronic Health Record at the time of receipt

Dawn	Townsend	2-12-21
Signature of Behavioral Health Staff Scanning/Scheduling Referral	*Print Name*	*Date*

North Carolina Department of Public Safety
Self-Injury Risk Assessment

Offender Name: [redacted], [redacted] Off #: 0618705
Date of Birth: [redacted] Sex: F Facility: ANSO
Date: 02/16/2021 14:31 Provider: Waterhouse, Stephanie J M.A. Staff Psychologist

Type of Housing: Restrictive Housing

FINDINGS

This assessment and the resulting recommendations are based on the following sources of information:
Clinical Interview, Custody Staff

Reason for Referral

Offender [redacted] identifies as transfemale. She prefers female pronouns (she/her/hers) and goes by Offender BROWN.

Offender BROWN stated to Custody staff that she "couldn't take it anymore" and could not wait 30 minutes to be seen by a Clinician.

Treatment Setting

Outpatient Program at Anson CI.

Current Self-Injurious Behaviors

Offender BROWN has not engaged in self-injurious behavior.

Current Plan to Self-Injure

Offender BROWN denies any current plan to engage in self-injury.

Current Suicidal Ideation

Offender BROWN denied any suicidal ideation.

Current Suicidal Intent

Offender BROWN denies any suicidal intent.

Current Mental Status

Level of Consciousness: Alert and Oriented

Psychomotor Activity: Normal

General Appearance: Normal

Behavior: Cooperative

Mood: Appropriate to Content

Thought Process: Appropriate

Thought Content: Normal

RISK AND PROTECTIVE FACTORS ASSESSED:

This writer screened the offender for a variety of empirically validated factors commonly associated with risk for self-harm.

The following **STATIC** risk factors were assessed to be present and may increase the inmate's risk for engaging in suicide related behaviors: Chronic Medical Condition, Family history of suicide attempt, History of childhood abuse (physical or sexual), History of inpatient psychiatric treatment, History of mental illness

The following **DYNAMIC** risk factors were assessed to be present and may increase the inmate's risk for engaging in suicide related behaviors: Anxiety/Panic

The following **PROTECTIVE** factors were assessed to be present and may decrease the inmate's risk of suicide: Able to cope with stress, Able to identify reasons to live, Adequate problem solving skills, Denial of suicidal ideation/intent/plan, Future orientation, Responsibility to loved ones/children, Supportive family relationships, View of death as negative, Willingness to engage in treatment

Offender [redacted] identifies as transfemale. She prefers female pronouns (she/her/hers) and goes by Offender BROWN.

Offender Name: [redacted], [redacted] Off #: 0618705
Date of Birth: [redacted] Sex: F Facility: ANSO
Date: 02/16/2021 14:31 Provider: Waterhouse, Stephanie J M.A. Staff Psychologist

Offender BROWN [redacted]. Offender BROWN reports that her mother attempted tried to commit suicide by jumping off of a bridge after receiving a cancer diagnosis. She was stopped by local law enforcement. Offender BROWN reports a history of swallowing pills which was labeled by the prison system as a suicide attempt. However, he reports that he had taken the pills to be moved from the men's prison. Offender BROWN reports a history of [redacted]. Offender BROWN has a history of inpatient psychiatric care only while incarcerated.

Offender BROWN reports feeling anxiety. She rates her current level of anxiety as a 7 out of 10 (1= low, 10= high).

Offender BROWN copes with stress by journaling, writing her book, talking to her family, and medication compliance. Offender BROWN wants to live so that she can be a lawyer, be with her husband, see her family, and "do great and I never want to come back to prison." Offender BROWN stated that her future is "going to be great for me." Offender BROWN stated she is Muslim, but does not have any religious beliefs against suicide. Offender BROWN feels that other offenders talk to her when they are going through problems, but are unavailable to talk when she needs them.

Offender BROWN was placed on precautions due to stating that she "could not take it anymore." When another Clinician was notified, Offender BROWN was advised that she would be seen in 30 minutes when the next clinician was available. Offender BROWN stated that she could not wait 30 minutes and therefore was placed on self-injury precautions for her safety.

Offender BROWN expressed frustration regarding communication from Medical staff. She stated that her kidney is not functioning well and that she is passing blood clots. She reports that Medical staff are aware of this, but she is unsure of what is going to happen. Offender BROWN stated that she should be seen by an Endocrinology and Urologist and is unsure of the status of these provider visits. Offender BROWN also stated that her UR for her hormone therapy will expire next month and expressed concern that it would not be renewed in time. Offender BROWN stated that she felt unheard and that her concerns were not being taken seriously. Further, Offender BROWN expressed frustration regarding the mental health referral process at Anson CI. She feels the communication between mental health staff and Offender BROWN could be improved. Offender BROWN was encouraged to continue discussing her frustrations with her primary therapist. This Clinician provided support and space for Offender BROWN to process her frustrations. She appeared to feel better at the end of the session and was advised that her primary therapist will be notified of this session.

At this time, Offender BROWN has not communicated any suicidal ideation, intent, or plan. Suicide precautions are not indicated and Offender BROWN was released to full custody control.

NMOS order was not completed in previous note due to high likelihood that Offender BROWN would be seen within the next 30 minutes. NMOS will be added and then discontinued.

RECOMMENDATIONS

Suicide Watch: Self-Injury Precautions not currently indicated.
Suicide Watch was initiated on: 02/16/2021 13:50

New Non-Medication Orders:

Order	Frequency	Duration	Details	Ordered By
Observation	One Time		placed on self-injury precautions by Mr. Messer	Waterhouse, Stephanie J M.A. Staff Psychologist

Discontinue Reason:
Order Date: 02/16/2021
End Date:

Offender Name: [redacted], [redacted] Off #: 0618705
Date of Birth: [redacted] Sex: F Facility: ANSO
Date: 02/16/2021 14:31 Provider: Waterhouse, Stephanie J M.A. Staff Psychologist

Completed by Waterhouse, Stephanie J M.A. Staff Psychologist on 02/16/2021 15:33

North Carolina Department of Public Safety
Mental Health Progress Note

Offender Name: [redacted], [redacted] Off #: 0618705
Date of Birth: [redacted] Sex: F Facility: ANSO
Date: 02/19/2021 11:05 Provider: Hahn, Patricia M Ph.D Asst. Dir.

Treatment Setting

Outpatient Program at Anson CI.

Reason for Services

Routine Follow-Up Session

Violence Alerts

Ms. [redacted] denied any current thoughts of wanting to harm others.

Escape Alerts

None currently noted.

Self-Injury Alerts

Ms. [redacted] denied any current thoughts or plans of wanting to harm herself; however, at times she does have thoughts of self-mutilation to get rid of the remaining part of her penis.

MSE/Behavioral Observations

Ms. [redacted] presented as a polite 39 year old Black -American female who appeared approximately her stated age. She was pleasant and cooperative during the therapy session. She displayed good eye contact and had no significant psychomotor agitation or retardation. Her speech was of normal rate, rhythm and volume. She was oriented to person, place, and time. Her attention and immediate memory appeared within normal limits. Her affect was somewhat dysphoric, ands he described her mood as "I don't know . . . I'm dull." She denied current suicidal or homicidal ideation. She did not currently show active symptoms of psychosis or a thought disorder. Her judgment and insight were at least fair.

Progress Towards Goal(s)

Ms. [redacted]'s main issue continues to be that her consult appointment with the urologist has not yet been scheduled. The barriers to this scheduling were discussed but it was unclear what has actually happened since there were some discrepancies between what each of us have been told. The main discrepancy is that it is unclear whether Ms. [redacted] is supposed to have her consult first or whether she is supposed to wait for her vaginoplasty to be approved by DPS. Ms. [redacted] stated one of her DTARC forms said Dr. Junker and Deputy Commissioner Harris agree with the disapproval of the vaginoplasty until the surgery consult was completed but HERO would not open the DTARC notes so this could not be immediately confirmed (and the undersigned wanted to finish her note). The undersigned will try to update Dr. Peiper before the 2/25/21 DTARC meeting. Ms. [redacted] would like the following to be considered: 1) she wants her UR approved urology consult, 2) she would like to have an endocrinologist appointment since she has not had one in eight months, and 3) she would like to be considered for compassionate release or ECL. Ms. [redacted] stated thoughts of self-mutilation are sometimes on her mind due to her gender dysphoria and not receiving her urology consult despite DTARC and UR approval. She expressed worry because she feels she is increasingly impulsive and her coping mechanisms have not been helping. Therapy focused on examining how the current generation is changing how transgender/non-binary issues are being addressed as to body image. Ms. [redacted] acknowledged that some transgender individuals she has met are not as focused on changing their physical characteristics and stated "I think I tried that but I don't think it's possible."

Ms. [redacted] indicated her Zoloft did not seem to be working as well, and the undersigned indicated she would ask Mr. Messer about psychiatry clinic. The referral process was also discussed, especially given her concern that she has been "super-impulsive" lately. Ms. [redacted] and the undersigned briefly discussed the idea of trying to meet with the offender regarding the incident but it was decided that was not a good idea because the woman may have contacted lawyers.

Plan/Diagnostic Changes

Ms. [redacted] has improved since her NCCIW admission but continues to be dysphoric.

Follow-up/Next Appointment

Ms. [redacted] will be seen for her next individual therapy appointment in the next 30 to 45 days, if not sooner. She knows to submit a referral if she needs to be seen sooner.

Offender Name:	[redacted], [redacted]			Off #:	0618705
Date of Birth:	[redacted]	Sex:	F	Facility:	ANSO
Date:	02/19/2021 11:05	Provider:	Hahn, Patricia M Ph.D Asst. Dir.		

Co-Pay Required: No **Cosign Required:** No

Telephone/Verbal Order: No

Standing Order: No

Completed by Hahn, Patricia M Ph.D Asst. Dir. of Beh. Health on 02/19/2021 13:17

North Carolina Department of Public Safety
Psychiatric Progress Note

Offender Name: [redacted], [redacted] Off #: 0618705
Date of Birth: [redacted] Sex: F Facility: ANSO
Date: 03/17/2021 08:58 Provider: Younus, Syeda R MD

Treatment Setting

Outpatient Program at Anson CI.

Violence Alerts

There is no apparent, current, significant risk of violence noted for inmate [redacted].

Self-Injury Alerts

There is no apparent, current, significant risk of self-injury noted for inmate [redacted].

SIRA was performed on 02/16/21.

Pt reports one suicide attempt in 2019 by OD "to get away from men prison."
She was admitted to inpatient NCCIW in December 2020 due to self harming thoughts.

Subjective

This is the 2nd incarceration for this 39 y.o. offender who was admitted to prison on 10/10/2017 on a primary charge of HABITUAL FELON with a project release date in 2025.

Pt was born biologically as a male but she identifies herself as female and going through transition of being female. She goes by Miss. Brown.

Pt was seen by Dr. Younus in January, at that visit Zoloft was continued. On 02/16/21 SIRA was performed. Pt was seen today, she feels Zoloft is not helping like before "may be I am immune to it now." She have still days when she feels sad and have lack of motivation. She is sleeping ok. She reports anxiety related to "who I am." She is trying to lose weight. Denies anger issues.

No SI, HI, AVH or manic symptoms.

She is married and her husband is supportive.
She has an adult son and she talks to him regularly.
Pt has tried only Zoloft.

Objective

Identifying Information:39yrs old, biologically born as male but identified herself as female and is in the process of transitioning to a female
Appearance: fairly groomed, wearing mask
Behavior: cooperative
Thinking: Logical
Perception: Denies
Mood: "blah"
Affect: constricted
Orientation: no evidence of delirium or confusion
Suicidal/Homicidal Ideation: Patient denies both.
Judgment/Insight: fair

Side Effects

Denies.

Response to Treatment

Positive.

Offender Name: [redacted], [redacted] Off #: 0618705
Date of Birth: [redacted] Sex: F Facility: ANSO
Date: 03/17/2021 08:58 Provider: Younus, Syeda R MD

Labs/Weights/AIMS/Vitals

Reviewed.

Diagnosis

Gender Dysphoria
Unspecified Anxiety Disorder
Medical: [redacted], low back pain, chronic pain and unspecified limb, myopia, hallux valgus right and left foot, hx/o localized swelling mass and lump/neck, h/o abnormal weight gain, tinea unguium absence and aplasia of testes.

Plan

Target Symptoms: Anxiety.

Medications: Increase Zoloft. Risk/benefits including worsening of mood and SI reviewed.
Referrals: None
Other Treatment/Labs: Cont therapy.
Follow-Up:2-3 months or sooner as needed.

New Medication Orders:

Rx#	Medication	Order Date	Prescriber Order
	Sertraline HCl	03/17/2021 08:58	100mg By Mouth at 11:00 a.m. x 90 day(s) Pill Line Only

Indication: Unspecified Anxiety Disorder

Discontinued Medication Orders:

Rx#	Medication	Order Date	Prescriber Order
A4330425	*SERTRALINE 50 MG TAB*	*03/17/2021 08:58*	*Take one (1) tablet by mouth daily at 11am ** Direct Observation Therapy **

Discontinue Type: *When Pharmacy Processes*
Discontinue Reason: *Order Changed*
Indication:

Schedule:

Activity	Date Scheduled	Scheduled Provider
Psychiatric Progress Note f/u	06/02/2021 00:00	Younus, Syeda R Psychiatrist

Patient Education Topics:

Date Initiated	Format	Handout/Topic	Provider	Outcome
03/17/2021	Counseling	Access to Care	Younus, Syeda	Verbalizes Understanding
03/17/2021	Counseling	Compliance - Treatment	Younus, Syeda	Verbalizes Understanding
03/17/2021	Counseling	Medication Side Effects	Younus, Syeda	Verbalizes Understanding

Co-Pay Required: No **Cosign Required:** No
Telephone/Verbal Order: No
Standing Order: No

Completed by Younus, Syeda R MD Psychiatrist on 03/17/2021 09:28

Offender Name:	[redacted], [redacted]			Off #:	0618705
Date of Birth:	[redacted]	Sex:	F	Facility:	ANSO
Date:	03/17/2021 08:58	Provider:	Younus, Syeda R MD		

North Carolina Department of Public Safety
Mental Health Progress Note

Offender Name: [redacted], [redacted] Off #: 0618705
Date of Birth: [redacted] Sex: F Facility: ANSO
Date: 03/26/2021 10:30 Provider: Hahn, Patricia M Ph.D Asst. Dir.

Treatment Setting

Outpatient Program at Anson CI.

Reason for Services

Routine Follow-Up Session

Violence Alerts

Ms. [redacted] denied any current thoughts of wanting to harm others.

Escape Alerts

None currently noted.

Self-Injury Alerts

Ms. [redacted] denied any current thoughts of wanting to harm herself.

MSE/Behavioral Observations

Ms. [redacted] presented as a polite 39 year old Black-American female who appeared approximately her stated age. She was pleasant and cooperative during the therapy session. She displayed good eye contact and had no significant psychomotor agitation or retardation. Her speech was of normal rate, rhythm and volume. She was oriented to person, place, and time. Her attention and immediate memory appeared within normal limits. Her affect was euthymic and more like her usual self. She described her mood as "a be all you can be mood." She denied current suicidal or homicidal ideation. She did not currently show active symptoms of psychosis or a thought disorder. Her judgment and insight were at least fair.

Progress Towards Goal(s)

Ms. [redacted] reported her Zoloft was recently increased. She indicated lately she is "not feeling my authentic self" and does not like the way she has been feeling for the last couple of weeks. She said she wakes up "hoping the day will be over with." She indicated she has been staying in her room and writing in her journal. She did indicate she was excited about the tablets and explained her family is sending her things to make her feel better. She attributes her bad feelings to her dysphoria and explained "I just want to be me and I can't be me."

Ms. [redacted] reported she wrote an 11-page letter about her vaginoplasty request to Commissioner Ishee but now "it's missing." The plan for getting her urology consult was discussed in that UNC now wants transgender individuals to go through a Transgender Health Management Program Team before a consult. She did acknowledge that the DTARC did appear to be trying to do all they can do. Ms. [redacted] does seem to somewhat underestimate the effect the pandemic has had on health care appointments, and this was addressed.

Ms. [redacted] indicated she has a job working with the tablets that provides 12 merit days a month, and she stated she is getting 4 days a month for staying out of trouble. She is also studying for her LSATs. She described an incident in which she avoided physical confrontation, although she did appropriately address an offender who called her "boy," a word that is both racist and transphobic. She said custody gave her positive feedback as to how she handled the incident. Ms. [redacted] is also trying to get velco shower shoes, for which she said she has a 490. Ms. [redacted] expressed some concerns about taking a medication for depression, and some psychoeducation was provided.

Plan/Diagnostic Changes

Although Ms. [redacted] indicated she does not feel like her "genuine self," the undersigned sees much improvement in her mood and outlook and believes Ms. [redacted] is presenting more like her usual self. Her depression appears to have improved since December and since taking Zoloft.

Follow-up/Next Appointment

Ms. [redacted] will be seen for her next individual appointment in 30 to 45 days. She knows to submit a referral if she needs to be seen prior to her appointment.

Offender Name: [redacted], [redacted] Off #: 0618705
Date of Birth: [redacted] Sex: F Facility: ANSO
Date: 03/26/2021 10:30 Provider: Hahn, Patricia M Ph.D Asst. Dir.

Co-Pay Required: No **Cosign Required:** No

Telephone/Verbal Order: No

Standing Order: No

Completed by Hahn, Patricia M Ph.D Asst. Dir. of Beh. Health on 03/26/2021 12:29

North Carolina Department of Public Safety
Mental Health Referral

Offender Name: [redacted], [redacted] Off #: 0618705
Date of Birth: [redacted] Sex: F Facility: ANSO
Date: 05/17/2021 13:25 Provider: Lutz, Shannon C M.A. Psych.

Treatment Setting

Outpatient Program at Anson CI.

Referral Source

Assistant Director Behavioral Health, Central Region

Reason for Referral

Asst. Director BH requested that this writer meet with offender Brown to address concerns that have arisen over the past three weeks.

Violence Alerts

There are no elevated risk factors presently noted for inmate [redacted].

Escape Alerts

There are no elevated risk factors presently noted for inmate [redacted].

Self-Injury Alerts

At the end of today's session, offender Brown denied any current thoughts, intent, and/or plan to hurt herself including thoughts to engage in self-mutilation to expedite the removal of her penis.

Screening Results

Ms. Brown was seen in this writer's office in close custody. She presented dressed neatly in clean clothing and exhibited good personal hygiene. She was cordial, pleasant and cooperative during the present session. She was fully alert and oriented in all spheres with no impairments in attention or memory endorsed or observed. She maintained consistent and appropriate eye contact and had no significant psychomotor agitation or retardation. Her speech was of normal rate, rhythm and volume. At the outset of the session, her affect was mildly dysphoric (frustrated), but being provided with a safe and healthy space to fully express her thoughts and emotions, her affect improved, smiling several times, laughing at this writer (appropriately so), and speaking of her frustrations with a more positive tone of voice and in a more realistic/practical manner. At the end of the session, she reported she felt "better about things, knowing that you actually took a step to find something out for me and I know from seeing you around here that you do follow through on things you say you will do even if that means you come back and tell me you don't know the answer or that you didn't get a response at all." In regards to current referral concerns precipitating this contact, Ms. Brown denied current suicidal (see above) or homicidal ideation, including current thoughts, intent, or plan to self-mutilate her genital to expedite the process and/or get "things resolved." She agreed that hurting herself in this manner would not be the right way to go about things or to have "my phallus removed." Ms. Brown did not currently exhibit any active symptoms of psychosis or a thought disorder. At present, her judgment and insight appear intact/adequate to meet situational demands but it is noted that these may wax and wane secondary to heightened emotions and situational stressors. Overall, there was no evidence of acute clinical distress noted/observed today, and thus, she does not warrant any special alert precautions from a mental health standpoint.

Mental Health Services Required

Yes

Disposition

Ms. Brown is currently on the active mental health and psychiatric caseloads and will continue to be seen as clinically indicated by both her primary clinician and psychiatry. This writer will remain available to assist with any additional case management and therapeutic contacts as clinically indicated and as directed to by Ms. Brown's primary clinician, the PPM, or other relevant parties.

Co-Pay Required: No **Cosign Required:** No

Telephone/Verbal Order: No

Standing Order: No

Offender Name:	[redacted], [redacted]	Off #:	0618705
Date of Birth:	[redacted]	Sex:	F
Facility:	ANSO		
Date:	05/17/2021 13:25	Provider:	Lutz, Shannon C M.A. Psych.

Completed by Lutz, Shannon C M.A. Psych. Serv. Coord. on 05/17/2021 14:40

Requested to be reviewed by Hahn, Patricia M Ph.D Asst. Dir. of Beh. Health.

Review documentation will be displayed on the following page.

From: "brian.sheitman@ncdps.gov" <brian.sheitman@ncdps.gov>
To: "Peiper, Lewis" <lewis.peiper@ncdps.gov>
Subject: Fwd: [External] Urgent
Date: Mon, 17 May 2021 11:17:47 -0400
Importance: Normal

Should you have the psychologist at her camp see her? She is at NCCIW I think.

Sent from my iPhone

Begin forwarded message:

From: "Catlett, Terri" <terri.catlett@ncdps.gov>
Date: May 17, 2021 at 11:08:50 AM EDT
To: "Peiper, Lewis" <lewis.peiper@ncdps.gov>, "Sheitman, Brian" <brian.sheitman@ncdps.gov>
Subject: Fw: [External] Urgent

FYI

Terri L. Catlett
Director of Healthcare Administration
NC Department of Public Safety
831 W. Morgan St.
MSC 4293
Raleigh, North Carolina 27699
Phone: 919-838-4000
Email: terri.catlett@ncdps.gov

From: Dionne Brown <dionnebrown37@yahoo.com>
Sent: Monday, May 17, 2021 11:07 AM
To: Catlett, Terri <terri.catlett@ncdps.gov>
Subject: [External] Urgent

or so. Today a Anson mental health behavior specialist came and told Kanautica that Mrs. Catlett wasnt in contact with the UNC provider and that Dr. Hahn would follow up again today with Mrs. Catlett.
Kanautica has voice to me that she is emotionally withdrawn and manically depressed. She has also informed out family that she desire to self mutilated her primary sex characteristics. Why do my wife has to entertain any of these thoughts just to get the medically necessary care that it needed to alleviate her dysphoria.
Is there a way that either one of you can correspond with me in reference to this issue so I can inform her so she can feel better and doesn't have to go through mental health challenges just to be her authentic self.
She has utter to me also that she witness other transgender offenders receiving the adequate treatment needed to alleviate their dysphoria. No transgender transition is the same but providing alleviation for one and not all isn't fair or acceptable.

This matter deserves immediate attention and with all due respect I will be seeking a reply within a reasonable time frame.

I am,

Dionne Brown

Sent from Yahoo Mail on Android

From: "Peiper, Lewis" <lewis.peiper@ncdps.gov>
To: "Bowman, Marvella" <Marvella.Bowman@ncdps.gov>
Cc: "Catlett, Terri" <terri.catlett@ncdps.gov>, "Sheitman, Brian" <brian.sheitman@ncdps.gov>, "Messer, Charles" <Charles.Messer@ncdps.gov>
Subject: FW: [External] Urgent
Date: Mon, 17 May 2021 16:28:02 +0000
Importance: Normal

Dr. Bowman, I see that Offender 0618705 spoke with Darlene Baker this morning and that Baker was going to communicate with you. Based on the timing of the original email below I believe Offender [redacted] (Zayre-Brown) may have called Dionne Brown following that contact and made some statements to him about depression and self-mutilation.

I recognize that Dr. Hahn addressed these topics in her individual session less than 3 weeks ago, but would you see that someone follows up with this offender today please?

Thanks,
Jon

Lewis Jonathan Peiper, Ph.D.
Director of Behavioral Health
NC Department of Public Safety
Division of Adult Correction - Prisons
Behavioral Health Services
831 W. Morgan Street
Raleigh, NC 27699-4277
(C) 919-306-4388
(O) 984-255-6072
(f) 919-733-1415
lewis.peiper@ncdps.gov
www.ncdps.gov

From: Catlett, Terri
Sent: Monday, May 17, 2021 11:09 AM
To: Peiper, Lewis <lewis.peiper@ncdps.gov>; Sheitman, Brian <brian.sheitman@ncdps.gov>
Subject: Fw: [External] Urgent

FYI

Terri L. Catlett
Director of Healthcare Administration
NC Department of Public Safety
831 W. Morgan St.
MSC 4293
Raleigh, North Carolina 27699
Phone: 919-838-4000
Email: terri.catlett@ncdps.gov

From: Dionne Brown <dionnebrown37@yahoo.com>
Sent: Monday, May 17, 2021 11:07 AM
To: Catlett, Terri <terri.catlett@ncdps.gov>
Subject: [External] Urgent

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This matter deserves immediate attention and with all due respect I will be seeking a reply within a reasonable time frame.

I am,

Dionne Brown

Sent from Yahoo Mail on Android

From: "Catlett, Terri" <terri.catlett@ncdps.gov>
To: "Peiper, Lewis" <lewis.peiper@ncdps.gov>, "Sheitman, Brian" <brian.sheitman@ncdps.gov>
Subject: Fw: [External] Urgent
Date: Mon, 17 May 2021 15:08:50 +0000
Importance: Normal

FYI

Terri L. Catlett
Director of Healthcare Administration
NC Department of Public Safety
831 W. Morgan St.
MSC 4293
Raleigh, North Carolina 27699
Phone: 919-838-4000
Email: terri.catlett@ncdps.gov

From: Dionne Brown <dionnebrown37@yahoo.com>
Sent: Monday, May 17, 2021 11:07 AM
To: Catlett, Terri <terri.catlett@ncdps.gov>
Subject: [External] Urgent

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This matter deserves immediate attention and with all due respect I will be seeking a reply within a reasonable time frame.

I am,

Dionne Brown

Sent from Yahoo Mail on Android

From: "Sheitman, Brian" <brian.sheitman@ncdps.gov>
To: "Peiper, Lewis" <lewis.peiper@ncdps.gov>
Subject: Fwd: [External] Urgent
Date: Mon, 17 May 2021 15:17:48 -0000
Importance: Normal

Should you have the psychologist at her camp see her? She is at NCCIW I think.

Sent from my iPhone

Begin forwarded message:

From: "Catlett, Terri" <terri.catlett@ncdps.gov>
Date: May 17, 2021 at 11:08:50 AM EDT
To: "Peiper, Lewis" <lewis.peiper@ncdps.gov>, "Sheitman, Brian" <brian.sheitman@ncdps.gov>
Subject: Fw: [External] Urgent

FYI

Terri L. Catlett
Director of Healthcare Administration
NC Department of Public Safety
831 W. Morgan St.
MSC 4293
Raleigh, North Carolina 27699
Phone: 919-838-4000
Email: terri.catlett@ncdps.gov

From: Dionne Brown <dionnebrown37@yahoo.com>
Sent: Monday, May 17, 2021 11:07 AM
To: Catlett, Terri <terri.catlett@ncdps.gov>
Subject: [External] Urgent

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Is there a way that either one of you can correspond with me in reference to this issue so I can inform her so she can feel better and doesn't have to go through mental health challenges just to be her authentic self.
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This matter deserves immediate attention and with all due respect I will be seeking a reply within a reasonable time frame.

I am,

Dionne Brown

Sent from Yahoo Mail on Android

From: "Catlett, Terri" <terri.catlett@ncdps.gov>
To: "Junker, Gary" <gary.junker@ncdps.gov>
Subject: Fw: KZB Follow-up
Date: Tue, 25 May 2021 14:33:27 +0000
Importance: Normal

Part of email chain regarding offender Brown. I will send you the mail from her family shortly.

Terri L. Catlett
Director of Healthcare Administration
NC Department of Public Safety
831 W. Morgan St.
MSC 4293
Raleigh, North Carolina 27699
Phone: 919-838-4000
Email: terri.catlett@ncdps.gov

From: Lutz, Shannon <Shannon.Lutz@ncdps.gov>
Sent: Monday, May 17, 2021 3:43 PM
To: Catlett, Terri <terri.catlett@ncdps.gov>
Cc: Peiper, Lewis <lewis.peiper@ncdps.gov>; Hahn, Patricia <Patricia.Hahn@ncdps.gov>
Subject: Re: KZB Follow-up

That is what I figured and tried to convey to Ms. Brown. Do you want me to provide this information to her today or hold off?

Shannon C. Lutz, M.A., LPA
Psychological Services Coordinator - Therapeutic Diversion Unit
NC Department of Public Safety
Division of Adult Corrections and Juvenile Justice
Anson Correctional Institution #4575
P. O. Box 280
Polkton, NC 28135
(704) 272- 4848 (office)
(704) 288-8641 (state cell)
(704) 694-1722 (fax)
shannon.lutz@ncdps.gov
www.ncdps.gov

From: Catlett, Terri <terri.catlett@ncdps.gov>
Sent: Monday, May 17, 2021 3:04 PM
To: Lutz, Shannon <Shannon.Lutz@ncdps.gov>
Cc: Peiper, Lewis <lewis.peiper@ncdps.gov>; Hahn, Patricia <Patricia.Hahn@ncdps.gov>
Subject: Re: KZB Follow-up

I have reached out for an appointment date. I have yet to get confirmation from UNC.

Terri L. Catlett
Director of Healthcare Administration
NC Department of Public Safety
831 W. Morgan St.
MSC 4293
Raleigh, North Carolina 27699
Phone: 919-838-4000
Email: terri.catlett@ncdps.gov

From: Lutz, Shannon <Shannon.Lutz@ncdps.gov>
Sent: Monday, May 17, 2021 2:08 PM
To: Bowman, Marvella <Marvella.Bowman@ncdps.gov>; Hahn, Patricia <Patricia.Hahn@ncdps.gov>; Catlett, Terri <terri.catlett@ncdps.gov>; Peiper, Lewis <lewis.peiper@ncdps.gov>
Cc: Messer, Charles <Charles.Messer@ncdps.gov>; Baker, Darlene <darlene.baker@ncdps.gov>
Subject: Re: KZB Follow-up

Good afternoon,

I am wrapping up with Mrs. Brown right now and during our session, she expressed strong distrust in the accuracy of information provided to her in reference to upcoming medically necessary appointments. She provided this as one example: being given multiple dates/timeframe deadlines for telehealth consultation with UNC Transgender Health Management Program Team as well as consultation and surgery with Dr. Bradley Figler. However, when these dates have arrived, there has not been any follow through to date. Additionally, she recently learned that UNC THP Program Manager Katherine Kroft issued a program statement indicating that UNC THP was temporarily pausing the intake of new patients into the THP. She is wondering how this affects her and any future scheduling of appointments and if it does, are there other providers available that DPS can utilize to expedite the process? From an emotional health standpoint, it does appear that Ms. Brown continues to experience acute dysphoria secondary to the length of time that has passed which has yet to resolve medically necessary treatment. Being able to trust the accuracy of information/dates given to her would certainly go a long way in reducing this distress. I am certainly happy to assist with clinical encounters and/or providing pertinent information to Ms. Brown moving forward, as from an emotional health standpoint. Please advise.....

Shannon C. Lutz, M.A., LPA
Psychological Services Coordinator - Therapeutic Diversion Unit
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(704) 272- 4848 (office)
(704) 288-8641 (state cell)
(704) 694-1722 (fax)
shannon.lutz@ncdps.gov
www.ncdps.gov

From: Bowman, Marvella <Marvella.Bowman@ncdps.gov>
Sent: Monday, May 17, 2021 1:13 PM
To: Hahn, Patricia <Patricia.Hahn@ncdps.gov>
Cc: Lutz, Shannon <Shannon.Lutz@ncdps.gov>; Messer, Charles <Charles.Messer@ncdps.gov>; Baker, Darlene <darlene.baker@ncdps.gov>
Subject: Re: KZB Follow-up

Dr. Peiper actually asked that someone see her due to the email from Mr. Brown. Ms. Lutz already spoke with her briefly earlier, but plans to make a formal contact shortly to address the concerns raised.

****

Marvella A. Bowman, Ph.D., HSP-P
Corrections Psychological Services Coordinator
NC Department of Public Safety
Division of Adult Correction and Juvenile Justice
Anson Correctional Institution #4575
Post Office Box 280
Polkton, NC 28135
Phone: (704) 695-1013
Direct: (704) 272-4853
State Mobile Phone: (828) 610-3648
Fax: (704) 694-1729
Email: marvella.bowman@ncdps.gov
Website: http://www.ncdps.gov/
PREVENT. PROTECT. PREPARE.

On May 17, 2021, at 13:10, Hahn, Patricia <Patricia.Hahn@ncdps.gov> wrote:

Thank you, Ms. Lutz and Ms. Baker for making sure someone spoke with Ms. Brown!

Mr. Messer and Dr. Bowman: I saw Ms. Brown on April 28 so if I see her on May 28 I'll still be a little on the early side for seeing her within a month! But Ms. Catlett did say she should be scheduled for her UNC-CH appointment in the next week or two (as of April 28), which I guess should have been by now. As you know, I did contact Ms. Catlett on Friday -- UNC has not gotten back to her and she said she will call. I will follow up on that with her in just a few minutes. I also received an e-mail from Dionne Brown, Ms. Brown's husband.

In the meantime, if you want everyone to complete a referral, please have someone tell Ms. Brown to submit a referral. And if you don't try to get everyone to submit an actual referral, then consider her request to Ms. Baker a referral and please have someone see her to address her current concerns.

Tricia Hahn, M.S.P.H., Ph.D., L.P.
Assistant Director, Behavioral Health, Central Region
North Carolina Department of Public Safety
Division of Adult Correction and Juvenile Justice
430 North Salisbury Street
Raleigh, North Carolina 27603

office (919) 582-6142
fax (919) 715-4179
patricia.hahn@ncdps.gov
www.ncdps.gov

From: Lutz, Shannon <Shannon.Lutz@ncdps.gov>
Sent: Monday, May 17, 2021 9:42 AM
To: Hahn, Patricia <Patricia.Hahn@ncdps.gov>
Cc: Messer, Charles <Charles.Messer@ncdps.gov>; Bowman, Marvella <Marvella.Bowman@ncdps.gov>; Baker, Darlene <darlene.baker@ncdps.gov>
Subject: Re: KZB Follow-up

Dr. Hahn,

Ms. Baker just spoke with Ms. Brown and relayed the information to her regarding her next appointment with you. Ms. Brown stated that Ms. Brown indicated she "needs to speak with someone because it's been almost a month and she hasn't heard anything about her appointment at UNC." She was provided with the dates you listed as possible appointment dates (05/26 or 06/04) and she stated she would like to speak with a clinician at this facility sooner than this if possible. Just passing her request along. Ms. Baker will be completing an OPSSC note once she is finished with psychiatric clinic this morning. Please advise if there is anything further that either I, myself, or my CBS team can do to assist. Have a great day!

Shannon C. Lutz, M.A., LPA
Psychological Services Coordinator - Therapeutic Diversion Unit
NC Department of Public Safety
Division of Adult Corrections and Juvenile Justice
Anson Correctional Institution #4575
P. O. Box 280
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(704) 272- 4848 (office)
(704) 288-8641 (state cell)
(704) 694-1722 (fax)
shannon.lutz@ncdps.gov
www.ncdps.gov

From: Hahn, Patricia <Patricia.Hahn@ncdps.gov>
Sent: Friday, May 14, 2021 11:17 AM
To: Lutz, Shannon <Shannon.Lutz@ncdps.gov>; Jackson, Rhonda <Rhonda.Jackson@ncdps.gov>; Baker, Darlene <darlene.baker@ncdps.gov>; Jarvis, Amani <Amani.Jarvis@ncdps.gov>
Cc: Messer, Charles <Charles.Messer@ncdps.gov>; Bowman, Marvella <Marvella.Bowman@ncdps.gov>
Subject: Re: KZB Follow-up

Thank you everyone! Ms. Catlett may have more information by then so I'll let you know if I hear anything. Thanks again for doing this!

Tricia Hahn, M.S.P.H., Ph.D., L.P.
Assistant Director, Behavioral Health, Central Region
North Carolina Department of Public Safety
Division of Adult Correction and Juvenile Justice
430 North Salisbury Street

Raleigh, North Carolina 27603
office (919) 582-6142
fax (919) 715-4179
patricia.hahn@ncdps.gov
www.ncdps.gov

From: Lutz, Shannon <Shannon.Lutz@ncdps.gov>
Sent: Friday, May 14, 2021 10:54 AM
To: Jackson, Rhonda <Rhonda.Jackson@ncdps.gov>; Baker, Darlene <darlene.baker@ncdps.gov>; Jarvis, Amani <Amani.Jarvis@ncdps.gov>
Cc: Messer, Charles <Charles.Messer@ncdps.gov>; Hahn, Patricia <Patricia.Hahn@ncdps.gov>; Bowman, Marvella <Marvella.Bowman@ncdps.gov>
Subject: Fw: KZB Follow-up

Would one of you kindly follow up with offender K. [redacted] regarding the information appearing in the email below from Dr. Hahn? This contact needs to be completed during the workday on Monday 05/17/2021. Let me know if you have any questions or concerns, as well as once you have spoken with offender [redacted]. Thanks!

Shannon C. Lutz, M.A., LPA
Psychological Services Coordinator - Therapeutic Diversion Unit
NC Department of Public Safety
Division of Adult Corrections and Juvenile Justice
Anson Correctional Institution #4575
P. O. Box 280
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(704) 272- 4848 (office)
(704) 288-8641 (state cell)
(704) 694-1722 (fax)
shannon.lutz@ncdps.gov
www.ncdps.gov

From: Messer, Charles <Charles.Messer@ncdps.gov>
Sent: Friday, May 14, 2021 9:15 AM
To: Hahn, Patricia <Patricia.Hahn@ncdps.gov>
Cc: Bowman, Marvella <Marvella.Bowman@ncdps.gov>; Lutz, Shannon <Shannon.Lutz@ncdps.gov>
Subject: Re: KZB Follow-up

Marvella or Shannon, please have a behind specialist share Dr Hahn's information with offender [redacted].
Chas

Sent from my iPhone

On May 14, 2021, at 8:05 AM, Hahn, Patricia <Patricia.Hahn@ncdps.gov> wrote:

I told Ms. Brown I would continue to follow up on her UNC appointment. I just e-mailed Ms. Catlett and she e-mailed me right back. She said she has not heard from the UNC provider but will follow-up with her

IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF NORTH CAROLINA
CHARLOTTE DIVISION

Civil Action No. 3:22-cv-0191

KANAUTICA ZAYRE-BROWN,

Plaintiff,

v.

THE NORTH CAROLINA DEPARTMENT OF PUBLIC SAFETY, et al.,

Defendants.

DEPOSITION OF BRIAN SHEITMAN, M.D.

(Taken by plaintiff.)

Raleigh, North Carolina

May 17, 2023, 10:59 a.m.

Reported By:
SUSAN GALLAGHER, CA CSR, CVR-CM

CONTAINS GENERAL CONFIDENTIAL INFORMATION

Q Were you aware at the time of the February 17th, 2022, DTARC meeting that Ms. Zayre-Brown had been admitted to -- as an inpatient at NCCIW?

A Yes.

Q Were you aware on February 17th, 2022, of whether or not Ms. Zayre-Brown had engaged in any self-harm?

A That was in the record. There was some in the record, I believe, yes.

Q Okay. And as best as you recall, was that self-harm through any particular part of her body?

A I think there was one episode where there was -- she reported there was a rubber band that she put around her penis, I think.

Q Okay. I'd next like to mark as Exhibit 17, DAC 681.

(Exhibit 17 marked for identification.)

BY MR. DAVIDSON:

Q So this is dated February 2nd, 2021. So five days after Exhibit 16. Do you believe that this is a document you've seen before?

A I think so.

Q In the second paragraph under "comment," it says, "Offender Brown attended today's FTARC and expressed her frustration and anger regarding

denial/delay of requested vulvoplasty." And then in the last sentence, it says, "Notably Offender Brown stated that she is willing to pay for surgery herself. And additionally stated that if she did not receive an update before Christmas, she would require surgery due to taking matters into her own hands."

Do you have any understanding of what that means?

A I would only be guessing, so I'd say no.

Q Okay. I'd like to mark as Exhibit 18 a one-page document, it's DAC 680.

(Exhibit 18 marked for identification.)

THE COURT REPORTER: Thank you.

BY MR. DAVIDSON:

Q It's also dated November 2nd, 2021, but it says 1500 -- I normally refer to it as 3:00 -- so a little later in the day, but then Exhibit 17, which said 1420 -- otherwise known as 2:20 p.m. And my question is with respect to Exhibit 18, have you ever seen this document before?

A I probably have.

Q Okay. And under "comment," this is -- this is also listed as provider Marvella Bowman just like the prior one. Under comments, it says, "Offender Brown made a statement of self-harm during today's FTARC,

indicating that if she did not receive an update about progress on the decision regarding DTARC determination re requested surgery, she would mutilate her phallus, referred to in earlier documentation as taking matters into her own hands."

So do you recall on seeing this whether you -- it raised any concerns on your part that Ms. Zayre-Brown might engage in self-harm such as mutilating her phallus?

A Yes. So it was mitigated by the next couple of statements, so --

Q Okay. What -- what mitigated it?

A "No risk assessment indicated." So this is like -- sometimes they do, they'll --

(Reporter clarification.)

THE WITNESS: A SIRA, S-I-R-A. Sorry.

So I know Dr. Bowman, and I think she's competent and -- and a good person. So the fact that she didn't think there was any risk assessment indicated at the time and that she would be following the person made me less concerned.

BY MR. DAVIDSON:

Q Next I'd like to mark as Exhibit 19 a two-page document. It says in the lower right DAC 666. I'm sorry. It's a three-page document.

(Exhibit 19 marked for identification.)

THE COURT REPORTER: Thank you.

BY MR. DAVIDSON:

Q This is dated December 6th, 2021, and also the provider, again, is listed as Marvella Bowman. Have you seen this document?

A I certainly -- I probably have because I would review the record.

Q Okay. If you look at the bottom of the first page, it says "progress towards goals." And then continuing on to the next page, it says, "Reduced feelings of dysphoria measured" -- paren, "measured by rating dysphoric feelings on a scale from 0 to 10, 0 equals dysphoria, 10 equals extreme dysphoria, by getting 5 or below at least three weeks -- three days a week."

So I'm trying to understand. Is it your understanding that what Dr. Bowman was saying that -- was that it was bold to try to reduce Ms. Zayre-Brown's feelings of dysphoria to 5 or below at least three days a week?

A I think so, yes.

Q And then it says, "Today Offender Brown reported a level of 11," quote, "it's high."

Do you have any reason to believe that that

that are done in the United States, do you have any view of -- of what percentage of those should not be performed because the risks outweigh the benefits?

A No, I don't. It's -- I mean, I don't.

Q I'd next like to mark as Exhibit 24 a five-page document. It says in the lower right-hand corner DAC, some zeros, and then 4550.

(Exhibit 24 marked for identification.)

THE COURT REPORTER: Thank you.

BY MR. DAVIDSON:

Q Okay. So -- so this document, if you hold it next to -- Exhibit 24 next to Exhibit 23, looks kind of similar, and -- although it doesn't say "case summary" at the bottom. And I guess my -- my question is, do you know whether this is perhaps an earlier draft of what's Exhibit 23?

A I don't know.

Q Okay. Well, there's a sentence that's bolded in the last paragraph on the first page. It says, "Patient also remains quite stable without any destructive, homicidal, or suicidal ideation, and describes normal sleep, appetite, and energy level." That doesn't appear in the case summary, Exhibit 23, and so I have a couple questions about that. Do you have any understanding of who would have written that

bolded sentence in Exhibit 24?

A I don't. I -- whoever authored this, it wasn't -- I didn't write this, so I don't know.

Q Okay. Do you have any understanding for why that sentence does not appear in the case summary?

A No.

Q And if you turn to the last page of that exhibit, there's, again, a part that's bolded. Did you -- did you write that bolded part?

A No.

Q Do you know who did?

A No.

Q And do you have any understanding about why that's in this -- in Exhibit 24 but not in Exhibit 23?

A No, I don't.

Q It says in the second sentence of that -- no -- yeah, the third sentence of that bolded paragraph on the last page of Exhibit 24, "Fortunately, in this case, these interventions have been both successful and sufficient in addressing the underlying gender dysphoria as evidenced by the lack of depressive or destructive behaviors, and the offender's well-adapted approach to the current environment."

Is that something you believed on February 22nd, 2017?

A I'm just reading it. Please give me one second. Yeah, I mean, I think it might be a little too strong in terms of "have been both successful and sufficient in addressing the underlying gender" -- I think she seemed to be doing better, but I think there's still some issues there. So it seems a little strong, to be honest.

Q Okay. If -- if you were going to try to make it more accurate, what words would you use?

A Have helped to manage the person's gender dysphoria as -- by the lack of severe depressive or -- and no destructive behaviors, and the offender's -- I'm not sure the well-adapted approach. Like, I'm not sure what I would substitute for that.

Q Okay. Well, I was trying to focus on the "successful and sufficient," which is what you pointed to before.

A Okay.

Q What -- what terms you might use?

A Helpful.

(Reporter clarification.)

BY MR. DAVIDSON:

Q Okay. All right. I'd next like to mark as Exhibit 25 a document, so it's a one-page document, in the lower right-hand corner DAC 3416.

(Exhibit 25 marked for identification.)

THE COURT REPORTER: One moment, please.

MR. DAVIDSON: Sure. Sorry.

THE COURT REPORTER: Thank you.

BY MR. DAVIDSON:

Q Do you believe you have ever seen this document before?

A I probably have, yes.

Q Okay. And it says, "Final determination of referred accommodations, the deputy commissioner and director of health and wellness reviewed documents related to the accommodation request" --

MS. BRENNAN: Jon -- Jon, I don't think he sees where you're reviewing that.

BY MR. DAVIDSON:

Q I'm sorry. It's under the final determination of referred accommodations on the first page. The only page of this document.

A Thank you.

Q It says, "The deputy commissioner and director of health and wellness reviewed documents related to this accommodation request. After review and discussion, we concur with the DTARC recommendation that requested accommodation is not supported."

Do you know who the "we" is referring to there?

individuals" --

A Sorry. Where are you?

Q Page 4. It's the second paragraph under the bullet.

A From the definition above?

Q It starts "In the case of GRS."

A Okay. Sorry.

Q And the second sentence says, "In fact, there are studies which cause great concern that a not insignificant portion of individuals who undergo the procedures not only fail to improve, but in many cases experience worse symptoms with quite concerning consequences."

Do you have any belief as to what portion of individuals who undergo gender-affirming surgeries experience worse symptoms after the surgery?

A I think there are probably studies that show both. So some studies I think show good outcomes. Some of these studies I'm sure do show bad outcomes. I think it's somewhat of an open question.

Q The next paragraph refers to a study in Sweden. Are you familiar with that study?

A I have not read it.

Q Okay. And in the paragraph that starts "Another important consideration" --

A Yes.

Q -- it says, "There is a growing body of research into what seems to be an increasing number of transgendered individuals who, at some point, de-transition."

So did you actually read articles about de-transitioning?

A Yeah, I've looked at some of the -- I didn't, you know, read it, like, cover to cover thoroughly, every detail, but I think there's also mixed literature on that.

Q Okay. Says, "A study published in the archives of sexual behavior over 2021 found a 24 percent rate of de-transition." Have you reviewed that study?

A I have not.

Q If you look at page 9. I asked you before if you knew who SEGM was, and in the middle of this -- this page 9 of this exhibit, it says, "For example, the Society For Evidence-Based Gender Medicine" -- read SEGM. Seeing the full name, is that an organization that you've heard of?

A No.

Q Okay. And on page 11, first full paragraph, it says, "In summary, based on the extensive and objective review, hundreds of studies, other publications, it is

quite clear that gender reassignment surgery as a course of treatment for gender dysphoria is, indeed, not a medical necessity."

So is it your understanding that that means it's not a medical -- is not -- is, indeed, not a medical necessity except in some cases?

A Well, I think I would rephrase it based on the lack of evidence of quality, long-term, medically-approved, evidence-type studies that it should not be considered a medically necessary -- a treatment of medical necessity in most cases. Something like that. I might've butchered it up, but you --

Q And then --

A Sorry --

MS. BRENNAN: Hold on. He's still -- he's still answering.

THE WITNESS: Yeah. I mean, I don't want to -- I mean, basically, my concern is -- is not so much what is in the literature. It's what's not in the literature. So that's -- that's where I would -- but, again, could it help in certain individual cases, it's possible.

If we have no other treatments -- I mean, again, the history of medicine is we do all these crazy things

to try to be helpful, and it ends up hurting people. I'm not exactly -- you know, this is not quite -- there's no evidence, but the quality of evidence is still not good enough.

MR. DAVIDSON: I'd like to go off the record for a minute.

(Recess.)

BY MR. DAVIDSON:

Q Dr. Sheitman, I'll remind you, you're still on the record and under oath.

Are you a member of the American Medical Association?

A No.

Q How about the American Psychiatric Association?

A I was, but I didn't continue my membership.

Q Was there any particular reason for that?

A I mean, more personal reasons. I thought that it became a little bit too much of an advocacy for themselves as opposed to the -- the larger issues, so I didn't really want to join.

Q So we -- we talked a little before about WPATH and about their standards of care. And are you generally familiar with their standards of care?

A Yeah.

Q And were you aware that the American Medical

Association has endorsed treatment protocols in accordance with the standards of care?

A Generally. I would have to review it, but I think in general.

Q Okay. And -- and how about the Endocrine Society as well?

A Yes.

Q And the American Psychological Association?

A Yeah, I think these advocacy organizations, though, sometimes don't, like -- they have an agenda beyond the medical literature at times, is my opinion. I'm not saying that WPATH does or is particularly bad at all, but my experience with this is it's not based on just what's in the literature.

Q Okay. Would that also be true of the World Health Organization?

A I think there's been some reports that at times it is true, but I'm not an expert on it.

Q Okay. So the WPATH standards of care -- I think this is actually from the 7th edition -- states, quote, While many transgender -- I'm sorry -- while many transsexual, transgender, and gender nonconforming individuals find comfort with their gender identity, role, and expression without surgery, for many others, surgery is essential and medically necessary to

IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF NORTH CAROLINA
CHARLOTTE DIVISION

Civil Action No. 3:22-cv-0191

KANAUTICA ZAYRE-BROWN,)
)
Plaintiff,)
)
v.)
)
THE NORTH CAROLINA)
DEPARTMENT OF PUBLIC)
SAFETY, et al.,)
)
Defendants.)
)

DEPOSITION OF TERRI CATLETT

(Taken by plaintiff.)

Raleigh, North Carolina

May 18, 2023, 8:59 a.m.

Reported By:
SUSAN GALLAGHER, CA CSR, CVR-CM

A I don't want to speculate, but I would think that that would have been information Dr. Peiper shared.

Q So your role of scheduling appointments for incarcerated people, how do you decide how urgent they need an appointment?

A Well, the provider would indicate that, whether it's urgent, routine, rush.

Q Okay. And after they indicate that to you, help do you go about, I guess, organizing those logistics?

A So someone in medical records would call. I would have the staff at medical records at the local facility call and make that appointment, and they would at that point, based on availability of officers and whatnot, you know, they would make that appointment, and then they would -- again, as I stated before, there's a process.

They initiate the appointment, and then they initiate the paperwork, and then custody at that point is informed as to, we have a trip. How may officers need to go? Maybe two officers, maybe four officers, maybe six officers depending on security level of the offender. So it's done locally.

Q If there's multiple people that have

appointments, how do you go about organizing the order of these people getting to their appointments?

A Again, it's based on the clinical provider. If it's urgent, if it's routine, and again, you've got to remember during this time UNC wasn't seeing our patients. So telehealth was the primary means of medical care, specialty medical care. Primary care is done at the facility, Specialty care through UNC, and telehealth was the primary means of care during this whole entire time.

Q Once someone indicates that an appointment's either urgent, routine, whatever classification they give it, are you required to report that to anyone?

A No.

Q Are there ever times where there's delays in getting people to their appointments?

A Again, during this particular time period, from March of 2020 until even now, the primary means of providing care is through telehealth. We are dependent upon the availability of the providers at the local level, at the local UNC, Blue Ridge, Vidant, wherever they are, to give us appointments.

So we can call and ask for the first available appointment, which is routinely what we do, but it may not be until three months or six months or nine months

until we get to the appointment.

Q Have you ever had an appointment and then on your end had to reschedule?

A For security reasons that happened from time to time. If the facility is locked down for security reasons, nobody moves. So it's rare, but from time to time there is a cancellation based on the operation of the facility. It isn't based on anything clinical or anything I have control over. It's clearly a security issue.

Q Okay. And once you're notified that an appointment has to be canceled for a lockdown, how quickly do you try to reschedule that --

A That very day. We call and see when can we get the next appointment. There's been a -- whether it's a security breach or an escape or whatever has happened, we call -- we call the provider's office and let them know that the inmate won't to be coming to the appointment for whatever security reason. Can they please provide us the next appointment.

Q Outside of security reasons, would there be any other possible reasons why an appointment would have to be canceled?

MR. RODRIGUEZ: Object to speculation.

You can answer.

my emails every day, but if I'm out of the country, like I was this week, I don't have access to email.

Q Okay. On the last exhibit with the email we just discussed, did you take any other further action regarding this email?

MR. RODRIGUEZ: Asked and answered.

You can answer.

THE WITNESS: I don't recall.

BY MS. DELGADO:

Q And did you ever follow up with Dr. Hahn to see if she received this email?

A Actually, Dr. Hahn and I had a conversation.

Q Can you tell me about that conversation?

A She called me.

Q And what was that?

A She was wanting to know when the date of the appointment for Ms. Kanautica Brown.

Q Okay. And were you able to give her that date?

A No. I had to check the telehealth schedule. I told her I'd get back with her.

Q Did you raise your concerns about what you read in that email?

A Dr. Hahn expressed to me what Kanautica was doing and that she was onsite and was managing her care, but she wanted to know when the appointment was

scheduled, and I didn't have access to the telehealth schedule at the time. I told her I would get back with her.

Q Did you get back with her?

A I got back with the facility to let them know so they could schedule it. Dr. Hahn isn't at the facility every day. So when I had access to the scheduler, I made sure that Kanautica had the first available appointment, even though I had to move other people around, and then I notified the facility.

Q Okay. All right. Moving on to the next document that I would like to be marked as Exhibit 11.

(Exhibit 11 marked for identification.)

BY MS. DELGADO:

Q Ms. Catlett, if you'll let me know when you're ready.

A I'm ready.

Q Okay. Do you recognize this?

A Yeah, I'm familiar with the discussion.

Q What was this discussion about?

A Ms. Brown's distrust or concerned that she had to speak to somebody right away at UNC, and they were just trying to find out when the appointment has been made, and as you can see by the email chain, I don't make the appointments. I call. I call. I call, and I

wait for UNC to respond, and at the end, the facility said no.

But this was, again, in the midst of lockdown COVID, and they weren't seeing patients, not only in the community, but certainly not our offender population. So many specialities said, "Don't send any of your inmates to us at all." I had to be diligent in calling, calling, calling to get appointments. I didn't always get them every time I called.

So this was just kind of like "Hey, Ms. Catlett is going to follow up," which I did. "She'll let us know as soon as the appointment," et cetera. So that's kind of what it is. You can see that I called. I haven't received confirmation. I called again. I didn't get confirmation, and Kanautica was being -- was impatient with all that.

Q You said that "Kanautica was impatient with all that." How did you determine that?

A Well, it appears that she -- based on what the psychologist wrote, that she was experiencing dysphoria because of the length of time that had passed.

Q Which psychologist said that?

A Shannon Lutz (phonetic) lots. She was a psychological services coordinator.

Q So you said that she said that Ms. Kanautica

Zayre-Brown was experiencing dysphoria because of the length of time?

A Yes.

Q And you understood that to mean she was impatient?

A No. Just inmates want an appointment the next day. If they don't get it, they get very impatient. It appears that she was experiencing dysphoria.

Q Drawing your attention to page 2 under Shannon Lutz's response, if you count six lines up from the bottom, there is a sentence that starts with "from an emotional health."

A Uh-huh.

Q Okay. I'm going to read that.

"From an emotional health standpoint, it does appear that Ms. Brown continues to experience acute dysphoria secondary to the length of time that has passed, which has yet to resolve medically necessary treatment."

Was that the sentence you were referring to when you mentioned length of time?

A No. I was referring to, she provided this -- the first two or three sentences. That's what I was referring to. "She expressed strong distrust in the accuracy of information in referencing upcoming

You can answer.

THE WITNESS: I think it would be certainly a training for all staff.

BY MS. DELGADO:

Q All right. We'll move onto the next exhibit -- All right. Drawing your attention to page 3, Ms. Catlett, there is an email in the center of the page that's from Joy Baugham. Who is that?

A She is the admin support for the telehealth department.

Q Okay. And what date did she send this email to you?

A June 21, 2021.

Q And it says, "There is a UR" or urology "consult with Dr. Figler, Re: Vaginoplasty approved 8/4/20, Authorization No. 001710079."

Did I read that correctly?

A You did.

Q Okay. Does this refresh your recollection regarding how long Mrs. Zayre-Brown had been waiting for a consult?

A Well, she was waiting for multiple consults, so this was just one of them apparently.

Q And it appears that -- well, this urology consult was approved on 8/4/20; is that correct?

A Right, that's correct.

Q And the date of this email is June 21, 2021; is that correct?

A That's correct.

Q What was the reasoning for such a long gap in time?

A You have to remember this is in the heat of COVID. We weren't sending anyone out of the facility, anyone, unless it was life-threatening. UNC didn't want to see any of our patients at all, period. So this was -- all of their staff were doing hands-on work on the floor.

So none of the patient's went out unless it was life-threatening. Telehealth was launched around the same time, and we were able -- the only way we were able to get specialty services done is through the process of telehealth. It wasn't until just last year that routine appointments started going out of the facility for appointments.

And it wasn't anything to do with DPS. It had to do with the fact that the providers were not seeing patients in their offices because of this "all hands on deck" at UNC, and the providers were working shifts taking care of COVID patients. So if there was a delay, it was because anything that -- it had nothing

to do with DPS. It had everything to do with -- patients were not being seen in the hospital because COVID was -- there was no vaccine at this point. Patients were dying, and all the doctors were focused on taking care of the dying patients.

MS. DELGADO: If I could have a moment.

(Recess.)

BY MS. DELGADO:

Q Ms. Catlett, we are actually going to go back to the most recent exhibit, No. 12. Okay. Still on the page of the symptoms I recently read, there is a UR urology, that page. Are you there?

A Uh-huh.

Q Okay. When we were discussing this email, you stated that this was during the height of COVID; is that correct?

A Yes.

Q And that there were no vaccines out during this time; is that correct?

A I did say that, yes.

Q Now that we've taken a break, do you still, like, keep the same sentiment, that there were no vaccines during that time of June 2021?

A I don't recall when the first vaccine became available.

Q Okay. You also mentioned that there were no -- you guys were not letting anyone in and out for appointments outside of the prison; is that correct?

A Typically. Unless it was life-threatening, patients typically did not go out into the community for care. Specialty care was managed primarily through the telehealth process.

Q You say "life-threatening," back to Exhibit 10, if you can pull that out, and if you go to page 2 and line 4 at the end that starts at the last sentence, "As a direct result of the continued denial of care, her family, including myself, has had to be in receipt of the voicing desires to commit suicide and engage in self mutilation."

Does that not sound like life-threatening to you?

MR. RODRIGUEZ: I'm going to object to the vagueness and form.

You can answer.

THE WITNESS: Again, I wasn't onsite with Ms. Brown during this particular time so I wouldn't have been -- I'm not the clinician. I wouldn't be able to determine if it was life-threatening or not. I think a life-threatening situation would be, from a medical perspective, say a cardiac arrest or difficulty

IN THE UNITED STATES DISTRICT COURT
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KANAUTICA ZAYRE-BROWN,)
)
Plaintiff,)
)
v.)
)
THE NORTH CAROLINA)
DEPARTMENT OF PUBLIC)
SAFETY, et al.,)
)
Defendants.)
)

DEPOSITION OF ARTHUR CAMPBELL, M.D.

(Taken by plaintiff.)

Raleigh, North Carolina

April 18, 2023, 4:36 p.m.

Reported By:
SUSAN GALLAGHER, CA CSR, CVR-CM

specific for a particular offender. This was a very large-scale attempt to try to standardize our evaluations of gender-affirming surgery surgery in the context of medical necessity so that we had an objective way of determining if and when offenders would meet that bar, and therefore, surgery would be indicated for them.

Q Did you utilize this document, which you created as a standardized way to make these assessments, while you were trying to make the assessment with regard to Mrs. Zayre-Brown's request for vulvoplasty?

MR. RODRIGUEZ: Objection as to vague as to which document.

MS. MAFFETORE: The medical position statement that we are currently discussing.

THE WITNESS: Which exhibit?

MS. MAFFETORE: Exhibit 10.

MR. RODRIGUEZ: Okay.

THE WITNESS: So I would say that this is -- you know, this is certainly not inconsistent with any version of this. So there is no version of this that conflicts with the others. They just include different aspects and different considerations and, again, represent an evolution of the document over time and

different versions that were being prepared.

BY MS. MAFFETORE:

Q Okay. So my question is, the considerations that are discussed in this medical director position statement, did you also consider these considerations as you were reviewing Mrs. Zayre-Brown's request for vulvoplasty?

A So these were considered in any cases --

Q So I'm asking you specifically about Mrs. Zayre-Brown's --

A Yes.

Q Okay. Thank you.

Did anything from your review of specifically Mrs. Zayre-Brown's case lead you to believe that she would experience increased suicidality if she received vulvoplasty?

A No.

Q If not, why did that factor into your medical analysis?

MR. RODRIGUEZ: Object to assumption of facts.

You can answer.

THE WITNESS: So as I discussed before, when you do that risk-benefit analysis, you do that with every case, and again, there's the -- I'll call it the positive and negative way of looking at it, the

converse way of looking at that analysis. So what is the risk of not providing a procedure for a particular offender in a particular situation? And if you do provide the procedure, what are those risks that you may see with that? So again, I think that consistent analysis occurs in every case, including Mrs. Zayre-Brown's.

BY MS. MAFFETORE:

Q Did you have any concerns of persistent or increased psychiatric morbidity or mortality with respect to Mrs. Zayre-Brown if she received vulvoplasty?

A So the consideration, as I have discussed and as the committee discussed, is that based on her current clinical condition and looking at her clinical condition and clinical mental health, particularly clinical encounters certainly over the past year, and the summaries provided by both Dr. Peiper and Dr. Sheitman was that she was not in a state where we felt that her condition was deteriorating or that she was in such a state that surgery would now be medically indicated.

Q So I was asking, did you believe -- did you have concerns about persistent or increased psychiatric morbidity or mortality if she did receive a

vulvoplasty?

A I don't remember those specific concerns for her, no.

Q Okay. To your knowledge, has Mrs. Zayre-Brown ever expressed regret for any of her prior gender-affirming surgery surgeries?

A Not to my knowledge, no.

Q Do you have any reason to believe that if Mrs. Zayre-Brown had a vulvoplasty, she would subsequently regret that?

A Difficult to say, again, for the same reason we talked about before is that we really don't know what leads to individuals having regret or -- you know, related to those procedures. So more research is needed for us to be able to make that determination objectively.

Q So does that mean that you don't have any specific reason to believe that Mrs. Zayre-Brown specifically would subsequently regret a vulvoplasty had she received one?

A No, I don't have any specific regret -- or that she had regret. I also don't have any specific evidence that it would be a tremendous benefit to her either because that's the state of the medical literature at this point.

North Carolina Department of Public Safety
Clinical Encounter

Offender Name:	[redacted], [redacted]			Off #:	0618705
Date of Birth:	[redacted]	Sex:	M	Race: BLACK	Facility: HARN
Encounter Date:	11/09/2017 11:47	Provider:	Calkins, Candace L RN		Unit: L3DM-

Wound Care Note encounter at Clinic.

Reason Not Done: No Show

Comments: set up wound care BID x 30 days clean and wet to dry with packing ribbon the gauze and athletic supporter (no tape or coverall

Cosign Required: No

Completed by Calkins, Candace L RN on 11/09/2017 11:48.

North Carolina Department of Public Safety
Clinical Encounter

Offender Name: [redacted], [redacted] Off #: 0618705
Date of Birth: [redacted] Sex: M Race: BLACK Facility: HARN
Encounter Date: 11/09/2017 11:32 Provider: Umesi, Joseph J MD Unit: L3DM-

Provider Evaluation encounter performed at Clinic.

SUBJECTIVE:

COMPLAINT 1 **Provider:** Umesi, Joseph J MD

Chief Complaint: Female Health Complaint

Subjective: Patient is a 36 year old transgender female who presents for various complaints especially for post orchiectomy evaluation. He has a surgical scrotal wound that has not completely healed. He says that he had spanx garment before incarceration which he says was putting pressure on wound and facilitating healing. He used to be on Estrogen, Spironolactone, and Progesterone but stopped taking them thirty days before surgery. The surgery was on August 25,2017, by Dr. Hope Sherrie, at Cosmetic Concierge, Charlotte, NC. She was referred to Dr. Sherrie by UNC CH Endocrinology who was managing him and did all pre-op evaluations. With orchiectomy, he no longer needs Spironolactone and Progesterone. Custody has already handled his housing and other accommodation matters. Beside's orchiectomy, he has undergone facial feminization surgery, vaser lipo surgery (lipo for abdomen, hips and buttocks), breast augmentation, ear lobe repairs.

Pain Location:

Pain Scale:

Pain Qualities:

History of Trauma:

Onset:

Duration:

Exacerbating Factors:

Relieving Factors:

Comments:

OBJECTIVE:

Temperature:

Date	Time	Fahrenheit	Celsius	Location	Provider
11/09/2017	11:56 HARN	98.1	36.7		Umesi, Joseph J MD
11/02/2017	19:03 HARN	98.8	37.1		Planco, Julieta T RN
10/30/2017	17:28 CRAV	97.7	36.5		Jones, Carolyn E RN

Pulse:

Date	Time	Rate Per Minute	Location	Rhythm	Provider
11/09/2017	11:56 HARN	78			Umesi, Joseph J MD
11/02/2017	19:03 HARN	84			Planco, Julieta T RN
10/30/2017	17:28 CRAV	81			Jones, Carolyn E RN

Respirations:

Date	Time	Rate Per Minute	Provider
11/09/2017	11:56 HARN	16	Umesi, Joseph J MD
11/02/2017	19:03 HARN	18	Planco, Julieta T RN
10/30/2017	17:28 CRAV	18	Jones, Carolyn E RN

Blood Pressure:

Date	Time	Value	Location	Position	Cuff Size	Provider

Offender Name: [redacted], [redacted] Off #: 0618705
Date of Birth: [redacted] Sex: M Race: BLACK Facility: HARN
Encounter Date: 11/09/2017 11:32 Provider: Umesi, Joseph J MD Unit: L3DM-

Date	Time	Value	Location	Position	Cuff Size	Provider
11/09/2017	11:56 HARN	131/87				Umesi, Joseph J MD
11/02/2017	19:03 HARN	114/75				Planco, Julieta T RN
10/30/2017	17:28 CRAV	127/81				Jones, Carolyn E RN

SpO2:

Date	Time	Value(%)	Air	Provider
11/09/2017	11:56 HARN	100		Umesi, Joseph J MD
11/02/2017	19:03 HARN	98		Planco, Julieta T RN

Height:

Date	Time	Inches	Cm	Provider
11/09/2017	11:56 HARN	71.0	180.3	Umesi, Joseph J MD
11/02/2017	19:03 HARN	71.0	180.3	Planco, Julieta T RN

Weight:

Date	Time	Lbs	Kg	Waist Circum.	Provider
11/09/2017	11:56 HARN	229.0	103.9		Umesi, Joseph J MD
11/02/2017	19:03 HARN	239.0	108.4		Planco, Julieta T RN

Exam:

General

Affect

Yes: Pleasant, Cooperative

Appearance

Yes: Appears Well

Eyes

General

Yes: PERRLA, Extraocular Movements Intact

Conjunctiva and Sclera

Yes: Normal Appearing

No: Conjunctival Injection, Watery Discharge, Hyperemia, Subconjunctival Hemorrhage

Ears

Positive for ear piercing

Neck

General

Yes: Supple, Symmetric, Trachea Midline

Thyroid

No: Diffuse Enlargement, Multinodular, Nodule, Tenderness

Pulmonary

Auscultation

Yes: Clear to Auscultation

Cardiovascular

Auscultation

Yes: Regular Rate and Rhythm (RRR), Normal S1 and S2

No: M/R/G

Abdomen

Inspection

Yes: Normal

Genitourinary

Offender Name: [redacted], [redacted] Off #: 0618705
Date of Birth: [redacted] Sex: M Race: BLACK Facility: HARN
Encounter Date: 11/09/2017 11:32 Provider: Umesi, Joseph J MD Unit: L3DM-

Exam:

Genital exam is significant for normal penis, but absent testes. A 2 -3 mm wound with malodorous drainage on inferior aspect of scrotum present. Upon cleansing of wound - base is beefy red and there is no thru - thru fistula

ASSESSMENT:

Gender Dysphoria in Adolescents and Adults, 302.85 - Current, Chronic, Treatment Goal Attained

Unspecified open wound of scrotum and testes, sequela, S31.30XS - Current, Chronic, Improved

PLAN:

New Medication Orders:

Rx#	Medication	Order Date	Prescriber Order
	Septra DS 800-160 MG	11/09/2017 11:32	800-160 mg By Mouth two times daily x 10 day(s) -- Use starter and start 11/09/17

Indication: Unspecified open wound of scrotum and testes, sequela
Start Now: Yes
Starter Dose Rx#:
Source:
Admin Method:
Stop Date: 11/19/2017 11:31
MAR Label: 800-160 mg By Mouth two times daily x 10 day(s) -- Use starter and start 11/09/17

New Non-Medication Orders:

Order	Frequency	Duration	Details	Ordered By
Nursing Instructions	Twice Daily	14 days	Cleanse wound with hydrogen peroxide and apply topical antibiotic and support with dry gauze	Umesi, Joseph J MD

Discontinue Reason:
Order Date: 11/09/2017
End Date:

Nursing Instructions	One Time		Please obtain medical record from UNC CH Endocrinology, and Plastic surgeon in Charlotte NC.	Umesi, Joseph J MD

Discontinue Reason:
Order Date: 11/09/2017
End Date:

Disposition:

Follow-up at Sick Call as Needed

Patient Education Topics:

Date Initiated	Format	Handout/Topic	Provider	Outcome
11/09/2017	Counseling	Plan of Care	Umesi, Joseph	Verbalizes Understanding

Offender Name: [redacted], [redacted]		Off #:	0618705
Date of Birth: [redacted]	Sex: M Race: BLACK	Facility:	HARN
Encounter Date: 11/09/2017 11:32	Provider: Umesi, Joseph J MD	Unit:	L3DM-

Co-Pay Required: No **Cosign Required:** No

Telephone/Verbal Order: No

Standing Order: No

Completed by Umesi, Joseph J MD on 11/09/2017 12:17

THE COSMETIC CONCIERGE

COSMETIC SURGERY AND IMAGE CONSULTANCY

Date: July 20, 2017
Regarding: Kanautica Zayre
DOB: [redacted]
SSN: [redacted]

Date of Surgery: July 20, 2017

To Whom It May Concern:

This is to certify that I, Hope Sherie, M.D., FACS performed irreversible Male to Female Gender Reassignment Surgery on the above-named patient. The reassignment surgery was performed and successfully completed in compliance with the WPATH (World Professional Association for Transgender Health) Standards of Care at The Cosmetic Concierge, PLLC in Charlotte, NC.

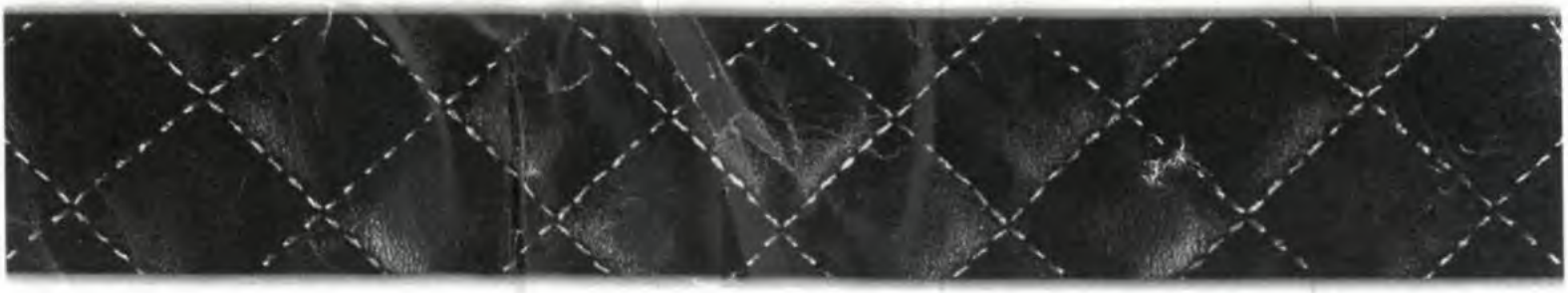
I declare under penalty of perjury under the laws of the United States that the forgoing is true and correct.

Should any questions arise concerning this procedure, please contact me at 980-938-0459.

Sincerely,

Hope Sherie, M.D. FACS
The Cosmetic Concierge, PLLC
325-B Arlington Ave.
Charlotte, NC 28203
www.cosmeticconciergemd.com
NPI #1902888977
NC License #193143

State of North Carolina County of Mecklenburg
The foregoing instrument was acknowledged before me this 1 day of October, 20 17
by Hope Sherie M.D.
ANDREW DORON, Notary Public #201614800152
My Commission Expires June 15, 2021



IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF NORTH CAROLINA
CHARLOTTE DIVISION

Civil Action No. 3:22-cv-0191

KANAUTICA ZAYRE-BROWN,)
)
Plaintiff,)
)
v.)
)
THE NORTH CAROLINA)
DEPARTMENT OF PUBLIC)
SAFETY, et al.,)
)
Defendants.)
)

DEPOSITION OF GARY JUNKER, PH.D.

(Taken by plaintiff.)

Raleigh, North Carolina

May 4, 2023, 9:06 a.m.

Reported By:
SUSAN GALLAGHER, CA CSR, CVR-CM

cited.

A That's right.

Q Okay. So you talked about -- in determining or in concurring with the medical-necessity determination, you talked about risks and benefits. Are there any other risks that you considered that would apply specifically to Ms. Zayre-Brown that lead you to concur with the DTARC's determination that surgery was not medically necessary for her to treat her gender dysphoria?

A I relied upon the summary document of the DTARC.

Q You also mentioned the fact that other procedures or other treatments were available that led you to concur with the DTARC's assessment that surgery was not medically necessary. What other treatments or procedures are available to treat Ms. Zayre-Brown's gender dysphoria that she has not already explored?

A Well, there is indication that what has been provided has had some benefit. I believe it may have been Dr. Figler's document that said that there was marked improvement regarding her response to hormone treatment. I'm not exactly sure, you know -- and again, in the context of what that marked improvement was referencing.

But the supportive counseling that's provided, the hormone treatment that's provided, her living in a female facility to be able to interact with other females. I mean, there's a supportive environment there within the female milieu. So a number of protective factors that, you know, are currently being addressed for her that I think are certainly a positive.

Q Understood. But even following receiving that care, is it your understanding that Ms. Zayre-Brown is still experiencing clinically significant distress associated with gender dysphoria?

MR. RODRIGUEZ: Objection. Speculation.

You can answer.

THE WITNESS: I don't know. I think a thorough psychological assessment and some objective instruments to determine levels of certain types of symptoms, you know, would probably help to determine that. I don't recall, -- you know, again, her 2017, that was related prior to putting a lot of things in place that we now have in place for individuals, but I think, you know, medication and her current circumstances -- and the summary from the DTARC is that she was psychologically stable and, you know, her mental status was -- it seemed to level off.

So I don't know, but it had no impact on her saying she's an 11 out of 10. That's really -- that's really difficult to say.

BY MS. MAFFETORE:

Q Do you dispute that Ms. Zayre-Brown is still suffering from gender dysphoria?

MR. RODRIGUEZ: Objection. Speculation.

You can answer.

THE WITNESS: I have no way to really fully and adequately determine that.

BY MS. MAFFETORE:

Q At the time of your consideration, did you dispute that Ms. Zayre-Brown was still suffering from gender dysphoria at that time, when she was being considered for gender-affirming surgery?

A She was still -- from what -- again, that's difficult to say in total, but it did you know say that, you know, her mental status was stable, and in another note it said that she was content, and so I would imagine, yes, she still is likely suffering from some level of gender dysphoria. Does it rise to the level of significant persistent distress? I, you know, would need to have someone conduct some further evaluation of her to know exactly.

Q Sure. So you noted several times that one

reason that you supported the conclusion that surgery is not medically necessary to treat Ms. Zayre-Brown's gender dysphoria is because she is stable. Didn't you testify earlier in this deposition that whether somebody -- somebody's mental health condition is stable is a criteria that would make them a good candidate for gender-affirming surgery?

A That's the difference between appropriate and medically necessary.

Q So why would it make Ms. Zayre-Brown -- why would it make surgery not medically necessary for Ms. Zayre-Brown if she is mentally stable if being mentally stable is a prerequisite to being a candidate for gender-affirming surgery?

A That's the dilemma that we face.

Q Okay?

A If you pathologize a condition then it becomes a difficult to make it a prerequisite, and it's difficult to not be able to disqualify yourself or make yourself appropriate for treatment if you're well, you know, I mean, if your dysphoria resolves and treatment is successful. That's the exact dilemma that I think we face here.

Q Isn't it the case that we reviewed her record previously where Ms. Zayre-Brown indicates she was

still having self-injurious thoughts, but was discouraged from having those self-injurious or acting on them because doing so would make her unstable in a fashion that would jeopardize her ability to obtain surgery?

A I hear you.

Q Are you aware of whether or not the DTARC employed the WPATH criteria in determining whether or not Ms. Zayre-Brown should receive gender-affirming surgery?

MR. RODRIGUEZ: Object to --

BY MS. MAFFETORE:

Q Are you aware of whether or not the DTARC employed the WPATH criteria in order to assess Ms. Zayre-Brown's request for gender-affirming surgery?

A I know that Dr. Peiper is very familiar with the DTARC criteria, and so I trust his input into this process as well. Again, he's very familiar with the WPATH criteria, and I would assume that that was weighed in the committee's conclusion.

Q Did you independently reference the WPATH criteria in considering whether or not Ms. Zayre-Brown should receive gender-affirming surgery?

A I did not, but I'm aware of, you know, certainly the general content of that criteria and,

UNITED STATES DISTRICT COURT

FOR THE WESTERN DISTRICT OF NORTH CAROLINA

CHARLOTTE DIVISION

KANAUTICA ZAYRE-BROWN,)
Plaintiff)
)
vs.)
)
THE NORTH CAROLINA DEPARTMENT)
OF PUBLIC SAFETY, et al.)
Defendants)

DEPOSITION

OF

JOSEPH V. PENN, M.D.

August 8, 2023 - 9:12 A.M.

NORTH CAROLINA DEPARTMENT OF JUSTICE
114 WEST EDENTON STREET
RALEIGH, NORTH CAROLINA

PREPARED BY: Susan A. Hurrey, RPR
Discovery Court Reporters
and Legal Videographers, LLC
4208 Six Forks Road
Suite 1000
Raleigh, North Carolina 27609
919-424-8242
www.discoverydepo.com

CONTAINS GENERAL CONFIDENTIAL INFORMATION

or impairment?

A. Yes.

Q. I'd now like to hand you what I would ask the court reporter to mark as Exhibit-10.

- - -

(Document marked as Exhibit-10 for identification.)

- - -

BY MS. MAFFETORE:

Q. The court reporter has handed you Exhibit-10 which is a document bates stamped DAC 728. I will represent to you that it is a North Carolina Department of Public Safety Mental Health Progress Note dated 4/28/2021 pertaining to Mrs. Zayre-Brown.

Do you recognize this document?

A. Yes.

Q. Under Progress Towards Goals -- do you see where I'm referring to?

A. Yes.

Q. It notes Mrs. Zayre-Brown expressed many concerns about not having her appointment with UNC-CH urology scheduled yet. She gave a number of examples of how this is increasing her dysphoria, and she decided to put a band on her penis until her appointment is scheduled. She said she has had the band on for a week and a half. She was cautioned about the effects of

impeding blood flow and risk of infection. As described above, the undersigned spoke with Ms. Catlett, and she was able to convey to Mrs. Zayre-Brown how Ms. Catlett has been on top of it and has worked hard to facilitate this appointment. Ms. Zayre-Brown then agreed to take the band off her penis. The rest of the session addressed her specific concerns about having part of a penis left and what defines a woman. She explained it does not bother her if she is called fat or ugly but stated if she is called a man there is no tool in the toolbox to manage that. She stated I can't live with this anymore, and said the situation was acute now and not chronic. She also stated she is not complete now and that I'm ready to be complete.

Did I read that correctly?

A. Yes.

Q. Did you review this medical record before concluding that Mrs. Zayre-Brown does not have significant mental distress and impairment?

A. Yes.

MS. MAFFETORE: I'm now going to hand you what I will ask the court reporter to mark as Exhibit-11.

- - -

(Document marked as Exhibit-11 for identification.)

- - -

BY MS. MAFFETORE:

Q. Exhibit-11 is a document that was produced in discovery bates marked DAC 695. I will represent it's the North Carolina Department of Public Safety Mental Health Progress Note dated September 16, 2021 pertaining to Mrs. Zayre-Brown.

Have you seen this document before?

A. Yes.

Q. Under Progress Towards Goals, the last two sentences note she admitted that she had briefly considered putting a rubber band around her phallus as a means of forcing surgical intervention. The writer explained that Ms. Brown would only undermine her chances for gender-affirming surgery if she was considered to be emotionally unstable for treatment. She acknowledged understanding.

Did I read that correctly?

A. Yes.

Q. Is this one of the documents that you reviewed before concluding that Ms. Zayre-Brown does not have significant mental stressor impairment?

A. Yes.

MS. MAFFETORE: I'm now going to hand the court reporter what will be marked as Exhibit-12.

- - -

(Document marked as Exhibit-12 for

identification.)

- - -

BY MS. MAFFETORE:

Q. Exhibit-12 is a document produced to us in discovery bates marked DAC 680. I will represent to you it is a North Carolina Department of Public Safety General Administrative Note dated November 2, 2021 regarding Mrs. Kanautica Zayre-Brown.

Do you recognize this document?

A. Yes.

Q. The document notes under comments, Offender Brown made a statement of self-harm during today's FTARC, indicating that if she did not receive an update about progress on the decision regarding DTARC determination re: requested surgery, she would mutilate her phallus, referred to in earlier documentation as taking matters into her own hands.

Did I read that correctly?

A. Yes.

Q. Did you review this medical record or this administrative note before concluding that Mrs. Zayre-Brown does not have significant mental distress or impairment?

A. Yes.

MS. MAFFETORE: I'm now going to hand you what I ask the court reporter to mark as Exhibit-13.

- - -

(Document marked as Exhibit-13 for identification.)

- - -

BY MS. MAFFETORE:

Q. Exhibit-13 is a document that was produced to us in discovery which is bates stamped DAC 666 on the first page. I will represent to you that it is a North Carolina Department of Public Safety Mental Health Progress Note, December 6, 2021, relating to Kanautica Zayre-Brown.

Do you recognize this document?

A. Yes.

Q. On page two of the document at the top. Document notes under the subheading Progress Towards Goals, which is at the bottom of the previous page, reduced feelings of dysphoria, measured by rating dysphoric feelings on a scale from zero to 10. Zero equals no dysphoria. 10 equals extreme dysphoria. By being five or below at least three days a week. Today Offender Brown reported a Level of 11, it's high.

Did I read that correctly?

A. Yes.

Q. Did you review this medical record before concluding that Mrs. Zayre-Brown does not have severe mental distress or impairment?

A. Yes.

Q. You can set that to the side. I'm done with that document. Can someone be close with their family members and still experience significant distress?

A. Yes.

Q. You note that Mrs. Zayre-Brown doesn't suffer from distress because she worked in the commissary. Are you aware of whether that employment ended in 2020?

MR. RODRIGUEZ: Objection. Mischaracterization of testimony. You can answer.

THE WITNESS: I don't know the specific reason, if she asked to terminate her employment or if it was because of her disciplinary. But the review of these documents does recall and refresh my memory that all of these threats of self-harming her phallus were conditional.

MS. MAFFETORE: I'm going to object to that answer as non-responsive because I asked you whether or not the employment at the commissary ended in 2020.

MR. RODRIGUEZ: And he answered that and then he was proceeding to discuss the exhibits that you just gave him to.

MS. MAFFETORE: I asked if he reviewed them. That was my question.

MR. RODRIGUEZ: Right.

MS. MAFFETORE: Right.

THE WITNESS: So what I was answering was that

she had received a major disciplinary case and was placed in restrictive housing because she assaulted a peer who had allegedly teased her about her phallus or made some statement about her phallus. So all of these suicidal or talk of self-harm to her phallus were all conditional. The first set that you showed me had to do with she was facing restrictive housing disciplinary status --

MS. MAFFETORE: I'm just once again going to object to this as nonresponsive. Your counsel will have opportunity to ask you follow-up questions, if he wishes. But I have a limited amount of time with you today, so I need you to be responsive to the questions that I'm asking.

MR. RODRIGUEZ: Hold on, Dr. Penn. So he answered the question --

MS. MAFFETORE: Should we go off the record for a second?

MR. RODRIGUEZ: No. No. We're going to stay on the record. He answered your question and now he's giving some testimony about the documents that you gave to him.

MS. MAFFETORE: Right. But I didn't ask him any other questions about the documents that he gave to me. If you would like to ask him questions about those documents you're more than welcome to.

MR. RODRIGUEZ: Oh, I know that I can ask questions. But are you telling him that you would no longer

like for him to speak about the exhibits that you gave to him?

MS. MAFFETORE: If I have follow-up questions about the exhibits I would be very happy for him to answer those questions.

MR. RODRIGUEZ: Fair enough. So we'll let her ask her next question and then you can answer.

BY MS. MAFFETORE:

Q. Can someone pursue educational opportunities and still be experiencing significant distress?

A. Yes.

Q. In your opinion, is Mrs. Zayre-Brown considered stable?

A. So I have to clarify my response to answer your question. And in my -- what was the question again?

Q. In your opinion, is Mrs. Zayre-Brown considered stable?

A. Yes. Because all of these were conditional suicidal statements of self-harm, putting a rubber band around her phallus because she was unhappy with the delay in getting referred to the surgeon, and then two, the other situation had to do with she was facing restrictive housing. It probably had an affect on her maybe losing her job, her employment, but she was hopeful and future oriented. In the documents you presented to me she talks about working in cosmetology, talking about losing weight to meet the criteria for the surgery, and

other things that were hopeful and future oriented. So yeah, I mean, anything is possible. But based on my review of these documents, to answer your question, Ms. Brown was stable, clinically stable.

Q. In your opinion, does Mrs. Zayre-Brown have any comorbid medical conditions or mental health conditions rather?

A. In my opinion, yes.

Q. And what is that based on?

A. So again, I requested the opportunity to perform an evaluation of Ms. Brown and that was declined or refused. But based on my video review -- sorry, my review of the videotaped deposition Mr. Rodriguez performed and the transcript, based on review of all the medical records and prison records, based on my review of Dr. Boyd's evaluation, based on -- and testing, based on my review of Dr. Ettner's report and records, Ms. Brown potentially has -- I can't definitively say, but she probably has significant trauma from childhood neglect and abuse because she had been raised in foster care. I think her mom was 13 when she gave birth to her. She was pretty much estranged from her mother, was put into Child Protective Services, had been in the Department of Public Safety for juvenile offending behaviors for I think five years. So she clearly had a trauma history. There's some allegations or -- sorry, not allegations. There are some references in records to possible [redacted]. So I don't have enough as we sit

here today to say definitively she has PTSD, but she definitely has features that are strongly suggestive of past trauma, abuse and neglect. There's also -- I can't remember. I believe Dr. Boyd on some of her testing there's the possibility of bipolar disorder symptoms or traits, and similarly there's a possibility of some antisocial versus borderline personality traits. And then from a medical perspective I understand the main issue is she's obese. She's overweight. I don't recall any other chronic medical diseases. And I think that's it.

Q. Is it your opinion that any comorbid condition from which Mrs. Zayre-Brown suffers is not well controlled?

A. What I would say is when Mrs. Brown doesn't get -- doesn't get or perceive to get what she thinks she should or is entitled to, she reacts very impulsively and puts herself at risk and that is strongly suggestive of a personality disorder and untreated trauma. I would say her comorbid complaints are stable at present but could definitely -- she definitely could benefit from additional counseling and therapy. It appears, in my opinion, that she has been focused a hundred percent on her gender surgery to the exclusion of seeking counseling or therapy to deal with impulse control, affect regulation, dealing with bad news or when things don't go her way impulse control, making better choices, social skills training, how to deal with individuals who might misgender her or make negative comments about her genitalia. So those are definite treatment

services that she would benefit from that would further help her achieve clinical -- further clinical stability.

Q. What is your understanding of whether under the WPATH standards an individual needs to be considered stable in order to be a candidate for gender-affirming surgery?

A. I'm not sure if there's language about stable. What I understand, the WPATH has changed. WPATH SOC 7 used to have a requirement that there had to be two, either psychologist and/or psychiatrist, or two psychiatrists or two psychologists, but they had to be both doctoral level and they had to essentially clear the individual and say there was no mental health contraindication to surgery. I understand in WPATH SOC 8 that that's been reduced. And I think now it's not necessarily a clearance or do they have the capacity for the surgery or there are not any mental health contraindications, but it's more of a referral. If a referring treating source mental health clinician refers -- I think only one letter is needed now and I could be wrong on that. But that's what my understanding of the new WPATH is. It's less prescriptive about the two evaluations done by doctoral level mental health staff.

Q. Is your understanding that someone needs to ascertain that an individual's comorbid mental health conditions are sufficiently under control for them to be a candidate for surgery?

A. I would say that's fair.

Q. On page 32 of your report, Exhibit-1. You note the lack of such indications of distress in a patient's medical chart is an important consideration when determining whether a given intervention is medically necessary. This is because if there is reason to believe that the intervention is necessary to prevent, and will be effective at ameliorating, such severe distress, harm, or disability, then the intervention might be said to be medically necessary.

Did I read that correctly?

A. I would say yes. But the sentence in front of that has to be read in conjunction with that last sentence that you said about that my review of Mrs. Kanautica Brown's medical records demonstrate that whatever distress she may have had as a result of her gender dysphoria, it was and is well managed, not severe, and is not causing any impairments to her daily living activities in a correctional setting.

Q. How frequently do you believe gender-affirming surgery has been ineffective in ameliorating gender dysphoria?

MR. RODRIGUEZ: Objection.

BY MS. MAFFETORE:

Q. Based on your expertise.

MR. RODRIGUEZ: Same objection. You can answer.

THE WITNESS: So my review of the Dhejnee

article -- I think it's D-h-e-j-n-e-e -- is that in that study -- it's the only study that I'm aware of that was published longitudinally looking at individuals who have undergone gender-affirming genital surgery -- had mixed results. And in fact some individuals engaged and completed suicide and others had other similar types of distress and I believe there was some regret. Some individuals recounted regret in having undergone the surgery. So to the best of my knowledge, based on my literature review, and I think Dr. Li also referenced that in her report, there is that real risk of the surgery not necessarily being curative or helpful and actually potentially being harmful.

Q. So I asked you how frequently do you believe that gender-affirming surgery has been ineffective at ameliorating gender dysphoria?

MR. RODRIGUEZ: Same objection. Speculation. You can answer.

THE WITNESS: Because it hasn't been formally studied in a prospective, controlled manner I'm not able to answer your question. I would say it's highly variable.

BY MS. MAFFETORE:

Q. Do you have reason to believe that gender-affirming surgery would be ineffective in ameliorating Mrs. Zayre-Brown's gender dysphoria?

A. My testimony would be that Mrs. Brown has some other

chronic mental health conditions. I mentioned the trauma, possible PTSD, possible personality disorder that the surgery will not do anything to correct or ameliorate. So it's possible that the surgery might help her gender dysphoria, but the other conditions will likely -- the surgery doesn't address or treat any of those other primary mental disorders, in my opinion.

Q. And so my question was do you have any reason to believe gender-affirming surgery would be ineffective in ameliorating specifically Ms. Zayre-Brown's gender dysphoria?

MR. RODRIGUEZ: Asked and answered. You can answer.

THE WITNESS: So I would say, as I testified to earlier, her whole focus to date has now been on the gender dysphoria and on the surgery. That's her whole life. In fact, as I understand it, she is -- there's some media coverage. There's some -- which is an additional stressor. At this point, as we sit here today, in my professional opinion, it's not -- it is not clear or definitive that she would -- that her gender dysphoria would be completely ameliorated by the surgery because there's other physical findings that she presents with that the gender genital surgery would not address.

Q. What are those findings?

A. Her physical presentation. She has several secondary sex characteristics, her body frame, her body appearance, her

habitus, her voice, her jawline, jaw structure, the breadth of her shoulders, her hand size, her size in general. I could go on and on, but there's multiple physical features that whether she has the surgery or not, people are probably going to continue to misgender her. And she has identified herself, repeatedly she stated that her biggest fear is that somebody will misgender her and whether she has a phallus or not. It's my professional opinion that she will likely continue to probably be misgendered, whether she has the surgery or not. And will then continue to demonstrate gender dysphoria, in my professional opinion.

Q. In any of the records that you reviewed did Mrs. Zayre-Brown identify her voice as a source of gender dysphoria?

A. I don't recall.

Q. In any of the records that you reviewed did Mrs. Zayre-Brown identify her height as a source of her gender dysphoria?

A. I don't recall.

Q. In any of the records that you reviewed did Mrs. Zayre-Brown identify the size of her hands as a source of her gender dysphoria?

A. I don't recall.

Q. In any of the records that you reviewed did Mrs. Zayre-Brown identify the width of her shoulders as a source of her gender dysphoria?

A. Not that I recall.

Q. In any of the records that you reviewed did Mrs. Zayre-Brown identify any physical feature other than her genitals as a source of her gender dysphoria?

A. Well, she has had -- she reported and I saw that in her medical chart, she's had multiple surgeries to date. A breast augmentation, fillers, body contouring, she had some chin procedure I can't recall the name of. She's had multiple surgeries, but I don't recall in the health care records or other records that I reviewed if she reported any other distress from any of those past surgeries. Sorry, I -- I'm trying to -- I thought I recalled that she did have distress from one of the surgeries. Yes, when she had the orchiectomy, the removal of the testicles, she experienced some postsurgical complications according to the medical chart, even though she was in the prison system and they were giving her wound care and dressings. I recall that she had pain and distress from that.

Q. So now I'll just reiterate that my question was other than her genitalia.

A. To the best of my recollection I don't recall any other distress from body appearance or both features in the records that I reviewed.

Q. Okay. Thank you. Are you aware of whether Dr. Boyd testified that surgery would be psychologically beneficial for

Mrs. Zayre-Brown in the treatment of her gender dysphoria?

A. I don't recall.

Q. Do you agree with Dr. Boyd that surgery would be psychologically beneficial to Mrs. Zayre-Brown in the treatment of her gender dysphoria?

A. I can't answer that yes or no because there's a risk that she might have a serious complication from the anesthesia or surgery and whether the surgery is successful or not, she could have significant complications. And it could worsen her overall life with or without affecting her gender dysphoria.

Q. So in your opinion, what are the risks of Kanautica specifically undergoing surgery?

A. Well, there's a laundry list. I would be happy to refer to Dr. Figler's evaluation where he lists them. But as I understand, and again, I'm not a surgeon or anesthesiologist, but there's a risk of death, heart attack, pneumonia, infection, paralysis, scarring, compartment syndrome. There's a term called cosmesis or something to that effect where one is not happy with the surgical -- their perception of how it's going to turn out doesn't match with how it turns out. And there's several other complications. Nerve injury. I used paralysis earlier. Fistula. There's a risk of hair is in the vaginal cavity. That could be problematic.

Q. Is your understanding that the procedure that Mrs. Zayre-Brown is seeking would create a vaginal cavity?

A. What I understand is she's seeking a vulvoplasty, but originally had been thinking of a vaginoplasty. But that's a whole separate issue because there's still ambivalence about what surgery would be best for her. According to Dr. Figler's report or his note there was some question about which would be appropriate for her. I am not a surgeon. I can't speak to this, but I believe that either when the vulvoplasty or vaginoplasty -- there's a risk of hair cells being in the vulva -- sorry, in the vaginal canal and that could cause problems. So the point I'm trying to make -- I'm getting away from the main things, infection, death, scarring, disfigurement. Those are all real conditions of anesthesia, to include death from cardiac arrythmia. Ms. Kanautica Brown is obese. She could have surgical complications for her weight. Pneumonia. So there's a laundry list of risks of surgery.

Q. Are the risks that you just identified unique to gender-affirming surgery?

A. I believe there are several risks that are specialized to gender-affirming surgery, but they also would apply to any kind of general anesthesia or alternatively being placed into the lithotomy position for extended periods of time. And I understand from Dr. Figler's note that she would have to be in that position for several hours to undergo the surgery.

Q. So you stated that Mrs. Zayre-Brown's weight is a concern. Are you aware of whether Mrs. Zayre-Brown was

required to lose a certain amount of weight in order to be considered a candidate for surgery by Dr. Figler's office?

A. Yes.

Q. Are you aware of whether she lost that weight?

A. I recall that she had lost -- I think she went from 275 to 240. But the videos that I reviewed both of the deposition and of the interview with Dr. Boyd -- again, I'm not trying to be insensitive, but Ms. Brown appeared obese, in my training as a physician. So I didn't see anywhere where a recent weight had been recorded. So I don't know her weight status as of today or the last week or so.

Q. Are you aware of whether at the time that the DTARC denied Mrs. Zayre-Brown's surgery whether or not she had achieved the weight goal set forth by Dr. Figler's office for her to receive the surgery?

A. I don't recall if they made a determination of that. I think she had dropped down to like 245. But whether that met their criteria, I don't recall, as we sit here today.

Q. If Mrs. Zayre-Brown had achieved the weight recommended by Dr. Figler's office to make her a candidate for surgery, do you have any other reason to believe that she is at high risk for complications for surgery?

A. Yes.

Q. What are those reasons?

A. Well -- and I already listed it earlier and I think

you interrupted me. I said she had a complication before when she had her orchiectomy. It didn't heal well and she had some pain. The wound dehisced, it spread. And so the best predictor of past is future -- I'm sorry, the best predictor of future is the past. Sorry, I got that backwards. So she has had a history of postsurgery complications and healing. Anyone is subject to surgical risks regardless of one's weight. Everyone theoretically could have risk from general anesthesia and surgery.

Q. In your opinion, is there any risk of Mrs. Zayre-Brown regretting the procedure?

A. Certainly.

Q. What is your basis for that opinion?

A. Well, it's based on the Dhejnee article that I mentioned earlier that the literature is limited, but the one study that shows longitudinal followup of individuals that have had the type of surgery that Mrs. Brown is seeking, there was some patients that experience complications and -- and I have read of other articles by urology -- in urology journals that describe the risks of complications with the surgery also.

Q. What specific to Mrs. Zayre-Brown's circumstances lead you to believe that she is at risk of regretting the procedure?

A. Because she's the only one that -- when she -- if and when the phallus is removed, she will be the only one that can identify that she no longer has a phallus. She still appears

typically as a male -- sorry, transgendered female. But she still has several secondary sex characteristics that would suggest her being transgendered. So in my professional opinion having genital surgery is not going to cure all of her gender dysphoria. Plus, she has the comorbid likely mental health conditions that I described earlier, that I testified to earlier.

Q. What risk, if any, do you think there is that Mrs. Zayre-Brown's gender dysphoria will worsen if she is not provided gender-affirming surgery before her release date?

A. Anything is possible. She has stated that she's put a rubber band around her phallus. She stated that she plans to scratch or rub the skin off her phallus. So it's possible that she could develop a skin infection, or alternatively, if she does in fact amputate or auto amputate her phallus, that could occur. So there are some risks that she will further attempt to self-harm her genitalia. That's fair.

Q. In your opinion, do you think Mrs. Zayre-Brown's gender dysphoria will improve if she is not given gender-affirming surgery, if she retains her phallus?

A. What I would testify to is that she is totally a hundred percent focused on this one surgery to the neglect of her other lifelong issues. I would say I don't currently have an opinion because my opinion is guarded without -- without knowing that she is making an effort to begin to work on her

other trauma and abuse and neglect issues and relational issues, in my professional opinion, my opinion is guarded. I don't have an opinion regarding what the surgery or not having the surgery, what impact it would have on her gender dysphoria.

Q. Understood.

MS. MAFFETORE: Can we go off the record for just one second?

- - -

(Discussion held off the record, 4:13 p.m. 4:13 p.m.)

- - -

BY MS. MAFFETORE:

Q. I would now like to look at your report, Exhibit-1 at page 33. So you state on page 33 at the top it is my opinion, based on my education, training, and experience, that there is a lack of high-quality scientific and medical literature indicating the long-term efficacy of gender-affirming surgery as a treatment for gender dysphoria.

Did I read that correctly?

A. Yes.

Q. Are you holding yourself out as an expert in the quality of scientific evidence in this case?

A. No.

Q. Are you holding yourself out as an expert in statistical methodology in this case?

IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF NORTH CAROLINA
CHARLOTTE DIVISION

Civil Action No. 3:22-cv-0191

KANAUTICA ZAYRE-BROWN,)
)
Plaintiff,)
)
v.)
)
THE NORTH CAROLINA)
DEPARTMENT OF PUBLIC)
SAFETY, et al.,)
)
Defendants.)
)

DEPOSITION OF LEWIS PEIPER, M.D.

(Taken by plaintiff.)

Raleigh, North Carolina

May 1, 2023, 11:04 a.m.

Reported By:
SUSAN GALLAGHER, CA CSR, CVR-CM

was experiencing high levels of dysphoria? I'm not asking you why you might believe it. I'm asking, do you believe she was not telling the truth?

MR. RODRIGUEZ: Objection. Vague as to time.

And you can answer.

THE WITNESS: So sir, I have to answer that within the context of working in the system where we work. We have to listen to all the information that's being shared and respond accordingly. There are some individuals that believe that "if I don't tell you it's and 11 on a scale of 0 to 10, you're not going to listen." But what do we do? We ensure that we are there. We are listening.

When they ask to schedule appointments more frequently, we are there to support the person in that. We're not there to call them a liar. We are there to support them in that process. That is what I see happening here, and I'm proud of the work that they did in supporting Kanautica through this situation.

BY MR. DAVIDSON:

Q I like to mark one more. I'll mark this as Exhibit 16, and it's DAC 366.

(Exhibit 16 marked for identification.)

BY MR. DAVIDSON:

Q This is a mental health progress note dated

February 7, 2022. That's ten days before the February 17, 2022, DTARC meeting. Have you seen this document before?

A Yes, I would have.

Q Under "progress toward goals," it states, "Offender is reporting increased dysphoria and associated anxiety." Have you read that before the DTARC meeting on December 17, 2022?

A Yes. I would've seen this note as part of her medical record review.

Q Do you have any reason to believe that Ms. Zayre-Brown was not experiencing increased dysphoria and associated anxiety at that time?

A The context of this in the document you provided reports feeling "increased distress" over not having updated information about her gender-affirmation surgery. She also had some concerns about her existing hormone treatments and what was going on with the endo and the healthcare services there.

Q Thank you. But do you have any reason to disbelieve that Ms. Zayre-Brown was reporting increased dysphoria and associated anxiety on October 7, 2022?

A Within the context of what is shared in this note, I recognize that she's reporting feeling "increased distress over not having updated information

about her gender-affirmation surgery."

I believe that to be the case, and I do believe that was documented in the case summary that you used in a prior line of questioning. I don't recall which exhibit it was, but it was titled "Case Summary Report," and I do recall you asking me a question about that.

Q Setting aside the documents for now, at the time of the February 17, 2022, DTARC meeting, did Ms. Zayre-Brown have clinically significant distress, depression, or anxiety associated with her gender dysphoria?

A Did you say December or February?

Q February 17, 2022.

A Okay. And you asked did she have distress?

Q Clinically significant distress, depression, or anxiety associated with her gender dysphoria.

A I do think we spent some time on this previously. I do have the same answer to the question. That is one of the criteria. I think it might even be Criteria B for the gender-dysphoria diagnosis. That's confirmed. It continued to be confirmed during this time period, and that level of distress continued to exist.

She continues to meet the diagnostic criteria

for the gender dysphoria diagnosis. My answer is yes.

Q Okay. I'd next like to mark as Exhibit 17 DAC 351.

(Exhibit 17 marked for identification.)

BY MR. DAVIDSON:

Q This is a mental health progress note dated April 26, 2022. Under "progress toward goals" it says, "Goals were not directly addressed during session as clinician wanted to provide offender with the results of the DTARC review. Offender was visibly upset when learning that surgery was denied because it was, quote, not medically necessary."

My question is, do you have any reason to believe that Ms. Zayre-Brown was not visibly upset when learning that her surgery was denied?

A I would sincerely believe that she was upset, was frustrated. I would absolutely believe that she did not like that result one bit. She shared as much, but no, I would sincerely believe that she was upset by that.

Q Okay. I'd like to mark as Exhibit 18 DAC 179 through 181.

(Exhibit 18 marked for identification.)

BY MR. DAVIDSON:

Q This is a mental health update dated May 26,

IN THE UNITED STATES DISTRICT COURT

FOR THE WESTERN DISTRICT OF NORTH CAROLINA

CIVIL ACTION NO. 3:22-cv-00191

KANAUTICA ZAYRE-BROWN,)
)
Plaintiff,)
)
vs.)
)
THE NORTH CAROLINA)
DEPARTMENT OF PUBLIC)
SAFETY, ET AL.,)
)
Defendants.)

DEPOSITION OF

SARA BOYD, PH.D.

9:08 A.M.

FRIDAY, AUGUST 4, 2023

NORTH CAROLINA DEPARTMENT OF JUSTICE

114 WEST EDENTON STREET

RALEIGH, NORTH CAROLINA

CONTAINS GENERAL CONFIDENTIAL INFORMATION

the -- the vulvoplasty or vaginoplasty that she wants. So those are the four primary opinions that I offered.

Q. Okay. You say primary opinions. Are there other opinions in here?

A. Well, the -- you know, for example, when I say that the con- -- Dr. Ettner's process was undermined by deficiencies, there's, like, secondary, you know, critiques to that that are --

Q. Uh-huh.

A. -- covered under that umbrella is what I mean.

Q. Okay. All right. I'm going to flip to Page 33 and I'm looking at Conclusion Number (1)(a). You write, A psychologist who lacks formal medical education and training should not offer medical opinions, e.g., medical necessity, or state that their opinions are reliable and valid to a reasonable degree of medical certainty.

Did I read that right?

A. Yes.

Q. All right. What is your basis for this opinion?

A. Ethically, we're obligated not to offer opinions that are outside the bounds of our competence and our training. If you're not a medical provider, you shouldn't be giving a medical opinion. So, for example, if I'm testifying in court and someone asks me to give an opinion that's fundamentally a neurological opinion --

Q. Uh-huh.

A. -- or a -- a question about, well, if we gave this person this medicine, do you think it would make them feel better, I can't answer that question because I'm not a medical doctor and that's what I would say is, that's a medical question. You need a medical doctor to answer that. It's outside the bound of my com- -- bounds of my competence as a psychologist.

Q. Okay. And you said it -- it -- it's an ethical matter. Is there a -- you know, a published ethical code that you follow?

A. Yes. So there's APA ethics code and then there's -- they call them guidelines. They're all guidelines, but the -- there's a forensic specialty guideline ethics code as

well.

Q. Okay. So are -- are you providing an opinion in this case on medical necessity?

A. No.

Q. All right. In your view, can a psychologist like yourself or Dr. Ettner ethically provide an opinion on whether something is psychologically necessary or perhaps, as you put it, can provide a psychological benefit?

A. Yes.

Q. All right. I'd like to spend a little bit more time on that term. What does -- what does it mean for something to have a psychological benefit or to be psychologically beneficial?

A. Right. So --

MR. RODRIGUEZ: Objection.

A. -- typically, we're talking about treatment in this context, right, some kind of intervention that would be delivered to the person. So beneficial generally refers to either we're managing the person's symptoms so that they don't get worse or we're actually ameliorating the symptoms so that they improve, which might not mean that

they're cured and it might not even mean that they no longer meet diagnostic criteria for it, but they might have a significant relief in terms of the emotional pain that they're experiencing or cognitive limitations or behavioral problems that they're having. In some cases it can, you know, kind of at the extreme be essentially curative whereby the symptoms are ameliorated to the point that you fall below the diagnostic threshold. You may still have some persisting symptoms that are bothersome to you, but you no longer meet criteria. Occasionally, there are interventions that can be essentially curative, but for many psychological conditions, we often don't necessarily think of them as being cured but, rather, in remission because of the tendency that a lot of psychological conditions have to come back.

Q. Uh-huh. And so psychologically beneficial would encompass all of those things that you just mentioned; is that right?

A. Yes.

Q. Okay.

A. But it's still important to make the distinction because we don't want to assume that because something is psychologically beneficial that that also makes it curative.

Q. Okay. And I think you told me what curative means a moment ago, but can you tell me again what -- what does it mean to be curative?

A. Well, curative is not a technical term.

Q. Uh-huh.

A. But essentially, what we mean is that there's either a condition where the person's symptoms drop below the level that's required -- the threshold that's required for a diagnosis, right. We use this Diagnostic and Statistical Manual. It has criteria that you have to satisfy in order to have a -- meet criteria to have a certain condition. You know, let's say that you have to have four of those criteria. With significant, you know, benefit from psychological treatment, you may drop down to only having two of them. You still have those two things. They might be bothersome to you, but because you don't have four, you don't qualify for the disorder anymore. So I would

not consider that curative; I would still consider that to be an amelioration. Curative would be you have no symptoms of the condition.

Q. Understood. So is there a difference between a treatment being psychologically beneficial and medically necessary or medically beneficial, whatever the correct term is?

MR. RODRIGUEZ: Objection, medical opinion, but you can answer.

A. Yeah. There is a difference and that's why I don't -- that's why I can give an opinion about benefit without giving a medical opinion. So, you know, if somebody asked me, you know, if this person has electroshock therapy, will their depression be cured, I wouldn't be able to give an opinion about that. What I could give an opinion about is, here's what seems to be contributing to their depression. Here's what parts of it appear to be biological or sort of mechanical issues with their brain.

Q. Uh-huh.

A. But here are the other things that may not be. And so here's why we have reason to

believe that the person may need more than ECT.

Q. Okay. When it comes to gender-affirming surgery, in your view, can that ever be -- or could it ever be psychologically beneficial but not medically necessary?

MR. RODRIGUEZ: Objection, medical opinion. You can answer.

A. So saying something's not medically necessary would be giving an opinion about medical necessity so I would not give that opinion. What I would endeavor to do instead would -- to be very clear about for psychological benefit, you know, what does that mean, when, how, who, what.

Q. Uh-huh.

A. What are the circumstances where the person is most likely to achieve the best psychological benefit that they can get. I wouldn't give an opinion about, you know, this surgical technique versus that surgical technique or this medication versus that medication.

Q. In your experience, in your training, are you aware of any patient who was seeking

gender-affirming surgery and their providers determined that, yes, it's psychologically -- it would be psychologically beneficial, but, no, it wouldn't be medically necessary?

A. I'm not typically privy to how the internal committees within the Virginia -- for example, Virginia DOC make those kind of determinations so I don't usually even know what necessarily happens in terms of the endpoint of those cases. So I'm not sure what kind of determination was made by those kinds of panels.

Q. Okay. So in your view, who would be qualified to make a determination on medical necessity for gender-affirming surgery?

MR. RODRIGUEZ: Objection, medical opinion, outside the scope of this expert's opinions. You can answer.

A. So if some were to -- someone were to ask me for a referral for that, I would say it would need to be a medical professional, but the type of medical professional could depend largely on the individual person, what their needs were and what they were asking for. So a lot of times, an interdisciplinary approach

is a pretty helpful one for that where you've got a couple of different kinds of medical doctors so you might have an endocrinologist as well as a surgeon and a psychiatrist, for example.

Q. And do you have a sense of how a medical provider would go about determining whether surgery's medically necessary?

MR. RODRIGUEZ: Objection, medical opinion, speculation. You can answer.

A. I don't feel enough -- I don't feel that I know enough to say whether or not I know enough about that. I'm not -- I'm not familiar enough with the decision-making processes that they utilize for medical necessity to be able to give an opinion about that.

Q. Okay. Are you familiar at all?

A. I've certainly read depositions where physicians were discussing medical necessity. The -- I don't think that I'm an expert on medical necessity. I wouldn't give an opinion about medical necessity.

Q. Okay. Let's flip to Page 5 of your report.

A. Uh-huh.

Q. So I am in the second paragraph, last sentence, and you write, I know other psychologists like Dr. Ettner and I who also perform similar evaluations related to gender-affirming care for transgender and gender-nonconforming individuals and, in my experience, it would not be typical for them to offer medical opinions.

Did I get that all right?

A. Yes.

Q. All right. Who were the other psychologists you're referring to?

A. So one would be Dr. Olezeski and her colleagues at the Yale clinic. These are the -- some of the folks that I was thinking of in particular because they conduct a lot of trainings. The last one they did was for the APA last year and although they don't offer medical opinions, they work collaboratively with medical doctors so they're not completely siloed off.

Q. Uh-huh. Anyone other than Dr. Olezeski, if I'm pronouncing that correctly?

A. Yes, you are pronouncing that correctly. So Sarah Miller, my coauthor. I don't believe

Dr. Campbell has offered those opinions, who's also my coauthor on that chapter.

Q. What is Dr. Campbell's first name?

A. Walter.

Q. Okay. So you say it's not typical for them to offer medical opinions. Do they ever offer medical opinions?

A. I can't say that I know enough about all of those individuals and everything they've ever said or did to be able to say they have never offered an opinion that I would not consider to be a medical opinion. So I can't -- I don't think I have the foundation and knowledge to answer that, but my understanding in my interaction with those folks is that they would -- their ethical principle would be not to offer one because it's outside the scope of their competence --

Q. Uh-huh.

A. -- and I've never known them to do that.

Q. Okay. So for this assertion in your report -- excuse me, your report concerning offering medical opinions when you're a psychologist, are you relying on anything beyond your personal professional experience?

A. Well, so we have authoritative texts that provide guidance on these topics. We -- there's a -- Mental Health Evaluations for the Courts by Melton and colleagues is sort of one of our foremost texts that we would cite to that talks specifically about the importance of maintaining -- staying within the bounds of your competency as a psychologist. This is reiterated in our ethics code broadly, in our forensic guidelines more narrowly. Additionally, you'll see this in virtually any discussion of forensic psychological practice because it's not just that we shouldn't give medical opinions -- that's one pitfall, one kind of potential land mine for us.

Q. Uh-huh.

A. -- but also that we ought not offer legal opinions. That's the other area where we're significantly cautioned is not to offer legal opinions unless we are -- you know, like I said, I have colleagues who are J.D./Ph.D.s. that they might, but if you're just a psychologist, you would not. So it's not specific just to medicine.

Q. Okay. And these authoritative texts, do they say specifically something along the lines of, you know, forensic psychologists cannot, should not make recommendations concerning medical necessity?

A. I don't have a specific recollection that that -- the exact language regarding medical necessity. I would have to look at the text and see if that's an accurate representation of what they say.

Q. Yeah. Well, I mean, I don't expect you to remember offhand exactly what it says.

A. Uh-huh.

Q. Do you recall that it says something like that?

A. No.

Q. Okay.

A. I don't have a recollection.

Q. Okay. So can a psychologist, in your view, refer a patient -- can a psychologist refer a patient seeking gender-affirming surgery to a medical provider?

A. Yes.

Q. Okay. That's permitted by WPATH standards?

A. Well, in fact, WPATH talks about an

interdisciplinary approach at times. But an interdisciplinary approach could come because somebody goes to a clinic and the clinic takes an interdisciplinary approach or they could come to an individual psychologist or other mental health care provider or even their doctor and that person could refer them for intervention.

Q. Okay. So in terms of just what a -- a patient's care looks like --

A. Uh-huh.

Q. -- in your view, it's appropriate for a psychologist to conduct an evaluation, say, I think this treatment, surgery, or whatever would have psychological benefit, and I'm going to refer you along to a surgeon, endocrinologist, whoever?

A. Right. You -- I mean, you would also typically discuss whether or not a diagnosis of gender dysphoria is present or absent.

Q. Okay. All right. So still on Page 5. Bear with me just one moment. All right. I'm sorry. So this is second paragraph and it's four lines down. Thus, my role in such cases is not to make determinations regarding

whether a person should or should not receive a given intervention.

Did I read that correctly?

A. Yes.

Q. All right. And then let's flip to Page 2. And you say that part of your role is to offer recommendations with respect to gender-affirming interventions; is that right?

A. Right.

MR. RODRIGUEZ: Can you --

MR. SIEGEL: I'm sorry.

MR. RODRIGUEZ: Where are you -- yeah, where are you reading?

MR. SIEGEL: I'm sorry. Where is it? I don't have it highlighted on my copy.

BY MR. SIEGEL:

Q. Sorry. Bear with me just one moment, y'all.

MS. MAFFETORE: It's the first line --

MR. SIEGEL: Okay.

MS. MAFFETORE: -- on the second page, to offer recommendations with respect to --

MR. SIEGEL: Okay. Thank you.

MS. MAFFETORE: -- gender-affirming --

BY MR. SIEGEL:

Q. All right. So it's -- yeah. It's the very first line after the comma, Part of your role is to offer recommendations with respect to gender-affirming interventions or building capacity to provide informed consent.

A. Uh-huh.

Q. All right. So did those statements that I just read, the one on Page 2 and the one on Page 5 -- is there any contradiction between those statements?

A. I think part of the difficulty that we're having here is that we're maybe confusing making recommendations with respect to gender-affirming interventions with recommending specific gender-affirming interventions.

Q. Okay.

A. So what I don't do is I don't say, this person needs to have this surgery or this person should not have this surgery. I don't --

Q. Uh-huh.

A. -- say either one of those things.

Q. Okay.

A. But what I might say is, you know, what this

person has articulated is that they would like to -- you know, for example, I might say, I think they should be provided with information about what their options would be for bottom half surgery because what they've described in terms of their ultimate goal might necessitate that based on how they've described the presentation that they want. So I might recommend, for example, like, they should be provided with more information about that and here's how they should be provided with that information. I might say, they would learn best -- if they're a bright person who likes to read, maybe give them a book. If they're not or they have literacy problems, I might make recommendations that are different. So it's not that I'm recommending what interventions they should have, but I'm providing recommendations related to gender-affirming interventions without saying that they should or should not have them.

Q. And so in this case, you -- are you providing an opinion whether Mrs. Zayre-Brown should or should not receive a certain treatment?

A. I haven't given an opinion about whether or not she should -- from my perspective she should or should not receive a given treatment, but what I have done and can do is describe what she has said she wants.

Q. Okay.

MR. SIEGEL: Let's take a short break, if that's all right with y'all.

MR. RODRIGUEZ: Yeah.

(Whereupon, there was a recess in the proceedings from 11:00 a.m. to 11:09 a.m.)

BY MR. SIEGEL:

Q. Welcome back, Dr. Boyd.

A. Uh-huh.

Q. All right. Changing gears somewhat. Are you familiar with the Division Transgender Accommodations Review Committee or DTARC?

A. I am familiar with their existence. I'm familiar with them to the extent that their activities were documented in the records that I reviewed, but I don't have independent knowledge of them outside of the information I reviewed in this case.

Q. Okay. So based on what you reviewed, excuse me, what is the DTARC?

A. It's a committee that I believe reviews requests and then provides approvals for various stages of the process. So there are administrative processes for approving evaluations, scheduling consultations, and then approving procedures.

Q. Do you know who's on it?

A. No.

Q. Are you familiar with their decision last year to deny Mrs. Zayre-Brown's request for gender-affirming surgery?

A. Yes.

Q. Do you have an understanding of how DTARC reached that decision?

A. No. My primary focus was about how Mrs. Zayre- -- Zayre-Brown received the news and responded to it --

Q. Okay.

A. -- more than the deliberation.

Q. Okay. I'm going to hand you another exhibit. I think this is Exhibit Number 3 that we're on.

(BOYD EXHIBIT 3, Division Transgender Accommodation Review Committee (TARC) Report, 2/17/2022, was marked for identification.)

BY MR. SIEGEL:

Q. Dr. Boyd, have you seen this document before?

A. This actually may have been included in the records that I reviewed. This front page does not look fam- -- as familiar, but the -- the second and third page does.

Q. Okay.

A. Although it's possible that it looks familiar because it was cut and pasted from another section of the records. That often happens.

Q. Okay. So take another moment to review if you'd like --

A. Sure.

Q. -- and then just let me know what this document is --

A. I will tell --

Q. -- or appears to be.

A. Yes. So this appears to be a report that documents a determination that was made by the -- the Division Transgender Accommodation Review Committee. So it documents what information they reviewed. It provides a brief narrative and a medical analysis is the latter portion. It details who was in attendance at the time of the meeting and on

the front -- on the cover sheet there's an indication that the purpose of the review was related to gender-affirmation surgery/vulvoplasty and the accommodations referred for final determination includes the decision that says, DTARC does not recommend gender-affirmation surgery stating, This surgery is not medically necessary.

Q. Okay. I think that sums it up. Are you familiar at all with the professional background of the -- the individual defendants in this case?

A. No. Be- -- not beyond what their title is as reflected in records.

Q. Okay. Do you -- do you know if any of them have medical training?

A. I believe some do. I believe your -- that, for example, your chief medical officer is a physician.

Q. All right. Any of the others to your knowledge?

A. My -- well, typically, the chief of psychiatry would be a psychiatrist, who's also a medical doctor, so it's likely that person is also a physician.

Q. Okay. So based on this document, the DTARC recommended that gender-affirming surgery was not medically necessary, correct?

A. That's what the form states, yes.

Q. Okay. So if any of the members of the DTARC who participated in this recommendation did not have medical training, would that have been appropriate in your view?

MR. RODRIGUEZ: Objection to form. You can answer.

A. So that's a -- this is a good example of why the interdisciplinary approach is important. So you can see there's a medical analysis section that -- there's a heading specific to that. I would suggest that someone without a medical degree should not be involved in the decision-making regarding, like, the deter- -- the actual determination as far as saying this is medically necessary or not. However, it may benefit the folks who have the background to men- -- make the medical determination to have the input from folks who have a background in mental health and/or who are administrative folks who know more about what the internal regulations and

requirements are so they can have input and they may provide information that the folks who make the medical determination find relevant and necessary. But as far as who signs off on the medical analysis and who drafts it, in my opinion, that should be a physician -- it should be someone with a medical degree.

Q. Understood. Okay. You can set this aside if you'd like. So a lot of your report is talking about informed consent and you've spoken about that some today. I'll just ask a very basic question of what is informed consent and why does it matter?

A. Right. So informed consent, broadly speaking, refers to the necessity for individuals who are participating in treatment or evaluation to knowledgeably agree to participate or receive that treatment or evaluation. So that's, like, in the very broadest sense. And informed consents in our practice as psychologists means that people are knowingly participating in -- whether it's an evaluation or treatment, that they are a -- given the

opportunity to be provided with the information that they need to understand the risks and the benefits, the costs, and, you know, have a reasonable and reality-based appraisal of that before they are asked to make a decision. There's two parts to it. One is making sure they have the information. The other part is the autonomy of the individual to choose to participate or not.

Informed consent in terms of providing care to folks who are transgender has -- is slightly different. So we still have the core informed consent obligations that we're required to maintain ethically in terms of our practice, doing evaluations or -- or doing treatment, but informed consent is also, somewhat confusingly, the name of a different kind of approach to assessing individuals and providing treatment to individuals who are transgender, whether they're in the community or a carceral setting. It's not specific to a setting. And what it means is that instead of saying that our role is to decide if somebody is trans or not, instead, our role is to make

sure that the person not only has the capacity, right -- which capacity doesn't mean you already have all the information; it just means you have the ability to understand and process that information, make decisions. Not only do they have the capacity, but have they been provided with the information that they need? Are they in a position to make a decision about it and do they have the support that they need to do that? So an informed consent approach to conducting these evaluations is different even though it uses the same terminology as informed consent in terms of an ethical obligation on the part of psychologists when they're conducting activities involving patients, clients, or research participants.

Q. Okay. So when you are evaluating patients for informed consent meaning, I think -- well, let -- I'll let you answer that. When you're evaluating a patient for informed consent, which one of those do you mean --

A. Right.

Q. -- and how do you do it?

A. Right. Well, unfortunately, another

complicated answer.

Q. Okay. Great.

A. So one version of looking at this could be, like, a Miran- -- a competency to waive Miranda evaluation, which is retrospective and it's looking at whether or not the person knowingly, intelligently, and voluntarily waived their rights to a custodial interrogation so you might look at their capacity. Do they have an intellectual disability, do they have a severe psychiatric problem, were they under severe stress, things like that. So that's one area where it's -- you know, that's one area where it's different.

But informed consent in this process refers more to positioning the individual who's seeking treatment in such a way that they can access the support that they need, have the information that they need delivered in -- to them in a way that they understand so that they can make a decision collaboratively with their treating professionals about what treatment they need, when they should get it, how it should be

delivered.

Q. In this case did you assess Mrs. Zayre-Brown's ability to provide informed consent?

A. I used an informed consent approach and part of that was assessing her capacity to provide informed consent and I did ultimately come to an opinion regarding that.

Q. Okay. How did you go about making that assessment?

A. I looked for the presence of any conditions that could potentially interfere with her capacity to provide informed consent and then I just asked her direct questions to ascertain her fund of knowledge and her beliefs about different kinds of scenarios and options.

Q. Okay. Could you be a bit more specific on --

A. Certainly.

Q. -- how you did that.

A. Yes. So in reviewing her records, for example, I looked for conditions that could be expected to potentially, even just in a time-limited way, impair her capacity to provide informed consent. So I looked at

mood issues, cognitive issues. Those are the -- those issues and psychosis are the most common kind of barriers to that.

After you see whether or not those things are present, if they are present, then you look to see, are they relevant? In other words, are they active now when the person -- or during the relevant time period when you're looking at the decision-making, which for Mrs. Zay- -- Zayre-Brown is now.

So she does have some cooccurring conditions. You know, in my view, though, at the time that I saw her, those symptoms were not so active or impairing that they would impair her capacity to understand what her options are and make decisions.

Q. Okay. Does that mean you concluded that she can provide informed consent?

A. I believe she has the capacity to provide informed consent in that, you know, narrow -- more narrow kind of ethical obligation of ensuring that she's not, for example, agreeing to a procedure when -- in a -- without a reality-based understanding.

Q. Okay. If you could flip to Page 31 of your

report. And this is beginning of Section E. Sorry. I'll wait till -- for you get there.

A. Yes.

Q. Oh, I'm sorry. It's actually the -- the first full paragraph on the page, which reads, Mrs. Zayre-Brown's expectancies for the surgical aftercare that would be available to her in prison were less realistic in light of history.

What does that mean?

A. So this interview was -- was video recorded.

Q. Uh-huh.

A. And this is a reference in part to the discussion that Mrs. Zayre-Brown and I had about her experience when she initially entered custody and had had surgery about a month before that -- be- -- before her sentencing. And so she was still recovering from a surgical procedure and that's where the -- part of where that relevant conversation started. We discussed what care she had already received and that's why I say in light of the history. When I say that her expectancies for surgical aftercare that would be available to her in prison were less

realistic, I say that because what she was describing in terms of what she expected to receive in terms of aftercare was a radical departure from what -- the care she described actually receiving.

Q. Okay. And the care that she described receiving with respect to recovering from the orchiectomy --

A. Yes.

Q. -- in 2017; is that correct?

A. Yes.

Q. All right. Was there a -- anything else in your assessment that contributed to your statement here that her views were less realistic about aftercare?

A. So here we're talking about surgical aftercare specifically --

Q. Uh-huh.

A. -- so not other elements of aftercare. And, yeah, so that particular statement is related to that discussion.

Q. Okay. And so my question is, was there any other statement that she made or any other part of your assessment that contributed to that observation you made?

A. The result of her formal testing by me --
Q. Uh-huh.
A. -- indicate that she has a personality style where she is -- she has a tendency to, like, idealize situations sometimes that are prospectively positive so that can cause her to be a little bit like a cork on the ocean where a good thing happens or something seems like it's going to be really promising and relieving and her mood goes up significantly. At the same time, when she gets news that something is not going to happen, her mood can drop down really dramatically. And in my view, that affects her ability -- when she's in those states, that does affect her ability to accurately appraise and anticipate what's going to happen in the future, but that could happen in either direction depending on the circumstance. I think this is an example of her idealizing what would be available to her. And I say idealizing it because she is com- -- I'm comparing it to what she has told me about her own experiences prior to that.
Q. Uh-huh.
A. And she was not able to provide me with

information that was -- would indicate that there were -- there was an evidence base for believing that the circumstances that she described as ideal for her and most likely to give her relief and benefit would actually happen in a prison setting.

Q. And what would be ideal?

A. So she articulated it herself and I describe it on that same page, the last paragraph before Section E. Her idea -- her view of an ideal surgery context would include, A, receiving medical care in the community, including aftercare and wound care management; B, the opportunity to receive care and support from her husband, friends, and family; and, C, participating in meaningful personal and professional development opportunities while she is preparing for surgery and recovering from surgery.

So this is her statement about what she sees as an ideal surgery context. Now, when I say she idealized things, I'm -- here that's not what I'm talking about. This is her -- just her self-report, her description

of what she thinks would be optimal for her --

Q. Okay.

A. -- clinically. What she described as far as what -- how she thought recovery -- what recovery from this procedure could look like in a prison setting, she described having more access to physicians, more regular care than she described having at the time that she initially entered prison in 2017.

Q. Got it. Do you have an understanding of what postsurgical care is like for a vulvoplasty?

A. I have some familiarity, but I can't give a medical opinion.

Q. Okay. I'm not a asking for a medical opinion, just to your knowledge. Is -- is it anything more complicated than basic wound care?

A. It depends on the individual. The vulvoplasty differs from vaginoplasty in that most individuals, you know, there wouldn't be a reason to use dilators, for example, but depending on how the procedure is done, how skillfully it's done, what the individual's history is -- she did have complications

through her wound care before from the orchiectomy but -- you know, it can be complicated for individuals, but it -- you know, it depends on the person. All I can rely on for her -- from her is what she tells me about what her prior experiences were with her ability to manage wound care. And I think it is fair to say that it's certainly a risk, probably a more significant risk for vaginoplasty compared to vulvoplasty, but both of them would carry risks and a physician would have to be the person -- a surgeon would have to be the person to give you an opinion.

Q. Okay. So other -- other than her experience in 2017, do you have any other reason to be concerned about the quality of aftercare provided in the state prison system?

A. I'm re- -- again, I'm relying on her report.

Q. Okay.

A. I'm relying on what she has personally experienced and the aftercare that's available in one facility or for one individual could be different even within the same prison system.

Q. Speaking very generally, do you have concerns about the quality of care offered in the prison setting versus the community setting?
A. With respect to mental health care, which is really what I'm able to comment on, yes.
Q. Okay. Could you tell me why.
A. Prisons are inherently stressful environments. Restrictive housing in particular is a highly stressful environment. It's well documented that it's incredibly psychologically stressful.
Q. Uh-huh.
A. The analogy I sometimes give is that depending on where you're at in the prison is the psychological equivalent of getting hit in the head -- or getting -- yeah, getting hit in the head with a hammer every day and wondering why your skull isn't recovering. You know, you could get medical treatment --
Q. Uh-huh.
A. -- you could get stitches, but if you're still getting hit in the head with a hammer every day, you're not going to get a lot better. And that's part- -- partly an issue of confinement. It's partly an issue of who

you're around, what your population is and -- and who your social community and your peer group is and whether they're dangerous to you or not. But from a mental health perspective it is -- you know, we would most -- I don't know any psychologist who would say that it's not a -- a psychologically stressful environment.

Q. Uh-huh.

A. So there's that aspect to it. Doesn't mean the community can't also be stressful. Being unhoused --

Q. Uh-huh.

A. -- for example -- you know, there are all kinds of ways that the community can also be stressful, but just as a baseline, it's a more stressful environment. Sometimes people have access to services in there that they don't have access to in the community, but overall just as a baseline, it's a different environment from a psychological perspective.

Q. Okay. So I'm going to give you a hypothetical. In your view, assuming that a treatment would be psychologically beneficial for a patient and is medically ne- -- excuse

me, medically necessary, would the quality of aftercare available be a valid reason to deny that treatment?

MR. RODRIGUEZ: Objection to form, medical opinion. You can answer.

A. Denying the treatment would be an administrative decision. It's not -- and that's not a process that I'm part of. I also think that the individual's perspective on whether they feel they could tolerate, you know, those circumstances would be something to take into account. It's difficult to answer that hypothetical just because it is somewhat broad.

Q. Okay. Well, I'll narrow it a little bit. So you can also assume that this person has requested the surgery and has been seeking it for years. And I'm not talking about really the administrative decision. I'm talking about a decision by the healthcare providers treating the patient. So assuming all of that -- so we've got patient who wants a treatment. Assume that it's psychologically beneficial. Assume that it's medically necessary. Patient has been advocating for

herself for years.

In that case, would the quality of aftercare available be a valid reason to deny the treatment?

MR. RODRIGUEZ: Objection, medical opinion, legal opinion, speculation, form. You can answer.

A. I wouldn't say -- I wouldn't say that exactly, but I would direct you to, actually, Ettner's second declaration, Paragraph 38 where she describes a Cornell study regarding outcomes for transgender folks after they've had procedures done and one of the things that predicts outcomes is the quality of the surgical procedure and, I believe also, the aftercare that's available to that individual. That does affect the outcomes that people have.

Now, you know, there's critique -- there's different ways to talk about that and think about that. Regret rates are also related to the fundamental effectiveness of the surgical procedure and whether or not the person ends up with the outcome that they want. Now, as I'm sure you know, regret

rates are very, very low, but even within that group, one of the things that does predict it is if you don't get the surgical outcome that you want physically.

Q. All right. So getting back to Kanautica and informed consent --

A. Uh-huh.

Q. -- were there any aspects of informed consent that you assessed and haven't mentioned yet today?

A. Yes. I discuss in my report -- and forgive me one second. I want to locate it, the section. Okay. On Page 10 in the section that has a header that starts with, Dr. Ettner discounts the importance of a psychologist's role in informed consent, the second full paragraph, A prospective patient's understanding of the likely outcomes of a procedure and the timing of these outcomes is key to their ability to make decisions while also weighing the risks and costs. Skipping down a little bit to the second-to-last sentence, for example, a patient who believes an intervention will be curative may accept more serious or higher

probability risks compared to a patient who believes that an intervention will alleviate but not cure their symptoms. Communicating to a prospective patient, continuing on to the next page, Page 11, that a surgical procedure will be curative carries significant risk of misleading the individual and influencing their decision-making with inaccurate information leading to exaggerated proc- -- expectancies.

And so here what I'm speaking about, and I continue to talk about in the report, is the narrative -- is the information essentially that Dr. Ettner provided to Mrs. Zayre-Brown saying, this will cure your gender dysphoria. That is something that I did get into and I discussed with Mrs. Zayre-Brown because of my concern that if doctors are -- authority figures are coming in and telling her, this will cure your gender dysphoria, and that's not true or at least we can't say it with that degree of confidence that that's definitely what's going to happen, then that person may decide to undertake procedures under riskier

circumstances, less optimal circumstances that are likely to produce less benefit because they think, this is what's going to fix the pain that I'm experiencing. And so I do certainly have that concern and I discuss it in my report with respect to informed consent, wanting to ensure that Mrs. Zayre-Brown has accurate, reality-based information so that -- so that she can make her own decision.

Q. Are you expressing an opinion in this case as to whether Mrs. Zayre-Brown has actually provided informed consent for gender-affirming surgery?

A. I gave the opinion that I don't believe her capacity to provide informed consent was significantly compromised at the time of my evaluation of her so her capacity to provide informed consent to most surgical procedures at this point, I think, is probably intact.

I mentioned the information that I think has been provided to her that is misleading and I -- you know, obviously, I want to make sure she knows that that is my perspective so she has that information, too, in making her

such as gender dysphoria, which has a diverse manifestation and is inextricably bound up in aspects of the person's life and circumstances that go far beyond the physical appearance of their genitals.

Did I read that right?

A. Yes.

Q. All right. So big picture question. Like, can gender dysphoria be cured?

A. I think there are certainly people who could get to the point that they would be subthreshold, right. That's an -- I -- I've talked before about how there's difference between subthreshold and having no symptoms. I think certainly for most people, there's the possibility of bringing somebody subthreshold for gender dysphoria, but it's usually not the case that there's a single intervention that's sort of like a magic bullet. It's usually a combination of things that deal with, you know, as I allude to here, not just what their genitals look like or their secondary sex characteristics but also what their social environment is, what their supports are --

Q. Uh-huh.
A. -- what their access to care -- all kinds of care is.
Q. Okay. So why is it that a -- a psychologist can't predict that a certain intervention will be curative of gender dysphoria?
A. Because of the fact that it -- there's so -- there's other contributing causes. I mean, like, really just what I said there. It's not just about the -- the appearance of somebody's physical body. There are other factors there. So it's more like I'm saying there's not one thing most of the time. And for her specifically -- getting into her specifics, she articulates repeatedly that there are other factors that contribute significantly to her gender dysphoria, specifically transphobia that she encounters from other people and also to some degree, I think, internalized transphobia when she feels that she's been recognized and identified and then treated differently because she's a trans woman.
Q. In your view, can a psychologist predict with confidence that a certain intervention

wouldn't be curative but that -- but that it's necessary to achieving a cure?

MR. RODRIGUEZ: Objection to form. You can answer it.

A. We would call that necessary but not sufficient --

Q. Uh-huh.

A. -- in -- in our terminology. So it's a piece of it, but it's not going to get you all the way there is the idea. That's one way of looking at that, yeah.

Q. Okay. Would that be true for any clinical psychologist?

A. I'm sorry. I -- can you ask that question in a different way?

Q. Would it be true for any clinical psychologist --

A. That --

Q. -- that you cannot predict that a certain intervention will be curative?

A. I think it depends on the intervention and it depends on the individual.

Q. Okay. Well, how -- how about yourself, would that apply to you?

A. Well, yes. I mean, I think it would depend.

If I have somebody that it's a very straightforward presentation and they -- let's say they have very physiological depression symptoms, in other words, they feel very tired, they have very little motivation, they can't -- just can't move their body to do the things that they need to do. Provided that there isn't an underlying medical condition and that's been ruled out through interdini- -- disciplinary practice or referral, then I would say we have good reason to believe that probably about 80 percent of people would achieve remission is what we would call it for -- for a condition like that. So I could tell -- I wouldn't tell somebody, I'm absolutely confident this will cure you.

Q. Uh-huh.

A. You know, something else could happen. Their parent could die. They -- you know, any number of things could happen that could interfere with their progress, you know, but I could say, you know, given the evidence base for the success rate of this intervention, given the complexity or lack of

complexity in your presentation, you know, here's how likely I think it is you would benefit, but I would never tell somebody, I am certain that this will cure you.

Q. Okay. Let's flip to Page 20. So I'm going to -- the last sentence of Subsection B you say, Likewise, surgical intervention alone is not likely to be curative and may not substantially ameliorate her suicidality --

A. Uh-huh.

Q. -- is that right?

A. Right.

Q. Okay. So are you making a prediction here about whether a certain treatment would be curative?

A. I think it's not likely it would be curative. I do -- I think it's likely she would achieve a benefit from it. It's really -- I think the debate is sort of the degree of that benefit. Secondarily, you know, the question of, like, substantially ameliorating her suicidality, I mean, it might, you know, but I don't think that we have confidence to say it will.

Q. Do you see any tension between your assertion

here and the assertion we spoke about a moment ago that a psychologist cannot predict with confidence that a certain treatment will be curative?

A. Yes, but that's basically making -- that's saying, this is -- this is how this is going to go. What I -- what I'm saying instead here when I'm saying it's not likely to be curative is -- what I'm saying is the most likely outcome is that it's going to fall short of that particular benchmark of being curative. Doesn't mean -- I'm not saying surgical intervention alone is not likely to provide psychological benefit or amelioration of the symptoms, but it's not -- I don't think it's likely to be curative specifically. That's a very high bar.

Q. Okay. But do you think that gender-affirming surgery would provide psychological benefit to Kanautica?

A. I think depending on the circumstances, if it's provided in the way that she details, which I described in my report on Page 31, receiving medical care in the community including aftercare and wound management,

receiving care and support directly from her support network, participating in meaningful personal and professional development opportunities both while she's preparing for it and while she's recovering from it, then, yeah, I think she -- I have no problem at all saying I think it's likely she would benefit from that and probably, I think, get significant relief both with respect to gender dysphoria and with respect to suicidality.

Q. Okay. Are you familiar with the treatments for gender dysphoria she has received so far?

A. I don't want to misrepresent my level of understanding. I have some understanding of what she's already undertaken, but I don't have a medical professional's level of knowledge.

Q. Okay. Do you know that she has been on hormone therapy?

A. Yes.

Q. Okay. Do you know that she has un- -- undergone social transitioning?

A. Yes.

Q. Okay. To your knowledge, have those

treatments cured her of gender dysphoria?

A. No.

Q. Okay. Other than surgery, is there any treatment that you're familiar with for gender dysphoria that she has not received?

A. So medical treatments, I couldn't speak comprehensively to that because I'm not a medical expert so I can't tell you what all of those options would be. I don't believe that she's done voice training. That's something that she could do. There might be other kinds of sort of plastic surgery-type interventions that she might want, but, you know, those are -- you know, the -- the surgery aspects are a medical intervention. And additionally, there -- this is such an evolving area of practice that there are new procedures all the time so the options today might not be the options next year. There could be other things that would help her.

She had -- she -- and she has had plastic surgery from what I understand in terms of what I discussed with her in her deposition, but when you read her description of it and talked with her about it, she

describes getting very, very limited gains from these prior medical interventions.

Now, you know, one of the questions would be if she got such limited benefit from the prior interventions, why do we believe we're going to make the jump to a hundred with the -- one single intervention, you know? I don't think there's a -- I don't think we have good reason to believe that based on her own characterization and recollection of her experiences with medical intervention.

Q. Uh-huh. So zooming out somewhat, like, big picture, what do you believe is causing her gender dysphoria?

A. So Mrs. Zayre-Brown has had a very -- from my understanding she has not had an easy life. She does have support in her marital relationship and evidently her family relationships, but living as a transgender person in the United States at this point in time is painful and difficult not only because of constraints on access to services or people not even knowing what's available to them sometimes or not being able to afford

it, but also, obviously, there's a cultural environment that's hostile to people and I believe that that cultural environment is a significant cause and contributor to her gender dysphoria.

On top of that, frankly, our gender binary is -- is highly, highly determined by essentially the -- the ancestry's eugenics and the beauty standards for women are difficult for anybody to achieve and fairly narrow. And I think if the aim is to not be identifiable as a trans woman, that's going to -- that's difficult. And if you are identified, then it may be because of some piece of your anatomy that somebody knows about, but it could also be your height. It could be your shoulders. It could be your voice. People who aren't even trans are getting -- people are telling them that they're trans because their shoulders are too broad or their voice is too low. There are all kinds of ways in which she, I think, experiences transphobia in ways that have, frankly, nothing to do with her primary sex characteristics, but I also believe that

there is a contribution that is coming from her own internal discomfort with continuing to have a phallus when that is not consistent with her gender identity. I do think that contributes to her gender dysphoria and it makes sense then rationally that coping with that is going to be a sensible step for her in terms of treatment.

Q. And to be clear, what do you mean by coping with that?

A. Well, I mean having -- having a procedure to -- you know, having bottom half surgery, whether that's a vulvoplasty or vaginoplasty, dealing with that component of it, of the internalized transphobia. And also, just the discomfort, emotional and psychological discomfort, with continuing to have a phallus, that is its own contribution. I think that's valid. I believe her when she says that.

Q. Do you have any reason to think that Mrs. Zayre-Brown can be cured of her gender dysphoria while she still has a penis or a phallus as she calls it?

A. Based on her statements, I think not. I

believe her self-report has consistently been that this is something that she sees as sort of a keystone intervention. I think the main difference really is just that in my view, she needs other things as well and that we want to be careful and mindful about the timing and the setting and the context of intervention to maximize the benefit that she's going to get so we can get as close to the benefit as she anticipates as we possibly can.

Q. Okay. You mentioned the -- the phrase necessary but not sufficient a little while ago.

Would you say that removing her phallus and having genital surgery would be necessary but not necessarily sufficient to cure her gender dysphoria?

A. Ultimately, yes. The question of the timing, I think, is a separate issue, but in the long-term sense, yes.

Q. Uh-huh. Did you find any contraindications for surgery?

A. So I can't speak to medical contraindications for surgery. And surgery, broadly speaking,

no, but as far as what she described -- you know, that's what I keep coming back to is what she's describing as the set of circumstances that are going to -- going to give her the most relief.

Q. Do you have any reason to think that if she underwent a vulvoplasty, she would later regret it?

A. I think it's possible if the -- not in and of its- -- not, like, per se. Not only because of, oh, I wish I had had another procedure. It's possible depending how -- how the procedure went that later on, she could have some amount of regret, not that she had a vulvoplasty but that she didn't have a vaginoplasty instead. I think that's possible. I don't think it's likely that she would experience regret in terms of saying, I wish I still had a phallus.

Q. If someone undergoes a vulvoplasty, are they able to also undergo vaginoplasty later?

A. My understanding of it -- and I want to be clear because I'm not a medical professional. I can't give a medical opinion. But my in- -- understanding from consulting with

medical professionals who do the procedures is that vulvoplasty is a less commonly done procedure so it's -- most of the surgeons who would do it will have less familiarity with doing that compared to vaginoplasty and also that with respect to both the orchiectomy and vulvoplasty, there's the necessity of maintaining a certain amount of tissue and certain structures in order to be able to later do a vaginoplasty, although there are alternative procedures that can be done if that tissue isn't there, and they may be more or less desirable to the individual. I think it has to be a highly individualized medical decision that's made between the doctor and their patient.

Q. Okay. Let's turn to Page 29 of your report, please. And I'm -- it's the final sentence of the third paragraph on the page. In other words, Mrs. Zayre-Brown's acute mental health crises in recent years were indirectly rather than directly related to her gender dysphoria. Additionally, by her account, significant contributions to her distress were associated with administrative processes

and delays related to her treatment.

Did I read all that correctly?

A. Yes.

Q. What does it mean for something to be indirectly related to gender dysphoria?

A. So the idea would be that there's a certain amount of distress that comes from what I just described as this sort of compartmentalized -- it may be internalized transphobia or may be some other manifestation of just dis- -- emotional and psychological discomfort with continuing to have a body part that you don't want to have or wishing you had one that you don't. The mental health crises appear to be in part -- again, it's like that cork on the ocean thing. The gender dysphoria is going to be -- I think for her it has ebbed and flowed to some degree, but I don't think there's a time when it hasn't been present as far as I can tell. But the interactions with authority figures who give her bad news, who she perceives as delaying things, or when she has feelings of abandonment, that also taps into, I think, some trauma-related issues

IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF NORTH CAROLINA
CHARLOTTE DIVISION
No. 3:22-CV-0191-MOC-DCK

KANAUTICA ZAYRE-BROWN, Plaintiff, v. THE NORTH CAROLINA DEPARTMENT OF ADULT CORRECTION, et al., Defendants.	)	**EXPERT REPORT OF JOSEPH V. PENN, MD, CCHP-MH, LFAPA**

I. Introduction and Expert Background

I was retained in this matter by Defendants based on my expertise in the provision of psychiatric, mental health, and certain other medical and health care services across correctional settings. I was asked to provide opinions and conclusions regarding the adequacy and appropriateness of policies and procedures used by the Department for evaluating and managing requests for accommodations by transgender patients. Additionally, I was asked to offer opinions and conclusions about the Department's formulation and application of the phrase "medical necessity" within state prisons. I was also asked to offer opinions and conclusions regarding Defendants' evaluation of Plaintiff's request for a vulvoplasty as a surgical intervention to treat her gender dysphoria.

A. Summary Statement of Qualifications

I am a correctional and forensic psychiatrist based in Conroe, Texas. I am a licensed physician triple board-certified in forensic psychiatry, general psychiatry, and child and adolescent psychiatry, and a Clinical Professor in the Department of Psychiatry and Behavioral Sciences at the University of Texas Medical Branch (UTMB), Galveston, Texas. Over the past 30 years, I have

devoted most of my professional time to the practice, teaching, and clinical research within general adult, child and adolescent, forensic, and correctional psychiatry. Since 1999, I have focused my clinical, administrative, and forensic work primarily within correctional settings.

I achieved and have maintained a specialized certification as a Certified Correctional Health Professional-Mental Health (CCHP-MH) since 2004, which is provided by the National Commission on Correctional Health Care ("NCCHC"). I am a NCCHC physician surveyor, serve on the NCCHC Accreditation and Standards Committee, and on the NCCHC board, representing the American Academy of Psychiatry and the Law ("AAPL"). I have also provided specialized technical assistance, trainings, and consultation to juvenile facilities, jails, and prisons nationally, internationally, and the US territory, Puerto Rico, most recently.

I am the Director of Mental Health Services of the UTMB Correctional Managed Care (CMC), a university-based correctional health care system. UTMB CMC provides direct medical, dental, nursing, psychiatric, mental health, gender dysphoria and other specialty care to state prisoners in the Texas Department of Criminal Justice ("TDCJ"), which is the largest state prison system in the country. In this position, I am responsible for, provide, and oversee the psychiatric, psychological, and mental health services at eighty state jail and state prison units throughout Texas. I have held this position since February 2008.

As a practicing correctional psychiatric physician, I evaluate, diagnose, treat, and oversee the provision of mental health services for incarcerated individuals with mental disorders and behavioral issues. Similarly, I evaluate, diagnose, and treat patients with gender dysphoria evaluation, and supervise other clinicians that do the same. Additionally, I directly oversee the statewide clinical evaluation and treatment program for TDCJ patients who seek treatment for gender dysphoria. I also provide consultation on particularly complicated patients.

I have developed and maintain clinical knowledge regarding the mental health and health care needs of incarcerated transgender and gender diverse individuals. As such, I am familiar with the *Standards of Care for the Health of Transgender and Gender Diverse People, WPATH 8* ("WPATH 8") and the prior Version 7, published by the World Professional Association of Transgender Health ("WPATH"). I am also generally familiar with other scientific and peer-reviewed literature relevant to the provision of health care to this patient population both in community and in correctional settings.

I am the Chair of the Joint Mental Health Work Group, and the Co-Chair of the Joint Gender Dysphoria Work Group. In this capacity I oversee the review and revision of all policies, procedures, clinical practices, disease management guidelines, formulary and non-formulary psychotropic and gender affirming medications for incarcerated TDCJ patients. Also, I have experience developing and implementing policies concerning the care and management of the incarcerated transgender and gender diverse population. More specifically, I oversaw the systemwide development, revisions, and implementation of a disease management guideline for the evaluation and treatment of incarcerated adults seeking evaluation and treatment for gender dysphoria.

I also provided input and assisted with revisions to the State of Texas's Correctional Managed Health Care Committee policy entitled Policy G-51.11 of the Correctional Managed Health Care Policy Manual, which concerns the treatment of incarcerated persons with intersex conditions and gender dysphoria. And, I assisted in revising and approving, the NCCHC's 2020 position statement entitled: *Transgender and Gender Diverse Health Care in Correctional Settings*."[1]

[1] https://www.ncchc.org/transgender-and-gender-diverse-health-care-in-correctional-settings-2020

Additionally, I oversaw the development, implementation, and expansion of a statewide specialized gender dysphoria referral and clinical program, a joint operation of the UTMB CMC, the TDCJ, and Texas Tech University. This program is used throughout the TDCJ system statewide. This program uses telemedicine to provide specialty clinics across the jurisdiction to undergo evaluation, diagnosis, treatment, and subsequent follow-up. Based on patient experience and feedback, and from health care, and custody staff's perspectives, the program has been a tremendous success. As a result of the program's success, we have received numerous external requests for lectures/presentations describing this novel program at several NCCHC and American Correctional Association annual meetings and other health care conferences, and other venues. I continue to oversee and maintain direct clinical involvement in this program.

I also have direct clinical and supervisory experience working with this patient population. I have personally evaluated, diagnosed, performed chart reviews, ordered or re-ordered gender affirming hormone medications, reviewed lab studies, performed second opinions, and consulted with other health care staff, including, endocrinologists, internal medicine physicians, family physicians, psychiatrists, and others. In total, I estimate that I have treated more than 1,500 incarcerated transgender patients with or without gender dysphoria. I also directly oversee mental health care providers in the UTMB CMC system who provide evaluation, diagnosis, and direct patient care to transgender patients. Additionally, I provide other consultation and behavioral treatment recommendations regarding this patient population to psychiatric and mental health, nursing, and medical staff and to TDCJ custody and health services leadership.

To gain additional direct patient care experience with this patient population, I completed a specialized clinical training program regarding the evaluation and treatment of this patient population. I completed this training between December 2014 and December 2016 with Dr. Walter

Meyer, Professor Emeritus, and now retired UTMB faculty psychiatrist and endocrinologist. Dr. Meyer is a respected international leader in transgender health care. For this training program, I would routinely travel to the UTMB CMC Hospital specialty clinics in Galveston, Texas, to train under the direct supervision of Dr. Walter Meyer. Much of this training consisted of additional readings, patient chart reviews, clinical supervision, and case discussion meetings with Dr. Meyer. During these discussions, Dr. Meyer and I would review relevant guidelines, and patient evaluations and treatment plans. I completed this additional specialized clinical training program to improve my diagnostic skills and competence in evaluating and managing this patient population and to attempt to optimize our health care delivery to this group. Subsequent to 2016, I continued my ongoing clinical collaboration and case discussion with Dr. Meyer up through his retirement a few years ago.

In addition to evaluating, diagnosing, treating, and consulting on patients in the TDCJ system, I have performed second opinion evaluations/consultations in other states. I have also served as a consultant to several state prison systems including Colorado, Kansas, New Jersey, and California regarding gender dysphoria diagnoses, evaluation and treatment programs, policies, and practices, and medical and surgical interventions for various state inmates. I have presented nationally and internationally regarding the evaluation and diagnosis, clinical management, and treatment of transgender and gender diverse individuals within correctional settings.

Due to my 30 years of direct patient care and administrative work and particular career focus within correctional settings, I maintain additional knowledge regarding the range of clinical, professional, ethical, legal, patient safety, and other correctional specific issues such as PREA (Prison Rape Elimination Act), health care and custody staffing and supervision, access to and continuity of health care, and organizational challenges to those who evaluate and treat

incarcerated transgender individuals with or without gender dysphoria. I also maintain necessary familiarity with custody and classification issues such as unit, program, and housing assignments, basic unit operations, disciplinary infractions, custody status, unit custody classification hearings, restrictive housing, custody supervision, custody classification issues such as age, gender, height, weight, and security threat group (gang affiliations), protective custody status, life endangerment claims, and the like.

For a more detailed statement of my education, training, and experience, see paragraphs 1 through 20 of my affidavit (DE-18-8), and my CV (DE-18-9) both of which have previously been filed in this case, and which I fully incorporate herein by reference.

B. Information Considered in Forming Opinions

In forming the conclusions and opinions set out in this report, I reviewed and considered a variety of materials and information, which are set forth in Appendix A. Generally speaking, these materials and information include various medical and health care records, and other records and documents maintained by the North Carolina Department of Adult Correction ("the Department") concerning Plaintiff, Mrs. Zayre-Brown, that were produced in discovery in this matter. I have also reviewed several legal filings in this matter, including those related to Plaintiff's motion for a preliminary injunction and Defendants' motion to dismiss.

Additionally, I have reviewed the report of Randi C. Ettner, Ph.D., Plaintiff's expert, dated February 2, 2023, and her previous declarations. I also reviewed WPATH 8 and its predecessor, version 7. And I have watched the January 28, 2023, video-taped deposition of Plaintiff and reviewed the transcript of the same.

I have reviewed the Department's policy, titled *Evaluation and Management of Transgender Offenders* ("Policy"). And I have reviewed the deposition transcripts of the

Department's 30(b)(6) deposition, as well as the transcripts of the depositions of Lewis Jonathan Peiper, Ph.D., Arthur Leslie Campbell, III, M.D., Brian Sheitman, M.D., Gary Junker, Ph.D., and Patricia Hahn, Ph.D.

Furthermore, I reviewed the expert reports of Fan Li, Ph.D., and Sara E. Boyd, Ph.D, including a recording of Dr. Boyd's June 20, 2023, in-person assessment of Mrs. Zayre-Brown.

C. Compensation, Other Expert Testimony, and List of Publications

For my work on this case, I am charging $500.00 per hour for all services that I render, except for time spent providing deposition or in-court testimony, for which I charge $750.00 per hour. A list of all other cases, during the previous 4 years, in which I have testified as an expert at trial or by deposition is attached as Appendix B. Lastly, a list of my publications can be found on pages 9 – 13 of my CV (DE-18-9).

II. Discussion

In this report, I discuss my conclusions and opinions, which can be aggregated into the following three categories. First, I address the Department's policies and processes for making determinations regarding the provision of medical care for transgender patients. Second, I discuss the formulation and application of the phrase "medical necessity" based on my education, training, and experience in the correctional health care context. Finally, I review the Department's decision to not approve Plaintiff's request for a vulvoplasty as treatment for gender dysphoria.

A. Summary of Opinions

Policy and Procedure. The Department's policy, *Evaluation and Management of Transgender Offenders* ("the Policy" or "the EMTO policy") sets out a framework for addressing requests for accommodations that may be made by transgender and gender diverse individuals in the correctional setting. Because these accommodations requests can and do include non-medical

requests (*e.g.*, housing assignments, clothing, and certain canteen items, etc.), medical requests (*e.g.*, gender affirming hormone therapy, medications, and surgical interventions), or both, it is essential that these requests be reviewed by a multidisciplinary panel. A multidisciplinary approach to reviewing such requests is common within correctional systems. Based on my education, training, and experience in correctional healthcare, the Department's policy is well designed and meets or exceeds what I would consider to be a reasonably adequate policy for addressing the myriad of requests for accommodations which can be made by the transgender and gender diverse population in the carceral setting.

Medical Necessity. There is no precise or singular definition of the phrase "medical necessity." A reasonable understanding of the phrase, however, can include a patient specific risk-benefit analysis and a determination of whether the proposed treatment is supported by rigorous scientific evidence. This determination involves two steps. First, the risk-benefit analysis examines whether the procedure is one which is necessary to protect life, to prevent significant illness or significant disability, or to alleviate severe pain. The second step involves assessing the efficacy of the intervention at issue demonstrated by rigorous scientific study. The formulation of "medical necessity" that Dr. Ettner advances does not involve either step. Instead, Dr. Ettner's "medical necessity" determination appears to turn on whether the contemplated intervention could provide some potential therapeutic benefit to the patient. Based upon my education, training, and experience in correctional healthcare, the formulation of "medical necessity" advanced by Dr. Ettner, a non-physician, community-based psychologist, who does not work within correctional settings, is unworkable and does not comport with a reasonable formulation of the phrase.

Review of Mrs. Zayre-Brown's Request. The Department, through the Division Transgender Accommodation Review Committee ("Division TARC"), concluded that the

requested vulvoplasty was not medically necessary to treat Mrs. Zayre-Brown's gender dysphoria. Based on my review of the materials referenced earlier in this report, the Division TARC's decision appears to be based on two points.

First, the Division TARC concluded, after reviewing medical, mental health records, and considering the recommendations by outside consulting providers, that there was no clinical indication that the requested surgical procedure was necessary to protect life, to prevent clinically significant illness or significant disability, or to alleviate severe pain.

Second, based primarily on the presentation of information by Arthur L. Campbell, III, M.D., the Department's Medical Director, the Division TARC concluded that there is a lack of high-quality scientific research indicating the long-term efficacy of gender-affirming surgery as an effective treatment for gender dysphoria.

The Division TARC's overall conclusion is consistent with my own ongoing review of the published evidence based empirical research on the topic. Additionally, this conclusion is supported by the report of Fan Li, Ph.D., from Duke University, who systematically analyzed more than 80 studies. It is my professional opinion, to a reasonable degree of medical/scientific certainty, based on my education, training, and experience, that given the lack of any ability to identify and quantify any baseline and outcomes of significant clinical markers of extreme and sustained distress identified by the Division TARC, and the absence of high-quality research on the efficacy of surgery as a treatment of gender dysphoria, and moreover the absolute lack of any published controlled studies or literature within any US correctional system to date, that the Division TARC's conclusion that the requested vulvoplasty was not medically necessary to treat Mrs. Zayre-Brown's gender dysphoria was a reasonable, appropriate, and well-supported evidence based health care decision.

B. The Department's Policy is Reasonable and Sound

Based on my decades of correctional health care experience, and my knowledge and training concerning the management of transgender patients with gender dysphoria in the carceral setting, it is my opinion that the Department's Policy comports with or exceeds what I would consider to be an acceptable standard for a comprehensive set of correctional healthcare protocols for the evaluation and management of such patients. Indeed, the Department's Policy and procedures are equivalent to those of other state prison systems, including some of the larger systems in the country.

For example, similar to other jurisdictions, the review of requests for accommodations in North Carolina includes input from multiple disciplines. Similarly, North Carolina, as in other states, uses a tiered review system where some requests are reviewed at the facility level review and others are either appealed to or reviewed at a higher level. In short, although there is some minor variability, in my professional opinion, the gender dysphoria review process utilized by North Carolina Department of Corrections falls well within accepted state prison correctional health care policies, procedures, and best practices.

1. Overview of the Policy and Review Process

The Department's Policy sets out a tiered review process for evaluating requests for accommodations made by transgender or gender diverse patients. The first tier of review is the Facility Transgender Accommodation Review Committee ("Facility TARC"). The Policy requires each prison facility to establish a Facility Transgender Accommodation Review Committee ("Facility TARC") that is tasked with reviewing "routine requests" for accommodations by transgender individuals. (DAC 3422-3425) The Policy defines "routine requests" as requests for

the continuation of hormone therapy, specific types of undergarments, particular cosmetic and other products, private showering, and intra-facility housing assignments. (DAC 3426)

The Department's review process as articulated in the Policy relies on input from multiple clinical and non-clinical disciplines. Each Facility TARC must include representatives from psychiatry (as needed), behavioral health, primary care, nursing, facility administration, unit management, and the facility Prison Rape Elimination Act (PREA) Compliance Manager. (DAC 3422)

Additionally, the Policy sets out basic parameters for how each review is to be conducted. The Facility TARC must be chaired by a psychologist or other health services representative. (DAC 3422) In the lead up to a review by the Facility TARC, synopses of any related medical examinations, any PREA related allegations and infractions history by the PREA compliance manager, any related behavioral health and psychiatric evaluations must be prepared in advance by the respective representative on the committee. (DAC 3425) For all reviews by the Facility TARC, the Policy sets out specific information which should be documented and summarized across disciplines. (DAC 3427-3428)

The Policy also permits an individual to appeal a decision by the Facility TARC for review by the Division TARC. (DAC 3423) The Facility TARC can also refer a request that falls outside these routine categories to the Division TARC. (DAC 3426) The Policy defines "non-routine requests" to include initiation of hormone therapy, gender-consistent facility assignment, and gender-affirming surgical requests—these requests are reviewed by the Division TARC. (DAC 3426-3427) The Policy also specifies which disciplines are required on the Division TARC by identifying specific positions to make up the committee. The Division TARC must, at a minimum,

be comprised of the Medical Director, the Chief of Psychiatry, the Behavioral Health Director, the Director of Rehabilitative Services and the PREA Director. (DAC 3422)

Additionally, the Policy also sets out a basic framework for each review. The Division TARC review shall include summary information regarding any psychological evaluation, relevant medical examination, prior medical and mental health records, and recent infraction history and PREA allegations, if any. (DAC 3427) For all reviews by the Division TARC the policy sets out specific information which should be documented and summarized across disciplines. (DAC 3427-3428) The Policy also requires that the Division TARC consider each request on a case-by-case basis. (DAC 3427) With respect to requests regarding surgical intervention or gender-identity consistent facility transfers, the recommendation of the Division TARC is referred to the Assistant Commissioner of Prisons and the Director of Health & Wellness Services for a final review and determination.[2] (DAC 3427)

In practice, the Division TARC meetings are co-chaired by the Department's Medical Director and the Behavioral Health Director. The Division TARC reaches a decision on a request by consensus and does so after discussion and consideration amongst the group. At these Division TARC meetings, the members of the group provide any relevant input from their respective disciplines.

In cases where clinical care is implicated by a request (*e.g.*, requests involving hormone therapy or surgical interventions) the Division TARC's discussion would largely be driven by input from the clinical members on the committee and not custody staff. In such instances, the Medical Director would present information based on a review of the patient's relevant medical

[2] It is my understanding that the position titles of the two individuals who conduct this final review have now changed with the restructure and move of prison operations out of the Department of Public Safety and over to the Department of Adult Correction.

history, including possible medical issues and comorbidities, chronic diseases, and other relevant health care conditions and, if necessary, discussion of research or other additional information to aid in the group's determination. Similarly, the Behavioral Health Director would provide information to the group based on a review of the patient's relevant mental and behavioral health records, including reference to any specific concerns indicated by the review. Likewise, the Chief of Psychiatry would provide input to the group based on a review of the patient's relevant psychiatric history, if any, and their mental health records, which would include any concerns of the potential risk to the same. The Division TARC would then discuss the case and arrive at a consensus decision. The non-clinical personnel on the committee may, depending on the factors of the case, provide relevant information to the committee as necessary.

Conversely, where the request at issue does not implicate clinical care, such as transfer requests, the non-clinical/custody-oriented members of the Division TARC would typically drive the discussion each providing input relative to their area of focus (*e.g.*, security, operations, programming, PREA). When reviewing a non-clinical request, the clinical personnel might provide information as needed and to the extent it may aid the committee in reaching a decision with respect to the non-clinical request at issue. However, the clinical personnel would largely defer to the custody-oriented personnel in such instances. And in cases that involve both clinical and non-clinical requests, the members of the committee would provide input from their respective focus areas each affording deference to other member's areas of focus.

2. Implications of the Policy and the Process

Several aspects of the Department's Policy and process contribute to its quality and effectiveness. First, the Department's multidisciplinary approach is critical to its comprehensiveness and efficiency. Because requests for accommodations by transgender or

gender diverse patients in the correctional setting may implicate clinical and non-clinical considerations, or both, it is essential to ensure that professionals from various disciplines are included in the decision-making process. As an example, when a transgender female requests a transfer to a female facility, the safety of and impact on both the requesting inmate and those already housed at the facility must be considered. A committee of decisionmakers without any experience in non-clinical areas, such as custody, security, programming, and operations would be ill-suited to adequately consider such a request alone.

Additionally, because the correctional environment is so interconnected, close coordination between custody, medical, and other staff is a must. For that reason, even when a request is clinical in nature, having non-clinical expertise present during those considerations is advisable as this provides the non-clinical side with the situational awareness necessary to execute its core functions in light of the Division TARC's decision. Even within the clinical sphere, the Policy requires input from multiple clinical disciplines, namely, medical, nursing, psychiatric, and behavioral health. Ultimately, the inclusion of clinical and non-clinical personal on the Division TARC enables it to reach those decisions based on all relevant and necessary input from across the agency.

Another significant feature, and a best correctional health care practice, of the Department Policy is that it requires a case-by-case review and evaluation of various requests for interventions. Gender dysphoria falls along a spectrum and presents differently from patient to patient. There is also a myriad of other reasons for which a transgender patient might seek one or more various requests. For that reason, there is no singular solution or approach that can be applied in all situations. Accordingly, the type of intervention required to adequately address a patient's medical and/or behavioral health needs will likewise vary significantly from person to person. Thus, a

policy that requires that each request for an accommodation is evaluated based on patient-specific circumstances is a highly appropriate and reasonable approach. The type of case-by-case approach provided for in the Policy is one that is endorsed in the NCCHC's Position Statement cited above. Additionally, WPATH 8 broadly endorses an individualized approach when considering various treatment options.

Third, the layered decision-making approach (*i.e.*, the Facility and Division TARCs and the final review) has many benefits. And each level of the process has an important function. Requiring the Facility TARC to initiate all requests permits those who interact with and are most familiar with the patient, and their needs, the ability to gather information and provide input. Additionally, starting all requests with a Facility TARC ensures that facility-level providers and custody personnel are aware of the request—this is important since they would be charged with facilitating the ultimate decision. This frontline input is thus valuable even with requests that the Facility TARC does not have the authority to decide. Furthermore, by authorizing the Facility TARC to make certain decisions, the Department can efficiently process requests and ensure that higher level review by the Division TARC is reserved for the non-routine requests or appeals from the Facility TARC.

The Division TARC is compromised of the some of the most senior clinical and non-clinical personnel. Thus, limiting their review to appeals from Facility TARCs and non-routine requests for interventions is an efficient use of their abilities and experience. With respect to reviewing requests for surgical interventions as a treatment of gender dysphoria, the clinical personnel on the Division TARC, namely the Medical Director, the Chief of Psychiatry, and the Behavioral Health Director are well positioned to review a patient's medical and mental health

records and objectively assess the totality of a patient's presentation to collectively determine the clinical need for given intervention.

Lastly, with respect to requests for surgical interventions or requests for gender-identity-consistent facility transfers, the final review step required in the Policy acts as a quality control device. The purpose of this final review is to ensure consistency and completeness of the process. This extra attention and dedication of resources is reflective of the Department's commitment to thoroughly and appropriately handling these types of requests.

Finally, the Department has a policy that requires that all of its policies are reviewed annually to allow for swift updates or modifications to the same. This feature is a benefit particularly in areas of healthcare where research is ongoing and best practices and recommendations are evolving. This is indeed the case with respect to healthcare practices related to the transgender and gender diverse patient population. Thus, that the Department is committed to actively monitoring this area for developments and can easily modify the Policy accordingly is an important attribute of the agency's approach to transgender and gender diverse healthcare. Indeed, the Department has already made revisions and updates to the Policy after adopting it.

3. The Review Process Articulated in the Policy Tracks with the Review Process of Other Medical Services.

In general, with respect to reviewing and approving certain medical services, the Department employs a utilization management process. This general policy is articulated in the Department's utilization management policy. The purpose of the Department's utilization management (UM) process is to evaluate the appropriateness of and medical necessity of services to patients. Based on my experience, such a process is routine, necessary, and is typically utilized in correctional healthcare systems, including larger county jails, and all state prison systems, and the federal system, which effectively operate as managed care organizations.

Under the Department's UM policy, a facility-based medical provider (*i.e.*, physician, physician assistant, family nurse practitioner) would submit a request for a medical service. The request would then be reviewed by a UM Physician Review who could defer the request, request additional information, or approve the request. The UM policy also provides for a higher-level review or appeal to the UM Medical Director. The tiered review process set out in the Department's Policy tracks this typical UM process but with a critical and necessary distinction. As explained above, requests for interventions by transgender and gender diverse persons in a correctional setting can implicate medical, behavioral health, and/or non-clinical custody issues such as housing assignments and access to a variety of gender affirming property issues such as hair extension, hair removal, bras, binders, undergarments, make-up, earrings, jewelry, and other personal items and privileges. Thus, in my professional opinion based on my 30 years of direct correctional health care experience, the typical UM process, which only involves medical staff and thus is not interdisciplinary, is insufficient to appropriately and efficiently address the array of such requests. This multidisciplinary review process allows for input from across the Department to ensure that all relevant considerations are made and allows for an efficient and standardized system of reviewing these requests.

Ultimately, the use of a multidisciplinary approach for reviewing requests for interventions by transgender and gender diverse prisoners rather than the typical UM process is a positive aspect of the Policy. The multidisciplinary approach takes into account the uniqueness of gender dysphoria, the variety, uniqueness, and spectrum of transgender individuals, and in particular that the condition presents in various ways and patients seek out various interventions which may implicate many disciplines. In short, a UM process that involves only medical personnel is sufficient for considering most requests for medical services, such as for dentures, eyeglasses, knee

replacement or a pacemaker, but that same process may be insufficient to appropriately consider a request for gender affirming treatment.

The fact that treatments approved by the Division TARC must be reviewed by the Commissioner and Director of Health Services is also helpful to ensure that requests are given full and fair consideration. Notably, certain medical interventions in the UR process similarly require higher level review by the Medical Director or that person's designee. The final review of Division TARC determinations in this evolving area serves to ensure that all appropriate factors are considered. In practice, the final review has never served to overrule any recommendation by the Division TARC to provide an accommodation. Rather, the final review process has been used to send certain recommendations back for additional consideration, where appropriate, and to ensure that all steps have been followed. This benefits the person requesting the accommodation by ensuring that the review is thorough and complete.

In closing, for the reasons stated above, based on my education, training, and experience, the Department's Policy reflects a thoughtful, reasonable, and appropriate approach to addressing the needs of the transgender and gender-diverse incarcerated population.

C. Discussion of Medical Necessity

There is no precise or singular definition of the phrase "medical necessity" as it is interpreted in different ways in various contexts. However, there are formulations and applications of that phrase that are reasonable and some that are not. One such formulation evaluates medical necessity by coupling a patient-specific risk-benefit analysis and an assessment of the efficacy of the proposed intervention as indicated by the scientific literature. This is the approach to medical necessity which the Department applies. On the other hand, Dr. Ettner, a non-physician psychologist who does not work in correctional settings (per available CV, declarations, and expert

report), appears to advance a formulation of "medical necessity" that unreasonably focuses only on the capacity of the intervention to provide some possible therapeutic benefit.

1. A Reasonable Formulation of Medical Necessity

The phrase "medical necessity" can and does mean different things in different contexts and from different perspectives. What a physician determines is medically necessary to adequately treat a particular condition will be guided by that clinician's education, training, and experience, and will be informed by the patient's presentation. Inherent in this determination is a patient-specific risk-benefit calculus and an assessment of whether the proposed intervention has been demonstrated, through rigorous medical research or other scientific evidence, to be an effective treatment of the target condition.

2. The Department's Formulation of Medical Necessity

I have reviewed the position statement (produced at DAC 3404-3415) written by Arthur L. Campbell III, M.D., the Department's Medical Director. In the position statement, Dr. Campbell articulates his understanding and use of the phrase "medical necessity." Dr. Campbell writes that "[b]roadly speaking, at the most basic level, a medically necessary procedure is one which is reasonable and necessary to protect life, to prevent significant illness or significant disability, or to alleviate severe pain." (DAC 3406) Dr. Campbell notes, however, that the phrase "medical necessity" has varying definitions across various stakeholders (*e.g.*, clinicians, insurers, legislators). (DAC 3406) Moreover, despite, these variations, Dr. Campbell describes some core components of medical necessity, namely: (1) a risk-benefit analysis; (2) that the procedure has been determined to be the "standard of care"; and (3) that effective treatment protocols have been developed based on rigorous medical or scientific research. (DAC 3406)

I concur with Dr. Campbell's formulation of medical necessity in the context of reviewing and approving requests for medical services. Dr. Campbell's articulation of medical necessity in the position statement reflects a well-reasoned understanding and application of the phrase. Moreover, it comports with my decades of experience in correctional health care, and in community and academic health care settings.

As discussed above, the Department's Policy, calls for a case-by-case review of requests for consideration of gender-affirming surgery and as such requires a determination of "medical necessity" as articulated in the position statement. This is because a thorough risk-benefit analysis will necessarily require an assessment of the severity of the target condition and potential efficacy of the contemplated intervention, as well as that of alternate treatment options. Additionally, the potential efficacy of an intervention is appropriately informed by the efficacy of the intervention in addressing the targeted condition as demonstrated in the medical literature. Thus, the rigor of the medical and scientific literature is an integral component of a reasonable medical necessity formulation. Lastly, gender affirming surgery, in particular any type of genital surgery, is largely irreversible, and this has significant implications which Dr. Ettner does not address.

3. Dr. Ettner's Formulation of Medical Necessity

Dr. Ettner does not offer a specific definition of "medical necessity." Instead, she makes general statements that simply assume medical necessity or reference statements by organizations like the American Medical Association (AMA) and WPATH. (*See* DE-13-1 ¶¶ 45, 48; Ettner Report ¶ 61). In contrast to Dr. Ettner, I am a physician, a member of the AMA, and I have an understanding of the role, agency, and mission of the AMA. I routinely interface with several correctional medical and psychiatric colleagues who have represented the AMA on the NCCHC

Board of Directors, and several forensic psychiatry colleagues who serve as AMA delegates on behalf of the AAPL.

Both WPATH and Dr. Ettner reference formulations of medical necessity that come from the AMA. *See* Ettner Report ¶¶ 62-63; SOC 8 at 16-17). WPATH specifically refers to and quotes the AMA's definition of "medical necessity" from a 2016 Health Policy, H-320.953, which is attached as Appendix C, and reads, in pertinent part:

> Our AMA defines medical necessity as: Health care services or products that a prudent physician would provide to a patient for the purpose of preventing, diagnosing or treating an illness, injury, disease or its symptoms in a manner that is: (a) in accordance with generally accepted standards of medical practice; (b) clinically appropriate in terms of type, frequency, extent, site, and duration; and (c) not primarily for the economic benefit of the health plans and purchasers or for the convenience of the patient, treating physician, or other health care provider.

As the WPATH 8 notes, the phrase "medical necessity" is a term of art that is "common to health care coverage and insurance policies globally." (SOC 8 at S16) Indeed, in the policy cited by WPATH, while the AMA advances a single formulation of "medical necessity," it simultaneously recognizes that various actors in the health industry develop and operate under varying formulations of the phrase, and in particular across a tremendously diverse variety of health care settings which are further complicated by health care staffing, staff and health care facility and equipment and other resource availability, geography (*e.g.*, major metropolitan versus rural, physician and health care staff shortage areas, and locations.) (Appx. C at 1) Moreover, this policy must be considered in its appropriate context. This particular policy, H-320.953, is one of 56 Health Policies published by the AMA and maintained in the "Medical Review" category.[3] The vast majority, if not all of the 56 policies, including the one cited by WPATH, in some fundamental

[3] https://policysearch.ama-assn.org/policyfinder/search/*/relevant/1/PolicyTopic:%22Medical%20Review%22

way concern physician reimbursement issues. That context must be considered when reviewing the AMA policy.

Similarly, Dr. Ettner references and quotes AMA Resolution 122 (A-08), which reads: "Health experts in GID (this outdated term, "gender identity disorder," is no longer used), including WPATH, have rejected the myth that these treatments are 'cosmetic' or 'experimental' and have recognized that these treatments can provide safe and effective treatment for a serious health condition." (Appendix D at 1) Just as with the Health Policy discussed above, the context of that Resolution is important. The subject of the resolution is titled "Removing Financial Barriers to Care for Transgender Patients." Thus, the express intention of this resolution is to articulate a basis for obtaining insurance coverage or reimbursement for certain types of care, again within community settings. These coverage and reimbursement issues are not applicable within jails and prisons and other correctional settings.

In short, the AMA's statements regarding medical necessity referenced by WPATH and Dr. Ettner are less about the practice of medicine and more about the administration and operation of the business of medicine in non-carceral community settings. As indicated in the AMA's background and mission[4] the organization is making major and admirable strides for improved access to care, removing insurance and reimbursement barriers that interfere with access to and continuity of care, and insurance reimbursement of all Americans regardless of their socioeconomic status. However, these references to AMA policies and resolutions do not dictate whether a particular procedure is medically necessary for a particular patient in a given situation, particularly an incarcerated patient with no insurance coverage.

[4] https://www.ama-assn.org/about

WPATH 8's references to medical necessity in Chapter 11 similarly do not add anything to the attempt to define this concept. Much of the discussion in Chapter 11 simply assumes "medical necessity" without any articulation of how that phrase is understood or applied. *See e.g.*, (SOC 8 at 104 ("TGD residents in carceral facilities report the lack of access to medically necessary transgender-specific health care"; "People should have access to these medically necessary treatments irrespective of their housing situation within an institution"); (SOC 8 at 106 ("TGD people with gender dysphoria should have an appropriate treatment plan to provide medically necessary surgical treatments that contain similar elements provided to persons who reside outside institutions"); (SOC 8 at 107) ("The denial of medically necessary evaluations for and the provision of gender-affirming surgical treatments and necessary aftercare is inappropriate and inconsistent with these Standards of Care.").

These sweeping statements simply assume that the care in question is "medically necessary." There is no articulation of what circumstances make the intervention "medically necessary," or what factors are appropriately considered in making that determination. These statements fail to recognize the role and function of qualified correctional medical or mental health professionals. Moreover, the statements appear to be overly dismissive of the essential need for an individual evaluation of each patient and an opportunity to carefully discuss and weigh the risks, benefits, and alternatives and the patient's ability to give informed consent for a recommended treatment intervention. Thus, these statements are of extremely limited value in determining whether a given intervention is "medically necessary."

Dr. Ettner notes that various organizations (e.g., WPATH, the AMA, and others) all support surgery in accordance with the SOC as "medically necessary" treatment for individuals with

"severe gender dysphoria."[5] (Ettner Report ¶ 51). Neither the most current American Psychiatric Association's Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition, (DSM-5) nor the DSM-5 TR (Text Revision) nor the current International Classification of Diseases (ICD-10) contain any language regarding "severe" or other levels of grading severity of gender dysphoria (*e.g.*, mild, moderate, severe, etc.). Thus, "severe gender dysphoria" is not the correct use or application of a currently accepted and accurate diagnostic nomenclature. Dr. Ettner also references policy statements and studies which support the "efficacy, benefit, and medical necessity" of treatments, including surgery. (*See* Ettner Report ¶¶ 51-61). Dr. Ettner concludes this section of her report by opining that "Given the extensive experience and research supporting the effectiveness of gender-affirming surgery spanning decades, it is clear that such surgery is a medically necessary, not experimental, treatment for severe gender dysphoria as demonstrated by, among other things, its inclusion as a medically necessary treatment in the SOC." (Ettner Report ¶ 61). A close review of the bases for Dr. Ettner's sweeping opinion on this point reveals precisely why her formulation of "medical necessity" (and by extension that of WPATH) cannot be summarily applied in the correctional context.

In paragraph 52, Dr. Ettner notes that research[6] indicates the "efficacy" and "benefit" of treatments. In paragraphs 53-60, Dr. Ettner refers to studies in support of her conclusion that

[5] Dr. Ettner does not define "severe" gender dysphoria, nor does she articulate clinical indications of what constitutes severe dysphoria. There is no uniform presentation of gender dysphoria. The symptoms of patients with gender dysphoria can vary widely, as do the degree to which these symptoms can impact their daily lives.

[6] The studies referenced by Dr. Ettner are low-quality studies subject to many limitations. Indeed, there is a lack of high-quality long-term research demonstrating the efficacy of gender-affirming surgery in treating gender dysphoria in US community settings. Even more concerning, there is no published literature demonstrating the efficacy of gender-affirming surgery in treating gender dysphoria in incarcerated individuals. The current research cited in WPATH SOC and proffered by Dr. Ettner is referenced below and more fully as addressed in the expert report of Fan Li, Ph.D.

gender-affirming surgeries are effective, therapeutic, and in some cases virtually eliminate dysphoria. Indeed, Dr. Ettner asserts that the requested surgery in this case would be curative. (DE-13-1 ¶ 92) In paragraph 56, Dr. Ettner refers to a meta-analysis by researchers at Cornell University, in which, among other conclusions, they state that "gender transition" improves well-being, quality of life, relationship satisfaction, self-esteem and confidence, as well as reducing anxiety, depression, suicidality, and substance use.

In paragraph 58, Dr. Ettner cites studies which she claims have "shown that by alleviating the suffering and dysfunction caused by ***severe*** gender dysphoria, gender-affirming surgery improves virtually every facet of a patient's life. This includes satisfaction with interpersonal relationships and improved social functioning, improvement in self-image and satisfaction with body and physical appearance, and greater acceptance and integration into the family." (Ettner Report ¶ 58) (emphasis added) Additionally, in paragraph 59, Dr. Ettner cites other studies which "have also shown that gender-affirming surgery improves patients' abilities to initiate and maintain intimate relationships." These improvements and benefits are in keeping with WPATH's overall goal of helping "people in accessing safe and effective pathways to achieving lasting personal comfort with their gendered selves with the aim of optimizing their overall physical health, psychological well-being, and self-fulfillment." (WPATH 8 at S5)

There are undoubtedly certain interventions that may improve people's lives to some degree. However, fully optimizing one's physical health, improving social functioning, and relationships, while laudable goals, cannot set the standard for medical necessity in any system with limited resources, including the correctional setting. This is because there are undoubtedly numerous interventions, related to gender dysphoria or other conditions, which may have the possibility of providing some benefit to the patient. But reasonable analyses of these possible

interventions also must take into account their potential benefits weighed against their potential risks, the evidentiary support underlying them, and the possibility that alternative treatments may be available and/or preferable. Otherwise, the term "medical necessity" is reduced to something more akin to "medically beneficial" and all types of possible treatments must always be pursued. In short, the possible capacity of an intervention to more fully optimize one's physical health, improve social functioning, and improve their relationships, simply cannot form the basis of a "medical necessity" determination. Such a standard would be wholly unworkable.

Under the formulation of the phrase "medically necessary" as used by Dr. Ettner and WPATH, an intervention which may provide some benefit vis-à-vis a patient's gender dysphoria becomes medically necessary. The implication of such a formulation goes beyond interventions to treat gender dysphoria. The same logic would make a host of other interventions "medically necessary" to treat other conditions. For example, a patient with a perception of a large or crooked nose, small breasts, skin wrinkles, droopy eyelids, acne scars/scarring, a large mole, or facial sagging or other distress or discomfort due to perceived facial or body features may derive a benefit from procedures targeting that body feature, such as a rhinoplasty, breast augmentation, botox injections, blepharoplasty (surgical rejuvenating procedure on the upper or lower eyelids), dermabrasion, or facelifts. Similarly, someone who experiences distress or discomfort from a mole, skin tag, birthmark, scar or tattoo, may derive a benefit from a dermatological procedure such as mole, skin tag, birthmark, scar, or tattoo removal utilizing laser treatments or the latest surgical technology or procedure. Under Dr. Ettner's logic these procedures would be "medically necessary" because they may well benefit the patient by alleviating, to some degree, their perceived distress from their physical appearance or characteristics or otherwise improving their lives.

As a further example, many incarcerated persons experience depressed or dysphoric (unhappy) mood due to being incarcerated and a variety of stressors such as living apart from family/loved ones, a perception of a lack of out of cell time, prolonged delays in postconviction appeals, prospect for parole, conflict with cellmates, other inmates, custody staff, and lack of contact or visitation, etc. Also, there are a variety of other potential correctional stressors or issues regarding custody-based rules, privileges, custody level, work assignments, educational and recreational opportunities, and past or pending disciplinary infractions. Additionally, there may be a variety of anxiety symptoms, insomnia, and other DSM-5-TR recognized mental disorders or adjustment disorders. If research indicates[7] that certain types of massages may provide a benefit to patients with such conditions by improving their mood, reducing anxiety, alleviating stress, or improving sleep, then under the formulation of "medical necessity" advanced by the Dr. Ettner, those massages become medically necessary for those patients. Indeed, Dr. Ettner agrees that massage therapy could be considered *medically necessary*. *See* DE-22-1 ¶ 43.

Under that sort of formulation, correctional systems would be required to approve and provide all manner of accommodations, treatments, and care, simply because they may improve a person's general well-being or self-esteem. Moreover, under this sort of formulation, there would be no reasonable basis for a correctional institution to deny requests for interventions beyond those related to gender dysphoria. For example, if as Dr. Ettner appears to agree, that massage therapy could be medically necessary for those with anxiety, depression, or sleep disorders, then so too would be liposuction for a person with clinical depression related to their obesity, perceived fat

[7] *See*, Barreto DM, Batista MVA. Swedish Massage: A Systematic Review of its Physical and Psychological Benefits. Adv Mind Body Med. 2017 Spring;31(2):16-20. PMID: 28659510, which is a meta-analysis that suggests that Swedish massage creates a sense of well-being and joy, reduces anxiety and stress and can improve sleep.

distribution in their abdomen, hips, thighs, buttocks, or any other possible body image preoccupation or concern. For those reasons, Dr. Ettner's formulation of "medical necessity" is flawed and cannot be appropriately reasonably applied in a correctional system.

Overall, in my professional opinion, the definition of medically necessary applied by the Department is far superior in that it is workable and appropriately accounts for factors that should be considered as part of these determinations – including an individualized risk/benefit/alternatives assessment and an assessment of the medical effectiveness of the requested intervention. The Department's definition is consistent with how these determinations are made, and must be made, in the real world.

D. Evaluation of Mrs. Zayre-Brown's Request

In this section of my report, I will discuss the Department's decision with regard to Plaintiff's request for a vulvoplasty as a treatment for gender dysphoria. This will include an evaluation of whether there were any clinical indications that the surgery was necessary to protect life, to prevent clinically significant illness or significant disability, or to alleviate severe pain. Additionally, in this section I will discuss the state of the scientific and medical research regarding the long-term efficacy of gender-affirming surgery as a treatment for gender dysphoria.

As explained above, the phrase "medical necessity" is subject to varying formulations. A reasonable and appropriate formulation of the phrase can include a patient-specific risk-benefit and alternatives analysis and a determination of whether the contemplated intervention has been shown, through rigorous high-quality research, to be effective at treating the target condition. As explained below, in this case, there was a lack of any clinical indication that without the vulvoplasty Plaintiff was at serious risk of some severe distress, harm, or disability. Additionally, there is a lack of high-quality research regarding the efficacy of such an intervention. Therefore,

it is my opinion, based on my education, training, and experience that the individualized review and analysis of her medical and mental health and other psychosocial history by the Department to not approve the requested vulvoplasty as a treatment for gender dysphoria was a reasonable and appropriate decision.

1. The Risk-Benefit Analysis in Plaintiff's Case

The risk-benefit analysis is informed by a determination of the harm a patient is or is likely to experience absent the intervention and how that is balanced against the potential benefit to the patient in proceeding with the intervention. In conducting that assessment, the Division TARC considered a comprehensive review of Plaintiff's medical and behavioral health history (DAC 3400, 3417) and did not identify any clinical indications that Plaintiff was suffering from any severe distress, harm, or disability. This is critically important in a risk-benefit analysis as the lack of some severe distress, harm, or disability absent the contemplated intervention indicates a lack of risks of not approving the surgery.

I reached this same conclusion in my review—that there was little to no clinical indications that Plaintiff was or would be at risk of some severe distress, harm, or disability absent the requested vulvoplasty. Thus, the Defendants' determination that surgery was not medically necessary was reasonable under the circumstances. These conclusions were informed by a review of Plaintiff's medical records, a review of her deposition testimony, and my review of the in-person psychological evaluation of her conducted by Dr. Boyd.

a. Plaintiff's Medical Records Do Not Demonstrate Clinically Significant Mental or Emotional Distress

The hallmark of gender dysphoria is clinically significant distress or impairment in social, occupational, or other important areas of functioning. In the correctional setting such distress or impairment can manifest itself in many ways. For instance, patients can wrestle with negative self-

image, poor body image, and signs and symptoms of other DSM-5 mental disorders such as depression, anxiety, PTSD, and other psychosocial distress. Clinical indicators of these conditions might include lack of appetite, impaired sleep, lack of energy, decreased interest in usual pleasurable activities, under or over-eating when distressed, guilt or preoccupations, decreased concentration, and weight loss due to depressive or anxiety symptoms, and suicidal ideation, intent or plan. In addition to these symptoms, patients with gender dysphoria may experience impairment in the activities of daily living. This impairment is often indicated by an inability to perform activities of daily living, such as not being able to obtain or maintain employment within the prison setting, impaired social and familial relationships. Importantly, these indicators can appear differently across patients and occur on a spectrum of severity.

Based on my review of Plaintiff's medical records, including her mental health visits, routine check-ups, sick calls, endocrinology appointments, and other medical records, the typical indicators of significant mental distress or impairment of the activities of daily living are not present. While Plaintiff's chart does indicate that she struggled to adjust to life in a men's prison, she appears to have adjusted well to life within the female unit of Anson Correctional Institution, which she was assigned from 2019 until May of this year (when she was moved to a minimum custody facility). Indeed, after an initial adjustment period, she testified that she had been doing fairly well at Anson, at least in the last two years leading up to her deposition—she rated her level of anxiety 5 out of 100. (Zayre-Brown Dep. 142:10-143-18) Additionally, she reports being close with her family members. (Zayre-Brown Dep. 15:6-12) She's also been productive while incarcerated, working in the commissary, and completing educational programming. (Zayre-Brown Dep. 27: 20 - 28:1, 165:24) In short, her records indicate that she has not experienced and

is not experiencing an impairment in her current activities of daily living that can be considered clinically significant.

Similarly, Plaintiff's medical records do not indicate that she has or is currently experiencing significant emotional or mental distress. Over the years she has routinely described herself as a happy person and denied experiencing depression or anxiety. Plaintiff has also consistently denied suicidal ideation. With regard to suicidality, Plaintiff has described an event on March 2, 2019, which she refers to as a suicide attempt. However, the medical records associated with that event call into question Plaintiff's accounting of it as a suicide attempt. For instance, there is no mention in any of the medical records both from the prison or the outside emergency department that Plaintiff mentioned ingesting a large number of pills, nor that any clinician suspected anything of the sort.

Additionally, there is one instance of a reported self-harm attempt in her medical records. In this incident, Plaintiff reported that she placed a band around her penis. However, this episode appears to be isolated, was self-reported, and most importantly was described contemporaneously by Plaintiff as a protest out of frustration with a perceived delay in the process of setting up a surgical consult, as opposed to an actual attempt at self-harm. Notably, the records indicate that she voluntarily removed the band without any injury or medical attention required. Also, there is no indication in any of her records that she required a nursing assessment or emergency medical evaluation, offsite transfer to an emergency department or hospital, a urology consultation or other intervention. Most importantly, there is no evidence of any other genital harm, injury, or attempted or completed auto-castration or attempted or completed auto-penectomy.

Lastly, there was an episode in December 2020, when Plaintiff reported having thoughts of self-harm. Importantly, however, within 24 hours of first reporting these thoughts and being

transferred to an inpatient mental unit[8], Plaintiff denied any suicidal ideation or thoughts of self-harm. Indeed, she would continue to deny any suicidal ideation or thoughts of self-harm for approximately the next month. Only upon being informed that she would be leaving the inpatient unit and returning to her assigned facility, did Plaintiff begin to threaten self-harm. Notably, after being returned to her assigned facility, there is no record of Plaintiff engaging any self-harm or expressing thoughts of the same.

In short, Plaintiff's medical records demonstrate that whatever distress she may have as a result of her gender dysphoria, it was and is well managed, not severe, and not causing any impairments to her daily living activities. The lack of such clinical indications of distress in a patient's medical chart is an important consideration when determining whether a given intervention is medical necessary. This is because if there is reason to believe that the intervention is necessary to prevent, and will be effective at ameliorating, such severe distress, harm, or disability, then the intervention might be said to be medically necessary. However, in Plaintiff's case there was and is no clinically significant indication that she was or is suffering from severe distress, harm, or disability as a result of her gender dysphoria. Thus, the Division TARC's recommendation to not approve the surgery as not medically necessary was reasonable based on the absence of any indication that without the surgery she was at risk of death, significant disability, or suffering from severe pain.

4. The Medical Literature is Inconclusive

The state of the scientific and medical literature regarding the efficacy of a particular intervention in treating a specific condition can be a critical component of determining medical

[8] The inpatient mental health unit was located at North Carolina Correctional Institution for Women, a facility that Plaintiff had repeatedly been requesting to be transferred.

necessity. To that end, it is my opinion, based on my education, training, and experience, that there is a lack of high-quality scientific and medical literature indicating the long-term efficacy of gender-affirming surgery as a treatment for gender dysphoria. Also, there is no literature within incarcerated patient populations.

The Division TARC evaluated the state of the scientific and medical literature and in particular the lack of high-quality scientific and medical literature regarding the long-term efficacy of gender-affirming surgery as a treatment for gender dysphoria in reaching its decision. (*See* DAC 3400-3403, 3417-3418). I am generally familiar with the research referenced by the Division TARC, and that which is cited by WPATH and Dr. Ettner regarding the long-term efficacy of gender-affirming surgery in treating gender dysphoria. It is my understanding that this body of research is lacking in robust high-quality studies. Moreover, the studies that do exist are of low quality and suffer from many basic design problems, such as: small sample sizes, lack of baseline psychological testing to identify baseline and pre-existing mental disorders and personality disorders in particular, lack of baseline and outcome measures, lack of validated measures, lack of a control group, lack of multiple sizes, lack of standardization for controlling outside variables (various relational and psychosocial stressors, substance use, and other conflicts unrelated to the surgery), sample bias, and more. Much of the literature is based on questionnaires re: perceived efficacy and satisfaction and the like which are not scientifically valid.

In addition, I have reviewed the expert report prepared and submitted in this case by Fan Li, Ph.D. In that report, Dr. Li reviews over 80 separate studies that were cited by Dr. Ettner and/or WPATH in support of various assertions. Dr. Li concludes that in her opinion, as an expert who specializes in statistical methodology for comparative effectiveness research, that the body of

studies that she reviewed do not provide rigorous and consistent statistical evidence of the benefits in quality of life and well-being of gender-affirming treatments.

As I stated above, the efficacy of the proposed intervention, as demonstrated through rigorous medical and scientific research, is an integral component of determining medical necessity. As Dr. Li's comprehensive report demonstrates, and as the literature review of Dr. Campbell (*see* DAC 3412) and that of my own (*see* DE-18-8 ¶¶ 53-60) indicates, there is a lack of high-quality research on the topic of the long-term efficacy of gender-affirming surgery in treating gender dysphoria. As such, in my professional opinion, the lack of such research is an appropriate consideration when determining whether gender-affirming treatment is medically necessary.

b. Conclusions Regarding the Department's Decision to Not Approve Plaintiff's Request for a Vulvoplasty

With regard to the Department's decision to not approve the Plaintiff's requested vulvoplasty as treatment for gender dysphoria as not medically necessary, the Department's policy provides for an individualized assessment of each request, and such an individualized assessment occurred in this case. There was no clinical indication that the surgery was required to protect life, to prevent clinically significant illness or significant disability, or to alleviate clinically significant severe pain. There is a lack of high-quality scientific research indicating the long-term efficacy of gender-affirming surgery as an effective treatment for gender dysphoria. Therefore, based on the foregoing and upon my education, training, and experience, I conclude that the Department's decision to not approve the requested vulvoplasty as a treatment for gender dysphoria was a well-reasoned and thus a reasonable and appropriate decision.

***

III. Conclusion

In closing, in this report I offer the following primary conclusions and opinions:

(1) The EMTO policy comports with or exceeds what I would consider to be an acceptable standard for a comprehensive set of correctional health care protocols for the evaluation and management of transgender health care.

(2) Regarding medical necessity,

a. the Department applied a reasonable definition of "medical necessity" that involved a patient-specific risk-benefit analysis coupled with a determination of the status of the scientific literature indicating that the proposed intervention is effective at treating the target condition; and

b. by contrast, the definition advanced by Dr. Ettner focuses solely on a possible therapeutic benefit to be had by the intervention and is unworkable in the correctional context (and otherwise).

(3) Regarding the Division TARC's decision to deny the request for gender affirming surgery, the denial was appropriate and reasonable, because:

a. there was no clinical indication that the surgery was necessary to protect life, to prevent clinically significant illness or significant disability, or to alleviate severe pain; and

b. there is a lack of high-quality scientific research indicating the long-term efficacy of gender-affirming surgery as an effective treatment for gender dysphoria.

The statements, conclusions, and opinions stated herein are based upon my education, training, and three decades of clinical and administrative experience in correctional health care,

which includes direct patient care and overall clinical and administrative responsibility for the provision of gender dysphoria evaluation and treatment within the TDCJ system for the last fifteen years, as well as my review of the various sources of the information as described herein. All of my conclusions and opinions are stated to a reasonable degree of medical, psychiatric, and mental health certainty. Additionally, I reserve the right to revisit and revise the conclusions and opinions stated herein based on newly acquired information or other evidence which may be presented to me at some later date.

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SIGNATURE PAGE TO FOLLOW

I, Joseph V. Penn, MD, pursuant to 28 U.S.C. § 1746, declare that the foregoing is true and correct.

This the 5th, day of July, 2023.

Joseph V. Penn, MD, CCHP FAPA

APPENDIX A – EXPERT REPORT OF JOSEPH O. PENN, M.D.

List of Materials Relied Upon in Drafting This Report

1. Plaintiff's complaint (DE-1)

2. Defendants' Motion to Dismiss and related briefs. (DE-9, 10, 17, and 21)

3. Plaintiff's motion for a preliminary injunction and related briefs, including the first and second declarations of Randi C. Ettner, Ph.D. (DE-13, 14, 18, and 22)

4. The Court's order denying Defendants' motion to dismiss and denying Plaintiff's motion for a preliminary injunction. (DE-25)

5. Defendants' Answer (DE-26)

6. The expert report of Randi C. Ettner, Ph.D., dated February 3, 2023, including all appendices.

7. The document tilted, *Standards of Care for the Health of Transgender and Gender Diverse People*, Version 8, published in the International Journal of Transgender Health.

8. The document titled, *Standards of Care for the Health of Transsexual, Transgender, and Gender-Nonconforming People*, Version 7, published by the World Professional Association for Transgender Health.

9. Mrs. Zayre-Brown health and related records (DAC 0001-3368, 3381-3403, 3416-3418)

10. The Department's policy titled *Evaluation and Management of Transgender Offenders* (DAC 3421-3430)

11. The Department's policy titled *Utilization Management*[1]

[1] This policy is publicly available at https://public.powerdms.com/NCDAC/tree/documents/2050350.

12. The March 23, 2022, Position Statement, written by Arthur L. Campbell, III, M.D. (DAC 3404-3415)

13. The video and transcript of the deposition of Mrs. Zayre-Brown.

14. The transcript of the Department's 30(b)(6) deposition (both parts).

15. The transcript of the deposition of Lewis Jon Peiper, Ph.D.

16. The transcript of the deposition of Arthur L. Campbell, III, M.D.

17. The transcript of the deposition of Brian Sheitman, M.D.

18. The transcript of the deposition of Gary Junker, Ph.D.

19. The transcript of the deposition of Patricia Hahn, Ph.D.

20. The transcript of the deposition of Brandeshawn Harris.

21. Expert report of Fan Li, Ph.D., dated June 17, 2023.

22. The recording of the in-person assessment of Mrs. Zayre-Brown conduct on June 20, 2023, by Sara E. Boyd, Ph.D.

23. The expert report of Sara E. Boyd, Ph.D., dated July 5, 2023.

APPENDIX B – EXPERT REPORT OF JOSEPH O. PENN, M.D.

List of Expert Testimony – Rule 26(a)(2)(B)(v)

2023

1. Carrie Roth-Walker, individually, and on behalf of the statutory beneficiaries of Branden Roth, deceased v. Christopher Nanos, Sheriff of Pima County; Pima County, Wellpath, et al; Jail Inmate on Jail Inmate Assault Resulting in Death

2022

1. John Rapp, in his Personal Capacity and as Personal Representative of the Estate of Nicholas Rapp v. NaphCare, Inc., Kitsap County, et al.; Jail Suicide

2. Mariah M. Walters, as Personal Representative of the Estate of Elizabeth Najar v. Board of County Commissioners of Chaves County, New Mexico and CorrHealth, LLC d/b/a CorrHealth LLC, Jail Suicide

3. G.H., et al., v. Eric S. Hall, Florida Department of Juvenile Justice and Secretary of the Department of Juvenile Justice, et al., United States District Court, Northern District of Florida, Risk of Mental Harm to Detained Juveniles Housed in Behavioral Confinement While in State of Florida Juvenile Detention Centers

4. G.H., et al., v. Eric S. Hall, Florida Department of Juvenile Justice and Secretary of the Department of Juvenile Justice, et al., United States District Court, Northern District of Florida, Risk of Mental Harm to Detained Juveniles Housed in Behavioral Confinement While in State of Florida Juvenile Detention Centers

5. Wilhen Hill Barrientos, et al. v. CoreCivic, Inc. United States District Court, Middle District of Georgia, Mental Risk of Harm to U.S. Immigration and Customs Enforcement

(ICE) Detainees Confined, with a Focus on ICE Detainees' Participation, Housing Assignments, and Privileges (or Loss Thereof) While Housed at the Stewart Detention Center, Lumpkin, Georgia

2021

1. Victor Parsons; et al., on behalf of themselves and all others similarly situated, and Arizona Center for Disability Law v. David Shinn, Director, Arizona Department of Corrections Rehabilitation and Reentry; and Larry Gann, Assistant Director, Medical Services Contract, Monitoring Bureau, Arizona Department of Corrections Rehabilitation and Reentry, in their official capacities: U.S. District Court, District of Arizona, Phoenix, Arizona. Arizona Department of Corrections State Prisoners: Unconstitutional Conditions of Confinement, Access to and Provision of Clinically Appropriate and Individually Determined Mental Health Evaluation and Treatment Services, Mental Health Intake Health Screening and Procedures, Mental Health and Psychiatric Evaluation and Treatment Services, Other Mental Health Policies and Procedures, Mental Health and Psychiatric Staffing, Suicide Prevention Policy and Procedures, Audits and Compliance Reports, Access to Mental Health and Psychiatric Care

2. Stephen Knox v. Rob Jeffreys, Dr. Kelly Renzi, Dr. Andrew Tilden and Wexford Health Sources, Inc., et al, United States District Court, Central District of Illinois, Mental Health Conditions and Treatments of Mr. Stephen Knox While Housed in Restrictive Housing

3. Bryan P. Bonham v. State of Nevada, Nevada Department of Corrections, et al, United States District Court, District of Nevada, Is Restriction of a State Prison Inmate's Out of Cell Activities Due to COVID Precautions Reasonable or Does This Pose Risk Of Mental Harm or Mental Disorder(s)

2020

1. William A. Ruda, MD and Sandra L. Ruda v. State of New Jersey Department of Human Services; Ann Klein Forensic Center; State of New Jersey Department of Corrections; Moises Polanco; Carrier Clinic, Inc. et al. Superior Court of New Jersey, Somerset County, Forensic Patient on Physician Assault Resulting in Injuries

2. Debra P. Vought and Eric Vought as the Permanent Guardians Acting on Behalf of Jared R. West v. San Juan County Regional Medical Center, Inc., Presbyterian Medical Services, Inc., et al; Aztec District Court, Aztec, New Mexico, Jail Mental Health Services Medical Malpractice Screening Panel Testimony (confidential by state statute) – I am unable to reference the name, issue, city, or state as it would identify the case

2019

1. State of Texas v. Pontrey Jones, Judicial District Court 403rd District Court, Travis County, Austin, Texas, General Practices and Procedures for Providing Mental Health Services to Texas Department of Criminal Justice (TDCJ) Offenders

2. Luis Alberto Mendez v. County of Sacramento; The Regents of the University of California; Gregory Sokolov, MD; Danielle Dass, LCSW; Charlene Williams, NP; Andrea Javist; Deputy Sheriff Tineley Sietz; Deputy Sheriff Alexander Egenberger; Deputy Sheriff Jordan Lee, United States District Court for the Eastern District of California Sacramento Division, Sacramento California, Jail Self Harm.

3. Connie McMillin, as Independent Executrix of the Estate of Lee B. Albin, Deceased, and Heather Albin and Claire McMillin-Albin v. Oceans Behavioral Hospital Lufkin; Oceans Behavioral Hospital of Lufkin, LLC; Oceans Healthcare, LLC; Vernon Johnson, MD; and Vernon Charles Johnson, MD, PA, Angelina County, Texas.

Medical Review

Definitions of "Screening" and "Medical Necessity" H-320.953

Topic: Medical Review	Policy Subtopic: NA
Meeting Type: Annual	Year Last Modified: 2016
Action: Reaffirmed	Type: Health Policies
Council & Committees: Council on Medical Service	undefined

(1) Our AMA defines screening as: Health care services or products provided to an individual without apparent signs or symptoms of an illness, injury or disease for the purpose of identifying or excluding an undiagnosed illness, disease, or condition.
(2) Our AMA recognizes that federal law (EMTALA) includes the distinct use of the word screening in the term "medical screening examination"; "The process required to reach, with reasonable clinical confidence, the point at which it can be determined whether a medical emergency does or does not exist."
(3) Our AMA defines medical necessity as: Health care services or products that a prudent physician would provide to a patient for the purpose of preventing, diagnosing or treating an illness, injury, disease or its symptoms in a manner that is: (a) in accordance with generally accepted standards of medical practice; (b) clinically appropriate in terms of type, frequency, extent, site, and duration; and (c) not primarily for the economic benefit of the health plans and purchasers or for the convenience of the patient, treating physician, or other health care provider.
(4) Our AMA incorporates its definition of "medical necessity" in relevant AMA advocacy documents, including its "Model Managed Care Services Agreement." Usage of the term "medical necessity" must be consistent between the medical profession and the insurance industry. Carrier denials for non-covered services should state so explicitly and not confound this with a determination of lack of "medical necessity".
(5) Our AMA encourages physicians to carefully review their health plan medical services agreements to ensure that they do not contain definitions of medical necessity that emphasize cost and resource utilization above quality and clinical effectiveness.
(6) Our AMA urges private sector health care accreditation organizations to develop and incorporate standards that prohibit the use of definitions of medical necessity that emphasize cost and resource utilization above quality and clinical effectiveness.
(7) Our AMA advocates that determinations of medical necessity shall be based only on information that is available at the time that health care products or services are provided.
(8) Our AMA continues to advocate its policies on medical necessity determinations to government agencies, managed care organizations, third party payers, and private sector health care accreditation organizations.

Policy Timeline

CMS Rep. 13, I-98 Reaffirmed: BOT Action in response to referred for decision Res. 724, A-99 Modified: Res. 703, A-03 Reaffirmation I-06 Reaffirmed: CMS Rep. 01, A-16

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 122
(A-08)

Introduced by: Resident and Fellow Section, Massachusettes Medical Society, California Medical Association, Medical Society of the State of New York

Subject: Removing Financial Barriers to Care for Transgender Patients

Referred to: Reference Committee A

Whereas, The American Medical Association opposes discrimination on the basis of gender identity[1] and

Whereas, Gender Identity Disorder (GID) is a serious medical condition recognized as such in both the Diagnostic and Statistical Manual of Mental Disorders (4th Ed., Text Revision) (DSM-IV-TR) and the International Classification of Diseases (10th Revision),[2] and is characterized in the DSM-IV-TR as a persistent discomfort with one's assigned sex and with one's primary and secondary sex characteristics, which causes intense emotional pain and suffering;[3] and

Whereas, GID, if left untreated, can result in clinically significant psychological distress, dysfunction, debilitating depression and, for some people without access to appropriate medical care and treatment, suicidality and death;[4] and

Whereas, The World Professional Association For Transgender Health, Inc. ("WPATH") is the leading international, interdisciplinary professional organization devoted to the understanding and treatment of gender identity disorders,[5] and has established internationally accepted Standards of Care [6] for providing medical treatment for people with GID, including mental health care, hormone therapy and sex reassignment surgery, which are designed to promote the health and welfare of persons with GID and are recognized within the medical community to be the standard of care for treating people with GID; and

Whereas, An established body of medical research demonstrates the effectiveness and medical necessity of mental health care, hormone therapy and sex reassignment surgery as forms of therapeutic treatment for many people diagnosed with GID;[7] and

Whereas, Health experts in GID, including WPATH, have rejected the myth that such treatments are "cosmetic" or "experimental" and have recognized that these treatments can provide safe and effective treatment for a serious health condition;[7] and

Whereas, Physicians treating persons with GID must be able to provide the correct treatment necessary for a patient in order to achieve genuine and lasting comfort with his or her gender, based on the person's individual needs and medical history;[8] and

Whereas, The AMA opposes limitations placed on patient care by third-party payers when such care is based upon sound scientific evidence and sound medical opinion;[9, 10] and

Whereas, Many health insurance plans categorically exclude coverage of mental health, medical, and surgical treatments for GID, even though many of these same treatments, such as psychotherapy, hormone therapy, breast augmentation and removal, hysterectomy, oophorectomy, orchiectomy, and salpingectomy, are often covered for other medical conditions; and

Whereas, The denial of these otherwise covered benefits for patients suffering from GID represents discrimination based solely on a patient's gender identity; and

Whereas, Delaying treatment for GID can cause and/or aggravate additional serious and expensive health problems, such as stress-related physical illnesses, depression, and substance abuse problems, which further endanger patients' health and strain the health care system; therefore be it

RESOLVED, That the AMA support public and private health insurance coverage for treatment of gender identity disorder (Directive to Take Action); and be it further

RESOLVED, That the AMA oppose categorical exclusions of coverage for treatment of gender identity disorder when prescribed by a physician (Directive to Take Action).

Fiscal Note: No significant fiscal impact.

References

1. AMA Policy H-65.983, H-65.992, and H-180.980
2. Diagnostic and Statistical Manual of Mental Disorders (4th ed.. Text revision) (2000) ("DSM-IV-TR"), 576-82, American Psychiatric Association; International Classification of Diseases (10th Revision) ("ICD-10"), F64, World Health Organization. The ICD further defines transsexualism as "[a] desire to live and be accepted as a member of the opposite sex, usually accompanied by a sense of discomfort with, or inappropriateness of, one's anatomic sex, and a wish to have surgery and hormonal treatment to make one's body as congruent as possible with one's preferred sex." ICD-10, F64.0.
3. DSM-IV-TR, 575-79
4. Id. at 578-79.
5. World Professional Association for Transgender Health: http://www.wpath.org. Formerly known as The Harry Benjamin International Gender Dysphoria Association.
6. The Harry Benjamin International Gender Dysphoria Association's Standards of Care for Gender Identity Disorders, Sixth Version (February, 2001). Available at http://wpath.org/Documents2/socv6.pdf.
7. Brown G R: A review of clinical approaches to gender dysphoria. J Clin Psychiatry. 51(2):57-64, 1990. Newfield E, Hart S, Dibble S, Kohler L. Female-to-male transgender quality of life. Qual Life Res. 15(9):1447-57, 2006. Best L, and Stein K. (1998) "Surgical gender reassignment for male to female transsexual people." Wessex Institute DEC report 88; Blanchard R, et al. "Gender dysphoria, gender reorientation, and the clinical management of transsexualism."J Consulting and Clinical Psychology. 53(3):295-304. 1985; Cole C, et al. "Treatment of gender

dysphoria (transsexualism)." Texas Medicine. 90(5):68-72. 1994; Gordon E. "Transsexual healing: Medicaid funding of sex reassignment surgery." Archives of Sexual Behavior. 20(1):61-74. 1991; Hunt D, and Hampton J. "Follow-up of 17 biologic male transsexuals after sex-reassignment surgery." Am J Psychiatry. 137(4):432-428. 1980; Kockett G, and Fahrner E. "Transsexuals who have not undergone surgery: A follow-up study." Arch of Sexual Behav. 16(6):511-522. 1987; Pfafflin F and Junge A. "Sex Reassignment. Thirty Years of International Follow-Up Studies after Sex Reassignment Surgery: A Comprehensive Review, 1961-1991." IJT Electronic Books, available at http://www.symposion.com/ijt/pfaefflin/1000.htm; Selvaggi G, et al. "Gender Identity Disorder: General Overview and Surgical Treatment for Vaginoplasty in Male-to-Female Transsexuals." Plast Reconstr Surg. 2005 Nov;116(6):135e-145e; Smith Y, et al. "Sex reassignment: outcomes and predictors of treatment for adolescent and adult transsexuals." Psychol Med. 2005 Jan; 35(1):89-99; Tangpricha V, et al. "Endocrinologic treatment of gender identity disorders. " Endocr Pract. 9(1):12-21. 2003; Tsoi W. "Follow-up study of transsexuals after sex reassignment surgery." Singapore Med J. 34:515-517. 1993; van Kesteren P, et al. "Mortality and morbidity in transsexual subjects treated with cross-sex hormones." Clin Endocrinol (Oxf). 1997 Sep;47(3):337-42; World Professionals Association for Transgender Health Standards of Care for the Treatment of Gender Identity Disorders v.6 (2001).

8. The Harry Benjamin International Gender Dysphoria Association's Standards of Care for Gender Identity Disorders, at 18.
9. Id.
10. AMA Policy H-120.988

Relevant AMA policy

H-65.983 Nondiscrimination Policy
The AMA opposes the use of the practice of medicine to suppress political dissent wherever it may occur. (Res. 127, A-83; Reaffirmed: CLRPD Rep. 1, I-93; Reaffirmed: CEJA Rep. 2, A-05)

H-65.992 Continued Support of Human Rights and Freedom
Our AMA continues (1) to support the dignity of the individual, human rights and the sanctity of human life, and (2) to oppose any discrimination based on an individual's sex, sexual orientation, race, religion, disability, ethnic origin, national origin or age and any other such reprehensible policies. (Sub. Res. 107, A-85; Modified by CLRPD Rep. 2, I-95; Reaffirmation A-00; Reaffirmation A-05)

H-180.980 Sexual Orientation as Health Insurance Criteria
The AMA opposes the denial of health insurance on the basis of sexual orientation. (Res. 178, A-88; Reaffirmed: Sub. Res. 101, I-97)

H-120.988 Patient Access to Treatments Prescribed by Their Physicians
The AMA confirms its strong support for the autonomous clinical decision-making authority of a physician and that a physician may lawfully use an FDA approved drug product or medical device for an unlabeled indication when such use is based upon

sound scientific evidence and sound medical opinion; and affirms the position that, when the prescription of a drug or use of a device represents safe and effective therapy, third party payers, including Medicare, should consider the intervention as reasonable and necessary medical care, irrespective of labeling, should fulfill their obligation to their beneficiaries by covering such therapy, and be required to cover appropriate "off-label" uses of drugs on their formulary. (Res. 30, A-88; Reaffirmed: BOT Rep. 53, A-94; Reaffirmed and Modified by CSA Rep. 3, A-97; Reaffirmed and Modified by Res. 528, A-99; Reaffirmed: CMS Rep. 8, A-02; Reaffirmed: CMS Rep. 6, A-03; Modified: Res. 517, A-04)

UNITED STATES DISTRICT COURT

FOR THE WESTERN DISTRICT OF NORTH CAROLINA

CHARLOTTE DIVISION

Case No. 3:22-cv-0191

KANAUTICA ZAYRE-BROWN,)
)
Plaintiff,)
)
vs.)
)
THE NORTH CAROLINA)
DEPARTMENT OF PUBLIC)
SAFETY, et al.,)
)
Defendants.)

DEPOSITION MARVELLA BOWMAN, Ph.D.

10:08 A.M.

THURSDAY, JUNE 29, 2023

NORTH CAROLINA DEPARTMENT OF JUSTICE

114 WEST EDENTON STREET

RALEIGH, NORTH CAROLINA

By: Denise Myers Byrd, CSR 8340, RPR

CONTAINS GENERAL CONFIDENTIAL INFORMATION

diagnostic opinion would change.

Q. Do you have any reason to believe that Mrs. Zayre-Brown will stop experiencing gender dysphoria as long as she has a phallus?

ATTORNEY RODRIGUEZ: Objection. Speculation.

You can answer.

THE WITNESS: I don't believe -- I believe that she will continue to express the same -- what she has communicated has not changed. As long as I worked with her, I don't think it would change. I can't imagine it would based off of my knowledge of her.

ATTORNEY MAFFETORE: We can go off the record.

(Discussion held off the record.)

ATTORNEY MAFFETORE: Dr. Bowman, I have no further questions for you. So unless your counsel has no questions, you're done.

ATTORNEY RODRIGUEZ: No, no questions.

THE WITNESS: Thank you.

[SIGNATURE RESERVED]

[DEPOSITION CONCLUDED AT 12:53 P.M.]

IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF NORTH CAROLINA
CHARLOTTE DIVISION
No. 3:22-CV-0191-MOC-DCK

KANAUTICA ZAYRE-BROWN, Plaintiff, v. THE NORTH CAROLINA DEPARTMENT OF PUBLIC SAFETY, et al., Defendants.	)	**EXPERT REPORT OF FAN LI, PHD**

I. Introduction and Expert Background.

I was retained in this matter by Defendants to offer opinions and conclusions regarding the research related to the effectiveness of sex reassignment surgery (also known as gender affirming surgery) as a treatment for gender dysphoria. More specifically, I was asked to review studies referenced in the Standards of Care for the Health of Transgender and Gender Diverse People, Version 8 ("WPATH 8") which is published by the World Professional Association for Transgender Health ("WPATH") and the report of Plaintiff's expert, Randi Ettner, Ph.D., to assess their quality, review their research design, analyze their outcomes, and determine whether the studies support Plaintiff's and her expert's assertions. Additionally, I offer opinions and conclusions about this body of research in terms of study design and statistical methodology.

A. Summary Statement of Qualifications.

I am a statistician and a tenured Full Professor in the Department of Statistical Science, with a secondary appointment at the Department of Biostatistics and Bioinformatics at Duke University ("Duke"). I am a nationally leading expert on statistical methods for causal inference and comparative effectiveness research. I am the co-director of the Comparative Effectiveness

Methodology at the Duke Clinical Research Institute, which is the largest clinical research organization in the world. I have published extensively on statistical methods and applications in causal inference in leading professional peer-reviewed journals in medicine, statistics, epidemiology, including Journal of American Medical Association (JAMA), Proceedings of the National Academy of Sciences, American Journal of Epidemiology, and Journal of the American Statistical Association. I have been awarded multiple research grants from government agencies and research organizations, including the U.S. National Institutes of Health ("NIH"), National Science Foundation ("NSF"), Patient Centered Outcome Research Institute ("PCORI"), and industry sponsors. I was elected Fellow of the American Statistical Association in 2022 for my contribution to statistics research and service. I am serving as the editor for Social Science, Biostatistics and Policy for the premier statistics journal 'The Annals of Applied Statistics', and an associate editor for the premier statistics journal 'Journal of the American Statistical Association'. In addition, I have served as a reviewer for a large number of academic journals, including JAMA, Science, and grant proposal for funding agencies including the NIH and NSF. I have supervised five PhD dissertations, four postdoctoral fellows, and many masters and undergrad students at Duke. In addition to my research work, I have presented numerous seminars in national and international conferences and taught classes on causal inference at Duke. My research work in statistics focuses on causal inference, biostatistics, missing data, Bayesian analysis, and applications to health, policy, and social sciences.

I received my PhD in Biostatistics from Johns Hopkins University in 2006 and a Bachelor of Science in Mathematics from Peking University in China in 2001. I completed a postdoctoral fellowship in statistics in the Department of Health Care Policy at the Harvard Medical School in 2008. My curriculum vitae further sets forth my qualifications and is attached as Appendix A.

I have not previously done any research in the specific area of transgender health care. Nor have I been a member of WPATH, or otherwise been involved with the issue of transgender health care. This affords me the opportunity to engage in this project based solely on my education, training, and experience and without any preconceived notions of what the evidence may or may not show.

B. Information Considered in Forming Opinions.

In forming the conclusions and opinions set out in this report, I reviewed and considered a variety of materials and information, including the most recent WPATH Standards of Care, Version 8; the expert report of Randi C. Ettner, Ph.D., dated February 2, 2023, and her previous declarations; and the more than 80 studies relied upon by WPATH or Dr. Ettner, which are listed in Appendix B to this report.

In addition, I referenced the following studies when preparing this report:

1. Imbens GW and Rubin DB. 2015. Causal inference in statistics, social, and biomedical sciences. Cambridge University Press.
2. Hernan MA and Robins JM. 2023. Causal Inference: What If. CRC Press, Boca Raton.

C. Compensation, Other Expert Testimony, and List of Publications

For my work on this case, I am charging $350 per hour for all services that I render, except for time spent providing deposition or in-court testimony, for which I charge $475 per hour. I have not previously testified as an expert. My publications can be found on my CV, which is attached hereto as Appendix A.

II. Discussion

In this report, I summarize my opinions, provide background information regarding comparative effectiveness research and causal inference, and explain my methodology and approach. I have separately provided a detailed chart that analyzes the relevant studies that I reviewed in preparing this report. That chart is incorporated herein and is Appendix B to this report.

A. Summary of Opinions

Dr. Ettner and WPATH make several specific assertions regarding the effectiveness of gender affirming treatments, including surgical interventions, to treat gender dysphoria. Those assertions are identified in this report and in Appendix B. However, the evidence cited by Dr. Ettner and WPATH does not provide reasonable support for those assertions. Among the dozens of studies reviewed, there is not a single randomized controlled trial. Most of the studies cited in support of those assertions are of low quality in terms of study design and statistical methodology. Specifically, the majority of the studies are based on observational retrospective designs, which are prone to severe confounding bias. The few prospective studies that are cited point to mixed conclusions. Additional methodological shortcomings include small sample size, nonresponse bias, non-representative population (i.e., selection bias), self-reported outcomes. Moreover, most of the studies do not have before-after comparison of the same patients, and thus do not provide direct evidence on the effects of the treatment of interest. Also, the vast majority of these studies do not compare the results of sex reassignment surgery with alternative treatments, and thus do not provide evidence on the necessity or advantage of sex reassignment surgery over available alternative treatments. In summary, based on my education, training, and experience, I conclude to a reasonable degree of statistical certainty, that these studies fail to provide rigorous and

consistent statistical evidence on the benefits in quality of life and well-being of sex reassignment surgery (SRS).

B. Background Regarding Comparative Effectiveness Research and Causal Inference

In medicine, the type of research used to evaluate the effects and safety of an intervention is broadly referred to as comparative effectiveness research. The statistical methodology for quality of life belongs to the general statistical field of causal inference.

1. Association v. Causation

Statistics measures associations between variables based on data. A first lesson in elementary statistics is that association does not imply causation. The main barrier to interpreting the association between the treatment and the outcome as a causal effect is the presence of factors that are associated with both the treatment and the outcome. These factors are commonly referred to as confounders or confounding variables or confounding factors. For example, patients with worse health conditions may be more likely to obtain a beneficial medical treatment. So directly comparing the outcomes of the treated and control patients, without adjusting for the difference in their baseline health conditions, would bias the causal comparisons and mistakenly conclude that the treatment is harmful. This type of bias is called confounding bias.

In the context of medical care for the transgender population, a hypothetical example is that transgender patients who received sex reassignment surgery (SRS) may be systematically different from the transgender patients who did not receive SRS, perhaps in terms of confounders such as physical and mental conditions or social economics status. So, the difference in the outcome (e.g., quality of life) between transgender patients who received SRS and those who did not receive SRS may be due to the difference in the confounders between these two groups of transgender patients.

When confounders are observed and measured, analysts can use statistical methods for causal inference, e.g., multivariable regression, propensity scores, matching (Imbens and Rubin, 2015; Hernan and Robins, 2020), to control for the bias due to the difference in the confounders between treatment and control groups. When confounders are unobserved or unmeasured, statistical analysis on the causal effect of a treatment based on the observable data is subject to confounding bias.

2. Types of Biases in Causal Interference

There are several types of bias that must be accounted for in assessing research regarding the efficacy of medical interventions. The primary types of bias are set forth and explained below.

a. Confounding Bias

As explained above, confounding bias occurs when the treatment and control groups of individuals differ in observed or unobserved factors that can also affect the outcome. Randomized controlled trials eliminates all confounding bias, and therefore the association between treatments and outcomes can be interpreted as causal effects. In contrast, observational studies, regardless of the statistical analytical methods used, cannot rule out confounding bias. Therefore, in order to interpret the association between treatments and outcomes as causal effects in observational studies, one must assume that there is no unmeasured confounding factor. Such an assumption is untestable and is almost always untenable.

b. Baseline Outcome

When a confounder is strongly predictive of the outcome(s), failing to adjust for it could induce particularly large confounding bias. In comparative effectiveness research, one of the most important confounders is the baseline outcome, i.e., the outcome measured before the treatment. For example, in studying the effect of SRS on quality of life, an important confounder is the pre-

operative measurement of quality of life. A comparison of the outcome of the same subject before and after the treatment would eliminate the confounding bias due to the difference in the baseline outcomes. In this example, this could be done through a paired t-test or a multivariable regression with the before-after difference of the outcome as the dependent variable.

c. Selection Bias

Selection bias occurs when participants of a study are selected in a way that does not make them representative—in observed or unobserved ways—of the population to which the study purports to apply. A special case of selection bias is attrition bias, which occurs when patients are lost to follow up in a longitudinal study as these patients may be systematically different from the patients who stayed in the study.

d. Nonresponse Bias

Nonresponse bias occurs when the response rate of a survey is less than 100 percent and those who do not respond to a survey may have answered differently than those who do respond. This can create biased results that do not accurately reflect the population of interest. The lower the response rate is, the more likely severe nonresponse bias occurs. Nonresponse bias is a special type of selection bias. See A Systematic Review of Nonresponse Bias.

e. Recall Bias

Recall bias occurs when participants in a research study do not accurately remember a past event or experience or leave out details when reporting about them. It can occur in studies that ask participants to provide information from memory, such as in case-control studies or retrospective cohort studies. See recall-bias.

3. Study Designs in Comparative Effectiveness Research

Understanding the type of study design is essential to assessing the strength of any conclusion regarding the effectiveness of a medical intervention.

a. Randomized Controlled Trials Versus Observational Studies

In medicine, the consensus gold standard for evaluating the efficacy, effectiveness, and safety of an intervention or treatment is the randomized controlled trials. For example, the U.S. Food and Drug Administration (FDA) requires evidence of efficacy and safety of a new product based on randomized controlled trials in the approval of the vast majority of new drugs and medical devices. When randomized controlled trials are not available, researchers resort to observational studies for comparative effective research.

In a randomized controlled trial, a sample of patients are randomly assigned to either a treatment or a control group, and after the treatment or control condition is applied, the outcomes of interest—also known as dependent variables—are measured and then compared. In addition, information on patients' baseline characteristics, e.g., age, sex, health conditions, is routinely collected before the treatment. Such factors are often referred to as prognostic factors, or pre-treatment variables, or baseline covariates. Randomized controlled trials are the gold standard for causal inference because it eliminates all confounding bias due to both measured and unmeasured confounders.

In observational studies, the process of determining which patients receive which treatment condition is unknown and uncontrolled by the researchers. The treated and control subjects may differ in their baseline characteristics. If these baseline characteristics are confounders, then failing to statistically adjust for them would induce bias in evaluating the causal effect of the treatment. In observational studies, there is no guarantee that the researchers observed all confounders. So,

in order to interpret the association between a specific treatment and outcomes as causal effect, one must make the untestable assumption that there is no unmeasured confounding factor. This assumption is likely violated to a certain degree of confounding factor(s) in most observational studies (Imbens and Rubin, 2015; Hernan and Robins, 2020). This is why observational studies are inferior to randomized controlled trials in causal inference.

b. Prospective Studies Versus Retrospective Studies (Types of Observational Studies)

In a prospective or prospective cohort study, the treatment of interest (e.g., a sexual reassignment surgery) has not occurred at the time the study is initiated, and the study subjects are followed with the information being collected at one or multiple time points during the study period. In contrast, in a retrospective study, the treatment of interest has already occurred at the time the study is initiated, and the study subjects are identified from existing data, e.g., medical records, and information is collected about their past.

Prospective designs are generally considered superior to retrospective designs, because prospective studies collect information as the subjects' characteristics or circumstances change whereas retrospective studies collect static information. Moreover, retrospective studies are more likely subject to recall bias. Note that randomized controlled trials are prospective studies, but not all prospective studies are randomized controlled trials.

c. Longitudinal Studies Versus Cross-Sectional Studies

A longitudinal study measures the same outcome of each subject multiple times over a period of time. A cross-sectional study measures the outcome of each subject only one time. Longitudinal studies are superior to cross-sectional studies because they generally provide more information, particularly on the trend or progression of an outcome. Both randomized controlled trials and observational studies can be either cross-sectional or longitudinal.

d. Before-After Study

An important type of prospective study is the before-after study, where the outcomes of the same patients are measured both before and after the treatment. A before-after comparison of the outcome eliminates the confounding bias due to the difference in the baseline outcomes, which are often the most important confounding factors.

4. Quality of the Designs

For causal inference, the best design is a randomized controlled trial, which eliminates all confounding bias. The next preferred design is a prospective observational study with outcomes measured both before and after the intervention, which, in combination with proper statistical methods, can eliminate confounding bias due to measured confounders, but cannot eliminate confounding bias due to unmeasured confounders. The design of the lowest quality is a retrospective observational study, which is prone to confounding bias from both measured and unmeasured confounders, particularly when the baseline outcomes are not recorded.

****

C. Assessment of Research Referenced by WPATH and Dr. Ettner

Throughout this report and in Appendix B, I use various abbreviations. SRS refers to sex reassignment surgery (SRS). The literature variably refers to surgical interventions as SRS, gender-affirming surgery, or gender-reassignment surgery. I use SRS for consistency. I use QoL for quality of life and GAT for gender-affirming treatments. GAT includes various interventions, which can include SRS or hormonal treatments.

1. Analysis of Plaintiff's Contentions

I have carefully reviewed and assessed Dr. Ettner and WPATH's conclusions and assertions on the evidence regarding SRS and find these assertions to not be well founded for the reasons discussed below. My investigation largely focuses on the specific assertions that relate to the efficacy of SRS and that purport to be supported by research. Appendix B is a table that collects and summarizes my analysis of these assertions and the studies referenced therein. The italicized text which appears after each numbered assertion below is a direct quote from the source material that forms the basis of the assertion analyzed.

2. Analysis of Key Assertions

In this section, I discuss select assertions made by WPATH and Dr. Ettner and analyze the studies cited to support those assertions. See Appendix B for a complete listing of the assertions and studies analyzed.

WPATH Assertion 1. *There is strong evidence demonstrating the benefits in quality of life and well-being of gender-affirming treatments, including endocrine and surgical procedures, properly indicated and performed as outlined by the Standards of Care (Version 8), in TGD people in need of these treatments.* (WPATH 8 at S18)

My examination of this assertion focused on the statement "there is strong evidence demonstrating the benefits in quality of life and well-being of gender-affirming treatments." This assertion cites 21 references. Given the number of studies cited in support of this assertion, I summarize my review of these studies by the design study and paper types. Note that not all these studies focus on SRS; many studies investigate non-surgery treatments such as hormone therapy (e.g., Wierckx, K., Van Caenegem, et al. 2014; T'Sjoen et al., 2019; Baker et al. 2021). Therefore, below I refer to the treatments in the studies cited in this assertion generically as gender-affirming treatments (GAT).

Among all the 21 studies reviewed relative to this assertion, there is not a single randomized control trial. In fact, in all the literature reviews cited here, only one randomized control trial (Pelusi et al., 2014) was mentioned, which involves 45 patients and focuses on hormonal therapy, but this paper is not cited in WPATH Assertion 1. So, all the studies cited in this assertion are subject to confounding bias.

Summary of the Prospective Studies Cited in Support of WPATH Assertion 1. There are five prospective studies (Wierckx, K., Van Caenegem, et al. 2014; Cardoso da Silva et al., 2016; Lindqvist et al, 2017; van de Grift, Elaut et al., 2018; Aires et al., 2020). Among these studies, Lindqvist et al. (2017) has the best study design, which is a prospective cohort study with before-surgery outcome and after-surgery outcome measured at multiple time point. Lindqvist et al. (2017) found mixed results on the effects of SRS on QoL. Specifically, Lindqvist et al. (2017) found that compared to before the treatment, QoL is better one year after operation but worse 3 and 5 years after operation.

Another prospective study with before-after outcomes (Cardoso da Silva et al., 2016) also found mixed results. Specifically, Cardoso da Silva et al., (2016) found that psychological health

and social relationships were significantly improved after SRS, but physical health and level of independence were significantly worse after SRS. Another prospective study (Aires et al., 2020) focuses on a special type of surgery of chondrolaryngoplasty or tracheal shaving and its effects on voice and visual aesthetic satisfaction. That study provides no information about the effects of the surgery on general QoL and well-being of the patients. Wierckx, K., Van Caenegem, et al. (2014) is a prospective study focusing on hormonal therapy, specifically it focuses on the safety and side effects of the intervention, not QoL. Despite being a prospective study, van de Grift, Elaut et al., 2018 does not provide before-after comparison of the same patients. In short, the prospective studies, at best, provide mixed results on the effects of SRS.

Summary of Retrospective Studies Cited in Support of WPATH Assertion 1. There are nine retrospective studies (Ainsworth & Spiegel, 2010; Buncamper et al., 2016; Yang, Zhao et al., 2016; Owen-Smith et al., 2018; Özkan et al., 2018; Al-Tamimi et al., 2019; Balakrishnan et al., 2020; Almazan & Keuroghlian, 2021; Mullins et al. 2021). None of these studies provide direct before-after comparison in QoL or well-being of the same patients. The comparisons are usually between people who received gender-affirming treatments and those who did not. So, this study does not provide direct evidence on the effect of GAT on individual patients, and is subject to severe confounding bias. In addition, four studies (Al-Tamimi et al., 2019; Buncamper et al., 2016; Özkan et al., 2018; Balakrishnan et al., 2020) are descriptive analyses (e.g., describing surgical techniques) and did not provide any type of comparison. Mullins et al. (2021) focuses on thrombosis and thrombosis risk factors among adolescent and young adult transgender population and does not discuss QoL.

Summary of Literature Reviews Cited in Support of WPATH Assertion 1. There are seven literature reviews (Poteat et al., 2016; White Hughto and Reisner, 2016; Nobili et al., 2018;

T'Sjoen et al., 2019; Eftekhar Ardebili et al. 2020; Baker et al. 2021; Javier et al., 2022). One study (Poteat et al. 2016) reviews the HIV epidemic among transgender population and does not directly discuss QoL and well-being related to GAT. Three studies (White Hughto & Reisner 2016; T'Sjoen et al., 2019; Baker et al. 2021) focus on the effects of hormonal therapy. One study (Nobili et al., 2018) reviews a combination of surgery and hormonal therapies. One study (Javier et al., 2022) found mixed results on the effects of GAT. Two studies (Nobili et al., 2018; Eftekhar Ardebili et al. 2020) provide meta-analysis of multiple studies, but do not provide information on the effects of GAT on QoL because of the lack of before-treatment outcomes.

Most of the review papers acknowledge the methodological shortcomings of the studies in this field. For example, Nobili et al. (2018) acknowledges "the majority of the studies were cross-sectional, lacked controls, and displayed moderate risk of bias…Better quality studies that include clearly defined transgender populations, divided by stage of gender affirming treatment and with appropriate matched control groups are needed to draw firmer conclusions." Baker et al. (2021) acknowledges "this conclusion is limited by high risk of bias in study designs, small sample sizes, and confounding with other interventions." T'Sjoen et al. (2019) acknowledges "current available research is based mostly on cross-sectional studies…long-term follow-up studies and studies involving large groups of people are needed to evaluate whether these improvements remain." Javier et al. (2022) acknowledges their review is based on "seventy-nine low quality studies." White Hughto & Reisner, Poteat et al. (2016) comments "prospective controlled trials are needed to investigate the effects of hormone therapy on the mental health of transgender people."

Overall Assessment of WPATH Assertion 1. Most of the studies cited in support of this assertion are of low quality in terms of study design and statistical methodology. There is not a single randomized controlled trial. All studies are observational studies. Among these, the few

prospective studies (which are of higher quality of retrospective studies) point to mixed conclusions regarding the effects of GAT on QoL and well-being of the transgender patients. Most of the studies are subject to confounding bias due to the potential difference between the transgender population who received GAT and those who did not. Most of the studies do not have before-after comparison of the same patients and thus do not provide direct evidence on the effects of GAT for individuals. In addition, none of the studies compare SRS with alternative treatments such as hormone therapy or compare between different types of SRS, and thus do not provide evidence for the comparative advantage of SRS over alternative treatments or one specific type of SRS over another. Moreover, most of the studies suffer from additional methodological shortcomings such as small sample size, nonresponse bias, non-representative population. In addition, often the outcomes are not measured using standardized and validated instrument. In summary, I conclude that contrary to the statement in the assertion, these studies fail to provide rigorous and consistent statistical evidence on the benefits in quality of life and well-being of gender-affirming treatments.

WPATH Assertion 2. *Gender-affirming interventions are based on decades of clinical experience and research; therefore, they are not considered experimental, cosmetic, or for the mere convenience of a patient. They are safe and effective at reducing gender incongruence and gender dysphoria.* (WPATH 8 at S18).

My assessment of this assertion focuses on the statement of "they are … effective at reducing gender incongruence and gender dysphoria." This is a statement on the comparative effectiveness of GAT because the term "reducing" indicates comparisons. This assertion cited 25 references, 15 of which were cited also in WPATH Assertion 1.

First of all, not a single study directly measures gender incongruence and gender dysphoria as the main outcome variable but instead used derivative measures, for example, satisfaction with surgery or quality of life in general. This shortcoming was also pointed out in Gijs and Brewaeys (2007), a reference cited in support of Ettner Assertion 2, which is discussed below. As a result, none of the studies provide direct evidence on the effects of GAT on gender incongruence and gender dysphoria.

Second, the study designs of these studies are generally of low quality. There is not a single randomized controlled trial, and all studies are observational studies. Among these observational studies, there are only four prospective studies with before-after comparison of the same patients (Wierckx, K., Van Caenegem, et al. 2014; Lindqvist et al. 2017; Aires et al., 2020; Aldridge et al., 2020), two of which (Lindqvist et al. 2017; Aldridge et al., 2020) reported mixed results in whether GAT improves various measurements of mental health, and two (Wierckx, K., Van Caenegem, et al. 2014; Aires et al. 2020) do not provide data on outcomes related to mental health or QoL. Specific to this assertion, it focuses on hormone treatments and provides no information on the effects of SRS. One paper (White Hughto, Reisner, Poteat et al., 2016) is a literature review of three prospective studies of the effects of hormone therapy on psychological functioning and QoL, and it calls for "prospective controlled trials." None of the rest 20 studies provide before-after comparisons of any outcome. In fact, seven of these papers focus on describing the surgical techniques of various SRS (Buncamper et al., 2016; Lo Russo et al. 2017; Wolter et al. 2015, 2018; Claes et al., 2018; Esmonde et al., 2019; Balakrishnan et al., 2020) and do not discuss mental health or QoL.

In summary, due to low quality study design, all the studies cited in support of WPATH Assertion 2 are subject to confounding bias, and most are subject to selection bias, nonresponse

bias and recall bias. Thus, it is my opinion that the cited references fail to provide rigorous statistical evidence to support the assertion that "gender-affirming interventions are … effective at reducing gender incongruence and gender dysphoria."

WPATH Assertion 6. *Controlled studies show clinically significant health and mental health disparities for justice-involved transgender people compared to matched groups of transgender people who have not been incarcerated or jailed.* (Brown and Jones, 2015). WPATH S104

Brown and Jones (2015) compares health disparities between transgender and non-transgender veterans, and found transgender veterans have an increased likelihood of justice involvement. This comparison is entirely different from the comparison stated in the assertion—regarding health disparities of justice-involved transgender people vs. non-justice-involved transgender people (i.e., comparison between different transgender populations). Therefore, Brown and Jones (2015) is not relevant to and does not support this assertion.

WPATH Assertion 10. *Gender-affirming vaginoplasty is one of the most frequently reported gender-affirming surgical interventions […] Although different assessment measurements were used, the results from all studies consistently reported both a high level of patient satisfaction (78–100%) as well as satisfaction with sexual function (75–100%). Although different assessment measurements were used, the results from all studies consistently reported both a high level of patient satisfaction (78–100%) as well as satisfaction with sexual function (75 100%). This was especially evident when using more recent surgical techniques. Gender affirming vaginoplasty was also associated with a low rate of complications and a low incidence of regret (0–8%)*. (WPATH 8 at S128-S129)

This assertion cites 26 references, 3 of which were cited also in WPATH Assertion 1. Among all the studies cited, there is not a single randomized controlled trial on the safety and effects of gender-affirming vaginoplasty (GAV). All studies are observational studies. Among these, there are only two prospective studies with before-after surgery comparisons: Papadopulos, Zavlin et al. (2017) evaluate a combined SRS technique instead of GAV alone and focused on short-term (6-month after surgery) outcomes; Cardoso da Silva et al. (2016) found mixed results in that psychological health and social relationships were significantly improved after SRS, but physical health and level of independence were significantly worse after SRS.

The rest of the 26 references do not provide before-after comparison or comparison between transgender patients who underwent GAV and who did not. Among the retrospective studies, Simonsen et al. (2016) is the one of the highest quality because it uses a national (Denmark) registry to investigate the entire Danish transgender population in 32 years. The results are inconclusive, as the authors concluded "generally SRS may reduce psychological morbidity for some individuals while increasing it for others." Buncamper et al. (2015) found high rate of sexual dysfunctionality following SRS. Most studies use self-reported outcomes instead of standardized instruments. Lastly, most studies do not discuss QoL outcomes.

In summary, the cited references suffer from several methodological shortcomings, including lack of randomized controlled trials and even prospective before-after studies (and thus subject to confounding bias), self-reported outcomes (e.g., satisfaction), nonresponse bias. None of the studies compare GAV with alternative treatments. This body of literature supports the high self-reported satisfaction rate among the patients who underwent GAV but does not provide any evidence for the necessity or advantage of GAV comparing to alternative treatments.

WPATH Assertion 11. *Gender-affirming surgical procedures have been shown to relieve symptoms of gender dysphoria and improve mental health.* (WPATH 8 at S173)

This assertion cites two references (van de Grift, Elaut et al., 2017; Owen-Smith et al. 2018), both of which were cited in previous Assertions. Neither study provides before-after SRS comparison of the same patients, and thus is subject to severe confounding bias, nor do they provide any direct evidence for the assertion that these procedures "relieve symptoms of gender dysphoria and improve mental health."

Ettner Assertion 1. *Decades of careful and methodologically sound scientific research have demonstrated that gender-affirming surgeries are safe and effective treatments for severe gender dysphoria and, indeed, for many people suffering from gender dysphoria, the only effective treatment.* (Ettner Report ¶ 50)

This assertion cited three references. None of the references provides evidence for the assertion that "for many people suffering from gender dysphoria, the only effective treatment." In fact, Pfafflin and Junge (1998) states "Sex reassignment…, is, however, *not the only powerful change agent in sex reassignment*." As elaborated in my assessment of WPATH Assertion 1, the statistical methodology in the field of comparative effectiveness of SRS is not up to the long-established standard in comparative effectiveness research in medicine. There has not been a single randomized control trial on SRS. All cited studies are observational studies. Among the observational studies, the vast majority of the studies are cross-sectional retrospective design instead of the prospective before-after design. Many of the methodological shortcomings have been repeatedly pointed out in numerous literature reviews in this field (e.g., several cited in WPATH Assertion 1). Therefore, I, as an expert who specializes in statistical methodology for

comparative effectiveness research, strongly disagree with Dr. Ettner's characterization of this research as "methodologically sound scientific research."

Ettner Assertion 2. *In 2007, Gijs and Brewayes analyzed 18 studies published between 1990 and 2007, encompassing 807 patients. The researchers concluded: "Summarizing the results from the 18 outcome studies of the last two decades, the conclusion that [gender-affirming surgery] is the most appropriate treatment to alleviate the suffering of extremely gender dysphoric individuals still stands: Ninety-six percent of the persons who underwent [surgery] were satisfied and regret was rare."* (Ettner Report ¶ 55)

Immediately after the quote contained in the above assertion (p. 215), the authors (Gijs and Brewayes) acknowledged that "[h]owever, even today this conclusion is based on methodologically less than perfectly designed studies." Specifically, the paper wrote "[n]ot one of the reviewed outcome studies was a controlled one...In many studies, sound psychometric instruments were not used. Especially disturbing is that many researchers did not directly measure gender dysphoria as the main outcome variable but instead used derivative measures, for example, satisfaction with surgery, sexual and interpersonal relationships, occupational and global functioning, or quality of life in general." The authors also acknowledge a few other methodological shortcomings, like attrition or selection bias of the patient sample, which echo my critiques with respect to WPATH Assertion 1.

Ettner Assertion 4. *Studies conducted in countries throughout the world likewise conclude that gender-affirming surgery is an extremely effective treatment for gender dysphoria.* (Ettner Report ¶ 57)

This statement overlaps with WPATH Assertions 1 and 2. As has already been discussed in the assessments of those Assertions, as well as to Ettner Assertion 1, it is my opinion that the

statistical analysis of the body of literature on the effectiveness of SRS is not methodologically sound and has failed to provide rigorous and consistent scientific evidence for the benefits of gender-affirming treatments on reducing gender dysphoria or improving and well-being of the patients.

Ettner Assertions 5-9. Assertions 5-9 are assessed together because they all concern the effectiveness of SRS. Collectively the assertions read: *Studies have shown that by alleviating the suffering and dysfunction caused by severe gender dysphoria, gender-affirming surgery improves virtually every facet of a patient's life. This includes satisfaction with interpersonal relationships and improved social functioning, […] improvement in self-image and satisfaction with body and physical appearance and greater acceptance and integration into the family. […] Studies have also shown that gender-affirming surgery improves patients' abilities to initiate and maintain intimate relationships.* (Ettner Report ¶¶ 58-59)

First, among the 24 cited references (half were cited in previous assertions), there is not a single randomized controlled trial. All studies are observational studies. Among these, there are only two prospective studies with before-after SRS comparisons (Smith et al. 2005; Johansson et al. 2009), and the rest are retrospective studies without not before-after comparison of the same patients.

Second, the conclusions from the cited references showed great variability in the outcomes and is not as consistent and clear cut as indicated in the Assertion. For example, Klein and Gorzalka (2009) is a literature review and it states, "From this review it is clear that there is great variability in the sexual functioning of post-operative transsexuals, and that no clear outcome can be predicted with respect to whether surgery will have a positive or negative impact on sexual function." Weyers et al. (2009) found "they suffer from specific difficulties, especially concerning arousal,

lubrication, and pain." Lobato et al. (2006) found that family relationship only improved in 1/4 of the patients. In addition, some of the papers do not report on outcomes concerning the specific assertion, e.g., Lawrence 2003 for Supplemental Assertion 6; Jarolím et al. 2009, Rehman et al. 1999 for the assertion regarding improved intimate relationships.

Third, two studies (Johansson et al. 2009, 2010) found a significant discrepancy between clinicians and patients' assessment of the same outcome, with patients reporting a higher favorable rate (e.g., 33% in Johansson et al. 2009) than the clinicians. This raises concerns as to the accuracy and reliability of the patient self-reported outcomes.

In summary, similar to my assessment of comparable assertions (namely, WPATH Assertions 1, and 2, Ettner Assertions 1, 2, and 4), it is my opinion that this body of literature on the effectiveness of SRS cited in Ettner Assertion 5-9 is not methodologically sound and has failed to provide rigorous and consistent scientific evidence for the benefits of gender-affirming treatments on reducing gender dysphoria or improving and well-being of the patients.

Ettner Assertion 10. *Research shows that the risk of suicide can be significantly diminished with prompt and effective treatment*. (Ettner Report ¶ 77)

I carefully reviewed the part of the paper that is relevant to the assertion. Specifically, the paper states (page 12 of 15), "The process of medically transitioning overall was more complex…We did not observe an increased risk in this sub-group among those who completed a medical transition (RR = 0.51; 0.07, 3.74)." Exact numbers are reported on the second page of Table 4 (page 11 of 15, top row); it shows that among the subjects who completed medical transition (100 subjects), the relative risk of suicidal attempt is 0.51 with 95% confidence interval (0.07, 3.74), which is ***not*** statistically significant. So, the claim of "significantly diminished" is not supported by the statistical analysis in this reference.

Ettner Assertion 11. *Gender dysphoric individuals have a profound discomfort or disgust of their genitalia. Without effective treatment as outlined above, this often leads to attempts at surgical self-treatment (SST), which can result in lasting physical trauma or death*. (Ettner Report ¶ 78)

This assertion cites Brown and McDuffie (2009), which does not provide any information on the frequency of this behavior. Moreover, on the bottom row of Page 187, the authors write "this (surgical self-treatment) rarely occurs in the community absent psychosis[.]" This is directly at odds with the sweeping assertion of that without surgery dysphoric individuals "often" engage in such behavior. During my review, I found Brown (2014), which reported that "five percent of [TG] inmates reported that they had attempted (2%) or completed (3%) autocastration while incarcerated." This percentage supports the occurrence is relatively rare rather than often. Moreover, Brown (2014) uses a highly selected sample of the letters written by transgender inmates—the representativeness of that sample of the general incarcerated transgender population is unclear.

Ettner Assertion 12. *[A] systematic meta-analysis on publications performed by German researchers included 1,100 post-surgery participants. Seven different measures of quality of life were employed. The researchers concluded that gender-affirming surgery positively affects well being, sexuality, and quality of life in general.* (Ettner Report ¶ 116)

The referenced study is Weinforth et al. (2019), which is a literature review of 13 studies. These studies adopt mixed designs (some prospective and some retrospective) and different measurements for outcome, and most studies focus on short term outcomes. Weinforth et al. (2019) only provided qualitative summaries, not any formal statistical meta-analysis. Only two studies are prospective (Cardoso da Silva et al.; Lindqvist et al.), which have been reviewed in my

assessment of WPATH Assertion 1, and both showed mixed to negative results. The other 9 studies are all of low quality; the methodological problems include retrospective cross-sectional studies, small sample sizes, no causal inference methods – no formal confounding adjustment other than regression. In fact, the authors acknowledged the methodological shortcomings and noted that "prospective studies with standardized methods of assessing quality of life and with longer follow-up times would be desirable." Similar to my assessment of the previous assertions, I determine that this reference fails to provide rigorous and consistent statistical evidence supporting the benefits of SRS.

3. Description of Appendix B – Table of Reviewed Studies

In preparing this report, I reviewed various portions of WPATH 8 and Dr. Ettner's expert report which contained assertions regarding the body of research on the effectiveness of various treatments, including surgery, in treating gender dysphoria and/or improving well-being. I reviewed the studies that were cited to support 11 assertions made in WPATH 8 and 12 assertions made by Dr. Ettner in her report. Those assertions are labeled in Appendix B as WPATH Assertion 1, 2, and so on, and Ettner Assertion 1, 2 and so on. Immediately beneath the assertion label is the text of that assertion, including the cited studies, along with the page reference. Below the assertion text, one row is dedicated to each study and for each the following summary information placed in corresponding columns:

- Study-design – category of study
- Methodology – brief description of how the study was conducted
- Aim/Objective – brief statement of the question the researchers sought to examine
- Conclusion – summary of the findings
- Strengths – self-explanatory

- Limitations – self-explanatory
- Notes – key takeaways, if any.

III. Conclusion

The studies that Dr. Ettner and WPATH rely upon in making their assertions regarding the effectiveness of SRS and other treatments do not constitute a rigorous and consistent body of statistical evidence. These studies are of low quality in terms of study design and statistical methodology, due to issues like confounding bias, small sample sizes, nonresponse bias, non-representative population, more. Additionally, most of the studies do not have before-after comparison of the same patients and thus do not provide direct evidence on the effects of the treatment of interest. Moreover, the vast majority of these studies do not compare the results sex reassignment surgery with alternative treatments, and thus do not provide evidence on the necessity or advantage of sex reassignment surgery over available alternative treatments. Thus, it is my opinion, to a reasonable degree of statistical certainty that the studies cited by Ettner and/or WPATH and reviewed in this report simply do not provide reasonable support for the assertions made by Dr. Ettner and WPATH relative to the benefits in quality of life and well-being of gender-affirming treatments.

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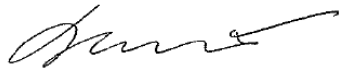
SIGNATURE PAGE TO FOLLOW

I, Fan Li, pursuant to 28 U.S.C. § 1746, declare that the foregoing is true and correct.

This the 17th, day of June, 2023.



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May 24, 2023

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PUBLICATIONS

Peer-reviewed Articles

(* student or postdoc supervised by FL)

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55. Zeng S*, Lange E, Campos F, Archie E, Alberts S, **Li F**. (2022). A Causal Mediation Model for Longitudinal Mediators and Survival Outcomes with an Application to Animal Behavior. *Journal of Biological, Environmental and Agricultural Statistics.* Forthcoming. arXiv:2104.08344.

56. Zhou T, Tong G, **Li F**, Thomas LE, Li F. (2022). PSweight: An R package for propensity score weighting analysis. *The R Journal.* 14(1):282-299.

57. Mäkinen T, **Li F**, Mercatanti A, Silvestrini, A. (2022). Causal analysis of central bank holdings of corporate bonds under interference. *Economic Modelling*. Forthcoming.

58. Papadogeorgou G*, Imai K, Lyall J, **Li F**. (2022) Causal inference with spatio-temporal data: Evaluating the effects of airstrikes on insurgent violence in Iraq. *Journal of Royal Statistical Society - Series B*. 84(5), 1969-1999. arXiv:2003.13555.

59. Li F, Tian Z, Tian Z, **Li F**. (2022). A note on identification of causal effects in cluster randomized trials with post-randomization selection bias. *Communications in Statistics – Theory and Methods*. Forthcoming.

60. Guo Q, Chen J, Wang D, Yang Y, Deng X, Carin L, **Li F**, Tao C*. (2022). Tight Mutual Information Estimation With Contrastive Fenchel-Legendre Optimization. *36th Conference on Neural Information Processing Systems (NeurIPS2022)*. arXiv:2107.01131

61. **Li F**, Ding P, Mealli F. (2023). Bayesian causal inference: a critical review. *Philosophical Transactions of the Royal Society A*. 381: 2022.0153.

62. Lange E, Zeng S*, Campos F, **Li F**, Tung J, Archie E, Alberts S. (2023). Early life adversity and adult social relationships have independent effects on survival in a wild animal model of aging. *Science Advances*. 9, eade717.

63. **Li F**, and Li F. (2023). Using propensity scores for racial disparities. *Observational Studies*. 9(1), 59-68.

Book Chapter

64. Zhang T, Sheng H, and **Li F**. (2016). Linear and Nonlinear Models for fMRI Time Series Analysis. *Handbook of Modern Statistical Methods: Neuroimaging Data Analysis*, Ombao H, Johnson W, Lindquist M, Aston J eds. Chapman and Hall - CRC Press.

65. **Li F**. (2022). Overlap weighting. *Handbook of Matching and Weighting Adjustments in Causal Inference*, J Zubizarreta, EA Stuart, D Small, PR Rosenbaum, eds. Chapman and Hall - CRC Press.

Discussions

66. Mealli F, and **Li F**. (2011). Discussion of "Transparent parametrization of models for potential outcomes" by Richardson, Evans and Robins. *Bayesian Statistics 9* (JM Bernardo, MJ Bayarri, JO Berger, AP Dawid, D Heckerman, AFM. Smith and M West eds.). Oxford University Press.

67. Papadogeorgou G*, and **Li F**. (2019). Discussion of "Penalized spline of propensity methods for treatment comparison" by Zhou, Elliot and Little. *Journal of the American Statistical Association*. 114(525):32-35.

68. Papadogeorgou G*, and **Li F**. (2020) Discussion of "Bayesian Regression Tree Models for Causal Inference: Regularization, Confounding, and Heterogeneous Effects" by Hahn, Murray and Carvalho. *Bayesian Analysis*. 15(3): 1007-1013.

Preprints

69. **Li F**, Yu Y, Rubin DB. (2012). Imputing missing data by fully conditional models: Some cautionary examples and guidelines. *Duke University Department of Statistical Science Discussion Paper 11-24*.

70. Zeng S*, Assaad S, Tao C, Carin L, **Li F**. (2021). Double-robust representation learning for causal inference. arXiv:2010.07866.

71. Chen J, Gan Z, et al., **Li F**, Carin L, Tao C*. (2021) Simpler, Faster, Stronger: Breaking The log-K Curse On Contrastive Learners With FlatNCE. arXiv:2107.01152.

72. Yang S*, Zhou R*, **Li F**, Thomas LE. (2023). Propensity Score Methods for Causal Subgroup Analysis with Time-to-Event Outcomes.

73. Liu B*, Wruck L, **Li F**. (2022). Principal stratification for noncompliance with time-to-event outcomes. arXiv:2301.07672

74. Chang* C-R, Song Y, **Li F**, Wang R. (2022). Covariate adjustment in randomized experiments with incomplete covariate and outcome data.

75. Cheng C, Guo G*, Liu B, Wruck L, **Li F**, F Li. (2023). Multiply robust estimation for causal survival analysis with treatment noncompliance. arXiv:2305.13443.

SOFTWARE PACKAGE

1. `PSweight` (2020): Propensity Score Weighting for Causal Inference. Tianhui Zhou, Guangyu Tong, Fan Li, Laine Thomas, Fan Li. `https://CRAN.R-project.org/package=PSweight`

2. `PStrata` (2022): Principal Stratification for Causal Inference. Bo Liu, Fan Li. `https://CRAN.R-project.org/package=PStrata`

GRANTS

1. Innovative Biostatistical Methods for Analysis and Assessment of Clinical Trials Augmented by Real World Data. Burroughs Wellcome Fund Innovation in Regulatory Sciences Award. 2021-2026. Role: Co-PI (PI: Laine Thomas). Total cost: $500,000.
2. COVID-19 Enhancement: Methods for the Design and Conduct of Subgroup Analysis in Observational Studies. PCORI ME-2018C2-13289, 2019-2023. Role: Co-I (PI: Laine Thomas). Total cost: $349,999.
3. New causal inference methods for cluster randomized trials with post-randomization selection-bias. PCORI ME-2019C1-16146, 2020-2023. Role: PI. Total cost: $946,222
4. Methods for the design and conduct of subgroup analysis in observational studies. PCORI ME-2018C2-13289, 2019-2022. Role: Co-I (PI: Laine Thomas). Total cost: $731,268
5. The biodemography of early adversity: social behavioral processes in a wild animal model. NIH 1R01 AG053308-01A1, 2018-2023. Role: Co-PI (PI: Susan Alberts). Direct cost: $1,542,592
6. A life course perspective on the effects of cumulative early adversity on health. NIH 1R01 AG053330-01A1, 2017-2022. Role: Co-PI (PI: Beth Archie). Total cost: $2,352,291
7. Religion, Spirituality and CVD Risks: A Focus on African Americans. NIH 5R01MD011606-02, 2017-2022. Role: Statistical Investigator (PI: Bentley-Edwards). Total cost: $2,831,644
8. Prospective Multicenter Observational Cohort Study of Comparative Effectiveness of Disease-Modifying Treatments for Myasthenia Gravis (MG). PCORI R-1609-35953, 2017-2020. Role: Statistical Investigator. (PI: Don Sanders). Total cost: $2,517,289
9. New weighting methods for causal inference. NSF-SES 1424688, 2014-2017. Role: PI. Total cost: $190,000.
10. Bayesian multivariate analysis for causal inference with intermediate variables. NSF-SES 1155697, 2012-2015. Role: PI. Total cost: $80,000.
11. Collaborative research: Statistical modeling and inference for high-dimensional multi-subject neuroimaging data. NSF-DMS 1208983, 2012-2015. Role: PI. Total cost: $71,100.
12. The Triangle Census Research Network. NSF-NCRN, 2011-2016. Role: Investigator (PI: Jerry Reiter).

MENTORING

Doctoral Advisees

Scott Schwartz	2010 Statistical Geneticist and Bioinformatics Scientist, Texas A&M University
Nghi Maggie Nguyen	2018 Research Scientist, Duke University Department of Neurology
Fan (Frank) Li	2019 (Biostatistics& Bioinformatics) Assistant Professor, Yale University Department of Biostatistics

Abbas Zaidi	2019 (co-advise with Sayan Mukerjee) AI researcher, Facebook
Elizabeth Lorenzi	2019 Statistical Scientist, Berry Consultants
Shuxi Zeng	2021 Research Scientist, Facebook
Siyun Yang	2022 (co-advise with Laine Thomas, B& B) Research Scientist, Facebook
Bo Liu	2021-
Yueqi Guo	2022-

Postdoctoral Mentees

Georgia Papadogeorgou	2018-2020 (co-advise with David Dunson) Assistant Professor, University of Florida Department of Statistics
Jason Poulos	2019-2021 Postdoctoral Fellow, Harvard Medical School Department of Health Care Policy
Chenyang Tao	2021 Applied Scientist, Amazon
Ruiwen Zhou	2021-2022 (co-advise with Laine Thomas)

Master Advisees

Ying Yang (Neurobiology, MS)	2011
Olanrewaju Akande (Statistical Science, MSEM)	2015
Eve Oh (Statistical Science MSEM)	2015
Shuo Wang (MSS), Joon Sup Park (MSS) Robert Wan (MIDS), Chengxin Yang (MSS)	2022

Undergraduate advisees

Colin Hwang	2011
Ekaterina Petrova	2012
Jack Fu	2013
Tracy Qi Dong	2014
Fiamma Li	2015
Anna Jiang	2016
Jerry Chia-Rui Chang	2019
Pei Yi Zhuo	2023

Doctoral thesis committee

2011 Hongxia Yang, Chiranjit Mukherjee
2012 Yajuan Si, Jochi Nakajima, Kai Cui
2013 Fangpo Wang, Jared Murray
2015 Monika Jincheng Hu, Tsuyoshi Kunihama
2016 Tracy Schifeling, Feifei Wang (Peking University)
2018 Victor Pena
2019 Olanrewaju Akande, Jodi Heck Wortman, Phil White
2020 Danni Lu (Virginia Tech)

Preliminary oral committee

2009 Hongxia Yang, Chiranjit Mukherjee, Minhui Shi
2010 Fangpo Wang, Yajuan Si, Jochi Nakajima
2011 Kai Cui
2012 Tsuyoshi Kunihama
2014 Michael Lindon
2015 Victor Pena
2016 Jody Heck Wortman, Elizabeth Lorenzi
2017 Kyle Burris, Abbas Zaidi, Olanrewaju Akande, Phil White
2019 Shuxi Zeng
2021 Serge Assaad

Master thesis committee

2010 Shouqiang Wang (Operational Research), Arturas Rozenas (Pol Sci)
2012 Yiting Deng (Computer Science)
2014 Yingjian Wang (ECE)
2019 Gauri Kamat, Yunji Zhou (B&B)
2020 Yangfan Ren
2021 Haoling Zheng, Marco Morucci (Pol Sci)
2022 Yi Liu (B&B)

Undergraduate thesis committee

2018 Andrew Cooper
2019 Vivek Sriram
2020 Daniel Spottiswood

TEACHING

(All in Department of Statistical Science, Duke University)

STA 130 Probability and Statistics in Engineering (2010F, 2012-14F, 2012S, 2015S)
STA 320 Design and Analysis of Causal Studies (2011F, 2014S, 2016S)
STA 440 Case Studies in the Practice of Statistics (2019F)

STA 610 Hierarchical models (2023F)
STA 611 Introduction to Mathematical Statistics (2008F)
STA 640 Causal Inference (2015F, 2017-18F, 2020F, 2021-2023S)
STA 723 Statistics Case Studies (2014-19S)
STA 732 Statistical Inference (2009-10S)
STA 790 Special Topics: Causal Inference (2009F), Bayesian Causal Inference (2022F)

PROFESSIONAL APPOINTMENTS AND SERVICE

Editorial Boards

2023-	Editor for Social Science, Biostatistics and Policy, *Annals of Applied Statistics*
2023-24	Guest Editor, Special Issue on "Causal Inference: past, present, and future" *The New England Journal of Statistics in Data Science (NEJSDS)*
2016-2023	Associate Editor, *Bayesian Analysis*
2019-	Associate Editor, *Observational Studies*
2020-	Associate Editor, *Journal of American Statistical Association - TM*
2016-2019	Associate Editor, *Journal of American Statistical Association - ACS*
2013-2017	Associate Editor, *Journal of Statistical Theory and Practice*
2018	Associate Editor, *The American Statistician* special issue on "Statistical inference in the 21th century"

Peer Review Activities

American Statistician, Annals of Applied Statistics, Annals of Internal Medicine, Bayesian Analysis, Biostatistics, Biometrics, Biometrika, BMC Research Methodology, BMJ, Canadian Journal of Statistics, Circulation, Computational Statistics and Data Analysis, Health Services and Outcomes Research Methodology, International Journal of Methods in Psychiatric Research, Journal of Causal Inference, Journal of Computational and Graphical Statistics, JAMA, JAMA Cardiology, JAMA Network Open, Journal of American Statistical Association, Journal of Applied Econometrics, Journal of Causal Inference, Journal of Royal Statistical Society (Series A, B, C), Journal of Statistical Planning and Inference, Neuroimage, Observational Studies, Psychometrika, Scandinavian Journal of Statistics, Statistical Methods in Medical Research, Statistica Sinica, Statistical Science, Statistics and Computing, Statistics in Medicine, Statistics and Probability Letters, Survey Methodology.

Grant Review Panel

National Science Foundation	2013, 2015, 2016, 2018
National Health Institute - BMRD	2016

Ad-hoc Review of Grant Proposals

Netherlands Organisation for Scientific Research (NWO)
Natural Sciences and Engineering Research Council of Canada (NSERC)
Canadian Statistical Sciences Institute (CANSSI)
Health Effects Institute

Conference and Workshop Organizing

2013-14 Group leader, Causal Inference working group, SAMSI CMSS program
2015 Organizer, the G70 Conference: A Celebration of Alan Gelfand's 70th Birthday, Durham
2017 Organizer, NISS workshop on causal inference and machine learning/high dimensional statistics at Atlantic Causal Inference Conference (ACIC), UNC-Chapel Hill
2018 IMS Program Chair, ENAR spring meeting, Atlanta
2019 Organizer, Bayesian causal inference workshop, MBI, Ohio State University
2019 Organizer, Opening workshop of SAMSI Causal Inference Program, Duke University
2020 Organizer, SAMSI Causal Inference Program
2021-22 Member, ISBA 2022 World Meeting Program Committee

Professional Societies

2018, 20 Member, Nominating Committee, International Society for Bayesian Analysis (ISBA)
2019 Member, Selecting Committee for the founding co-editors of the IMS Data Science Journal
2022 Member, Mitchell Prize Selection Committee, ISBA
2023-2024 Member, Committee on Nominations, Institute of Mathematical Statistics

Promotion and External Reviews

2019- Promotion review (Yale, Peking, U Wisconsin at Madison, U Michigan)
2022 Member of External Review Panel of Department of Statistics and Data Science, Wharton School of Business, University of Pennsylvania

ACADEMIC SERVICE

Department of Statistical Science

2009-10, 17 First Year PhD Exam Coordinator
2009-16, 19-20 PhD Admissions Committee
2010-12 Seminar Series Coordinator
2013, 16-17 Master's Program Admissions Committee
Master's Program Director
2017- Master's Program Advisory Committee
2018, 22 Tenure-Track Faculty Search Committee
2019 PhD Program Evaluation committee
2021 DST faculty search committee chair

Duke University

2014 Faculty compensation equity committee
2014-16 Academic Council
2017-22 Academic Program Committee (APC)
2018-19 Search Committee for Chair of Department of Biostatistics & Bioinformatics
2019-20 Search Committee for Executive Vice Chancellor at Duke Kunshan University
2020-21 Duke Strategy Team 2030 Faculty Group
2021 Duke 2030 Working Group on Research
2021-2023 Duke Kunshan University (DKU) Faculty Hearing Committee
2022 Review Committee of the Executive Vice Provost

PRESENTATIONS

Short Course and Tutorial

1. (2011) Short course on "Statistical Methods in Causal Inference". Finnish Society of Epidemiology. Helsinki, Finland.
2. (2017) Tutorial on propensity score methods in traffic safety research. Transportation Research Board Annual Meeting. Washington, DC.
3. (2017) Short course on "New weighting methods in comparative effectiveness research". Duke-Industry Statistics Symposium 2017. Durham, NC.
4. (2018) Tutorial on "Causal inference". Duke Plus Data Science, Durham, NC.
5. (2019) Short course on "Bayesian causal inference". Atlantic Causal Inference Conference, Montreal, Canada.
6. (2019) Tutorial on "Bayesian causal inference". Bayesian Causal Inference Workshop, Ohio State University, Columbus, OH.
7. (2020) Tutorial on "New weighting methods for comparative effectiveness research." International Conference on Health Policy Statistics 2020, San Diego, CA.
8. (2023) Tutorial on "Propensity score weighting for comparative effectiveness research: methods, new developments and software". International Conference on Health Policy Statistics 2023, Scottsdale, AZ.
9. (2023) Short course on "Bayesian causal inference". Applied Bayesian Summer School 2023, Florence, Italy.
10. (2023) Short course on "Causal inference". Columbia University, Department of Statistics.

Seminars

1. (2023) McGill University, Department of Epidemiology, Biostatistics and Occupational Health, Keynote speaker at Student Career Day
2. (2023) University of Cambridge, MRC Biostatistics Unit (virtual)
3. (2023) University of Michigan, Department of Statistics
4. (2022) Texas A&M University, Department of Statistics
5. (2022) Georgia Tech ISyE Statistics Seminars
6. (2022) DCRI Clinical Research Fellowship Program
7. (2022) Duke University Department of Philosophy Causation Group
8. (2022) Michigan State University Department of Statistics and Probability (virtual)
9. (2022) Online Causal Inference Seminar (OCIS) Series (virtual)
10. (2022) OHDSI Methods Working Group, UCLA
11. (2022) International Biometric Society Journal Club

12. (2022) Criteo AI lab (virtual)
13. (2021) Online interdisciplinary seminars on statistical methodology for social and behavioral research, University of Connecticut (virtual)
14. (2021) Duke University, Department of Population Health Sciences (virtual)
15. (2021) Harvard School of Public Health, Working Group on Causal Inference and Machine Learning (virtual)
16. (2021) University of Pennsylvania, Center for Causal Inference (virtual)
17. (2021) Carnegie Mellon University, Department of Statistics and Data Science (virtual)
18. (2021) Online Causal Inference Seminar (OCIS) Series (virtual)
19. (2020) Icahn School of Medicine at Mount Sinai, Institute for Translational Epidemiology (virtual)
20. (2020) University College London, Department of Statistical Science (virtual)
21. (2020) Duke University, Plus Data Science, COVID-19 Data Science Seminar (virtual)
22. (2020) University of Chicago, Department of Statistics
23. (2020) Vanderbilt University, Department of Biostatistics
24. (2019) University of Michigan, Department of Biostatistics
25. (2019) Brown University, Department of Biostatistics
26. (2019) University of Pennsylvania, Department of Statistics
27. (2018) University of Pennsylvania, Department of Biostatistics, Epidemiology and Informatics
28. (2018) Johns Hopkins Bloomberg School of Public Health, Department of Biostatistics
29. (2018) North Carolina State University, Department of Statistics
30. (2018) University of Texas School of Public Health, Department of Biostatistics and Data Science
31. (2018) SAS, Cary, NC
32. (2017) Virginia Tech, Department of Statistics
33. (2016) University of California, Berkeley, Department of Statistics, Neyman Seminar
34. (2016) Duke University, Comparative Effectiveness Research Program
35. (2016) Duke Clinical Research Institute, Duke University
36. (2016) University of Maryland at Baltimore, Department of Mathematics
37. (2015) Tsinghua University (China), Center for Statistical Science
38. (2015) University of Turku (Finland), Department of Mathematics
39. (2015) University of North Carolina at Chapel Hill, Causal inference research group
40. (2014) University of North Carolina at Chapel Hill, Department of Biostatistics
41. (2013) Durham Veterans Administration, Division of Health Services Research and Development

42. (2013) Cornell University, Weill Medical College, Department of Public Health, Division of Biostatistics and Epidemiology
43. (2013) Collegio Carlo Alberto, University of Turin, Italy
44. (2012) University of Florence, Department of Statistics, Italy
45. (2012) University of North Carolina at Chapel Hill, Center for Developmental Science
46. (2012) Ohio State University, Department of Statistics
47. (2012) IBM Watson Research Center
48. (2012) Columbia University, Department of Psychiatry, Division of Biostatistics
49. (2011) University of Pennsylvania, Department of Statistics
50. (2011) University of North Carolina at Chapel Hill, Causal inference research group
51. (2011) University of Virginia, Department of Statistics
52. (2011) Brown University, Center for Statistical Sciences
53. (2008) Duke University, Department of Statistical Science
54. (2008) University of Maryland at College Park, Department of Epidemiology and Biostatistics
55. (2008) University of North Carolina at Chapel Hill, Department of Biostatistics
56. (2007) Fox Chase Cancer Center, Biostatistics Facility
57. (2006) Harvard University, Department of Health Care Policy
58. (2006) Group Health Cooperative, Center of Health Studies
59. (2006) University of Chicago, Department of Health Studies
60. (2006) University of Pittsburgh, Department of Statistics
61. (2006) Ohio State University, Department of Statistics

Invited Conference Presentations

1. (2023) ENAR Spring Meeting, Nashville, TN
2. (2022) BAYES2022 - Bayesian Biostatistics Conference, Bethesda, MD
3. (2022) JSM 2022, Washington DC
4. (2022) ISBA World Meeting, 2022, Montreal, Canada
5. (2022) Workshop on Complex Data with Missingness, Measurement Errors, and High Dimensionality, Banff International Research Station (virtual)
6. (2021) Workshop on Computational Advertising, Banff International Research Station (virtual)
7. (2021) Pacific Causal Inference Conference (PCIC) 2021 (virtual)
8. (2021) JSM 2021 (virtual)
9. (2021) ISBA 2021 World Meeting (virtual)

10. (2021) SAMSI Opening Workshop on Data Science in the Social and Behavioral Sciences (virtual)
11. (2020) SAMSI Games, Decisions, Risk and Reliability (GDRR) Program Transportation Workshop, Durham, NC
12. (2019) Translating Duke Health Immunology & Transplant Initiative Symposium, Duke University, Durham.
13. (2019) JSM, Denver, CO
14. (2019) ICSA China Conference, Tianjin, China
15. (2019) Atlantic Causal Inference Conference 2019, Montreal, Canada
16. (2019) ENAR Spring Meeting, Philadelphia, PA
17. (2019) University of Florida, Gainsville. UF Winter Statistics Workshop.
18. (2018) JSM, Vancouver, Canada
19. (2018) Conference on Evidence and the Individual Patient: Understanding Heterogeneous Treatment Effects for Patient-Centered Care. National Academy of Medicine, Washington, DC
20. (2018) Webinar, Predictive Analytics and Comparative Effectiveness (PACE) Center, Tufts Medical Center.
21. (2018) ENAR Spring Meeting. Atlanta, GA
22. (2017) International Workshop on Objective Bayes Methodology (O-Bayes17). Austin, TX
23. (2017) SAMSI summer workshop on transportation statistics, Durham, NC
24. (2017) Joint Statistical Meeting, Baltimore, MA
25. (2017) European Meeting of Statisticians, Helsinki, Finland
26. (2017) Atlantic Causal Inference Conference 2017, UNC-Chapel Hill
27. (2016) University of Columbia, Department of Statistics, Causal Inference Conference
28. (2016) Fourth International Conference on the Interface between Statistics and Engineering, Palermo, Italy
29. (2016) ISBA 2016 World Meeting, Sardinia, Italy
30. (2016) Atlantic Causal Inference Conference, New York City
31. (2016) Technical Advisory Committee (TAC) annual meeting, Federal Highway Adminstration, McLean, Virginia
32. (2014) SAMSI Computational Methods in Social Sciences Program Transition Workshop, Durham, NC
33. (2014) ENAR spring meeting, Baltimore, MD
34. (2013) Technical experts meeting on statistical methodologies, Federal Highway Adminstration (FHWA), Durham, NC
35. (2013) International Workshop on Objective Bayes Methodology, Durham, NC
36. (2013) Joint Statistical Meeting, Montreal, Canada

37. (2013) ENAR spring meeting, Orlando, FL
38. (2013) SAMSI Computational Methods in Social Sciences Program Opening Workshop, Durham, NC
39. (2013) SAMSI Neuroimaging Data Analysis Summer Program, Durham, NC
40. (2012) ISBA 2012 World Meeting, Kyoto, Japan
41. (2012) ENAR spring meeting, Washington, DC
42. (2012) 5th Annual Bayesian Biostatistics Conference, Houston, TX
43. (2011) Joint Statistical Meeting, Miami, FL
44. (2011) IISA Conference on Probability, Statistics, and Data Analysis, Raleigh, NC
45. (2010) The Eighth ICSA International Conference, Guangzhou, China
46. (2007) Joint Statistical Meeting, Salt Lake City, UT

WPATH Assertion # 1

There is strong evidence demonstrating the benefits in quality of life and well-being of gender-affirming treatments, including endocrine and surgical procedures, properly indicated and performed as outlined by the Standards of Care (Version 8), in TGD people in need of these treatments (e.g., Ainsworth & Spiegel, 2010; Aires et al., 2020; Aldridge et al., 2020; Almazan & Keuroghlian, 2021; Al-Tamimi et al., 2019; Balakrishnan et al., 2020; Baker et al., 2021; Buncamper et al., 2016; Cardoso da Silva et al., 2016; Eftekhar Ardebili, 2020; Javier et al., 2022; Lindqvist et al., 2017; Mullins et al., 2021; Nobili et al., 2018; Owen-Smith et al., 2018; Özkan et al., 2018; T'Sjoen et al., 2019; van de Grift, Elaut et al., 2018; White Hughto & Reisner, Poteat et al., 2016; Wierckx, van Caenegem et al., 2014; Yang, Zhao et al., 2016). Page S18.

Name	Study Design	Methodology	Aim/Objective	Conclusions	Strengths	Limitations	Notes
van de Grift, Elaut et al., 2018 DOI: 10.1080/0092623X.2017.1326190	Prospective, no before-after for most outcomes	Multicenter, cross-sectional prospective study (follow up time 4-6 years) of 201 persons diagnosed with gender dysphoria who applied for medical interventions from 2007 until 2009. Main outcome measures were procedure performed, self-reported complications, and satisfaction with surgical outcomes (standardized questionnaires), QoL (Satisfaction With Life Scale, Subjective Happiness Scale, Cantril Ladder), gender dysphoria (Utrecht Gender Dysphoria Scale), and psychological symptoms (Symptom Checklist-90). The majority of trans women had undergone a vaginoplasty, and some also received mamma augmentation.	Assesse the outcomes of **gender-affirming surgery (GAS)** 4 to 6 years after first clinical contact, and the associations between postoperative (dis)satisfaction and quality of life (QoL).	Postoperative satisfaction was 94% to 100%, depending on the type of surgery performed. Only a few study participants reported feelings of regret. Satisfied respondents'QoL scores were similar to reference values; dissatisfied or regretful respondents' scores were lower. Psychological symptoms and life dissatisfaction at baseline were associated with treatment dissatisfaction at follow-up.		1. Only the SymptomChecklist 90-R (SCL-90) measure of gender dysphoria is measured both before and after SRS, all other outcomes (e.g. QoL) are only measured after SRS. 2. Selection bias due to low response rate: 201 out of 546 (37%) eligible subjects responded. The paper provides a justification that the respondent and non respondents baseline characteristics are similar, but provided no data. 3. Missing data: 20% to 67% missing data in all but one self-reported outcomes.	Despite being a prospective study, this paper has several methdological shortcomings, as outlined in the limitations section. It focuses on comparing the dissatified and satistified groups, and comparing to reference groups, but **didn't conduct direct before-after comparison** of the same patients (e.g. paired t-test). This paper finds that psychological symptoms and life dissatisfaction at baseline were significantly associated with treatment dissatisfaction at follow-up. This shows the importance of adjusting for the baseline mental status, which is available in most studies in this field.
Cardoso da Silva et al., 2016 DOI: 10.1016/j.jsxm.2016.03.370	Prospective, before-after	Prospective study of 47 Brazilian male-to-female transsexual individuals. QoL is measured using the WHOQOL-100 (100-item World Health Organization Quality of Life Assessment) and sociodemographic questions. Initial assessment and 1 year after SRS (sex reassignment surgery).	Assess the impact of **surgical interventions** on quality of life (QoL) of male-to-female transsexual individuals.	The participants showed significant improvement after SRS in domains II (psychological) and IV (social relationships) of the WHOQOL-100. In contrast, **domains I (physical health) and III (level of independence) were significantly worse after SRS.** Individuals who underwent additional surgery had a decrease in quality of life reflected in domains II and IV one year after SRS. Domains for the environment and spirituality, religion, and personal beliefs domains did not change after SRS	Prospective study, with pre- and post-measure of the same patients		This is a prospective studies which provide pre- and post- surgery comparison of the same patients. And **the results are mixed**. In particular, it found "domains I (physical health) and III (level of independence) were significantly worse after SRS"

Lindqvist et al., 2017 DOI: 10.1007/s00238-016-1252-0	Prospective cohort, before-after, longitudinal	A prospective cohort study on 190 patients undergoing male-to-female GRS at Karolinska University Hospital between 2003 and 2015. SF-36 QoL score pre-operatively, 1, 3, and 5 years post-operatively.	examine the QoL of transgender women undergoing **gender reassignment surgery (GRS)**.	1. SF-36 scores are higher 1 year post-GRS compared to pre-operatively (but the statistical significance is on boundary, <0.05), and are lower 5 years post-GRS compared to pre-operatively. There is a strong statistical significant trend of decline health trendy post 1 year. 2. On most dimensions of SF-36, transgender women reported a lower QoL than the general population.	Prospective cohort, with data on both pre- and post-operation at multiple time points	the statistical significance declared on the increase in QoL in year 1 compared to year 0 is only at p=0.05 level, while the later decrease is much more stronger level (p=0.0001)	The paper in fact **shows that 3 and 5 years post-operation the QoL is worse than pre-operation**, but didn't report the associated stat significance of the comparison between year 3/5 and year 0 among transgender women; neither did they report that of the comparision in general population. Only vaguely commented that the downward trend is similar between transgender women and general population, but again without any accurate measure of similarity or the stat significance in the comparisons in general population
Aires et al., 2020 DOI: 10.1080/26895269.2020.1848690	Prospective, before-after	**Prospective cohort** of transgender women submitted to **chondrolaryngoplasty** between March 2018 and October 2019. Two before and after measurements: (1) voice analysis by therapist (GRBAS score), before and 1-month after; (2) visual analog scale for aesthetic satisfaction, before and 6-month after. Sample size: 15	To assess and compare acoustic and perceptual voice outcomes and aesthetic satisfaction of transgender women submitted to **chondrolaryngoplasty (or "tracheal shaving", cosmetic surgery to reduce the laryngeal prominence)**	1. No difference in GRBAS score pre- and post- surgery. 2. Significant improvement in the visual analog scale for aesthetic satisfaction.	Prospective	Small sample size (15); short follow-up period (6 months)	This paper focuses on a special type of surgery of chondrolaryngoplasty or tracheal shaving. The outcomes are specific to voice and visual aesthetic satisfaction; there is no information on mental outcomes such as QoL, gender dysphoria or general physical outcomes.
Wierckx, K., Van Caenegem, et al. (2014). Journal of Sexual Medicine, https://doi.org/10.1111/jsm.12571	Prospective, before-after	Multicenter 1-year prospective study in 53 trans men and 53 trans women.	Report the short-term effects of **cross-sex hormone therapy** (CHT) on hormonal and clinical changes, side effects, and adverse events in trans men (female-to-male gender dysphoric persons) and trans women (male-to-female	Current treatment modalities were effective and carried a low risk for side effects and adverse events at short-time follow-up	Prospective cohort study with short follow up, with data on both pre- and post-treatment data		This paper focuses on the effect of **hormone therapy**, specifically on safety, not quality of life. It stated "Data on the effects of cross-sex hormone therapy (CHT) are limited due to the low prevalence of gender dysphoria, small number of subjects treated at each center, lack of prospective studies, and wide variations in treatment modalities."

Ainsworth & Spiegel, 2010 DOI: 10.1007/s11136-010-9668-7	Retrospective cross-sectional	**Facial Feminization Surgery** outcomes evaluation survey and the SF-36 quality of life survey were administered to male-to-female transgender individuals via the Internet and on paper. Sample size is 247.	To determine the self-reported quality of life of male-to-female (MTF) transgendered individuals and how this quality of life is influenced by **facial feminization and gender reassignment surgery.**	(1) Mental health-related QoL was statistically lower (P<0.05) in transgendered women without surgical intervention compared to the general female population and transwomen who had gender reassignment surgery (GRS), facial feminization surgery (FFS), or both. (2) no statistically significant difference in the mental health-related quality of life among transgendered women who had GRS, FFS, or both. (3) Participants who had FFS scored statistically higher (P<0.01) than those who did not in the FFS outcomes evaluation		Retrospective study. **No pre-post comparison of the same participate**; subject to confounding.	This paper focuses on QoL of MTF transwomen following **facial feminization surgery**. It is a retrospective study, no before-after comparison of the same participant
Almazan & Keuroghlian, 2021DOI: 10.1001/jamasurg.2021.0952)	Retrospective cross-sectional	**Secondary analysis the 2015 US Transgender Survey** (27715 respondents total). Two comparison groups: 3559 (12.8%) underwent 1 or more types of GAS at least 2 years prior to survey, 16401 (59.2%) endorsed a desire for GAS but denied undergoing any of these.	Evaluate **associations between gender-affirming surgeries (GAS)** and mental health outcomes	Statistically significant association between gender-affirming surgery and improved mental health outcomes (past-month psychological distress, past-year smoking, past-year suicidal ideation), all at 0.001 level. But no significant association between with GAS and past-month binge alcohol use.	Large sample size (largest existing data set containing comprehensive information on the surgical and mental health experiences of TGD people)	(1) Restropective study: no pre- and post- information of the same subject. Lack the single most important predictor: baseline mental health status. **The paper gave a post hoc justification:** "Our post hoc analysis demonstrates that lifetime suicidality and substance use behaviors are not associated with the exposure variable in this sample. Therefore, prior mental health factors do not appear to confound associations between gender-affirming surgery and subsequent mental health outcomes in our study." **The "justification" is statistically unfounded and deeply flawed, has no scientific merit**. (2) GAS was associated with lower odds of past-year suicidal ideation, but no statistically significant association between GAS and past-year suicide attempts; (3) (1) **Association study, no causal inference adjustment**	It is a large restrospective study, but lacks pre- and post- surgery information of the same patients. Therefore, the analysis did not adjust for the confounding bias due to the difference in the baseline outcome -- the most important confounder.

Al-Tamimi et al., 2019 DOI: 10.1016/j.jsxm.2019.07.027	Retrospective cross-sectional	Retrospective descriptive study of 83 transgender men who went through **secondary phalloplasty (a type of genital GAS**). Main outcome measures are surgical techniques, patient motivation, and outcomes of secondary phalloplasty after metoidioplasty in transgender men.	Explore the reasons for secondary phalloplasty, describe the surgical techniques, and report on the clinical outcomes.	A wide variety of surgical techniques were used to perform secondary phalloplasty. Several types of complications are reported on some patients. (Intraoperative complications (revision of microvascular anastomosis) occurred in 3 patients (5.5%) undergoing free flap phalloplasty. Total flap failure occurred in 1 patient (1.2%). Urethral fistulas occurred in 23 patients (30.3%) and strictures in 27 patients (35.6%))		Retrospective study	This is a descriptive study, describing the surgical techniques, and reporting on the clinical outcomes. **It is not a comparative study on the effect of the surgery. It did not report QoL or satisfaction.**
Mullins et al. 2021: DOI: 10.1542/peds.2020-023549	Retrospective	A retrospective chart review was conducted at a pediatric hospital-associated transgender health clinic. The primary outcome was incidence of arterial or venous thrombosis during gender-affirming hormone therapy (GAHT). Secondary measures included the prevalence of thrombosis risk factors.	To examine thrombosis and thrombosis risk factors among an exclusively **adolescent and young adult transgender population.**	These data suggest that GAHT in youth, titrated within physiologic range, does not carry a significant risk of thrombosis in the short-term, even with the presence of preexisting thrombosis risk factors.		Retrospective	This paper examines thrombosis and thrombosis risk factors among adolescent and young adult transgender population who received GAHT. The paper **does not provide any information in the effects of GAHT on quality of life and well-being.**
Balakrishnan et al., 2020 DOI: 10.1097/PRS.0000000000002684	Retrospective	A retrospective study of 42 transwomen performed from 2007 to 2017 in one hospital, followed up for 45 months. A validated institutional score for subjective assessment and objective assessment were used at the end of follow-up period.	Assess the esthetic outcomes of PAM (**Augmentation Mammoplasty**) - a type of surgery.	92.85% of transwomen achieved grade-A score with both subjective and objective assessment scoring system.		retrospective, descriptive (not comparative)	This study is a **descriptive analysis** of the outcomes of PAM; it is **not a comparative effectiveness analysis: doesn't compare QoL between pre- and post- PAM; or between PAM and non-PAM subjects.**
Buncamper et al., 2016 DOI: 10.1055/s-0040-1709427	Retrospective	Retrospective study of 475 patients who underwent penile inversion vaginoplasty	Assess intraoperative and postoperative complications after **penile inversion vaginoplasty**	Successful vaginal construction without the need for secondary functional reoperations was achieved in the majority of patients. Intraoperative complications are scarce. Postoperative complications occur frequently but are generally minor and easily treated.		retrospective, and descriptive (not comparative)	This is a **descriptive analysis** of the clinical outcomes (e.g. complications) of penile inversion vaginoplasty. There is no pre- vs. post- surgery or surgery vs. non-surgery comparisons. No discussion about the necessity of the surgery

Owen-Smith et al., 2018 DOI: 10.1016/j.jsxm.2018.01.017	Retrospective cross-sectional	Cross-sectional comparison of self-reported outcomes between patients who had GCT vs. not. A cohort of transgender individuals recruited from 3 health plans in Georgia, Northern California, and Southern California who completed a survey. Outcomes of interest included body-gender congruence, body image satisfaction, depression, and anxiety.	Examine the association between gender confirmation treatments (GCT) and individuals' body-gender congruence, body image satisfaction, depression, and anxiety in cohorts of transmasculine (TM) and transfeminine (TF) individuals.	The proportion of participants with low body-gender congruence scores was significantly higher in the "no treatment" group compared to the definitive bottom surgery group (PR 3.96). The PR for depression comparing participants who reported no treatment relative to those who had definitive surgery was 1.94; the corresponding PR for anxiety was 4.33.) No significant difference in any other comparisons (outcome and surgery types).	Sample include both transman and transwoman	1. Retrospective cross-sectional. No before- and after- surgery comparison. 2. May not be representative of the transgender population in the United States because (i) the study sample is collected from only three health systems in GA and CA; (i) Low response rate (33% 697 out of 2136). 3. **No comparison between non GCT and surgery types other than definitive bottom surgery**. 4. Reporting is **cherry picking**: many comparisons (different outcomes (e.g. body image), different surgery groups), only reported the ones which are statistically significant (3 out of 10 comparisons)	Combination of several treatments, including hormone therapy (HT) and/or surgical change of the chest and genitalia ("top" and "bottom" gender confirmation surgeries). The results are mixed, but the reporting focuses on the subset of statistically signficant ones.
Yang, Zhao et al., 2016 DOI: 10.1016/j.jsxm.2016.03.369	Retrospective cross-sectional	Cross-sectional analysis of 247 transwomen in Shenyang, China. Self reported QOL. Only 4 underwent SRS	To assess QOL (both physical and mental) of trans women in Shenyang, China and associated factors	Chinese transgender women reported high levels of physical QOL but low levels of mental QOL. Their mental QOL was more pronounced than their physical QOL. Transition status and sexual partnership played the most important roles in physical and mental health. Furthermore, mental QOL was best predicted by assessing positive capabilities, such as levels of hope.	Focus on non-western transwomen population	Retrospective cross-sectional study. **Only 4 out of 247 subjects underwent gender-reassignment surgery (GRS)**. The sample size is too small to include GRS status as a predictor in the multivariable regression, and thus **provided no information on the effect of GRS on QOL**.	This study focuses on the transwomen population in one city in China. It is a retrospective cross-sectional study, no before-after comparison. **Only 4 out of 247 subjects underwent gender-reassignment surgery (GRS)**. The sample size is too small to include GRS status as a predictor in the multivariable regression, and thus **provided no information on the effect of GRS on QOL**.
Özkan et al., 2018 DOI: 10.1080/2000656X.2018.1444616	Retrospective	A retrospective study of 43 patients.	Describe the surgical technique, long-term results and sexual outcomes of patients who underwent **vaginal reconstruction with the modified rectosigmoid**	Vaginal reconstruction with denervated rectosigmoid held in an ischemic state appears to be a reasonable option among several available reconstruction techniques.		Retrospective cohort	This is a descriptive study, not a comparative effectiveness study, not providing any information on the effect of treatments
Poteat et al., 2016 Global epidemiology of HIV infection and related syndemics affecting transgender people DOI:	Literature review (but on a different topic)	The citation appears to be incorrect: it is a literature review the HIV epidemic among transgender population, not related to QoL and psychological functions.					**This citation might be incorrect**: it is literature review of the HIV epidemic among transgender population, doesn't seem to related to QoL and psychological functions.

Nobili et al., 2018 DOI: 10.1007/s11154-018-9459-y	Literature review, and formal statistical meta-analysis	Random effects meta-analysis of 29 studies up to July 2017.	A review of quality of life of treatment-seeking transgender adults	Transgender people display poor QoL, independent of the domain investigated. Meta-analysis in a subgroup of studies looking at QoL in participants who were exclusively post-CHT(**Cross-sex Hormonal Treatment**) found no difference in mental health QoL between groups. Insufficient data for a pre-treatment subgroup.			This is a review and meta analysis. It combines several types of treatments (e.g. surgery and hormone therapy). It noted "**the majority of the studies were cross-sectional, lacked controls, and displayed moderate risk of bias…Better quality studies that include clearly defined transgender populations, divided by stage of gender affirming treatment and with appropriate matched control groups are needed to draw firmer conclusions.**"
White Hughto & Reisner, 2016. A systematic review of the effects of hormone therapy on psychological functioning and quality of life in transgender individuals. Transgender Health, 1(1), 21–31. https://doi.org/10.1089/trgh.2015.0008.	Literature review (of three prospective studies)	Review of three uncontrolled prospective cohort studies, enrolling 247 transgender adults. The studies measured exposure to hormone therapy and subsequent changes in mental health (e.g., depression, anxiety) and quality of life outcomes at follow-up.	A review of prospective cohort studies to study the effects of **hormone therapy** on psychological functioning and quality of life in transgender individuals	Two studies showed a significant improvement in psychological functioning at 3–6 months and 12 months compared with baseline after initiating hormone therapy. The third study showed improvements in quality of life outcomes 12 months after initiating hormone therapy for FTM and MTF participants; however, only MTF participants showed a statistically significant increase in general quality of life after initiating hormone therapy.	Focus on **prospective cohort** studies		This is a literature review on the effects of **hormone therapy**; no information on the effects of SRS. The paper acknowledge several weaknesses that are common in the transgender literature: "Hormone therapy interventions to improve the mental health and quality of life in transgender people with gender dysphoria **have not been evaluated in controlled trials**. **Low quality evidence** suggests that hormone therapy may lead to improvements in psychological functioning. **Prospective controlled trials are needed** to investigate the effects of hormone therapy on the mental health of transgender people."
T'Sjoen et al., 2019: Endocrinology of transgender medicine. Endocrine Reviews, 40(1), 97–117.https://doi.org/10.1210/er.2018-00011.	Literature review, no meta-analysis	Comphrehensive review of hormal treatments of transgender people	To review recent data on **hormonal treatment** of transgender population and its effect on physical, psychological, and mental health.	A summary of the procedure and outcomes of hormonal treatments of transgender people.		Qualitative summaries, no formal meta-analysis.	This is a literature review. It cited three papers in suporting the statement in abstract of "Mental health problems such as depression and anxiety have been found to reduce considerably following hormonal treatment," but provided no data. The paper acknowledges "current available research is based mostly on cross-sectional studies…long-term follow-up studies and studies involving large groups of people are needed to evaluate whether these improvements remain."

Eftekhar Ardebili et al. (2020) DOI: 10.1186/s12955-020-01510-0	Literature review, simple meta-analysis	**Meta analysis (weighted mean)** of 8 studies, 1099 patients	To conduct a systematic review and meta-analysis about the quality of life (QoL) of individuals during the post **transsexual surgery** period.	The results of this systematic review may support the approaches to transsexuality that facilitates sex reassignment. In this review, the means of quality of life after surgery were not compared to the means of quality of life before surgery or even before hormonal therapy which was due to inadequate number of primary studies		Retrospective design: the means of quality of life after surgery were not compared to the means of quality of life before surgery or even before hormonal therapy which was due to inadequate number of primary studies. **So it provides no information regarding the effect of surgery on the QOL.**	**Meta-analysis**. No pre-surgery information, and thus **provides no information regarding the effect of surgery on the QOL.**
Baker et al. 2021. Hormone therapy, mental health, and quality of life among transgender people: A systematic review. Journal of the Endocrine Society, 5(4),https://doi.org/10.1210/jendso/bvab011.	literature review	Literature review of 20 studies reported in 22 papers that evaluate quality of life (QOL), depression, anxiety, and death by suicide in the context of gender-affirming hormone therapy among transgender people of any age. Fifteen were trials or prospective cohorts, one was a retrospective cohort, and 4 were cross-sectional.	To provide a systematical review the effect of gender-affirming **hormone therapy** on psychological outcomes among transgender people.	Hormone therapy was associated with increased QOL, decreased depression, and decreased anxiety. Associations were similar across gender identity and age. Could not draw any conclusions about death by suicide.			This paper is a literature review focusing on effects of hormonal therapy on QoL and mental health; **it doesn't provide any information on the effects of SRS** (surgery). The authors acknowleges that "this conclusion is limited by high risk of bias in study designs, small sample sizes, and confounding with other interventions."
Javier et al., 2022 DOI: 10.1080/26895269.2022.2038334	Literature review, no meta-analysis	A qualitative literature review of seventy-nine low quality (e.g., small sample sizes, lack of control/comparison groups)	A systematic literature review into the longer-term (i.e., ≥ 1 year) surgical satisfaction and quality of outcomes following various forms of **gender-affirming surgery** in transgender populations.	Seventy-nine low quality studies suggest that most transgender patients are satisfied with surgical outcomes when assessed at least one-year post-surgery. Low quality research also indicates that transgender women and men typically report positive psychological and sexual wellbeing post-surgery, and similar wellbeing outcomes as those who have not had surgery.		**Qualitative summaries, no formal meta-analysis**, **all the studies are low quality** (e.g., small sample sizes, lack of control/comparison groups)	**Conflicting findings but the conclusion gears towards the positive summaries**. Not all longer-term outcomes following GAS reported in this review were positive. A small minority of transgender men and women among the studies reviewed reported low levels of surgical satisfaction (e.g., Ainsworth and Spiegel, 2010; Bouman et al., 2016; Fakin et al., 2019; Leriche et al., 2008). A small minority of transgender women and men also reported regretting having surgery (e.g., Amend et al., 2013; Antoszewski et al., 2012; Garcia et al., 2014; Neuville et al., 2021).

WPATH Assertion # 2

Gender-affirming interventions are based on decades of clinical experience and research; therefore, they are not considered experimental, cosmetic, or for the mere convenience of a patient. They are safe and **effective at reducing gender incongruence and gender dysphoria** (e.g., Aires et al., 2020; Aldridge et al., 2020; Al-Tamimi et al., 2019; Balakrishnan et al., 2020; Baker et al., 2021; Bertrand et al., 2017; Buncamper et al., 2016; Claes et al., 2018; Eftekhar Ardebili, 2020; Esmonde et al., 2019; Javier et al., 2022; Lindqvist et al., 2017; Lo Russo et al., 2017; Marinkovic & Newfield, 2017; Mullins et al., 2021; Nobili et al., 2018; Olson-Kennedy, Rosenthal et al., 2018; Özkan et al., 2018; Poudrier et al., 2019; T'Sjoen et al., 2019; van de Grift, Elaut et al., 2018; White Hughto & Reisner, Poteat et al., 2016; Wierckx, van Caenegem et al., 2014; Wolter et al., 2015; Wolter et al., 2018). Page S18

Name	Study-Design	Methodology	Aim/Objective	Conclusions	Strengths	Limitations	Notes

Aldridge et al., 2020 https://doi.org/10.1111/andr.12884	Prospective, before-after	Participants (n = 178) completed a socio-demographic questionnaire, the Hospital Anxiety and Depression Scale (HADS), the Multidimensional Scale of Perceived Social Support (MSPSS) and the Autism Spectrum Quotient—Short Version (AQ-Short) at pre-assessment (T0) and at 18 months after initiation of GAHT (T1).	To investigate the effect of 18-month GAHT on depression and anxiety symptomatology and the predictors on mental health outcomes in a large population of transgender people, using a longitudinal study	From T0 to T1, symptomatology was significantly decreased for depression (P < .001) and non-significantly reduced for anxiety (P = .37). Scores on the MSPSS predicted reduction in depression, while scores on the AQ-Short predicted reduction in anxiety.	Prospective, before-after comparison		The results are mixed: depression was significantly reduced, but anxiety is not. Even though this is prospective before-after comparison, it is still subject to unmeasured confounding.
Lo Russo et al. 2017	Prospective, but no before-after outcomes	25 FTM transgender patients underwent surgical procedures to create a masculine chest-wall contour. In our study, we just considered 16 patients who have undergone chest surgery with the double incision method. Outcomes are on surgical complications, scar, etc. Outcome on satisfication is aesthetically pleasing and surgeon evaluations.	To propose a new technical approach (chest-wall contouring surgery) and describe indications for FTM transgender patients' surgery.	The patients' survey revealed a high satisfaction rate with the aesthetic result.		No before-after comparison. No outcomes on gender incongruence and gender dysphoria.	The paper focuses on describing a new surgical technique. There is no before-after comparison. The satisfaction outcome is limited to aesthetic results. There is no outcome on gender dysphoria.
Olson-Kennedy, Rosenthal et al., 2018. Health considerations for gender non-conforming children and transgender adolescents. Guidelines for the primary care of	Guidelines						This is part of the "Guidelines for the Primary Care of Transgender and Gender nonbinary people." It is not an individual scientific study.
Marinkovic & Newfield, 2017 https://doi.org/10.1080/15532739.2017.1349706.	Retrospective	Data on 14 patients who underwent chest reconstruction surgery. Outcomes include self-reported satisfication on aesthetics of the surgical outcome and complication	To present data about chest reconstructive surgeries in transgender youth from a Pediatric Gender Management (GeM) clinic.				The paper presents data about chest reconstructive surgeries in transgender youth. The outcomes do not include measures of gender dysphoria, only self-reported satisfaction of the surgical outcome. There is no before-after comparison.

Poudrier et al., 2019 https://doi.org/10.1097/PRS.0000000000005113	Retrospective	An anonymous online survey was distributed to 81 of the senior author's former top-surgery patients. The survey response rate was 72 percent (58 respondents). Responses were analyzed to investigate quality of life, sexual confidence, mental health, satisfaction with top surgery, and patient attitudes toward top surgery's role in gender affirmation.	To assess Quality of Life and Patient-Reported Satisfaction with Masculinizing Top Surgery.	Top surgery had major positive effects on all mental health and quality-of-life metrics.		1. retrospective; 2. nonresponse bias; 3. self-developed survey, self-reported outcomes, not standardized instruments	The paper obtains data from a retrospective cross-sectional survey. The questions are directly on the self-reported improvement of QoL, Sexual Confidence, and Mental Health, but this is not actual measurements of the same outcome before and after the SRS (as would be the case in a prospective before-after design). So it is not an objective before-after comparison, and is subject to recall bias. The response rate is 72% and thus is subject to nonresponse bias. Finally, the outcomes are all self-reported using a self developed survey, and there is no direct measurements on geneder dysphoria.
Wolter et al., 2018 https://doi.org/10.1016/j.bjps.2017.09.003.	Retrospective	Compare an earlier cohort and a later cohort with new preventive measures. The outcomes are complication rate, patient satisfaction and secondary revision rate	To describe and assess new preventive measures in subcutaneous mastectomy in female-to-male transsexuals	By implementation of peri- and postoperative preventive measures and additional application of an algorithmic care path we could achieve a significant reduction of complications, particularly of the hematoma evacuation rate			This paper describes and assesses new preventive measures in subcutaneous mastectomy in female-to-male transsexuals. It does not provide any information on geneder dysphoria.
Wolter et al., 2015 https://doi.org/10.1016/j.bjps.2014.10.016.	Retrospective	The records of 173 patients (346 mastectomies) from were retrospectively reviewed. The authors conducted four different surgical techniques depending on breast volume, grade of ptosis and skin elasticity. The outcome parameters such as complication rate, patient satisfaction with the aesthetic result, nipple sensitivity and surgical correction rate were obtained and related to the employed technique.	To introduce an algorithm to facilitate choosing the appropriate mastectomy technique depending on morphological aspects.	Introduced an algorithm for choosing mastectomy technique			This paper focuses on developing an algorithm to facilitate choosing the appropriate mastectomy technique depending on morphological aspects. There is no information on gender dysphoria.
Bertrand 2017 DOI: 10.1016/j.anplas.2017.05.005	Retrospective cross-sectional	22 patients contacted, 16 respondents, self reported based on questionaire	Evaluate patient satisfaction following **bilateral mastectomy** for female-to-male gender	The mean aesthetic score was 332/378, corresponded to "very satisfied" in the questionnaire. The psychological score was 54.5/60.		1. No comparison groups, only cross sectional summary of a single group who responded, nonresponse bias 2. No information on pre-surgery measurements. 3. Very small sample size	The paper is in French; I only reviewed the English abstract. The study has no comparison groups, only cross-sectional summary of subjects who responded, subject to nonresponse bias. There is no information on pre-surgery measurements and thus no before-after comparison. The sample size is small.

Claes et al., 2018 DOI: 10.1016/j.cps.2018.03.010	No study sample, no design	Description of chest surgery	Describe the surgerical techniques of c**hest surgery** for Transgender and Gender		Description of the clinical aspect of Chest Surgery, **no information on effects on mental and physiology outcomes**. No specific study sample
Esmonde et al., 2019 DOI: 10.1093/asj/sjy166	Retrospective cross-sectional	A retrospective review of 458 patients who underwent chest-affirming procedures in a single institution based on a questionnaire on quality of life and body image outcomes	Describe a single-institution experience of chest-affirming procedures performed in nonbinary patients, including patient characteristics, surgical	Retrospective, no before-after comparison	This paper focuses on describing the surgical techniques of chest affirming surgery. There is no before-after comparisons, and thus provides no data supporting the claim in the abstract that "patients reported improved quality of life."
Aires et al., 2020 DOI: 10.1080/26895269.2020.1848690	Duplicate				Reviewed in Assertion 1. Specific to this Assertion, there is no outcome measures on gender dysphoria or general mental or physical well-being, and thus **provides no direct evidence supporting the Assertion** of "effective in reducing gender incongruence and gender dysphoria"
Al-Tamimi et al., 2019 DOI: 10.1016/j.jsxm.2019.07.027	Duplicate				Reviewed in Assertion 1. Specific to this Assertion, this is a descriptive study, describing the surgical techniques, and reporting on the clinical outcomes; not a comparative study on the effect of the SRS. Specific to this Assertion, there is no outcome measures on gender dysphoria or general mental or physical well-being, and thus **provides no direct evidence** supporting the Assertion of "effective in reducing gender incongruence and gender dysphoria"
Balakrishnan et al., 2020 DOI: 10.1080/26895269.2022.2100644	Duplicate				Reviewed in Assertion 1. Specific to this Assertion, this is a descriptive study of the outcomes of a specific type of surgery; it is not a comparative effectiveness analysis, and there is no outcome measures directly measureing gender dysphoria. Thus it **provides no evidence supporting the Assertion** of "effective in reducing gender incongruence and gender dysphoria"
Buncamper et al., 2016 DOI: 10.1080/26895269.2022.2100644	Duplicate				Reviewed in Assertion 1. Specific to this Assertion, this is a description of the surgical outcomes (e.g. complications) of penile inversion vaginoplasty. It is not a comparative effectiveness analysis, and there is no outcome measures measureing gender dysphoria. Thus it **provides no evidence** supporting the Assertion of "effective in reducing gender incongruence and gender dysphoria"

Eftekhar Ardebili DOI: 10.1186/s12955-020-01510-0	Duplicate	Reviewed in Assertion 1. Specific to this Assertion, this study focuses on QoL of SRS. However, because non of the studies reviewed contain pre-surgery information, the analysis provides no information regarding the compariative effectiveness of surgery on the QOL. Also, the studies reviewed do not contain direct measures on gender dysphoria, and thus provides no evidence supporting the Assertion of "effective in reducing gender incongruence and gender dysphoria"
Javier et al., 2022 DOI: 10.1080/26895269.2022.2038334	Duplicate	Reviewed in Assertion 1. It is a qualitative summary of 97 low quality studies and found conflicting findings. Indeed, not all longer-term outcomes following GAS reported in this review were positive.
Lindqvist et al., 2017 DOI: 10.1007/s00238-016-1252-0	Duplicate	Reviewed in Assertion 1. It is one of the few prospective studies with before-after SRS data of the same patients. Specific to this Assertion, this paper in fact shows that 3 and 5 years post-operation the QoL is worse than pre-operation. This paper focuses on general QoL outcome and provides no data on direct measure of gender dysphoria. Thus it provides no direct evidence supporting the Assertion of "effective in reducing gender incongruence and gender dysphoria"
Nobili et al., 2018 DOI: 10.1007/s11154-018-9459-y	Duplicate	Reviewed in Assertion 1. It is a meta-analysis of 29 studies, focusing on the outcome of QoL. It does not study the safety of the treatments, and does not provide any information on direct measure of gender dysphoria, no before-after comparison. Thus it **provides no direct evidence supporting the Assertion** of "effective in reducing gender incongruence and gender dysphoria"

van de Grift, Elaut et al., 2018 DOI: 10.1080/0092623X.2017.1326190	Duplicate							Reviewed in Assertion 1. Specific to this assertion, the study has measures on various post-SRS outcomes (e.g. complications, satisfaction, QoL, happiness, psychological symptoms). However, except for psychological symptoms, it didn't collect before-after data on any other outcomes, and thus could not conduct a direct before-after comparison of these outcomes of the same patients. Therefore, it **provides no direct evidence supporting the Assertion** of "effective in reducing gender incongruence and gender dysphoria"
White Hughto & Reisner, Poteat et al., 2016 DOI: 10.1097/QAI.0000000000001087	Duplicate							Reviewed in Assertion 1. Specific to this assertion, it focuses on hormone treatments and provides no information on the effects of SRS. It also calls for "Prospective controlled trials"
Baker et al., 2021	duplicate							Reviewed in Assertion 1. Specific to this assertion, it doesn't provide any information on the effects of GAT
Mullins et al., 2021	duplicate							Reviewed in Assertion 1. Specific to this assertion, this paper does not provide any information on the effects of GAT on gender dysphoria, quality of life and well-being.
T'Sjoen et al., 2019	duplicate							Reviewed in Assertion 1. Specific to this assertion, this literature review does not provide any data in supporting the statement in abstract of "Mental health problems such as depression and anxiety have been found to reduce considerably following hormonal treatment." The outcomes do not directly measure gender dysphoria.
Özkan et al., 2018	Duplicate							Reviewed in Assertion 1. Specific to this assertion, this is a descriptive study, not a comparative effectiveness study, not providing any information on the effect of GAT
Wierckx, van Caenegem et al., 2014	Duplicate							Reviewed in Assertion 1. Specific to this assertion, this paper does not provide information on the effects on gender dysphoria.

WPATH Assertion # 3							
However, the recommendations put forth here apply to all institutions that house TGD individuals, both carceral and noncarceral (Porter et al., 2016). Page S104							
Name	**Study-Design**	**Methodology**	**Aim/Objective**	**Conclusions**	**Strengths**	**Limitations**	**Notes**

Porter, 2016 DOI: 10.1080/07317115.2016.1203383	Literature review		To provide a context from which clinicians from all disciplines, not only psychology, can apply the American Psychological Association (APA) 2015 Guidelines to provide competent and affirming services to older (transgender and gender nonconforming) TGNC	Interpret the APA Guidelines using a gerontological lens to elucidate specific issues faced by the TGNC older adult along with the practice and policy implications for this population.			This paper focuses on older TGNC adults. Its applicability to general TGNC population is unclear

WPATH Assertion # 4

People should have access to these medically necessary treatments irrespective of their housing situation within an institution (Brown, 2009). Page S104

Name	Study-Design	Methodology	Aim/Objective	Conclusions	Strengths	Limitations	Notes
Brown, 2009 DOI: 10.1080/15532730903008073	Opinion						This is an opinion piece (specifically, recommended revisions to WPAH Standards of Care Section on Medical Care for Incarcerated Persons with Gender Identity Disorder). It is not a scientific study; there is no study design or methodology or data.

WPATH Assertion # 5

TGD residents in carceral facilities report the lack of access to medically necessary transgender-specific health care (see Chapter 2—Global Applicability, Statement 2.1), which is ranked as their number one concern while incarcerated (Brown, 2014; Emmer et al., 2011). Page S104

Name	Study-Design	Methodology	Aim/Objective	Conclusions	Strengths	Limitations	Notes
Brown, 2014 DOI: 10.177/1078345814541533	Retrospective cross-sectional	Qualitative analysis of 129 transgender inmates' correspondence	To identify transgender inmates' concerns	Claims of inadequate care for transgendered patients that have sufficient merit to be fully litigated in U.S. courts appear likely to produce verdicts in favor of plaintiff inmates			The paper **provides evidence for the Assertion**, on page 336, it states "transgender health care issues accounting for the largest number (55%) (of concerns) by a wide margin"
Emmer et al., 2011: Emmer, P., Lowe, A., & Marshall, R. B. (2011). This is a prison, glitter is not allowed : Experiences of trans and gender variant people in	Retrospective cross-sectional	Self-developed survey of TG immates, respondent rate is 68 out of over 100.	To provide a report on the experiences of trans and gender variant people in Pennsylvania's Prison System				The report found "Requests for and delivery of gender-related health services were often met with ignorance and ntimidation."

WPATH Assertion # 6

Controlled studies show clinically significant health and mental health disparities for justice-involved transgender people compared to matched groups of transgender people who have not been incarcerated or jailed. (Brown and Jones, 2015). Page S104

Name	Study-Design	Methodology	Aim/Objective	Conclusions	Strengths	Limitations	Notes

Brown and Jones, 2015 DOI: 10.1089/lgbt.2015.0052	Retrospective cross-sectional, matched case-control	Studied a large cohort of transgender TG veterans who received care in Veterans Health Administration (VHA) facilities during 2007–2013 (n = 4,793) and a 3:1 matched control group of veterans without known TG identification (n = 13,625). Three hundred twenty six (326: 138 TG, 188 TG) had received VHA services in programs designed to address the needs of justice involved veterans. Linked patients in each of the three groups to their medical and administrative data.	To investigate health disparities in transgender veterans involved with the criminal justice system	TG veterans experience a number of health risks compared to non-TG veterans, including an increased likelihood of justice involvement.	matched case-control study	focus on U.S. veterans, generalizability to general population is unclear.	The study compares health disparities between **TG and non-TG** veterans, and found TG veterans have an increased likelihood of justice involvement. **This comparison is entirely different from the comparison stated in the Assertion**, namely, **justice-involved TG people vs. non justice-involved TG people** (i.e. comparison between different TG populations). Therefore, the study is not relevant to the claim in this Assertion.

WPATH Assertion # 7

Too often the agencies, structures, and personnel that provide care are lacking in knowledge, training, and capacity to care for gender diverse people (Clark et al., 2017) Page S104

Name	Study-Design	Methodology	Aim/Objective	Conclusions	Strengths	Limitations	Notes
Clark et al., 2017 DOI: 10.1016/j.socscimed.2017.09.052.	Cross-sectional interview	Interview of 20 correctional healthcare providers (e.g., physicians, social workers, psychologists, mental health counselors) from New England	To examine correctional healthcare providers' knowledge of, attitudes toward, and experiences providing care to transgender inmates.	Transgender inmates do not consistently receive adequate or gender-affirming care while incarcerated.		Small sample size in one region.	The paper provided facts supporting the Assertion. The limitation is that the sample size is small (20) and is restricted to one region (New England).

WPATH Assertion # 8

We recommend the application of the Standards of Care (SOC) to people living in institutions as basic principles of health care and ethics (Beauchamp & Childress, 2019; Pope & Vasquez, 2016). S105

Name	Study-Design	Methodology	Aim/Objective	Conclusions	Strengths	Limitations	Notes
Beauchamp & Childress, 2019 Am J Bioethics	Opinion						This is an opinion piece (guest editorial of a journal). It is not a scientific study; there is no study design or methodology or data.
Pope & Vasquez, 2016: Ethics in psychotherapy and counseling: A practical guide	Book						This is a 496 page long book. It made the call as stated in the Assertation, which is an opinion (recommendation of care). There is no study design or methodology or data.

WPATH Assertion # 9

TGD people with gender dysphoria should have an appropriate treatment plan to provide medically necessary surgical treatments that contain similar elements provided to persons who reside outside institutions (Adams v. Federal Bureau of Prisons, No. 09-10272 [D. MO June 7, 2010]; Brown 2009; Edmo v. Idaho Department of Corrections, 2020). Page S106

Name	Study-Design	Methodology	Aim/Objective	Conclusions	Strengths	Limitations	Notes

Brown, 2009 DOI: 10.1080/1553273090300	Duplicate						Reviewed in Assertion 4. It is an opinion piece, not a scientific study; there is no study design or methodology or data.

WPATH Assertion # 10

Gender-affirming vaginoplasty is one of the most frequently reported gender-affirming surgical interventions; 8 prospective (Buncamper et al., 2017; Cardoso da Silva et al., 2016; Kanhai, 2016; Manero Vazquez et al., 2018; Papadopulos, Zavlin et al., 2017; Tavakkoli Tabassi et al., 2015; Wei et al., 2018; Zavlin et al., 2018), 15 retrospective cohort (Bouman, van der Sluis et al., 2016; Buncamper et al., 2015; Hess et al., 2016; Jiang et al., 2018; LeBreton et al., 2017; Manrique et al., 2018; Massie et al., 2018; Morrison et al., 2015; Papadopulos, Lelle et al., 2017; Raigosa et al., 2015; Salgado et al., 2018; Seyed-Forootan et al., 2018; Sigurjonsson et al., 2017; Simonsen et al., 2016; Thalaivirithan et al., 2018), and 3 cross-sectional cohort studies have recently been reported (Castellano et al., 2015; Owen-Smith et al., 2018; van de Grift, Elaut et al., 2018). Page S128

Although different assessment measurements were used, the results from all studies **consistently reported both a high level of patient satisfaction** (78–100%) as well as satisfaction with sexual function (75–100%). This was especially evident when using more recent surgical techniques. Gender-affirming vaginoplasty was also associated with a low rate of complications and a low incidence of regret (0–8%). S128-129

Name	Study-Design	Methodology	Aim/Objective	Conclusions	Strengths	Limitations	Notes
Buncamper et al., 2017 DOI: 10.1097/PRS.0000000000003108	Prospective	Prospective study of 100 patients	provide data to enable an evidence-based discussion on the controversy of whether or not to use additional full-thickness skin graft in penile inversion vaginoplasty.	The authors can confirm neither of the suggested arguments, for or against full-thickness skin graft use, in penile inversion vaginoplasty.			This paper focuses on the debate of a specific surgical detail, and analyzed the association between the surgical technique and the patient-reported aesthetic outcome, overall satisfaction with the neovagina, sexual function, and genital self-image, and found no assocations. There is no discussion on QoL, necessity, statisfaction of any particular technique.
Kanhai, 2016 DOI: 10.1007/s00266-016-0620-2	Prospective, but no before-after outcome	Prospective study of 50 patients	Describe Sensate pedicled-spot plasty: a new technique to create a sexual arousal organ in the anterior wall of the	Sensate pedicled-spot plasty is a safe innovative technique which lead to adequate sexual functionality in all patients.			Description of a new technique in SRS. Nothing about pre- and post- SRS comparison. No outcome measures other than sexuality functionality
Manero Vazquez et al., 2018 DOI: 10.1097/SAP.0000000000001532	Prospective, but no before-after outcome	97 Ninety-seven patients in one medical center. All clitoroplasties and vulvoplasties were completed in the same surgical stage as the vaginoplasty	describe a new clitoroplasty and vulvoplasty technique in male-to-female sex reassignment surgery and its outcome.				Description of the authors' clitoroplasty and vulvoplasty technique. Outcomes are all clinical outcomes, n**o information on other outcome measures such as QoL.**

Papadopulos, Zavlin et al., 2017 DOI: 10.1097/PRS.0000000000003529	Prospective, before-after	Prospective study of **39** patients, QoL based on self-developed questions as well as standarized questionaries during both pre- and post- operative (6 months) periods	**Evaluate QoL among MTF SRS using combined technique**	Statistically significant improvements were found in the paired T test (pre- and post-SRS) regarding Questions on Life Satisfaction, Modules (German version), especially for the items "partnership," "ability to relax," "energy," "freedom from "anxiety," "hair," "breast," and penis/vagina" ($p < 0.01$). Furthermore, the patients appeared more emotionally stable ($p = 0.03$), showed higher self-esteem ($p = 0.01$), and showed much lower depression/anxiety ($p < 0.01$).	**Prospective**: information of the same patient pre- and post- (6 months) SRS.	Small sample size, short term follow-up	One of the few studies focusing on QoL and with different comparison pre-and post- SRS. A **multiple testing** issue: too many hypothesis testing (41) on too few patients (39). Multiple testing is a serious statistical program in hypothesis testing: the more tests you conduct on the same set of data, the more likely you will have false positives. For example, if you use p=0.05 as a threshold hold, among 100 tests, you will expect to have at least 5 false positives just by random chance. This is not specific to a single type of SRS, but a combined SRS technique.
Tavakkoli Tabassi et al., 2015 DOI: 10.1007/s00238-014-1038-1	Prospective, but no before-after outcome	112 previously circumcised MTF subjects underwent a modification of penile inversion vaginoplasty	Description of a surgical technique of male-to-female (MTF) transsexual vaginoplasty when subjects have short penile skin flap because of circumcision				Description a special type of vaginoplasty. **No comparison groups. No information on other outcome measures, e.g. qualify of life. Didn't address the necessity of the surgery**. Only described the satisfaction rate of the patients of a special type of technique.
Wei et al., 2018 DOI: 10.1007/s00266-017-0977-x	Prospective, but no before-after outcome	Nine male-to-female transsexual patients received our new method of vaginoplasty from July 2010–October 2015. mean clinical follow-up period of 25.3 months and phone interview follow-up of 50.3 months	described the details of the surgical procedure and evaluated the long-term anatomical and functional outcomes.	All the patients were sexually active and reported sexual satisfaction		Small sample size, no comparison between pre- and post- surgery	Description a new technique of vaginoplasty. **Focuses on long-term anatomical and functional outcomes. No comparison groups. No information on other outcome measures, e.g. qualify of life. Didn't address the necessity of the surgery**.
Zavlin et al., 2018 Aesthetic Plastic Surgery, 42(1), 178–187. https://doi.org/10.1007/s00266-017-1003-z.	Prospective, but no before-after outcome	A prospective study of 40 MTF patients undergoing SRS using **Combined Vaginoplasty**. The outcome are measured using self-developed (by the authors) indication-specific questionnaires to evaluate the aesthetic, functional, and sexual outcomes of SRS 1 day before stage 0 and 6 months after stage 1.	Assess Satisfaction of MTF patients undergoing SRS using Combined Vaginoplasty.			1. no comparison groups; 2. standardized and validated SRS-specific questionnaires are lacking; 3. short follow up. 4. small sample size	No information on qualify of life. **No comparison groups; didn't address the necessity of the surgery. No standardized and validated SRS-specific questionnaires**

Bouman, van der Sluis et al., 2016 DOI: 10.1016/j.jsxm.2016.06.009	Retrospective	A retrospective survey of 31 transwomen	Assess patient-reported functional and esthetic outcomes, quality of life, satisfaction, and sexual well-being after **primary total laparoscopic intestinal vaginoplasty** in transgender women.	Low Female Sexual Function Index scores (FSFI); satisfactory functional and esthetic results of the neovagina and a good quality of life		restrospective study, no pre- and post- SRS comparison, small sample size	No before and after comparison, small sample size, self-reported outcome. low score on sexual functionality, which is consistent with the founding in Buncamper et al. 2015.
Buncamper et al., 2015 DOI: 10.1111/jsm.12914	Retrospective	Retrospective survey study on 49 transgender women. Primary outcomes were self-reported functional and aesthetic evaluation. Secondary outcomes were the aesthetic evaluation of the vaginoplasty by an independent panel.	Assess if **penile skin inversion neovaginoplasty** performed in transgender women achievers satisfactory functional and aesthetic outcomes, as well as the physical and sexual well-being and	56% patients are sexually dysfunctional according to the Female Sexual Function Index (FSFI) score. Majority of the patients are satisfied with both the functional and aesthetic results of neovaginoplasty using penile skin inversion			No comparison groups. No information on other outcome measures, e.g. qualify of life. Didn't address the necessity of the surgery. Indeed recorded that **56% patients are sexually dysfunctional following the surgery.**
Hess et al., 2016 DOI: 10.1159/000443281	Retrospective	Retrospective review of 96 MtF transgender patients in a single Brazil medical center	Assesses sensitivity of the neoclitoris following a new preparation in MTF SRS.				Description of the surgical procedure (Modified Preparation of the Neurovascular Bundle in MTF patients). **No comparison groups. No information on other outcome measures, e.g. qualify of life. Didn't address the necessity of the surgery.**
Jiang et al., 2018 DOI: 10.1016/j.jsxm.2018.03.085	Retrospective	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	describe the factors influencing patient choice or surgeon recommendation of **vulvoplasty** and to assess the patient's satisfaction with this choice	Vulvoplasty patients were older and had higher body mass index than those seeking vaginoplasty. The majority (63%) of the patients seeking vulvoplasty chose this surgery despite no contra-indications 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		retrospective, non-validated questions, short-term follow-up, and selection bias in how we offer vulvoplasty	Description of the factors influencing patient choice or surgeon recommendation of vulvoplasty and to assess the patient's satisfaction with this choice. **No comparison groups. No information on other outcome measures, e.g. qualify of life. Didn't address the necessity of the surgery.**

LeBreton et al., 2017 DOI: 10.1016/j.jsxm.2016.12.005	Prospective, but no before-after outcome	Prospective study on 28 transgender women at least 18 years old operated on at least 3 months before the study by a single surgeon. Outcomes are clinical outcomes such as medical complications, and self reported questionnaires on general and sexual satisfaction, sexual function, depression, and psychological well-being.	investigate genital sensory detection thresholds in male-to-female transgender women postoperatively (**Vaginoplasty**) and their relation to psychological well-being and variables of satisfaction	Gender-affirming surgery yields good results for satisfaction with appearance and function. Genital sensitivity showed the best results with pressure and vibration		No pre- and post- SRS comparison of the same patient	**Despite being a prospective study, only provided one item to assess sexual satisfaction before and after GAS**. All other outcomes are measured post-SRS. Small sample size; self-reported outcome on statisfication. Focus on genital sensations
Manrique et al., 2018 DOI: 10.1097/PRS.0000000000004122	Retrospective	retrospective chart review of **15** transgender women who underwent gender-confirmation surgery using the **pedicle transverse colon flap**.	present the clinical outcomes and sexual function evaluation when using the pedicle transverse colon flap for gender-confirmation			restrospective, no before-after comparison. small sample size (15)	This paper focus on the clinical outcomes and sexual function evaluation. No discussion on satisfaction or quality of life. No before- and after-comparison.
Massie et al., 2018. Predictors of Patient Satisfaction and Postoperative Complications in Penile Inversion Vaginoplasty DOI: 10.1097/PRS.0000000000004427	Retrospective	retrospective chart review of 117 patients from a single surgeon's experience with **penile inversion vaginoplasty** (performed between July of 2014 to June of 2016). Report on both postoperative complications and patient-reported outcomes.	report both postoperative complications and patient-reported outcomes from the largest cohort in the United States to date to undergo penile inversion vaginoplasty	Most common complications were granulation tissue (26 percent), intravaginal scarring (20 percent), and prolonged pain (20 percent). 94 percent patients reported "feeling positively about their genitals" and 94 percent reported "would do this operation again"). **Seventy-one percent of patients reported resolution of their gender dysphoria**.		restrospective study, no pre- and post- SRS comparison	It is restrospective study. **No pre- and post- SRS comparison.** Patient statisfication is self-reported.
Morrison et al., 2015 DOI: 10.1097/PRS.0000000000001459	Retrospective	A retrospective review of 83 MTF patients who had undergone **rectosigmoid neocolporrhaphy** by a single doctor over 22 years	provide an objective investigation into the safety and efficacy of rectosigmoid neocolporrhaphy for vaginoplasty in male-to-female transsexual patients.	Rectosigmoid vaginoplasties are safe and effective, and have good long-term results in primary and secondary vaginoplasties. Forty-eight patients (58 percent) had complications, but the majority (83.3 percent) were minor and consisted mainly of introital stricture or excessive protrusion of the corpus spongiosum. Overall patient satisfaction with appearance and sexual function was high.		restrospective study, no pre- and post- SRS comparison	Restrospective study, no pre- and post- SRS comparison. Focus on a specific type of vaginoplasty.

Papadopulos, Lelle et al., 2017 DOI: 10.1016/j.jsxm.2017.01.022	Retrospective	Retrospective survey of 47 patients after SRS. Outcomes are reported on self-developed indication-specific questionnaire on postoperative satisfaction and a standardized self-assessment questionnaire (FLZ) on satisfaction and QOL	Analyze patient satisfaction and QOL after SRS.	Self-developed indication-specific questionnaire showed that 91% experienced an improvement of QOL. or the FLZ, the sum score for general life satisfaction (P < .001) was significantly lower than the normative data, whereas the sum score of the satisfaction with health module (P = .038) did not reach statistical significance.		restrospective study, no pre- and post- SRS comparison, subjective to recall bias	restrospective study, no pre- and post- SRS comparison
Raigosa et al., 2015 DOI: 10.1111/jsm.12936	Retrospective cross-sectional	A Retrospective Review of Surgical Technique and Complications in 60 Patients	Review of Surgical Technique and Complications in MTF genital reassignment surgery (GRS)	GRS can provide good functional and aesthetic outcomes in patients with male-to-female GD. However, despite a careful planning and meticulous surgical technique, secondary procedures are frequently required to improve the function and appearance of the neovagina.			This paper focuses on reviewing the surgical technique, clinical outcomes and complications of GRS, no information on other outcomes such as QoL, satisfication, or necessity of the GRS
Salgado et al., 2018 DOI: 10.1155/2018/4907208	Retrospective cross-sectional	A retrospective review of **12** patients in a single hospital	To describe the surgical technique and outcomes in primary sigmoid vaginoplasty in transwomen	Sigmoid vaginoplasty is a reliable technique for achieving a satisfactory vaginal depth that is sexually functional.			The study focuses on description of surgical techniques and functional outcomes. No data on patient satisification, no before-after comparison
Seyed-Forootan et al., 2018 DOI: 10.1007/s00266-018-1088-z	Retrospective cross-sectional	A retrospective comparison of 24 male-to-female transsexual patients based on their complications and levels of satisfaction (16 patients received amnion grafts with fibroblasts, and 8 patients received only amnion grafts without any additional cellular lining.)	compare the results of amnion grafts with amnion seeded with autograft fibroblasts in Reconstruction of Neo-vagina in Male-to-Female Reassignment Surgery.	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.		Retrospective cross-sectional	This paper focuses on comparing two specific surgical techniques in reconstruction of neo-vagina in MTF reassignment surgery. It does not compare with other surgical techniques. The outcomes are most clinical outcomes (e.g. the size of neo-vagina, secretion, sensation). No outcomes are on satisfication or QoL
Sigurjonsson et al., 2017 DOI: 10.1016/j.jsxm.2016.12.003	Retrospective	A retrospective review of **22** patients, with a mean follow-up of 37 months after initial surgery. Main outcome measures are Tactile and vibratory sensitivities of the neoclitoris and questionnaire on satisfaction with orgasm, sexual function, and general satisfaction.	To examine the sensitivity of the neoclitoris and its relation to orgasm and sexual function at least 1 year after GRS.	The vast majority of patients who undergo male-to female GRS experience orgasm and are satisfied with the surgery.	follow up is long term (37 month on average)	Retrospective, no before-after comparison.	This paper focuses on the clinical/functional outcome of SRS, only one summary question about the satisfaction of the SRS, no before-after comparison, no data on general health or QoL.

Simonsen et al., 2016 DOI: 10.3109/08039488.2015.1081405	Retrospective	A retrospective registery study of 104 sex-reassigned individuals in Demark.	(1) To investigate **psychiatric morbidity before and after sex reassignment surgery (SRS)** among Danish individuals who underwent SRS during 1978-2010., (2) To investigate mortality among Danish individuals who underwent SRS during 1978-2010.		Long term natioal sample: the sample comprised 98% (n = 104) of all transexual individuals in Denmark. The outcomes are identified from national registries (Danish Psychiatric Central Research	Despite the over-representation of psychiatric diagnoses both pre- and post-SRS the study found that only a relatively limited number of individuals had received diagnoses both prior to and after SRS. **This suggests that generally SRS may reduce psychological morbidity for some individuals while increasing it for others.**	This study has several strengths: (1) exhaustive national sample over a long period of time; (2) outcome from national registries, not self reported. The results are inconclusive, as the authors concluded "**generally SRS may reduce psychological morbidity for some individuals while increasing it for others**."
Thalaivirithan et al., 2018 DOI: 10.4103/ijps.IJPS_62_18	Retrospective	Retrospective review of 30 transwomen who underwent embryonic equivalents-based sex reassignment surgery (MFEEbSRS) by two independent surgeons	To evaluate the esthetic and functional outcome of **embryonic equivalents-based male-to-female sex reassignment surgery** in transwomen using the institutional scoring	The aesthetic and functional outcome in all the patients was good.			The study focuses on aesthetic and functional outcomes. No data on satistification, QoL, mental well-being. No before-after comparison.
Castellano et al., 2015 DOI: 10.1007/s40618-015-0398-0	Retrospective, case-control	Case-control of 60 pairs of transsexuals and healthy people in Italy. Outcomes measures are testosterone,estradiol, LH and World Health Organization Quality of Life (WHOQOL-100) self-reported questionnaire. Student's t test was applied to compare transsexuals and controls. Multiple regression model was applied to evaluate WHOQOL's chosen items and LH.	To gather information on QoL, quality of sexual life and body image in transpeople at least 2 years after SRS,to compare these results with a control group and to evaluate the relations between the chosen items and hormonal status.	This study highlights general satisfaction after SRS. In particular, transpeople's QoL turns out to be similar to Italian matched controls. LH resulted inversely correlated to body image and sexual life scores.	some confounding control via the case-control design	retrospective, no before-after information of the same subject.	This study is the only matched case-control study in the cited references here. There is no before-after comparison of the same patients, only compared transexual people and healthy people. The controls are matched only a few demographic and SES covariates, can not rule out unmeasured confounding (e.g. mental well-being before SRS, family background, work environment).
Cardoso da Silva et al., 2016 DOI: 10.1016/j.jsxm.2016.03.370	Duplicate (prospective, before-after)						Reviewed in Assertion 1. This is one of the few prospective studies which provide pre- and post-surgery comparison of the same patients. Specific to this assertion, the results on the QoL measures are mixed. In particular, it found "domains I (physical health) and III (level of independence) were significantly worse after SRS." So it is not as clear cut as stated in the Assertion.

Owen-Smith et al., 2018 DOI: 10.1016/j.jsxm.2018.01.017	Duplicate (retrospective)					Reviewed in Assertion 1. Besides the methodological limitations pointed out earlier, a limitation specific to this assertion is that the paper did not directly report the satisfaction rate of patients population and only compared non-treatment vs. treatment groups. Also, the outcome measures (include body-gender congruence, body image satisfaction, depression, and anxiety) do not include measures on physical and sexual functions
van de Grift, Elaut et al., 2018 DOI: 10.1080/0092623X.2017.1326190	Duplicate (prospective, no before-after)					Reviewed in Assertion 1. Specific to this assertion, the paper indeed reports high satisfication rate among SRS patients, but is subject to nonresponse bias because of the low respondent rate; it also has a substantial portion of missing data

WPATH Assertion # 11

Gender-affirming surgical procedures have been shown to relieve symptoms of gender dysphoria and improve mental health (Owen-Smith et al., 2018; van de Grift, Elaut et al., 2017). Page S173

Name	Study-Design/Methodology	Aim/Objective	Conclusions	Strengths	Limitations	Notes
Owen-Smith et al., 2018 DOI: 10.1016/j.jsxm.2018.01.017	duplicate					Reviewed in Assertion 1, 10. Specific to this assertion, the study didn't have before-after SRS comparison. It focuses on the comparison between people who received SRS vs not re-received SRS. As commented earlier, such comparison is subject to severe confounding, and does not provide direct evidence for the Assertion of "relieve symptoms of gender dysphoria and improve mental health"
van de Grift, Elaut et al., 2017 DOI: 10.1097%2FPSY.0000000000000465	duplicate					Reviewed in Assertion 1, 2, 10. Specific to this assertion, the study has measures on various post-SRS outcomes (e.g. complications, satisfaction, QoL, happiness, psychological symptoms). However, except for psychological symptoms, it didn't collect before-after data on any other outcomes, and thus could not conduct a direct before-after comparison of these outcomes of the same patients. Therefore, it provides no direct evidence supporting the Assertion of "relieve symptoms of gender dysphoria and improve mental health"

Ettner Assertion # 1

Decades of careful and methodologically sound scientific research have demonstrated that gender-affirming surgeries are safe and effective treatments for severe gender dysphoria and, indeed, **for many people suffering from gender dysphoria, the only effective treatment**. Ettner Report Para. 50.							
Name	**Study-Design**	**Methodology**	**Aim/Objective**	**Conclusions**	**Strengths**	**Limitations**	**Notes**
Pfafflin & Junge (1998) https://www.researchgate.net/publication/299412537_Sex_Reassignment_Thirty_Years_of_International_Follow-up_Studies_after_Sex_Reassignment_Surgery_A_Comprehensive_Review_1961-1991	Literature review	Literature review of thirty years of international follow-up studies of approximately two thousand persons who have undergone sex reassignment surgery in 1961-1991. It includes more than seventy individual studies and eight previously published reviews from many countries and four continents	A comprehensive literature review of thirty years of international follow-up studies of approximately two thousand persons who have undergone sex reassignment surgery.				This is a 300 page book in German, reviewing a large literature that involves 2000 person who underwent SRS between 1961-1991. I reviewed the 6 page translated English abstract. The abstract states " Sex reassignment, properly indicated and performed, has proven to be a valuable tool in the treatment of individuals with transgenderism. It is, however, **not the only powerful change agent in sex reassignment**." So this **directly contradicts** the Assertion of "for many people suffering from gender dysphoria, the only effective treatment"
Smith et al., (2005) DOI:10.1017/s0033291704002776	Prospective	A prospective study of 162 (out of 325 applicants) transexual patients who underwent SRS in the Netherlands. Gender dysphoria was measured with the Utrecht Gender Dysphoria Scale. Follow-up time is 1-4 years	To study the outcomes of sex reassignment, potential differences between subgroups of transsexuals, and predictors of treatment course and outcome.	The results substantiate previous conclusions that sex reassignment is effective. Still, clinicians need to be alert for non-homosexual male-to-females with unfavourable psychological functioning and physical appearance and inconsistent gender dysphoria reports, as these are risk factors for dropping out and poor post-operative results.	prospective		This study uses **before-after SRS comparison of the same patients** to provide evidence for SRS in reducing gender dysphoria as well as improvement in various outcomes on body image and psychological functioning. However, the paper focused solely on the population who underwent SRS, it **provides no evidence** for the Assertion of "for many people suffering from gender dysphoria, the only effective treatment." It is also dated (published in 2005). It is unclear whether the conclusion's applicability today.
Jarolim (2009) - DOI: 10.1111/j.1743-6109.2009.01245.x	Retrospective	A retrospective **3-month follow-up** study of MTF patients' opinions following SRS in 129 patients having a primary procedure. Main outcomes are sexual functions and complications 3 months after surgery. The surgical techniques are described in detail.	To evaluate the results of surgical reassignment of genitalia in male-to-female transsexuals.			Retrospective	The paper focuses on describing the surgical details and outcomes of sexual functions and complications. It did not discuss the effect SRS on gender dysphoria, **nor did it provided any evidence for the Assertion** of "for many people suffering from gender dysphoria, the only effective treatment."

Ettner Assertion # 2						
In 2007, Gijs and Brewayes analyzed 18 studies published between 1990 and 2007, encompassing 807 patients. The researchers concluded: "Summarizing the results from the 18 outcome studies of the last two decades, the conclusion that [gender-affirming surgery] is the most appropriate treatment to alleviate the suffering of extremely gender dysphoric individuals still stands: Ninety-six percent of the persons who underwent [surgery] were satisfied and regret was rare." Ettner Report Para.						
Name	**Study-Design/Methodology**	**Aim/Objective**	**Conclusions**	**Strengths**	**Limitations**	**Notes**

Gijs, L., & Brewaeys, A. (2007).	Literature review	Literature review of 18 studies, involving both MTF and FTM, including many reviewed here (e.g. Smith et al. 2005; Lawrance, 2003, Lobato, et al. 2006; Rehman, et al. 1999; Hepp et al., 2002; De Cuypere, et al. 2005). Qualitative summary	To provide a literature review of SRS in transgender people				Immediately after stating the statement quote in the Assertion (p. 215), the authors acknowledged that "However, **even today this conclusion is based on methodologically less than perfectly designed studies**." Specifically, the paper wrote "Not one of the reviewed outcome studies was a controlled one...In many studies, sound psychometric instruments were not used. **Especially disturbing is that many researchers did not directly measure gender dysphoria as the main outcome variable but instead used derivative measures**, for example, satisfaction with surgery, sexual and interpersonal relationships, occupational and global functioning, or quality of life in general." It also acknowledges a few other methodological shortcomings, like attrition or selection bias of the patient sample.

Ettner Assertion # 3

In 2019, Cornell University published a literature review called What Does the Scholarly Research Say about the Effect of Gender Transition on Transgender Well-Being? The researchers enumerated the following conclusions (omitted here due to length): Ettner Report Para. 56.

Name	Study-Design	Methodology	Aim/Objective	Conclusions	Strengths	Limitations	Notes
Cornell University What We Know: The Public Policy Research Portal (2019). https://whatweknow.inequality.cornell.edu/topics/lgbt-equality/what-does-the-scholarly-research-say-about-the-well-being-of-transgender-people/	Website						This website collects 51 studies, about half of which are reviewed here. The strengths and weaknesses have been discussed in our review. Overall, the vast majority of the studies in this collection suffers from many methodogical problems, as pointed out also in multiple literature reviews (e.g. Gijs and Brewaeys, 2007; T'Sjoen et al., 2019; White Hughto & Reisner, 2016; Nobilli et al. 2018). Many results are not as clear cut or of direct evidence as stated in the assertion.
Colizzi, M. , Costa, R., & Todarello (2014)	Prospective	A prospective longitudinal study of 118 patients underwent **hormone therapy**	To evaluate the presence of psychiatric diseases/symptoms in transsexual patients and to compare psychiatric distress related to the **hormonal intervention** in a one year follow-up	Hormonal treatment seemed to have a positive effect on transsexual patients' mental health.	prospective study		This study focuses on hormone therapy, not directly related to SRS.

Ettner Assertion # 4							
studies conducted in countries throughout the world likewise conclude that gender-affirming surgery is an extremely effective treatment for gender dysphoria. For example, a 2001 study published in Sweden states: "The vast majority of studies addressing outcome have provided convincing evidence for the benefit of 27 [gender-affirming] surgery in carefully selected cases." Ettner Report Para. 57.							
Name	**Study-Design**	**Methodology**	**Aim/Objective**	**Conclusions**	**Strengths**	**Limitations**	**Notes**
Landen, M. et al. (2001). Done is done – and gone is gone: Sex reassignment surgery is presently the best cure for transsexuals. Lakartidningen, 98(30-31), 3322–26.	Retrospective	Article in Swedish, only reviewed English abstract, which provides no information on study design or methodology.	To summarize the state of the art regarding work-up and treatment of transsexuals.			Small sample size.	This article is in Swedish. I couldn't find the original paper and thus only reviewed the English abstract, which does not contains any information about the study design, methods and outcomes. The paper states indeed stated that the evidence for the benefit of 27 [gender-affirming] surgery is in "**carefully selected cases**." The study is dated (2001) and short; most later literature review (e.g. Gijs, L., & Brewaeys, A. 2007) acknowledges caution about the methodology and conclusion in this field

Ettner Assertion # 5							
Patient satisfaction is an important measure of effective treatment. Achieving functional and normal physical appearance consistent with gender identity alleviates the suffering of gender dysphoria and enables the patient to function in everyday life. Studies have shown that by alleviating the suffering and dysfunction caused by severe gender dysphoria, gender-affirming surgery improves virtually every facet of a patient's life. This includes**satisfaction with interpersonal relationships and improved social functioning**. Ettner Report Para. 58.							
Name	**Study-Design**	**Methodology**	**Aim/Objective**	**Conclusions**	**Strengths**	**Limitations**	**Notes**
Rehman, J., Lazar, S., Benet, A., Schaefer, L, & Melman, A. (1999).	Retrospective	A retrospective review of self reported sex and surgery satisfaction among 28 MTF transsexual patients post SRS. Self-developed questionaire was used to collect data. 11 patients have additional data from in person interviews	Investigate sex and surgery satisfaction among MTF transsexual patients post SRS.	Twenty-seven of the 28 patients reported high satisfaction in their perceptions of the quality of their lives. Seventeen reported satisfaction in their employment after surgery. Twenty-one reported that SRS solved most of their emotional problems. However, some were, to a degree, **disappointed because of difficulties experienced postoperatively in adjusting satisfactorily as women both in their relationships with men and in living their lives generally as women**.		1. Retrospective study, no information before SRS, no before-after comparison. 2. Low response rate (28 out of 44 alive patients responded, 3 died), **selection/respondent bias.**	The first weakness is that it is retrospective and cross-sectional; no data obtained before SRS, no before-after comparison. The second weakness is the potential nonresponse bias, only 60% of the patients respondents. The non-respondents and the respondents might be systematically different, e.g. it is likely that patients who feel more satisfied were more likely to respond.

Johansson, A., Sundbom, E., Ho jerback, E., et. al. (2009).	Prospective	A prospective and longitudinal study of 42 patients: 5 years in the process and 2 years post surgery	To investigate outcome in terms of clinicians' and patients' evaluation of the process of sex reassignment.	The clinicians rated the global outcome as favorable in 62% of the cases, compared to 95% according to the patients themselves, with no differences between the subgroups. **The general evaluation of the surgery treatment** showed that of 33 patients (32 with genital surgery and one with only mastectomy), 22 (66.7%) were satisfied, seven (21.2%) were neither/nor, and four (12.1%) were dissatisfied	prospective and longitudinal		There is a large discrepancy between global outcome evaluation by clinicians and patients, with the patients reporting a much higher favorable rate (33%) than the clinicians. This shows the potential bias in self-reported satisfaction in patients, pointing to the necessarity of independent physician review. Also, 22 out of 33 (66.7%) patients were satisfied with the SRS treatment. So it is certainly not as consistent and overwhelmingly positive as the Assertion.
Hepp U, Klaghofer R, Burkhard-Kubler R, Buddeberg C. (2002).	Retrospective	In a retrospective study, 33 transsexual patients, 22 male-to-female transsexuals (MFTS), and 11 female-to-male transsexuals (FM-TS), were interviewed 53–121 months after their first referral to the psychiatric department of a university hospital. 25 patients had gone through surgical sex reassignment, while 29 were currently undergoing hormonal treatment.	physical and psychosocial well-being was satisfactory. Psychometric measures yielded normal values, with some pathological findings regarding personality traits. In the majority of patients, self- and observer-rating appraisals of gender-specific physical apearance were equally positive.			1. retrospective; 2. no control group; 3. small sample size.	The article is in German; I only reviewed the English abstract, which does not contain all the information on the outcome measures and statistical analysis, e.g. it is unclear whether the study measured outcome directly on " interpersonal relationships and improved social functioning." Similar as many studies in this literature, it has at least three methodological shortcomings: (1) retrospective; (2) no control group; (3) small sample size.
Ainsworth, T. & Spiegel, J. (2010)	duplicate						Reviewed in Assertion 1. Specific to this assertion, the paper has outcomes measured social functioning. But it suffers the same methodogical shortcomings (e.g. retrospective) as pointed notes on Assertion 1.
Smith et al. (2005)	duplicate						Reviewed in Supple. Assertion1. Specific to this assertion, this paper reported results on various measures of psychological functioning (e.g. shyness, anxiety, depression, negativism, sensitivity), but none of these are specific to "satisfaction with interpersonal relationships and improved social functioning"

Ettner Assertion # 6
continued from Ettner Assertion #5 …improvement in self-image and satisfaction with body and physical appearance… Ettner Report Para. 58.

Name	Study-Design	Methodology	Aim/Objective	Conclusions	Strengths	Limitations	Notes
Lawrence, A. (2003).	Retrospective	A retrospective survey of 232 MTF patients using self-developed questionaire. (**The study design and patient sample is the same as in Lawrence 2005, 2006)**	To examined factors associated with satisfaction or regret following sex reassignment surgery	Participants reported overwhelmingly that they were happy with their SRS results and that SRS had greatly improved the quality of their lives. None reported outright regret and only a few expressed even occasional regret. Dissatisfaction was most strongly associated with unsatisfactory physical and functional results of surgery.The physical results of SRS may be more important than reoperative factors in predicting postoperative satisfaction or regret.		(1) retrospective; (2) low response rate of survey (32%)	The study has four post-SRS outcomes: (1) overall happiness with SRS result; (2) Improved QOL; (3) Regret; (4) Reversion (to living as a man after SRS). **None of these outcomes is specific to "improvement in self-image and satisfaction with body and physical appearance " as stated in the Asssertion.**
Weyers, S. et al. (2009)	Retrospective	A retrospective review of fifty transsexual women who had undergone SRS 6 months earlier were recruited in the Netherlands. Self-reported physical and mental health using the Short-Form-36 (SF-36) Health Survey; sexual functioning using the Female Sexual Function Index (FSFI).	To gather information on physical, mental, and sexual well-being, health-promoting behavior and satisfaction with gender-related body features of transsexual women who had undergone SRS.	Transsexual women function well on a physical, emotional, psychological and social level. With respect to sexuality, **they suffer from specific difficulties**, especially concerning arousal, lubrication, and pain.		(1) retrospective; (2) did not report the follow-up duration other than it is six months. (3) potential recruitment bias (50 out of 70 responded).	The results are not clear cut positive across all outcomes as stated in the Assertion. In addition, the paper has a number of shortcomings: (1) retrospective and cross-sectional, no before-after comparison; therefore no data supporting the Assertion of "**improvement** in self-image and satisfaction with body and physical appearance". (2) did not report the follow-up duration other than all patients had SRS at least six months ago. So it is the definition of long-term is unclear; (3) there is a potential recruitment bias (50 out of 70 responded. The paper stated “A study of the medical records of nonresponders and nonparticipants revealed that a volunteering bias may have been unlikely: we found non-significant differences in age, interval since surgery, psychiatric morbidity, operative techniques and complications between the study population and nonparticipating individuals. " However, such a justification is weak and doesn't consider the high possibility of unmeasured confounding.

Smith et al. (2005)	duplicate						Reviewed in Supple. Assertion 1. Specific to this assertion, this paper **reported evidence supporting** the assertion of "improvement in self-image and satisfaction with body and physical appearance"

Ettner Assertion # 7

continued from Ettner Assertion #5 ...and greater acceptance and integration into the family… Ettner Report Para. 58.

Name		Study-Design/Methodology	Aim/Objective	Conclusions	Strengths	Limitations	Notes
Lobato, M., Koff, W, Manenti, C., Seger, D. et al. (2006).	Retrospective	Follow-up study of 19 patients post SRS in Brazil; outcomes are obtained via questionnaire. Follow-up time is between 1-2.5 years	To examine the impact of sex reassignment surgery on the satisfaction with sexual experience, partnerships, and relationship with family members in a cohort of Brazilian transsexual patients.	Sexual experience was considered to have improved by 83.3% of the patients, and became more frequent for 64.7% of the patients. For 83.3% of the patients, sex was considered to be pleasurable with the neovagina/neopenis. In addition, 64.7% reported that initiating and maintaining a relationship had become easier. The number of patients with a partner increased from 52.6% to 73.7%. **Family relationships improved in 26.3% of the cases, whereas 73.7% of the patients did not report a difference.**		1. retrospective, 2. small sample size; 3: respondent rate is 73% (19 out of 26) - potential respondent bias	The paper found that "Family relationships improved in 26.3% of the cases, whereas 73.7% of the patients did not report a difference. " Therefore, **it is not a clear cut as stated in the Assertion**. The paper in fact showed that that **family relationship only improved in 1/4 of the patients.**

Ettner Assertion # 8

Studies have also shown that gender-affirming surgery **improves patients' abilities to initiate and maintain intimate relationships**. Ettner Report Para. 59.

Name	Study-Design	Methodology	Aim/Objective	Conclusions	Strengths	Limitations	Notes
Lawrence (2005), Sexuality after male-to-female sex reassignment surgery. Archives of Sexual Behaviour, 34(2), 147–166. https://doi.org/10.1007/s10508-005-1793-y. (full cite not provided in appendix, found in WPATH reference list)	Retrospective	A retrospective survey of 232 MTF patients using self-developed questionaire	To investigate sexual behaviors and attitudes before and after MTF SRS	Description of the prevalence of various sexual behaviors and attitudes before and after MTF SRS.		1. retrospective; 2. low response rate of survey (32%)	This is a descriptive study, not a comparative study. It describes the prevalence of various sexual behaviors and attitudes before and after MTF SRS. But there is no formal before-after comparative analysis or conclusions. There is no result in this paper supporting the Assertion "Studies have also shown that gender-affirming surgery improves patients' abilities to initiate and maintain intimate relationships." Two weakness of the methodology: (1) retrospective; (2) low response rate of survey

Imbimbo, C., Verze, P., Palmieri, A., et al (2009).	Restrospective	163 male patients who had undergone gender-transforming surgery at the authors' institution were requested to complete a patient satisfaction questionnaire, 139 (85%) responded. Follow-up time is 12-18 months.	To arrive at a clinical and psychosocial profile of male-to-female transsexuals in Italy through analysis of their personal and clinical experience and evaluation of their **postsurgical satisfaction levels SRS**.	Almost all of the patients were satisfied with their new sexual status and expressed no regrets. **Statement related to the Assertion** "75% had a more satisfactory sex life after SRS"	1. restrospective survey, 2. the questionnaire was not validated due to the inexistence of a validated questionnaire in this area of study.	This is a descriptive study, not a comparative study. There is no before-after SRS comparison. Because it is a retrospective survey, it is subject to recall bias. There is **no direct evidence in the paper** that supports the Assertion of "gender-affirming surgery improves patients' abilities to initiate and maintain intimate relationships." The only relevant statement of "75% had a more satisfactory sex life after SRS" is vague and can be purely on physical functions.
Klein, C. & Gorzalka, B. (2009)	Literature review	Outline cross-sex hormone therapy and SRS techniques, discuss the potential roles of cross-sex hormone therapy and SRS on sexual function, and **review the peer-reviewed literature** published in English on postoperative sexual functioning in MtF and FtM transsexuals.	To discuss the potential impact of cross-sex **hormone therapy and SRS** on sexual function and to summarize the published empirical research on postsurgical sexual functioning in male-to-female (MtF) and female-to-male (FtM) transsexuals.	Transsexuals appear to have adequate sexual functioning and/or high rates of sexual satisfaction following SRS. Further research is required to understand fully the effects of varying types and dosages of cross-sex hormone therapies and particular SRS techniques on sexual functioning.		This is a qualitative literature review on sexual function post both hormone therapy and SRS. The authors noted "From this review it is clear that there is **great variability in the sexual functioning of post-operative transsexuals**, and that **no clear outcome can be predicted with respect to whether surgery will have a positive or negative impact on sexual function**." Therefore, it does not support the Assertion.
De Cuypere, G., T'Sjoen, G., Beerten, R., Selvaggi, G., et al. (2005).	Restrospective	A long-term follow-up study of 55 transsexual patients (32 male-to-female and 23 female-to-male) post-sex reassignment surgery (SRS) in the Nethelands	To evaluate sexual and general health outcome post SRS	After SRS, the transsexual person's expectations were met at an emotional and social level, but **less so at the physical and sexual level** even though a large number of transsexuals (80%) reported improvement of their sexuality.	1. retrospective; 2. low response rate (55 out of 107, 51.4%)	The authors concluded that "After SRS, the transsexual person's expectations were met at an emotional and social level, but less so at the physical and sexual level even though a large number of transsexuals (80%) reported improvement of their sexuality." So this at least shows the effect of SRS on relationships is not a clear cut as stated by the relevant Assertion
Lawrence (2006) (full cite not provided in appendix, found on Cornell website)	Retrospective	A retrospective survey of 232 MTF patients using self-developed questionaire. (The study design and patient sample is the same as in Lawrence 2005, 2006)	To examine preoperative preparations, complications, and physical and functional outcomes of male-to-female sex reassignment surgery (SRS)	Satisfaction with most physical and functional outcomes of SRS was high; participants were least satisfied with vaginal lubrication, vaginal touch sensation, and vaginal erotic sensation.	(1) retrospective; (2) low response rate of survey (32%)	The paper focuses on surgical complications and physical and functional outcomes. It doesn't provide direct data supporting this Assertion (Suppl. 8) on "patients' abilities to initiate and maintain intimate relationships. "
Lobato et al., 2006	duplicate					Reviewed in Supple. Assertion 7. Relevant to this Assertion (Suppl. 8), the paper found "64.7% reported that initiating and maintaining a relationship had become easier" Therefore, **it is not a clear cut as stated in the Assertion**

Jarolím et al. (2009)	duplicate	Reviewed in Supple. Assertion 1. It focuses on describing the surgical details and outcomes of sexual functions and complications, **none of which is specific to this Assertion** (Suppl. 8) on "patients' abilities to initiate and maintain intimate relationships. "
Smith et al. (2005)	duplicate	Reviewed in Supple. Assertion 1. This paper reported results on various measures of psychological functioning (e.g. shyness, anxiety, depression, negativism, sensitivity), but none of these are specific to the Assertion on "patients' abilities to initiate and maintain intimate relationships. "
Rehman et al. (1999)	duplicate	Reviewed in Supple Assertion 5. The paper **did not report any outcome specific to this Assertion**, namely " patients' abilities to initiate and maintain intimate relationships. "

Ettner Assertion # 9

Multiple long-term studies have confirmed these results. Ettner Report Para. 60.

Name	Study-Design	Methodology	Aim/Objective	Conclusions	Strengths	Limitations	Notes
Johansson et al. (2010) doi: 10.1007/s10508-009-9551-1 (not listed in the appendix – found from the Cornell website)	Retrospective	Follow-up study of 42 Swedish transexuals (5 year in the process or 2-year post SRS). Outcomes are extracted via semi-structured interview.	To evaluate the outcome of sex reassignment as viewed by both clinicians and patients, with an additional focus on the outcome based on sex and subgroups.	The clinicians rated the global outcome as favorable in 62% of the cases, compared to 95% according to the patients themselves, with no differences between the subgroups. Based on the follow-up interview, more than 90% were stable or improved as regards work situation, partner relations, and sex life, but 5–15% were dissatisfied with the hormonal treatment, results of surgery, total sex reassignment procedure, or their present general health.		1. Retrospective 2. Attrition (42 out of 60 patients, 70% respondent rate)	Besides the common methodological shortcomings (retrospective and attrition), the paper found a large discrepancy between clinician and patients assessment (patients more positive than clinician), similar to the previous finding by the same author (Johansson et al. 2009). There are 5–15% patients who were dissatisfied with the hormonal treatment, results of surgery, total sex reassignment procedure, or their present general health. So the results are not as clear cut as stated in the Assertion.

Vujovic S, Popovic S, Sbutega-Milosevic G, Djordjevic M, Gooren L. (2009).	Retrospective	A retrospective review of subjects applying for sex reassignment in 20 years in Serbia. 147 patients in total	To describe a transsexual population seeking sex ressignment treatment in Serbia	The relatively young age of those applying for sex reassignment and the sex ratio of 1:1 distinguish the population in Serbia from others reported in the literature.		Retrospective	This paper focuses on describing the demographic characteristics of transexual population. **It does not specify any outcome measures (e.g. QoL, satistification)**. The only related statements about post-SRS outcomes are (1) "In our population, there were no cases who regretted sex reassignment treatment", and (2) "After sex reassignment surgery, they feel more attractive and confident to live the lives of women", but **there is no data supporting the claim.**
Weyers et al. (2009)		duplicate					Reviewed in Supple Assertion 6. Related to this specific Assertion, a few shortcomings: (1) did not report the follow-up duration other than all patients had SRS at least six months ago. So it is not clear how long term is the follow up. (2) The results are not clear cut positive across all outcomes as stated in the Assertion, e.g. the paper found " **they suffer from specific difficulties, especially concerning arousal, lubrication, and pain**"
Hepp et al. (2002)		duplicate					Reviewed in Supple. Assertion 5. It is in German and I only reviewed the English abstract. It is indeed a long-term follow-up (53–121 months). Besides the methodological shortcomings, it is unclear whether the study measured outcome directly on all the outcomes stated in Supple Assertions 5-8
Imbimbo et al. (2009)		duplicate					Reviewed in Supple. Assertion 8. Besides the shortcomings that were pointed out, the follow-up time is 12-18 months, which is unclear to fit into the definition of "long term"
Lobato et al. (2006)		duplicate					Reviewed in Supple. Assertion 5, follow up time is 1 to 2.5 years, whether that fits in the definition of long-term is unclear. As reviewed before, the results are not clearcut.

Ettner Assertion # 10

Research shows that the risk of suicide can be significantly diminished with prompt and effective treatment. Ettner Report Para. 77.

Name	Study-Design	Methodology	Aim/Objective	Conclusions	Strengths	Limitations	Notes

Bauer, G., Scheim, A., Pyne, J. et al. (2015).	Respondent-driven sampling survey	Respondent-driven sampling (RDS) survey of 380 transgender people on suicide outcomes. Among these, 110 subjects are used in the counterfactual analysis related to medical transition.	To identify intervenable factors (related to social inclusion, transphobia, or sex/gender transition) associated with reduced risk of past-year suicide ideation or attempt, and to quantify the potential population health impact.	Large effect sizes were observed for this controlled analysis of intervenable factors, suggesting that interventions to increase social inclusion and access to medical transition, and to reduce transphobia, have the potential to contribute to substantial reductions in the extremely high prevalences of suicide ideation and attempts within trans populations. Such interventions at the population level may require policy change.	Statistically rigorous (one of the most statistically advanced studies in the field); used the concept of counterfactual modeling (standard causal inference terminology),	no control of the different characteristics between intervention and intervention group.	Relevant to the assertion, the paper states (page 12 of 15) "The process of medically transitioning overall was more complex …We did not observe an increased risk in this sub-group among those who completed a medical transition (RR = 0.51; 0.07, 3.74)". Exact number is reported on the second page of Table 4 (page 11 of 15), top row: among the subjects who completed medical transition (100 Subjects), the relative risk of suicidal attempt is 0.51 with 95% confidence interval (0.07, 3.74), which is not statistically significant. So **the claim of "significantly diminished" is not supported by the statistical analysis**.

Ettner Assertion # 11

Moreover, gender dysphoric individuals have a profound discomfort or disgust of their genitalia. Without effective treatment as outlined above, this often leads to attempts at surgical self-treatment (SST), which can result in lasting physical trauma or death. Ettner Report Para. 78.

Name	Study-Design	Methodology	Aim/Objective	Conclusions	Strengths	Limitations	Notes
Brown, G. & McDuffie, E. (2009)	Survey	Information of respondent of a survey to transgender inmates in prison systems in the U.S. was qualitatively analyzed and summarized.	Provide a summary of health care policies on transgender inmates in prison systems in the United States.	Note: not relevant to the assertion		Low response rate of the survey (46 respondents, 6 states no response).	The assertion that "this **often** leads to attempts at surgical self-treatment (SST)" is **not supported by the cited paper**, which states "**this rarely occurs in the community absent psychosis** " and reports (but without detailed data) that "the authors have firsthand knowledge of completed autocastration and/or autopenectomy in six facilities in four states." The paper contains no information on the **frequency** of this behavior. During my review, I found Brown (2014) reported that "Five percent of inmates reported that they had attempted (2%) or completed (3%) autocastration while incarcerated." **This percentage supports the occurance is rare rather than often.**

Ettner Assertion # 12

In addition, a systematic meta-analysis on publications performed by German researchers included 1,100 post-surgery participants. Seven different measures of quality of life were employed. The researchers concluded that gender-affirming surgery positively affects well being, sexuality, and quality of life in general. Ettner Report Para. 116.

Name	Study-Design	Methodology	Aim/Objective	Conclusions	Strengths	Limitations	Notes

Weinforth, et al., 2019.	Literature review	Review of 13 studies (2 prospective, 11 restrospective)	Provide a review of the currently available data on QoL after male-to-female SRS		Mixed prospective and retrospective designs, different questionaries used for outcome. Most are short term outcomes. No meaningful summaries.	This is a literature review, not meta-analysis, no formal statistical synthesis, only qualitative summaries. Mixed prospective and retrospective designs, different questionaries used for outcome, most studies are on short term outcomes. No meaningful summaries. Only two studies are prospective (Cardoso da Silva et al.; Lindqvist et al.), which have been reviewed in Assertion 1 and both showed mixed to negative results. The other 9 studies are all of low quality (retrospective/cross sectional studies, small sample sizes, no causal inference methods – no formal confounding adjustment other than regression. The authors acknowledges "prospective studies with standardized methods of assessing quality of life and with longer follow-up times would be desirable.

UNITED STATES DISTRICT COURT

FOR THE WESTERN DISTRICT OF NORTH CAROLINA

CHARLOTTE DIVISION

Case No. 3:22-cv-0191

KANAUTICA ZAYRE-BROWN,)
)
Plaintiff,)
)
v.)
)
THE NORTH CAROLINA)
DEPARTMENT OF PUBLIC)
SAFETY, et al.,)
)
Defendants.)

Deposition of FAN LI, Ph.D.

(Taken by the Plaintiff)

Raleigh, North Carolina

Friday, August 11, 2023

Reported by: Marisa Munoz-Vourakis -
RMR, CRR and Notary Public

Okay. So what this study is proposed to do is try to use real world data, real world data means like observational study or the historical data, historical clinical trial or current like electronic health record, use that data to combine that data, this clinical trial data, and that is, yeah, so there are a lot of challenges, methodology challenges there, and then that's what this grant is supposed to do to develop those methods.

Q. Okay. So it's about finding methods to be able to use that real world data?

A. Well, combination, basically clinical trials. Like you can have clinical trials. You can also have external data. How do you properly combine them?

Q. Okay. And can you tell me about the second grant that is listed?

A. Oh, the second one, that's a funny one. So the second one is this Covid-19 Enhancement. So this actually is better to read it. So second and fourth actually kind of connected.

So the fourth one is my, again, I'm just -- I'm not the primary investigator there. So if you look at that it's called Co-I, it's a coinvestigator.

So the number four, that was the kind of

the mother grant with my collaborator Laine Thomas got the grant from PCORI. PCORI stand for Patient Centered Outcome Reference Institute.

So that was the primary grant, and then when Covid-19 hit, the agency had more money, and so then we asked, like we basically ask for supplement to do additional methodology work. So that's why you have this number two. So that's actually just, again, a supplement of the grant number four.

Q. Okay. And at a very high level, what was grant number four?

A. Oh, again --

Q. What was the goal?

A. The goal is try to develop statistical methods to improve the design and the conduct of the observational study, particularly this type of subgroup analysis. So high level is the observational study, so the methodology and the design and the methodology. There are challenges, and we propose new methods to solve those challenges.

Q. Okay. So going back to the substance of your report, can you summarize your conclusion in your report for me?

A. Absolutely. Give me a minute.

So I will just read it.

Q. Actually, I don't want you to read it. Can you summarize it for me?

A. Yeah, I know. So I think I should -- okay, I should start with what my assignment was. So I was asked to assess whether the assertions made by Dr. Ettner and WPATH, the specific assertions made by them are supported by the reference they cited. And my conclusion is I do not believe that their assertion, specific assertions point by point are supported by those -- well, supported by the body of literature they cited.

In other words, I will say that the evidence cited by Dr. Ettner and WPATH do not provide reasonable or sufficient support for the assertions, specific assertions.

Q. Okay. And what do you mean by reasonable?

A. What do I mean by reasonable is reasonable judged by me, my expertise as an expert in the so-called comparative effectiveness research.

Like I'm an expert, so as a statistician, my expert is actually called inference. Well, the inference is essentially to determine what kind of evidence needed to establish the effectiveness, effectiveness or safety of a treatment, and that's my expertise. And based on my expertise, after I review,

the references cited by them and look at the specific assertion, I don't think that they provide support, provide -- it's just not enough.

Like if I'm a medical -- if I'm a reviewer of a medical journal, if you submit a paper with those assertions and those references, I would reject it on the ground that the evidence is not enough.

Q. Okay. And so how much is enough?

MR. RODRIGUEZ: Objection, vague. You can answer.

A. Yeah, I think your question is very vague, and it's beyond more than being vague, it's also this is all very case by case.

So I read a paper, for example, if it says if you want to establish the effectiveness of say a vaccine, and then I would expect to see evidence, clinical evidence from a randomized trial or well-designed observational study, and if it does not provide that, or the study does not have good quality, for example, those retrospective study assay, then I will judge it's not enough. So it's highly case by case.

So, again, that's why I was very specific. So in my report, I provide not a blanket statement. I went case -- point-by-point the assertion and exam

one-by-one and say why I believe that is not enough.

So in order to answer that question, I think it's better for you to actually go through the details.

Q. So at the bottom of page four in your report, so at the end of the second line, you said: I conclude, to a reasonable degree of statistical certainty, that these studies failed to provide rigorous and consistent statistical evidence on the benefits and quality of life and well-being of sex reassignment surgery. Do you see that?

A. Yes.

Q. What do you mean by statistical certainty there?

A. Oh, statistical certainty, again, because I'm a statistician, right, I look at the papers, those papers and the papers, that actually a big quantity of papers, 80-some studies, and the statistical certainty means that my statement is based on the kind of data, the data of those 80-some papers I reviewed.

So that's what I meant by statistical certainty. It means that I -- my judgment or my opinion is based on data, again, data in this case, those papers.

Q. And how did you calculate that statistical

certainty?

A. I don't calculate that statistical certainty. That is a phrase, and, yeah, you cannot calculate. But I based on my expertise as a statistician, my expertise in this field.

Q. Okay. So the phrase is not that there is certainty supported by numbers, but rather that you are confident and you relied on statistics?

A. Yes.

Q. Okay. And what do you mean by rigorous and consistent statistical evidence?

A. Oh, rigorous and consistent, okay, so rigorous is, again, rigorous is based on the strengths of the study. So my judgment of the strengths of the design quality, the quality of the study, that means rigorous.

So in science, we always say whether this study is conducted with vigor. So things with more vagueness, or like with a lot of authenticity and noise, we call that that's not rigorous.

And consistent, that is consistent means if you read through my report, you will see that I review this 80-some documents and I divided the papers into different categories by design. So they are -- one of my studies, they are prospective studies, and they are

retrospective studies, and the prospective studies, I cited many of them, there are not too many, there are five of them. They provide mixed results, mixed results about the benefit of the sex reassignment surgery on quality of life and well-being of the -- well, quality of life.

So they are mixed results.

And so, yeah, by consistent, I mean all the studies suggest, point to the same thing, and I don't see it here.

So that's what I meant by rigorous and consistent, and the documents, the papers that I reviewed do not provide rigorous or consistent evidence.

Q. Okay. And only randomized control trials qualified as rigorous?

A. No, I didn't say that. I never say that in my opinion. I mentioned in my opinion randomized study is to establish the treatment -- effectiveness of a treatment. They are hierarchy of study designs. The gold standard is randomized study, but I didn't say that's the only one or that it must. I said is the gold standard is randomized study, and then the second one, when that is not available, you can resort to observational study, but it need to be well designed.

The best quality of observational study design is prospective study, this before and after comparison, and that is doable, that is visible, and that is reported in some of this 5 of these 80-some studies.

And the last, the worst quality of all of this is the retrospective study results, before/after comparison, and that was the bulk of the study that was cited.

So that was my argument. I never said RCT, randomized trial is the only -- is the only one that is rigorous.

Q. Okay. And you mentioned kind of the mixed results. How many or what percentage of studies have to show the same results for them to be considered consistent?

A. You cannot make that judgment. That's not a good question, because you can have a bunch of very low quality ones, one hundred -- and all of them are very deeply flawed methodology wise, and one hundred percent of them point to -- point to one direction.

And then if you have a small bunch of high quality study, they all point to the other one, other direction. In that case, I would take that small bunch of quality over the large bunch of low quality studies.

So you can never say -- you can never say that oh, how much, what the percentage has to be, what's the percentage of the signals has to be in the studies, then it can be regarded as enough. You don't do that. You judge by the first, so their order in the judgment, so their order in the criterion. Well, the first order of business or the criterion would be the quality of the design.

So, yes, if there are two randomized study, if there are only one of two randomized study, show me one direction. And then I have one hundred very methodologically flawed low quality retrospect study shows the treatment from the other direction, I probably will trust -- well, not probably, I will trust, and FDA will trust a randomized study, take the randomized study result, which is much more -- consider that is much more reliable or valid evidence.

Q. Okay. So stepping away from the quality of the design, we're talking about consistency. You've concluded here that they are not consistent?

A. Yes.

Q. So I guess I'm trying to understand where that line is? What makes it consistent versus what makes it not consistent? And how do you know here to conclude that it is not consistent?

A. Yes. If you go to my expert report, consistent -- it's hard to find this, let me see. I think for the assertion -- let me see, the WPATH assertion one. So it's on page 12.

Q. Okay.

A. So I state very carefully, so first of all, there's no RCT, but that is not end of the world, because they are -- actually they do have five prospective studies. And so I wrote this very clear. I don't need to read it, but I cited to see that, you know, they have mixed results for them to Lindqvist -- if you read page 12, the second to the last paragraph: Lindqvist, et al, found mixed results on the effects of SRS on quality of life. Specifically, they found that comparing to before treatment, quality of life is better one year after operation but worse three and five years after operation.

So that is -- so that's one. And also if you flip to the next --

Q. So is that finding sufficient for you to find that there's not consistent statistical evidence?

MR. RODRIGUEZ: Li, she's still answering your question.

A. Yeah, I'm not done yet.

Q. Okay.

A. Because that is several -- so there are actually five prospective studies cited here, and those are of higher quality than the retrospect study.

And then here, one-by-one I actually specific tell what their findings. And not -- the Lindqvist one I read. I don't know whether I should read all of it, but you can read, you can read it yourself to say that the other one, so let me see, like the --

Q. I don't need you to read the actual citing. That's not my question. So maybe I can rephrase. Would that be helpful?

A. Yeah, again, before you rephrase, I just answer that you say not consistent, yes.

So what I wrote here is the five higher quality of higher quality observational study, they find mixed results. They don't find all that it's helpful for quality of life, and this is every paper is like, and, yes, that's my answer.

Q. Okay. So stepping away from this report, I guess I'm trying to understand how you determine when it's consistent or when it's not.

And so is it that, you know, one study out of five, is it -- you know, I don't need an exact percentage, but is the expectation that all of the

studies are consistent?

MR. RODRIGUEZ: I'm going to object to form. You can answer.

A. Oh, again, this is same kind of problems I have with your previous question is vague. It's -- well, let me say this: So consistent, again, so I have -- so, again, you have -- so this is already you cannot just take the consistent out of context.

So here there's five prospective studies, right. And I think at least three of them, the results are saying that the result is not beneficial or some of the result are beneficial, some of the outcomes are not beneficial. And so that is just -- that's inconsistent. I mean, there because you have five different -- you have five studies, and the five studies say -- have very different conclusions. And that is inconsistency. I cannot name whether there's one out of five or three out of five because that is inconsistent. Like here, at least three out of five they are showing mixed result. And also this is just mixed result, and those result are different from the direction that from the large body of low quality retrospective studies.

So that's what I meant by not consistent, because you have both retrospective study and

prospective study and observational studies, and they are of different results.

Q. Okay. Going to page 25 of your report, to the conclusion.

A. Yes.

Q. At the end, you state your opinion to a reasonable degree of statistical certainty that the studies cited by Ettner and/or WPATH and reviewed in this report simply do not provide reasonable support for the assertions made, and then it continues.

A. Yes.

Q. What do you mean by reasonable support?

MR. RODRIGUEZ: Asked and answered.

You can answer.

A. I think I answered your question before.

A reasonable -- I already said a formal reviewer of a medical journal, and you submit things, you make assertions of this, and then you submit your -- and your paper or your report, you submit evidences. And based on like those -- the reference they cited, I would reject it, because I don't -- I already explain many times why I think that's -- the quality is low. The better quality of study that is available show mixed results. The lower quality ones, they are subject to a lot of methodology flaws. And

even their own expert, like even their own -- many of the papers they cited, I reviewed, call for better design studies. In that instance, I would not think -- I would not regard the evidence that they showed or in this case it's the reference they cited, provide reasonable or provide support, sufficient support for their argument.

Q. Okay. And this -- so the standard of reasonable support that you're using is sufficiently supported for you to accept it for publication in a medical journal?

MR. RODRIGUEZ: Objection, mischaracterization of testimony.

You can answer.

A. No, I use that as analogy, but I'm just saying as a scientist, how do you establish evidence for something? Okay. You actually go to the, like in this case, you want to establish the effectiveness of medical intervention. And there are ways of study -- there are different ways, study designs you can do. You can conduct those studies. And then you can analyze the data.

And, again, as an expert, I am involved in many of like this type of study, not about gender dysphoria, but just to kind of establish the

effectiveness of treatment. And my expertise, my experience tell me, based on that, I judge that what they cited here do not support their assertions. So it's overstretched.

Q. Okay. Can prospective observational studies provide reasonable support?

A. So the answer to that is not black and white.

So the best one, if possible, there would be a randomized study that's gold standard, but that is -- when that is not available, if you --

Q. Okay. Continue.

A. So that's the gold standard. I'm just stating a consensus in the field. When that is not available, then you have, yes, then you try to do the best quality observational study.

So, yeah, prospective study can be used, prospective study can be used as part of the evidence, but whether that can be viewed towards -- can be taken as the foundation for treatment recommendation, that's not a question that I can answer, because I'm not a medical doctor. But I can just tell you that the prospective study, yes, it is well conducted. If it's repeated many times with consistent result, then, yes, I believe that that would -- some medical doctors can

take that as a strong evidence. But whether that can -- again, who made that decision, I don't know, and I'm not going to -- like that's not the question I'm going to answer, like I'm supposed to answer, because that's not my expertise.

Q. Okay. Just to clarify on that, you said you're not opining on whether treatment recommendations can be made from this?

A. Well, yeah, so treatment recommendations, so evidence needed to make treatment recommendation is a different point, it's a different question from how do you establish the effectiveness of a treatment? Those two are different things.

So my assignment as a statistician, I can answer the first. I can answer the later question. I can answer the question of how do you establish the effectiveness of a treatment, but that is not equivalent to how do you make a treatment recommendation, because making a treatment recommendation, from my understanding, involves a lot of, you know, other considerations.

So -- but my, again, my scope is on whether the treatment, it's not treatment effectiveness. Arguably, that's one of the most important point consideration in making treatment recommendation.

Arguably that's the most important one, but that might not be the only one.

But, again, my scope is to answer the question, the more focused, specific question about whether you can establish the treatment -- the effectiveness of a treatment.

Q. Okay. So what is the significance of your conclusion that the studies failed to provide reasonable support for the assertions made by Dr. Ettner and WPATH?

MR. RODRIGUEZ: Objection, vague and form. You can answer.

A. Yeah, what do you mean by what is the significance? The significance in what aspect? In terms of what?

Q. So, okay. So you're talking about -- your question is about establishing the effectiveness of the treatment. So is your conclusion that the effectiveness of the treatment has not been established to a degree of statistical certainty?

MR. RODRIGUEZ: Objection, mischaracterization of the report, and her previous testimony as to what her conclusions are. You can answer.

A. So, again, I don't quite understand what

you are trying to ask here.

So my conclusion is, yes, based on my expertise and the document I reviewed, I conclude that the body of literature they cited do not support their assertions.

And you asked me is that significant? Again, sorry, I don't understand. What do you mean? What do you want me to say? I mean, what do you mean? Can you phrase this again?

Q. Yeah. Well, let me ask a follow-up question on that, because you're saying that the evidence does not support the assertion. And in layman's terms, I'm wondering if support has a different meaning, right, because is it that they don't support it with vigor, or that they don't support it at all?

A. Oh, okay. Oh, it's just they make assertion -- if you look at the assertions, some are very -- okay, let's go to specifics.

So, for example, some of the assertions I -- yeah, what do you mean by support? You want me to elaborate on that. I can do that.

So, for example, page 11 on my report, WPATH assertion one: There is strong evidence demonstrate the benefit of the quality of life. And so

I focused on this strong evidence.

So they claim this is strong evidence. I don't think that has strong evidence, okay, so that's what I meant by no support.

And the second, to give you another example, I should probably go to Dr. Ettner's assertion, let me see.

Q. And we will go through these one-by-one later, so you know.

A. Okay. That's even more fun. But, yeah, that's what I meant. Like I was very specific in this specific point-to-point discussion.

So when I say do not support, I meant, yeah, point-by-point, yeah, it's better point-by-point, then you go and see the problems. I mean, they do not support. It's often exaggeration or overstatement or sometimes just factually mistake, factual mistake. Sorry, go ahead.

Q. Are you saying that the WPATH standards of care are wrong?

MR. RODRIGUEZ: Objection, mischaracterization of the report and the testimony. You can answer.

A. No. It's a long document with many different opinions. I cannot just say it's wrong, no

it's not. I was talking about the assertions they made are not supported by -- well, again, as I just described not -- yeah, supported by their -- well, in other words, that it's often an overstretch, exaggeration, over characterization of the -- of things, of opinions. I didn't say it's strong.

Q. Are you saying that the WPATH standards of care should not be followed?

MR. RODRIGUEZ: Objection, mischaracterizes testimony. You can answer.

A. No, I didn't say that. I don't have the expertise to say things like that.

Again, my opinion is very focused on specific -- the assertions to counter or to exam the specific assertions, and I didn't make any statement about whether they should follow WPATH.

Q. Are you saying that WPATH should not rely on the studies that are cited in your report?

MR. RODRIGUEZ: Same objection, mischaracterization of the evidence and the report. You can answer.

A. I didn't say. Again, WPATH, what kind of document they want to decide on is they decide. It's not my opinion about. My opinion is about they cite, they decide, they cite a bunch of papers, references.

And, again, I try to judge that, whether the reference they cited support their assertions. So that's a different concept.

Q. Okay. Dr. Ettner stated in her report that the standards of care for treatment of gender dysphoria are currently set forth in the WPATH standards of care.

Do you disagree with that statement?

MR. RODRIGUEZ: Objection, outside of the scope of this witness' opinion. You can answer.

A. Yeah, yes, I agree with Orlando that is outside my scope.

Again, my job is to exam the specific assertions of Dr. Ettner and WPATH, and what you just asked is not part of the assertions I was asked to provide opinions on.

Q. Okay. So you are not providing an opinion on whether the standards of care for the treatment of gender dysphoria, or you are not providing an expert opinion on the standards of care for treatment of gender dysphoria?

MR. RODRIGUEZ: You can answer.

A. No, I was not -- I'm not providing opinions on that.

Q. Okay. And Dr. Ettner also stated that the

WPATH standards of care are the internationally recognized guidelines for the treatment of persons with gender dysphoria and informed medical treatment throughout the world.

Do you disagree with that statement?

MR. RODRIGUEZ: Objection, outside of the scope of the witness' opinions.

You can answer.

A. Yeah, that's outside -- that's not what I'm asked to write opinion on. It's outside the scope of my expert opinion.

Q. Okay. Dr. Ettner also stated that the American Medical Association, the Endocrine Society, the American Psychological Association, the American Psychiatric Association and a host of other entities all endorse treatment protocols in accordance with the standards of care.

Do you disagree with that statement?

MR. RODRIGUEZ: Same objection, outside the scope of the witness' opinions.

You can answer.

A. Same answer. It's outside my opinion, my report.

Q. Do you think that all of those medical associations should not endorse treatment protocols in

going to be considered low quality evidence?

MR. RODRIGUEZ: Objection, lacks foundation. You can answer.

A. As I said I don't -- I'm not familiar with the GRADE system. So I don't know whether that is what you just asked, whether observational study always considered low or high. I repeatedly said that my expertise, my experience with observational study, even with -- observational study is a very vast, a range of studies. Some designs are of higher quality. Some are lower quality. But, again, where do they fall into the GRADE system, now who decide that? I don't know.

Q. Give me one minute.

(Pause.)

Q. Okay. Do you always consider observational studies as low quality evidence?

A. No. I said clearly in the world of comparative effectiveness research, there's a hierarchy, RCT randomized study is the best. Observational study, there are good ones. There are bad ones. There are high quality ones. There are low quality ones. I don't blankedly(sic) say observational study are all of low quality. I never said that.

Q. Okay. Does a study being low quality, in your opinion, mean that it does not have value?

MR. RODRIGUEZ: Objection, vague and ambiguous. You can answer.

A. That's not my opinion is about. I don't stretch anything. I just purely say that when I say low quality, I meant there are flaws. There are serious flaws in the study design, that has rendered the conclusion be unreliable or subject to noise. And so more studies are needed.

So I didn't say that whether they have value or not. That's not up to me to judge.

Q. Do you have an opinion on whether low quality studies should be used in treatment recommendations?

MR. RODRIGUEZ: Objection, outside the scope of the witness' testimony. You can answer.

A. I don't have opinion on that.

Q. Okay. So going back to your report --

A. My report?

Q. Yes.

A. Okay.

Q. On page 9.

A. Yes.

Q. You discuss prospective studies and retrospective studies. Those are both types of

observational studies, correct?

A. Oh, caveat, yes. So observational study can -- so randomized experiment also belong to the broad spectrum of prospective study. But -- well, because prospect and retrospect means the time, the timing of when you collect the data, yes.

But to answer your question so observational study indeed can have both retrospective study and prospective study. They are just two different designs.

Q. Okay. So you see the prospective observational study is generally considered superior to retrospective observational study, correct?

A. Correct.

Q. Okay. And then on page 10, you also say that the design of the lowest quality is a retrospective observational study?

A. Yes.

Q. Do you see that?

A. Did I say --

Q. It's kind of at the bottom of page 10.

A. Yes. Okay. So to be clear, here I say the lowest quality that is of course I have a scope. I meant among, you know, if you have like three categories, you can, of course, further define them,

refine them into more categories. But I'm saying that randomized study, prospective observational study and retrospective observational study, this is -- among the three, this is of the lowest quality.

Q. Okay. And does that mean that retrospective observational studies do not have value?

MR. RODRIGUEZ: Objection, vague and outside the scope of the witness' opinions.

You can answer.

A. Yeah, well, I think you asked a similar question before saying whether this has value. Again, I don't provide opinion on that. They are studies. Those studies have, I call them low quality, because they have flaws in the designs, renders the conclusion to subject to be -- subject to all different biases. So they might not be reliable. But whether they have value or not, that's not what I'm -- I'm not providing opinion on that.

Q. When you say unreliable, you mean that they should not be relied upon?

A. I think that's an English word, unreliable has its obvious English meaning. It means that -- when I say unreliable, I mean that the conclusion is subject to a lot of biases.

So if you want to interpret that as

something strong or interpret that, interpret that those results -- you have to interpret the results with much caution and caveats. That's what I meant reliable, and they are -- those caveats or like those assumptions, if those are violated to any degree, then the result invalid.

So that's what I meant unreliable. They are just more subject to all sorts of challenges and, you know, biases.

Q. Okay. But you are not stating that they should not be relied upon?

A. I did not say that. But, of course, from common sense, if you have high quality, you want to make your decisions on high quality studies rather than low quality studies.

Q. Okay. So go to page 5 of your report.

A. Yes, I'm there.

Q. So in the second line under section 1, you say that: The main barrier to interpreting the association between the treatment and the outcome as a causal effect is the presence of factors that are associated with both the treatment and the outcome. These factors are commonly referred to as confounders or confounding variables or confounding factors.

A. Correct.

Q. Is the presence of confounders called confounding bias?

A. Yes. That's precisely why, again, as I later said, that's precisely the presence of confounding factors, that's precisely why retrospective study resolved before/after this data is viewed as low quality, because they cannot control at all the confounding factors.

Q. Okay. And that inability to control the confounding factors is inherent to a retrospective observational study?

A. It's inherent to -- so confounding bias is inherent to all observational study, whether it's prospective or retrospective. But prospective study do a better job in controlling those confounding bias by providing the before and after comparison.

Q. Okay. In going to page 6, you have a subsection called confounding bias. You state that randomized controlled trials eliminates all confounding bias.

Are there situations where that would not be true?

A. Again, that's -- we can get to too technical academic.

So, again, per se, if you have a study --

so raising the scope, if you do a randomized study that is because you flip a coin, so that is -- so for that specific study population, you're operating on the randomized study, yes, it does take into account, eliminate all the observed and unobserved confounding bias. So any confounding bias. So that's true. But then, of course, there are other things, if you want to put them a stretch, that a randomized study to a different population, then that's a different matter.

So, yes, so for the study per se, if you do a randomized study, operating on the population, the target population that you are operating the randomized study, yes, it eliminates all the confounding bias, and that's why it is regarded as gold standard.

Q. What if there's a very small sample size in a randomized control trial? Is it possible that would not eliminate all confounding factors?

A. Technically that's a different problem. So it still eliminate confounding bias just by design.

Small sample size is a different problem. Small sample size will give you larger extended error, or, in other words, the procedure, it will not be that precise. There is a statistical concept called standard error or variance. So that's a different one, like that's a second other problem.

So in confounding bias, the study design, randomized study design will admit no matter how small the sample size is. The small sample size, the key question is it will erode the procession of the study. So, again, statistically, it's like first order problem second order problem.

Q. Are there types of bias that can be present in randomized controlled trials?

A. Again, this is highly depend on the specifics, what do you mean? Like what type of bias?

As I mentioned, that if you want to stretch -- so the -- so confounding bias -- no, so the answer is so randomized study is subject to other type of bias, but not for the treatment effect for this population you study on. It's subject to other type of bias. For example, the randomized study, the population does not representing the general population, but that's a whole different matter.

And -- but always your first, again, like in FDA, if you want to have a new drug or treatment or medical device, you always first -- first order you do a randomized study. But that is understandable that it's not always feasible, but I won't go into that.

So your question, yeah, there are all sorts of different biases, but that is, again, we're talking

about first order problem and second order problem.

So why randomized study is prized is because the biggest problem to interpret the barrier from association to causation is confounding bias, and this randomized study is the most -- I mean, it's the single most effective design to admit that.

So that's a first order problem. Yeah, there are all sorts of other type of bias, but the second order problem and all the other observational study also subject too.

Q. Okay. So on page 6 and 7 of your report, you talk about different types of biases, and so selection bias, is that -- can that be present in a randomized controlled trial?

A. Oh, yes, that can be presented in randomized study or retrospect or prospective, but that's a different -- again, I say that's a second order problem, but yes.

Q. What about nonresponse bias?

A. Nonresponse bias, again, in randomized, yes, all of this study can be subject to that. But in randomized study, usually the way it's conducted, usually the nonresponse rate is controlled, because the study is controlled. So it's controlled by the -- highly controlled by investigated.

So it's usually subject to less of that kind of bias than the observational studies.

Q. Can recall bias be present in a randomized control trial?

A. Yeah, again, recall bias can present in all of these studies. But, again, because of the way that the randomized study is conducted, is well controlled by -- highly controlled by investigators, the occurrence of that is, the chance of that is much less than observational study, particularly for retrospective study. Because retrospective study often, like you don't design, because at the time you do the study, all these things already happened. So then that's a time lag.

That make it -- so in randomized study, you conduct the study. It's a prospective -- randomized study is prospective study. So you follow them. So, of course, there's much less chance of recall bias.

Q. Okay. What does it mean to mask or double mask a study?

A. Sorry, say it again, match?

Q. Mask or double mask, also known as blinding or double blinding?

A. Oh, I didn't say it here, yeah, double blinding, yeah, that is just a -- so that is you flip a

coin. Yeah, double blind, that means you don't -- so basically the treatment assignment, whether you get the true, the control or treatment is not known -- it's not revealed to the patient, and in some cases also not revealed to the people who conduct the study.

Q. So double masking means neither the participant or the conductors know who --

A. Correct.

Q. So if a randomized control study is not masked or double masked, can that induce bias?

A. Well, that can. I mean, I can give you a statistical lesson. Yes, it always -- like none of the study is perfect. Some are more imperfect. Others are less perfect. Yeah, so you're talking about double blindness. Yeah, the studies are not double blind. It's not always. So the problem of a double -- okay, so why do we want to do double blind study is try to reduce the chance of the so-called placebo effect. The placebo effect, like the psychological placebo effect, and, again, that is a possibility, like if you don't do double blind, there's a possibility that there's a placebo effect that will bias your result. But, again, comparing to other sorts of unmeasured confounding, there's a bigger problem. This is minor concern.

Q. On page 6, when you're talking about

confounding bias, you say: Therefore, in order to interpret the association between treatments and outcomes as causal effects in observational studies, one must assume that there's no unmeasured confounding factor. Such an assumption is untestable and is almost always untenable.

What do you mean by untenable here?

A. That means just almost always violated. There's always presence, in observational study, there almost always unmeasured confounded. And why I say it's untestable, because there's no unmeasured confounding. So it's unmeasured. How do you know whether there is or not? So, I mean, that's just common sense. That is like a standard in the literature.

Q. I'm not sure I followed. Can you explain it a little differently by what you mean? I get the untestable part, but can you tell me a little bit by what you mean untenable?

A. Untenable means, again, it's always violated to a certain degree, because you are basically saying -- so I'll give you an example.

If people say there's association between smoking and lung cancer, and then you calculate the association, so it's strongly correlated. But then if

you say smoking indeed caused lung cancer from observational study. If you want to make that statement, you basically say that well, then in my analysis, all the confounding factors, all the confounding factors that can affect both smoking and lung cancer has been collected and controlled in my analysis. And that is almost always weighted, because we can collect as much information about smoking and lung cancer, but there's always something missing, for example, like whether there might be genetic reasons, like your parents' -- like your parents' genes, or your parents' health, behavior, that kind of thing, you don't collect it.

So that's why I say it's always -- almost always they are -- you don't collect the whole universe of data.

So that's always -- this all matching confounding assumption in observational studies almost always violated. That's a consensus in the field, and that's actually the whole point like why people like me, a methodologist try to deal with this problem.

Q. Okay. So are you saying that observational studies can never be used to support treatment recommendations because there is a risk of confounding bias?

MR. RODRIGUEZ: Objection, asked and answered. Mischaracterization of testimony and report. And you can answer.

A. I think you asked this question or similar question many times. So I'll answer again.

I didn't make -- I didn't -- I don't come here or write my report to say that whether you can -- I didn't make the blanket statement to say that you cannot use observational study as the evidence for treatment recommendation. I purely said that they are different methods, different studies that can provide -- establish the treatment effectiveness of a treatment, and there are some better designs, some of worse design, and there's a reason I clearly describe here why there's a reason the confounding bias is the reason.

But, again, the answer has always been the same. I didn't say that because they are -- I didn't say that whether you should use it or not for your treatment recommendation, and that's not my scope. And I say again, I hope you don't ask this again, because my answer will always be the same.

Q. Is the concern that an outcome is the result of a confounding factor, rather than the treatment, mitigated by the number of studies

evaluating the treatment?

A. Can you say that again?

Q. So is the concern that an outcome is the result of a confounding factor, rather than the treatment being validated, is that concern mitigated by the number of studies evaluating the treatment?

A. I think your question mixed a lot of -- why I didn't first get it is I think you mixed a lot of statistical concepts.

So a confounding factor, a confounder is, by definition, is associated with both the treatment and the outcome, okay.

So I vaguely understand your question you're asking that whether this problem, this -- the problems of the existence of confounding bias or confounder is mitigated by the -- like the more study you do, like you are less concerned about that. Again, the answer of that is it depends on the quality of the study.

So if you give me one hundred studies, and one hundred studies are all very low quality, don't do a good job in controlling for confounders, if you give me 101, it doesn't matter, because they are all subject to the same problem. But if you give me a few high quality studies that did it good job in conjoining for

confounding bias then, yeah, it would be mitigated. But the sheer number, the number of study does not have nothing to do. The quality trumps quantity -- the quality trumps quantity here in terms of the studies.

Q. Okay. So you just gave the example it doesn't matter if it's a hundred or a thousand, so if you had a thousand observational studies with similar outcomes, you're saying that's still not as useful as having a few high quality studies?

A. Well, to answer your question, let's just look at the study I reviewed, right. Here I reviewed 80-some studies. So my -- based on my count, I think probably like 50 or, I don't know, 50 of them, I mean, not solvent. There's no solvent studies, but 50 of them are basically retrospective study resolved before/after comparison, and there are five prospective study that has the before/after comparison. And I explain why before after is important, because the before/after study provide you the most important confounder, which is the baseline measure of the outcome. So that's why it's regarded as better.

So I already said that, you know, you have 50, those 50 studies, even their own expert, even the own literature review say that they are low quality, and I'm calling for better prospective study, yeah, but

there are 50 of them providing the result. I would not, because they all have the same problem, they all subject to the confounding bias of, in this particular case, the confounding bias, particularly they're lacking the baseline. The most important confounder is that's the baseline outcome. They are basing that.

So they are all subject to that. Then, of course, you can do 50, you can do 100, you can do 1,000. That is just all subject to the same problem. Why do you repeat the mistake?

So that's why I don't -- I view that the evidence provide by a few high quality studies is better than 100 repeated, the studies low quality study repeat the same problem.

That being said, I do believe that it's better to have even -- the best would be to have both quality and quantity, means the best would be I have a high number of prospective studies. If you cannot do RCTs, that's fine. But if you can have a high number of high quality prospective study that all show consistent result, that's the best. But we don't have that, and actually the only ones they have have mixed results.

Q. When you say high quality studies, are you referring to randomized control trials?

A. No. I said that that's the best, but it's not always available. High quality, I meant that well designed, before/after retrospective study, if it's done nicely, done properly, yes, it can be viewed as high quality.

But, again, this is not the -- what is high quality or low quality is for any single study, of course, it's a subjective concept.

But here when I'm using the high quality and low quality I'm mostly talking about the, you know, from the perspective of whether it control for confounding bias. And why I say that is because confounding bias is the single most important barrier between the association and the causation, or that's the single most important barrier before you can establish the effectiveness of the treatment.

Q. So when you talk about high quality/low quality, you are not using those terms as they are used in the GRADE system?

A. Again, I'm not very familiar with the GRADE system. I don't know who decide that, and I don't know who decide that, and I'm not referring to GRADE system.

I already explained earlier in my case, I said there's at least three broad class of designs; one is randomized study, the other is prospective

observational study, and the last is retrospective observational study. And I say higher quality, low quality and lower quality is missing that. I have a hierarchy, one, two three, and I don't need to repeat that.

Q. And your hierarchy is yours and is not the GRADE system?

MR. RODRIGUEZ: Asked and answered.

You can answer.

A. Well, it's mine, but remember, I'm a national leading expert in inference, in study designs. So yes, it's mine. So I -- it's mine, but also I can tell you with confidence that is also the consensus in the field in terms --

Q. In terms of statistics?

A. In the field of causal inference comparative effectiveness research. That also include epidemiologist.

If you go out to any statistic, statistician, epidemiologist, ask them rank these three type of studies, they will give you exactly the same order as I just gave you. Randomized study is the top, and prospect is the second, and the retrospective third. So that's what I meant.

Q. I'm not trying to dispute that ranking. I

think I'm trying to understand, make sure that we're using the same language here.

And so my understanding from what you just said is you consider high quality studies to be randomized control trials or well designed prospective before and after observational studies, is that accurate?

A. Yes. Again, even there, yeah, randomized is still better than the other, yes, higher quality. But, again, even prospective before/after, you can still mess it up.

But, yeah, if it's like well, well studied, like it's well designed, yes, it can be considered as a high quality. But I didn't say every single prospective study is high quality, but it's still better than retrospective study.

Q. Are there ever reasons why a randomized control trial might not be ethical?

MR. RODRIGUEZ: Objection, outside the scope of this witness' opinions.

You can answer.

A. Yeah, I -- I don't think that whether a randomized study is ethical or not has anything to do with my opinions.

My opinion is about like whether the

treatment effectiveness is separate from the question of clinical recommendations?

A. Correct.

Q. Turning back to your report, how would you decide which WPATH assertions to evaluate?

A. How do I decide?

Q. Yes.

A. Oh, Orlando come to me and then he already, he gave me this numbers of assertions, asked me to examine that, and that's how I decide. I examined them one by one.

Q. Okay. Did you consider evaluating the assertions by the Endocrine Society and its clinical practice guidelines on the treatment of gender dysphoria?

A. Sorry. Can you ask that again?

Q. So the Endocrine Society also have clinical practice guidelines on treatment for gender dysphoria. Did you consider evaluating the assertions by the Endocrine Society in that guideline?

A. No, I didn't review. I'm not aware of that document, and I didn't review that.

Q. Okay. And in WPATH, in terms of care, are there recommendations made in that document?

A. I don't know. I don't remember. Again, I

focused on my opinion, or my expert report was focused on the specific assertions that was presented by Orlando to me, ask me to take a look.

So I didn't -- yeah, I glanced through that document, but I didn't remember everything that was said there or anything beyond that.

Q. Did you read the sections of the assertions that you were evaluating were in?

A. Oh, yes, I read, but, I mean, that's -- basically that's bullet points. Yes, I read those sections very quickly, but I think I actually did a good job in picking those assertions out is a good summary of the -- yeah, I mean that's paragraph.

Q. When you reviewed it, do you recall that there were recommendations numbered similar to what we just saw in the Pediatric Obesity Guideline?

A. I don't.

Q. Okay. And so you were not providing an opinion on the recommendations themselves?

A. No.

Q. Your chart at the end of your report lists Assertions 1 through 11. Are they numbered that way in the standards of care?

A. I don't know. I guess not. I mean, I don't know, because I didn't pay attention to the

standard of care.

Q. Okay. Were they numbered that way when Orlando gave them to you?

MR. RODRIGUEZ: Object, borderline on getting into communications between counsel and the retained expert.

A. I don't remember clearly. I believe that was the order he gave me, because I just then take it, and then it's like dealing with, paper -- I mean, it's dealing with one by one. So I didn't change the order or anything.

Q. Okay. In your report, you only include your evaluation of Assertions 1, 2, 6, 10 and 11. Why only those ones?

A. Say it again? So I only -- I believe that everything Orlando asked me to -- the assertion I indeed reply. Oh, 1 through 6? Why the -- okay. I need to look at the -- let me take a look.

Oh, did I say -- again, I don't remember clearly. I think the -- again, this I need -- actually, if I have a computer, I can see what is the original Assertion 7 to -- 7 to 9. I need to look. I don't know.

So if I didn't respond to that, it's -- oh, it's because --

THE WITNESS: Do you have the charge?

MR. RODRIGUEZ: Keep on looking through the rest of that.

THE WITNESS: Oh, okay.

A. Just give me some time. I look through the charge, then I know. Almost there.

So Assertion 7, so let me see, Assertion 7 says: Too often the agency's structure and personnel provide care are lacking in knowledge, training and capacity of care for gender diverse people.

So the paper -- well, oh, I see. So why I didn't, because this has nothing to do with my expertise, because my expertise was talking about -- it established the effectiveness or the safety of a medical intervention.

So for this assertion, I don't have opinion to provide, because I don't have expertise on this. So that's why I didn't provide.

So I think the same thing for the 8 and 9. So I provide the -- so there are a bunch of assertions, but I provide the opinions on the assertion that I feel that I have expertise on to judge.

Q. Okay. So you were not providing an opinion on Assertions 3 through 5 or 7 through 9?

A. I think -- yes. Yes.

Q. Okay. Well, let's go to Assertion 1 in the body of the report, not the chart.

A. Let me get there.

Q. I think that's page 11.

A. Yes, I found it.

Q. Okay.

A. Yes.

Q. Okay. So what do you mean when you conclude that studies failed to provide rigorous and statistical evidence on the benefits of quality of life and well-being of gender-affirming treatments? And apologies, I should have directed you to where that quote is. It's at the very end of your discussion of Assertion 1.

A. Okay.

Q. Page 15.

A. Yes. Yeah, so the end I said: I conclude, yeah, contrary to the statement in the assertion, these studies failed to provide rigorous and statistical evidence on the benefit of life and quality and well-being of gender-affirming treatments. Yes.

So your question? Can you repeat your question, please?

Q. Okay. Yeah. So I know earlier we talked about rigorous, and in this context, what do you mean

by rigorous?

A. Well, I explain that, okay. So if you look at the assertion, it says: There is strong evidence demonstrating the benefit, okay. So what do I mean by strong evidence? Okay. So I focused on that strong evidence. So as I go through my assertion, so I -- strong evidence, I show that they cited 21 studies, and so there are five prospective studies, which, again, in my GRADE, that is higher quality ones, and those have mixed results. And then they are now retrospective studies and others of lower qualities, and they have their lower qualities, and they are -- I describe all sorts of flaws in the design. And also I have, I said, there are also seven literature reviews.

So the literature reviews point out themselves that, you know, acknowledge the current available research based mostly on cross-sectional studies and call for -- so they acknowledge it's low quality studies.

So, I mean, rigorous, again, it's not rigorous. So they have this retrospective studies, and you would not cite those as rigorous, and the consistency part I already mentioned, because the higher quality prospective studies, actually the results show mixed. It's not always provide benefits

for that.

And 7, actually quite a sizable number of literature reviews point out, acknowledge the shortcomings and flaws in the current state of the research.

So that's what I meant it's not rigorous or consistent.

Q. Would there have needed to be a randomized control study here for you to find that there was rigorous and consistent statistical evidence to support this assertion?

A. If there's one that will add to the reader -- that will definitely add to the reader, there's none, which, again, that's not the end of the world, but they do have some higher quality ones, prospective ones. Unfortunately, they show the result of the benefit on quality of life is mixed. They find some positive, some are negative.

So, again, I don't -- I mean, I don't have an opinion. Like, again, it would be great if they have randomized study, but they don't have that, but I don't think that's the end of the world.

So I judge, I judge this, because they say that the assertions say there's a strong evidence. By my knowledge -- but by my examination of the literature

they reviewed, I find that's really a stretch, because the higher quality ones states actually mixed results.

I'm not going to repeat, but, yeah, that's what I meant.

Q. So if there are no randomized control studies, and the observational studies did not have mixed results, would you find that their assertion was supported by rigorous and consistent statistical evidence?

A. Can you say that again? Can you say -- sorry, I didn't hear clearly.

Q. Okay. So my last question was, you know, if there was a randomized control study, would you find that there was rigorous and consistent statistical evidence? And you said the lack of a randomized control study was not the end of the world. And so my next question is, you know, if there are no randomized control studies, and the prospective observational study has consistent results or not mixed results, would you find that there was rigorous and consistent statistical evidence to support this assertion?

MR. RODRIGUEZ: Object to speculation.

You can answer.

A. Yeah, this is speculation. So this is speculation. So I can only speak to the five, like the

studies they cited.

But to answer your question, yes, if they have like -- they have other prospective studies and well done, and they described nicely, it described very clearly the methodology and the result not mixed, I would feel a bit more confidence in -- like then, yeah, that definitely is some more strong evidence than what is currently presented here.

Q. And is there a set number of additional prospected numbers that would be needed?

A. No, I don't. Again, the better, the higher number, the better quality, it's better. But there's no number I can say well, you need five studies, you need ten studies. We don't have that.

Q. Okay. So I guess I'm trying to find where the line is for you, right. You've concluded that this is not rigorous and consistent. And so you must have some sense of what is, and like how do you make that determination? And it sounds like there's some gray areas. There's a lot of factors. How do you make that determination?

A. So the key thing, actually, I made my -- I made my opinion or my opinion, not like what you're saying that I don't need to make a line. I examine what is cited there, and what is cited there -- what

was cited there, the high quality ones already show you a mixed result. I don't think that I need to go further and say how much evidence I need to make this recommendation? Because I examine what is presented to me, what is cited by them. They cite it for a reason. They cite it for -- I assume they cite those papers to support the opinion. But what is cited there, if you close exam, provide mixed result that I think is enough. I don't need to -- for your question, it's beyond my scope to say oh, where should I draw that line? I judge -- I examine what is presented, what is cited by them, and thus result is not consistent, and I don't think that constitute a strong evidence for the -- strong evidence for treatment effectiveness, and that's what my opinion is about.

Q. And you know that this is not enough evidence to be considered rigorous and consistent, but you don't know how much would be needed to be rigorous and consistent?

A. Correct.

Q. Okay. So in here, you're talking about mixed results in the prospect area. Are you talking about is it the Lindqvist study?

A. That's one of the studies. I mention many. I also -- not many. I mean, there are just five,

right.

So Lindqvist is one. So, again, I went one by one. The other is before -- after.

Okay, so the other one, that is the Cardosa da Silva paper also find mixed results. Specifically they found that psychological side -- help and social relationship was significantly improved after SRS, but physical health and level of independence was significantly worse.

So that's another one. And another one is -- so another one, again, I don't know whether I need to read through, I mean, this says very clearly that the other one is a prospective study. So they focused on specific type of surgery, and they, the study does not provide no information about the fact of the surgery on general quality of life or well-being.

So then the other one, again, the five specific, the other one, the 2014 one, is focused on the safety and side effects of intervention, not quality of life. And the other one is prospective study, but that did not provide before/after comparison of the same patients.

So you can see that I list carefully there are five studies. There are five studies, and I mention that some of them do result mix. Some of them

simply do not provide information about quality of life, which is -- in the assertion, they say assertions about strong evidence of the quality of life or well-being.

So I'm saying that, okay, so there are two studies talk about that, the result is mixed. And then there are other studies that do not provide information for quality of life. So you cannot use that for evidence.

And the other one, the last one did not provide a before and after comparison of the same patient.

So that's why I clearly examined them one by one in five study, and then why I tell you that, you know, they're essentially among the five studies, there are two studies actually specifically talking about quality of life, and they are of high quality and the results are mixed.

Q. Okay. I'm trying to look at the document quickly. All right. So let's mark Exhibit 5, the Lindqvist study.

(The document referred to was marked Deposition Exhibit Number 5 for identification.)

A. Yes, I have it.

Q. And is this the study that you reviewed as part of your expert report?

A. Let me look at it. I believe so. It must be this, yes. Yes.

Q. Okay. And in the abstract, can you read the last sentence or the second to last sentence that starts with GRS?

A. The last sentence says: GRS -- so no, the abstract, they have background, they have methods, they have results, which one are you talking about?

Q. On the very first page where it says abstract, the last sentence of that section on the upper right side it says GRS.

A. Oh, GRS.

Q. Gender --

A. Yes, I read that: GRS lead to an improvement in general well-being as a trend, but over the long term, quality of life decreased slightly in line with that of comparison group.

Q. Does GRS refer to gender reassignment surgery?

A. Yes.

Q. Okay. And so this study, the people who conducted this study, did they conclude that gender reassignment surgery leads to an improvement in general

well-being?

A. Well, it said it proved as a trend but, but the key thing is but over long term, quality of life decreased slightly.

Q. Right. And what does it mean to decrease in line with that of the comparison group?

A. Well, he said that the comparison group also decreased, and the quality of life, yeah, it's -- I need to read more carefully what the comparison group, so who they compared to. I mean, it's one of the many papers. But the comparison group, I don't know what the comparison group is, without looking carefully. Is the comparison group -- I mean, they have a comparison group. I don't know that the comparison group is -- actually, I don't know here.

Oh, okay. So -- okay. So I'm now on page 225, and so the last sentence: Our findings on lower quality of life in transgender woman compared to the general population of women is in line with the same previous studies, and in contrast to others. However, one of those were performed on transgender men only.

So, again, they have a comparison. So I guess it's a comparison compared to the general population of women? I assume. Like that's my understanding, just quickly reading through this.

Q. Okay. And so you've described this study as having mixed results, why?

A. Well, because the first -- again, by mixed, I mean the initial, there's the increase, and then what I describe here then over the years at three years and five years, it's decreased. So that's mixed. It's not like by mixed I mean the trend of direction, the direction of the outcome is not one-sided, like maintain the same over years. That's what I meant, mixed.

Q. Okay. And you conclude that even though the comparison group had a similar decline with the same timing?

A. Again, that's their conclusion. They say it's similar. But if you look at the numbers, I don't know how similar that is, whether that's significant.

What they say is yes, that is in line, basically the comparison group, like, it's the general population, I assume, yes.

Q. So is it possible to interpret this as not mixed, because everyone is going to have a slight decline in quality of life at that time?

A. No, this is -- no, this is -- I cannot interpret that way, because this is about -- because the treatment in fact is on the population, on the

patient who received the treatment.

So you're talking about for this person, for those patients who receive the treatment, so then it's going up and then going down. You cannot stretch that to well, then there's -- like the fact is that there's indeed decrease. And what happened about the general population, I don't know, and that's not because they don't provide data for that. They are just saying oh, that is acknowledged by other, other studies.

Q. Okay. So do you disagree with the conclusion of this paper that gender reassignment surgery needs improvement in general well-being as a trend, but over the long term, the quality of life decreases slightly in line with that of the comparison group?

A. Not the conclusion. I take it at face value. I don't disagree. I mean, that's what they said, and then I just use that as one of the many papers. I mean, I don't know whether I agree. I take that at face value, this is what they said.

Q. But do you agree with it?

MR. RODRIGUEZ: Asked and answered.

You can answer.

A. Well, according to their study, according

to what they described, I agree with the conclusion. Again, they clearly try to spin it, make it sound more positive than it is. But that's what we all do when you write papers, because you get published that way.

But, yes, I mean, I think what their conclusion is supported by their data.

Q. You said they clearly tried to spin it. Where is that clear?

A. Where is that clear? So let's look at the numbers. Again, this is getting too details, but I can try.

So there's a decrease of general health. I'm looking at page 225. Again, this is one of the many studies. So I'm now doing on cite examine the paper for you. Where I say the main clinical -- so okay. So this is what I -- let me see, this is year one, okay. So that's year one.

Let's look at table two. So you have year two, table two that's individuals in this study. Okay, all of that year 0, 1, 3, 5, okay, then let's look at the general -- I see. I see what -- okay. Because they didn't provide data actually about the general population, so if you look at this study, is table two is providing information about all individuals in the study. They are on this through, you know, the

treatment. They didn't provide any information about the general population. There's nothing qualitative about their decrease. They purely just say oh, there are other papers. There's general decrease of the quality of life, and I don't, at least as far as I can see here, they don't provide information, quality of information, don't provide data to talk about the comparison group. So that's why I say that it's really a stretch, because they just say oh, there are other studies, but this paper did not provide that data, and they just say that it's inline, but there's no data supporting their argument, so, but, yeah.

Q. Do they --

A. Sorry, keep going.

Q. Go ahead.

A. No, I was just saying, it was very clear that -- but the trend talking about the patients in this particular study, as far as increase then decrease, that is clear. That is supported by the data by table 2. But then saying that is in line with the other general populations, that aspect, I don't see data supporting them. So that's why I see clear.

Q. Did you read this paper in your entirety in preparation for your expert report?

A. Yes, I read through that question quickly.

I focused more on the design and the data points. Yes, I read through that.

Q. Did you read fully all of the studies cited in your expert report?

A. Again, how do I define fully, right? I mean, I skim through them, and I focus -- I know the abstract, the conclusion. I skim through the -- very quickly the paper, but I focus mostly on the statistical methodology and the results and the numbers, that aspect. But, again, I guess that is entirety, but there's no -- I didn't check all the references and stuff, because that's -- that will take an infinite of time.

Q. So going back to WPATH Assertion 1 on page 11 of your report.

A. Okay. Yes, I'm there.

Q. Okay. So do you disagree that there are benefits in quality of life and well-being of gender-affirming treatment, including endocrine and surgical procedures?

MR. RODRIGUEZ: Objection, scope.

You can answer.

A. So, I mean, again, my opinion is about whether the references cited provide strong evidence for, as they claimed, for the benefit of quality of

life, and that's all my opinion is about.

So sorry, what are you asking?

Q. I was asking if you disagree that there are benefits in quality of life and well-being of gender-affirming treatment, including endocrine and surgical procedures, properly indicated and performed, and outlined by the standards of care?

A. As I said, they are papers that they cite that shows that -- again, those papers show, yeah, there is benefit in quality of life, but unfortunately, those studies are of low quality, and they are subject to all sorts of biases and the design flaws. So then how reliable that evidence is, that's questionable.

And so that's why I disagree with these assertions that say there's strong evidence, because this is at best pretty flimsy evidence.

Q. Okay. So the scope of your opinion is just as to whether or not there is strong evidence?

A. Yes.

Q. Okay. And you are not providing an expert opinion on whether there are benefits in quality of life and well-being of gender-affirming treatment?

A. No.

Q. Okay. Going to page 15, still in Assertion 1.

A. Yes, I'm there.

Q. On the fourth line down, oh, sorry, a little bit further down, I think roughly the sixth line, you said: None of the studies compare sexual assignment surgery with alternative treatment.

So what alternative treatment are you thinking of?

A. Oh, any. Like, so -- there so, again, this is also kind of academic in the sense that you compare.

So I say this it's because -- so they might be, again, gender dysphoria, I'm not an expert on that, but I'm saying that, for example, heart disease. There might be assorted different medications, right. So often we study -- in comparative effectiveness research, often we kind of do studies or trials, observational study, to see that among these different alternative, like four different medications, which one is the best? So that's what I meant by alternative treatments.

So here I say that, you know, this is -- they're not talking about, they're just talking about one particular type of treatment. And then I don't know whether there are other alternative treatments, but I'm just saying that in the statement, that here, they don't talk about -- like maybe their hormone

therapy. I don't know. But they don't compare like the surgery versus hormone therapy. Because, again, I over here, because later, in the later assertion there, the reason I'm thinking Dr. Ettner's point she made that, she made the one statement something like this is the only effective treatment.

So I think that is -- when I wrote that part, I was having that in mind. It's like well, all of these studies, particularly about having this treatment versus, I guess, not having this treatment, but not versus alternative treatment, for example, hormone therapy, things like that. So that's what I meant.

Q. But you're not aware of any alternative treatments?

MR. RODRIGUEZ: Object to the scope. You can answer.

A. Again, this is -- this depends on like, yeah, I'm not an expert of that. I don't know. I cannot say, have a blanket statement say that there's no alternative treatments or I am aware of that, because it obviously depends, there's different type of surgeries out there. I know that there's surgery versus hormone therapy. That's probably more or less -- and I also know there's different types of

surgeries.

So that's what I have in mind when I wrote that alternative treatment. I'm just saying that they are all -- all the studies here is comparing having this versus not, but not different treatment. You know, that's what I meant.

Q. So let's move on to WPATH Assertion 2 and looking at the bottom of page 16.

A. Yes.

Q. So you summarize that because the studies are all of low quality and they're subject to selection bias, nonresponse bias and recall bias, that they fail to provide rigorous and statistical evidence for the assertion, is that correct?

MR. RODRIGUEZ: Objection, incomplete -- incomplete recitation of the opinion. You can answer.

A. Yes, correct. I mean, you were basically reading out the rigorous and statistical sentence of mine. I reported on that point, yes. Yes, that's my opinion.

Q. Okay. And earlier we talked about nonresponse bias and recall bias, both being present in randomized control trials as well as observational studies, correct?

A. Correct.

Q. Okay. And so is it your opinion here that because there are no high quality randomized control trials, there could not be rigorous statistical evidence to support the assertions?

A. That's not my opinion. My opinion, as I said, that there are different -- there are different classes of study. Randomized control study is the best. If it's not available and not always available, then you resort to observational study. But even in observational study, there are good quality and poorer quality ones, higher quality or lower quality ones. And that I didn't say, I didn't say like there's no randomized study then -- like I didn't make my statements or opinion based on, entirely based on the lack of randomized study. Yeah, it is one of the weakness, but that is not the end of the world. I am more focused on actually the higher quality ones that are there. You know, there are very few high quality ones, and the results are mixed, and most of them are low quality ones. And I explain that, why they are low quality, what kind of bias they are subject to.

Q. And is it your assertion that the studies are subject to selection bias based on the fact that they are not randomized control trials?

A. No, that's not -- no, it's a different, it's a different aspect. So randomized, again, as I explain earlier, so why do you want to randomize study? All the classification of the quality of the study including inference.

The big -- like there are all sorts of considerations, but the biggest hurdle is confounding.

So randomized trial is good in dealing with that, okay. And so that was my point. And then as I said, the other type of bias, selection bias or nonresponse bias, yeah, those are all the studies subject to, but they are more of the second order issue. And also randomized subject is subject to those, but because of the ways randomized study is highly controlled by the investigators, the chance of those biases are much smaller than the observational studies.

So that's why randomized studies always prized, but I repeatedly said that without that, it's not the end of the world. There's still plenty of good well-designed observational study that, you know, can be valuable.

Q. You say that most of these studies are subject to selection bias. Why do you say that?

A. Well, because that's just the way it is.

Okay. I can go into details.

So one thing I can think of is many of the studies are from like a single, like a patient -- like a doctor from all the patients he has treated, or like they are locally in one hospital, one medical center over the years have done.

So again, in that case, then the patient, the patient population they consider might not be representative of the general population.

So that's what I meant. I mean, that's just a general, like if you read through the studies and I found that most of them have that kind of issue.

But I do note that they are studies, like -- I don't know whether it's here -- somewhere there's a study of like the Danish study of all the national registry over 20 years of the whole population. Yeah, that one I think, as I said, the quality is higher, because it's a more general population. But even that, it's still like focused on the Danish population. Whether that is representing the whole universe of transgender people, I don't know, and most likely it's not.

Q. Okay. And is your assertion that most of these studies are subject to recall bias based on the fact that some of the studies are retrospective?

A. Not some of them, yes. If they're retrospective, they are more likely subject to recall bias.

Q. Okay. So retrospective studies inherently have a degree of recall bias?

A. Yes, because, again, because this happened. You usually collect the data once things already happened. So that is -- you don't like collect the data -- the happening of the thing. Yes, it's inherent.

Q. And why do you conclude that these studies are subject to nonresponse bias?

A. Oh, well, nonresponse bias, as I mentioned, that when you have -- there's some patients who just do not provide data. And it's pretty well-known methodology that, you know, the people who do not respond to -- there's a reason they don't respond. They don't provide information.

So most likely they are different from the people who respond, who provide information.

So, again, or if you want to make them -- if you -- like only if you make the assumption that these two people, the people who respond versus people who don't respond are exactly the same, like if you want to say there's no nonresponse bias, basically you

are saying that the people who respond versus people who don't respond, they are the same. But that assumption most likely is, you know, not plausible.

So that is why I say that they're all subject to nonresponse bias. And I read in many of the studies, actually the nonresponse rate is pretty high, like they send out the surveys to the patients, and often the response rate is like 30 percent. That's really low.

Q. Okay. And are all types of study designs subject to nonresponse bias?

A. Yes, that's correct. But as I said, that some of the studies, like a randomized study, because you are -- you closely monitor them. Like you sign agreement, I think. So there are ways of improving that, but among all of the -- like the retrospective study, again, has the highest -- like is most vulnerable to that, because you have very little control over the response.

Q. Looking at the assertion itself, do you disagree with the statement that gender-affirming interventions are not considered experimental, cosmetic or for the mere inconvenience of a patient?

MR. RODRIGUEZ: Object to incomplete statement of the actual text.

You can answer.

A. This is not -- again, my opinion is -- so if you see that in what I wrote, I focused on the last sentence: They are safe and effective in reducing the gender, the gender dysphoria.

So my statement was not about like whether they are considered experimental, cosmetic for the convenience of patients, because, again, I'm not an expert in the medical practice of transgender people. So I cannot make -- I don't think I have the expertise to make a statement on that. But my statement is more about the second sentence, is they are safe and effective in reducing gender dysphoria, because that is -- fall into my expertise in comparative effectiveness research.

Q. And you are not providing an expert opinion on whether gender-affirming interventions are safe and effective at reducing gender incongruence and gender dysphoria, correct?

A. Well, I'm actually providing an opinion on whether this statement is supported by the references they cited, because they make this statement obviously based on, based on those references. And I want to examine that. And I find that statement is I disagree with that statement. Well, it's not I disagree with

the statement. My opinion is about that statement is not supported by the reference they cited.

Q. Okay. And so you are not providing an opinion on the safety and efficacy of gender-affirming interventions?

A. I don't, but if you read the sentence, they say they are safe and effective. And I say that this is not supported by the reference they cited.

So if you -- if you just not even stretch, if you continue on that argument, I don't think there's enough evidence to support that statement.

But, again, yeah, I'm not saying that whether this is -- whether those are safe and effective. I can only say those papers they cite do not provide evidence for this statement.

Myself don't have opinion on whether they are safe and effective, because I don't have enough evidence. At least all the evidence they provided, I would not make this kind of statement based on the references they cited. That's -- yeah. That is my opinion.

So based on the documents or the papers they cited, I would not make this kind of statement.

MS. NOWLIN-SOHL: Okay. We've been going for about an hour. Are you good to

keep going? Would you like a break?

THE WITNESS: Maybe five-minute break. Again, I drink too much water.

MS. NOWLIN-SOHL: Five-minute break. Sounds good.

(Off the record at 2:11 p.m.)

(On the record at 2:16 p.m.)

BY MS. NOWLIN-SOHL:

Q. We're back on the record. I'd like to move on with the WPATH number 10, which is on page 17.

A. Yes, I am there.

Q. Okay. So on page 18 in the middle paragraph at the end, you see the last point: Most studies do not discuss quality of life outcomes?

What is the significance of the fact that most studies do not discuss quality of life outcomes?

A. Okay. Let me look at the assertion first, just to refresh my mind.

So it says: Although different assessments result from -- okay. So the assertion says: Although different assessment measurements were used, the results from all studies consistently reported both a high level of patient satisfaction as well as satisfaction with sexual function. Although different measures -- assessment measurements were used, the

results from all studies consistently reported both high level -- oh, did I repeat? I think this is --

MR. RODRIGUEZ: Yes.

A. It's a typo.

So this was especially evident when used more recent surgical gender techniques. Gender-affirming, this surgery was also associated with low level -- low rate of complication and a low incidence of regret.

So then I wrote -- so you mentioned that I say most of the study is not -- which one -- did not provide -- which sentence -- did not provide quality of life. Did I -- sorry, I was just trying to -- can you repoint out like which sentence you are referring to?

Q. Yes, it's on page 18, the bottom of the middle paragraph.

A. Oh, bottom of the middle paragraph. Okay. Okay. Oh, most of the -- most studies use self-reported outcomes, instead of standardized instrument. And lastly, most study do not discuss quality of life.

Oh, so if you ask about the last sentence, most of the studies do not discuss quality of life specific to this assertion. They -- so, yeah, they talk about patient satisfaction and the satisfaction

with sexual functions.

So in that regard, yeah, they don't discuss quality of life. It's not a problem for this assertion. But also -- but I'm still reviewing the whole thing in the context of also the general forming my opinions. My general, like my overall opinion then in that case those studies that cited here don't talk about quality of life, then that is a concern, because my opinion was it was a part of that. It was about quality of life. Specific to this, to this assertion, this is not a concern.

Q. Okay. And then the bottom of page 18, the last full sentence you say: This body of literature supports the high self-reported satisfaction rate among the patients who underwent gender affirming vaginoplasty.

And how do you conclude that it supports that?

A. Oh, so are you referring to my sentence that says: But does not provide any evidence for the necessity or advantage of GAV comparing to alternative treatments? Are you asking me how I make that conclusion?

Q. It's that sentence, but I'm just asking about the first half of it right now.

A. Okay. So the body supports high self-reported among the patients who underwent -- yes, that is a fact, yes. That is a fact, yeah. This body of literature indeed support that, because that's a fact. And -- but the emphasis here is the self-reported, as I earlier discuss, self-reported also acknowledged by many of the expert in this field, in these papers.

So the self-reported outcomes often have -- it's also subject to some methodology flaw.

So in terms of this sentence, yes, that's just a state of fact, that's correct.

Q. You said that's a fact?

A. I mean, that's a fact that taking their numbers and their numbers says that consistent report, both a high level -- I'm saying the assertion, if you go back to the assertion, page 17, it said that results from all the studies consistently reported both a high level of patient satisfaction, so 78 percent to 100 percent, yeah, I mean, if you take that at face value, take that, then that is indeed a high satisfaction rate. I mean, that is a fact. A fact in the sense that the number stated there, and I trust that they didn't make up that number.

Q. Okay. And so you find that that body of

literature can support the high satisfaction rate even though there's no randomized control trial?

MR. RODRIGUEZ: Object to the mischaracterization of the actual text.

You can answer.

A. Yeah, here the English, I probably shouldn't say support. The body of literature basically just reports. I would say the body of literature report a high self-reported satisfaction.

So you can cross this supports, but I would use it as a reports, and that's what I meant the literature indeed reports that number.

Q. All right. And then the second half of your sentence says: But does not provide any evidence for the necessity or advantage of gender-affirming vaginoplasty comparing to alternative treatments.

Can you explain to me what you mean by that conclusion?

A. Yes. So as I earlier discussed to you, that -- so all of these studies is talking about this one particular surgery, GAV. So the study subjects are all the people who underwent GAV, and then they go to, as far as I remembered, the researchers surveyed those patients and asked whether they are satisfied, and, you know, their satisfaction and things like that. But it

didn't compare to people who could take alternative treatment, for example, hormone therapy or, you know, other -- I don't know. I only know hormone therapy.

So it did not compare GAV with anyone who takes say hormone therapy. Also, it didn't compare people who take GAV versus people who didn't take GAV.

So that's what I meant.

So you are just saying the statement, the study decided is focused on the people who indeed take this surgery, right, and then ask them whether you are satisfied. But there's nothing comparing there, because they didn't compare in the comparative world that had this person not take the treatment or had the person taken another treatment, like hormone therapy, what it would be.

So in that regard, that's like you can say oh, we've satisfied this, but there's no comparative statement. That's what I meant.

If there's no comparative statement, then you cannot say oh, this is the only one, that you must take this, because you don't know what will happen to those people that had they taken different treatment.

So the key thing is what I -- to summarize what I just said, it definitely means that these studies does not -- did not provide like any

information about comparisons, comparisons of this treatment versus control versus no treatment or other treatment, so that's what I meant.

Q. You mentioned hormone therapy as an alternative. Are you aware that the WPATH standards of care and the Endocrine Society recommend that people have at least 6 to 12 months of hormone therapy prior to undergoing gender-affirming surgery?

A. I'm not aware of that. Again, that's not my expertise. I say hormone therapy, it's just because when I review the literature, and I see people mention hormone therapy. I can -- I say hormone therapy, but when I put my sinus hat on, it would be treatment A versus treatment B. So hormone therapy would be treatment B.

Q. And do you know if anyone undergoes gender-affirming vaginoplasty or vulvoplasty without having hormone therapy?

A. I don't know. That sounds like a medical question that I cannot answer. I don't know.

Q. And your other conclusion does not provide any evidence for the necessity of gender-affirming vaginoplasty. Where does it say that that is what it is attempting to do?

A. Oh, it didn't. It's just, again, I just

rolled it. Probably when I rolled that, again, I was thinking -- well, okay.

So, yeah, it didn't, but I just make the statement because based on the fact -- based on the fact that none of this study comparing the treatment to alternative or to no treatment. So then once you don't have that, you know, you cannot say anything about this is necessary. Yes, this is not on the assertion. So this is -- I just roll that as if you don't have comparison, then you cannot, like there are a bunch of possibles, then you cannot say this is must, this is next.

I guess when I wrote that, I probably crossed -- was still thinking about some point of like this is the only effective thing or something like that.

So yes, you are right. In terms of in this -- specific to this assertion, they didn't, in this assertion, didn't say anywhere that it's necessary, okay. And I made -- yeah, I didn't -- well, this assertion actually is, yeah, I didn't make that statement. But, again, I was just based on the -- on the review I did, I add this -- I mean, I add this phrase there. That is accurate. The phrase is accurate. But, yeah, it is not, it's not stated in the

assertion, that is correct.

Q. Okay. And for the women who have been receiving hormone therapy and continue to have significant gender dysphoria, are you aware of any alternative treatments besides gender affirming surgery?

MR. RODRIGUEZ: Object to the scope.

You can answer.

A. No, that's, again, that's not my expertise. So I don't have answer to that. I don't have enough information about that.

Q. But you don't know if there are alternative treatments?

A. I don't know.

Q. Okay. Let's go to page 19, which has Ettner Assertion 1.

A. Yes, I'm there.

Q. Okay. And so in that -- your first paragraph after the assertion, about the fourth line down you say: As elaborated in my assessment of WPATH Assertion 1, the statistical methodology in the field of comparative effectiveness of SRS is not up to the long-established standard in comparative effectiveness research in medicine.

A. Correct.

Q. What is comparative effectiveness research?

A. Oh, comparative effective research, as I wrote in page 5 of my report, I said in medicine, the type of research used to evaluate the effects and safety of an intervention, it's broadly referred to as comparative effectiveness research. The statistical methodology for, again, here's a typo, for the comparative effectiveness research is generally -- belongs to the general statistics field of causal inference, which I am an expert on.

So basically in medicine and health studies, like the whole type of study I tried to establish the effectiveness, the safety, or efficacy of treatment is broadly referred to as comparative effectiveness research.

Again, you can see that there's emphasis, the two things: One is effectiveness, the other is comparative. So it's a comparison, yeah. That's what I meant.

Q. Okay. And did you mention there was a typo?

A. Yeah, the typo was -- so the last sentence says: The statistical methodology for quality of life, it shouldn't be quality of life. It's statistical methodology for comparative effectiveness research

belongs to the general statistical field called inference.

Q. Got it. That's the one we identified earlier?

A. Yes.

Q. Okay. So going back to page 19, what is the long-established standard that you're referring to in comparative effectiveness research in medicine?

A. Oh, well, as I said, that is -- that would be in the best case scenario, when available, you do a randomized experiment or maybe multiple randomized experiment. And when that is not available, you resort to observational study but well-designed observational study, and, for example, prospective before/after studies, and this like a more represent -- like a large study sample, things like that. And then like the other would be considered good or like acceptable. And then long-established, that, as I said, the consensus is then this kind of retrospect study resolved before/after measurement those -- and why you have also a lot of nonresponse as more sample size those of low quality.

So, again, that's what I meant by long-established standard and comparative effectiveness research in medicine.

Yeah, so like when you try to publish something, like about comparative effectiveness of treatment, then you expect to provide either randomized study or high quality observational study. So that's what I meant.

Q. And must that standard be met before a treatment can be provided to a patient?

MR. RODRIGUEZ: Objection to scope.

You can answer.

A. Not necessarily, because there's a lot of -- so, okay, different, different medical conditions like FDA. For example, if we are talking about new drugs and new medical devices, FDA would almost always -- well, most of the time would require a randomized study, right, but that's not the end of it, because they would do phase one, phase two, phase three randomized study, and then after approval, they will actually also do the post marketing, they call post marketing analysis.

Like, for example, we now all use Covid vaccine, right? We use Covid vaccine. So after Covid vaccine is proved, then actually there will be continuous study, actually to like in real world scenario. When Covid-19 vaccine is used, and then what's the population? So you go to continue. In that

case, you cannot do an online study, right. But you do an observational study for a large population, and then you calculate -- you study the effect in real life.

So, again, I think your question is like whether you should have kind of treatment provided before the -- sorry, can you rephrase? I cannot -- can you rephrase your question?

A. Yes. So you're talking about the methodology in the field of comparative effectiveness of sex reassignment surgery is not up to the long-established standard in medicine. And so I'm asking if that standard must be met before treatment can be provided?

MR. RODRIGUEZ: Objection, scope.

You can answer.

A. I think that's a different question from what I tried to -- from what my opinion is about, because I don't have -- I mean, I don't have answer to that.

What I can just say is the current state on the research on the sex reassignment surgery, at least based on the document they cited that I reviewed, do not -- because most of them are low quality, and the better quality ones have mixed results. Based on that, I would not -- I don't think that would meet the high

standards -- the high standard that people expect in, you know, he recommend -- I'm not going to recommend, just in reporting the effectiveness of those surgeries.

Q. So you are not providing an opinion on whether the evidence meets the standard in comparative effectiveness research, impacts whether treatment can be provided?

MR. RODRIGUEZ: Objection, scope.

You can answer.

A. Correct. I'm not providing opinion on that. I focused on Ettner's assertion. I focused on her assertion saying that studies show that gender-affirming surgery as safe and effective, safe and effective. And also she said that indeed for many people, this is the only effective treatment.

So my assertion is about whether she has enough evidence from those references she cited to support this two statement: One is whether they are safe and effective; the other is this is the only effective.

As I mentioned earlier, the only effective, that's kind of the necessity my understanding is. But when you say only effective, you have to compare, you have to can see that there's a possibility of alternatives. And that's one thing. And the first

sentence about safe and effective, I already said many times why, why the studies they decided do not meet the standard in providing rigorous and consistent evidence for that statement.

Q. Okay. And you're also not providing an opinion on what degree of statistical methodology is needed for a treatment to be included in a clinical practice guideline, correct?

MR. RODRIGUEZ: Asked and answered and scope. You can answer.

A. Correct. I'm not providing opinion on that. Again, I provided opinion on whether those assertions are supported or, yeah, by the documents they cited.

As I said, I would not, based on -- if I'm an expert in this field, which I am not in gender dysphoria, and if I'm an expert, and if I read this document -- no.

I'm a statistician, and I read those documents. I should say I'm a statistician. I read all the documents they cited, and then I would not make the statement as they make it. That's a better summary of what I want to say. Because I would say that there would not be enough evidence. I don't think there's evidence strong enough for me to make this kind of

statement.

Q. You disagree with Dr. Ettner's assertion describing the research as methodologically sound?

A. I disagree with that statement, and I think I said I don't think it's methodologically sound, and I already clarify why I think that many of the studies are fraud. And, again, that opinion has been -- that statement has been made in multiple, in large literature review in that field. So it's not -- yeah.

Q. Okay. And your first sort of comment after the sentence we were just talking about, comparative effectiveness research is that: There has not been a single randomized control trial. Is that the primary reason that you view the research is not methodologically sound?

A. No. As I said many times, that's not the end of the world, but it's one thing you can easily point out.

So my statement is -- my argument of -- basically my opinion consists of four things: First is there's no randomized study. Second is that's not the end of the world. You can still do good quality observational study, that is prospective before/after study. And then they don't -- and in the study they cited, they indeed have a few of them and the result

are mixed. And the third part of the argument is that in the vast majority of the study they cite are low quality retrospect study that subject to a lot of confounding bias and all sorts of biases. And the fourth component of my argument is that even in their -- many of their own large scale systematic review, literature review, they -- the expert are calling for better methodology or more prospective studies and call the current state of many of the studies of low quality.

So that's my -- like my statement has four components, and they are all integral.

So the lack of randomized study, that's the first component, but that's not the only component, and also that's not the only reason I made my statement.

So I think it's -- those four components are equally important.

Q. Are all cross-sectional retrospective studies methodologically unsound?

A. Well, all retrospect -- again, as a scientist, you don't make this kind of blanket statement. But what I can say, as I already repeatedly said, that you can have a prospective study if it's before/after data, that is far superior than retrospective study without before/after data. And the

reason of that is the confounding. The reason of that is the baseline measure of the outcome is often the most important predictive, the most important confounder out there. But retrospect studies do not control for that. So that's why it's low quality.

But I would not say that, you know, I would not blankedly(sic) say that every single retrospect study is garbage. No, that's not my point.

Q. Okay. But here, for this assertion, you're saying that the cross-sectional retrospective studies are not methodologically sound?

A. Yes, correct. In the studies they cite, I look at their methodology. They are, yeah, they're all lacking the baseline -- they're all lacking baseline measure of the outcomes, and they are subject to very severe confounding bias and they are not methodologically sound.

Yes, I stand by that statement in the context of what I reviewed.

Q. And are all retrospective studies subject to severe confounding bias?

A. Again, it depends on how much. So the answer is it depends on how many things you control for, how many confounders you control for, right. And as I said, that if in retrospective study, that if they

they use.

Q. Let's go back to the Ettner assertion, which is number 2 on page 20.

A. Yes, correct.

Q. In your report, you do not disagree with this assertion, correct?

A. Let me see. I need to read the conclusion. So I'm just reading it. The conclusion that is the gender-affirming surgery is the most appropriate treatment to elevate suffering of extreme gender dysphoria individuals still stands. 96 percent of patients who underwent that surgery were satisfied, and the regret was rare.

So what did I say? I said that: Immediately after the quote contained in this assertion, the authors themselves acknowledged. However, even today, this conclusion is based on methodologically less than perfect design studies. Okay. I guess I don't need to read it. But this is -- said very well what I think, right. And then this says, that this paper actually wrote that none of the study was a controlled one. So basically this paper described what are the -- why they say this methodologically less than perfectly -- less than perfect, right.

So the authors also acknowledge a few other methodological shortcomings, like attrition, or selection bias of the patient sample, which echo my critiques with respect to the WPATH Assertion 1. Yes.

Again, mine was based on -- so this particular assertion, so they analyzed that. So Ettner's assertion is -- yeah, so Ettner's assertion say that those -- they conclude that, and then I say that even as authors themselves that acknowledge the methodology is not perfect or is less than perfect.

Q. Okay. But you're not disagreeing with the statement?

A. I didn't provide opinion on this. Well, I didn't assess, because, again, as an expert, I'm a statistic expert, right. So then I can judge on the, again, from statistical aspect, whether this statement is based on like what kind of statistical strengths -- statistical evidence they have. And then I go to say -- well, I go to acknowledge, I go to find that the authors themselves acknowledge that those studies, you know, it's not -- the foundation is not most perfect, and I didn't direct -- in this assertion, I didn't directly say that -- yeah, I didn't provide opinion on whether that this is what I feel about this statement. Again, that's not what my opinion is about. My opinion

is about whether this is supported by the references, yeah.

Q. So looking at the Assertion 5 through 9, which is on page 21.

A. Correct.

Q. In your conclusion at the end of that section, does your use of the phrase rigorous and consistent scientific evidence, does that have the same meaning that we've discussed previously?

A. Correct.

Q. So if I were to tell you that 1 in 20 high schoolers in America die by suicide, would you say that America's high schoolers often die by suicide?

MR. RODRIGUEZ: Objection, speculation. You can answer.

A. That's how do we define often? Like my training is in mathematics, and you always say you need to give me a definition.

So if my definition is below -- is 10 percent -- if often is 10 percent, then it's not. If it's 5 percent, yes. So it depends on how you define often.

So my answer of this would be by definition tied to the definition of often, so I'm not going to speculate that.

Q. Okay. And how does one define often? How does one go about defining that?

A. Does that have anything to do with what we are talking about here?

Q. Yes.

A. So you're talking about a hypothetical about the high school, this like 1 out of 20. And as I said -- so as I said that if, I mean, I don't know, there's an English word, also if you want to go jargon, you can define this 5 percent or 10 percent. So --

Q. Does the context matter whether something is often or not?

A. Again, the definition matters. The definition matters, not the context. It's the definition.

Q. Okay. So if we say 10 percent is often, that would be often in every scenario that we can think of?

A. Again, you need to first define things. Like as a mathematician, we always first define a thing, especially if you want to attach, if you talk about numbers, you talk about often, yeah, the frequency. So the frequency, if I define -- if I say that by often I mean more than 10 percent, then that is often. But -- yeah, I really don't know how to further

elaborate this.

Q. Okay. How do you define often?

A. As I said -- well, as I said, that it's -- okay. So now I get to a point you say that depends on the context. I mean, I use this English word, and usually when I say often, it probably means something like over 50 percent.

So now I see your point. So, okay, so maybe it depend on the context.

So, again, this plain language or common sense often versus if you're talking about scientifically. So that's why in papers we don't write often, because this is like vague, non-defined terms, yeah.

Q. Okay. So let's move forward to page 23 and Assertion 11.

A. Yes.

Q. So midway through your paragraph, you comment on the Brown study, which reports that 5 percent of transgender inmates report that they had attempted or completed autocastration while incarcerated. And then you continue: This percentage supports the occurrence is relatively rare rather than often.

How did you define often and rare in that

assertion?

A. Well, okay, as I said, as common sense, I think often is probably 2 percent or 1 percent is not often, because that's 100 incidents. Then 100 times 2 or 3 times happen. I don't -- again, I don't -- I went from a layperson just a common sense. I would not say that's often.

Often, I would feel that is, if you say 10 percent or 20 percent, that sounds often.

So now I see your point. So you're going through this one, okay.

But as I said, I would not -- I mean, from a common sense perspective, regard 2 percent or 3 percent as often.

Q. Okay. Just a few minutes ago you said you would consider often as generally more than 50 percent?

A. No. As I said -- as I said, that is -- there's like if you want to go statistically, that I can say probably what you should write is probably Dr. Ettner or whatever should say by often, I mean this. And she didn't provide any of the numbers there. She just said often. I don't know what she mean by often. I'm just using the numbers I see at 2 percent or 3 percent, and I say that common sense, this is not often.

Q. But that assumes often is objective or consistent, doesn't it?

A. What do you mean by often is objective and consistent? Again, if you go to grab anyone on the street and ask them something happened 2 percent of the time, is it often? I bet you'd probably 99 percent of people tell you that's not often. That count as not often.

Q. Okay. We're talking about 5 percent here. So if I told you that 1 in 20 high schoolers, which is 5 percent, die by suicide in America, would you think that was often?

MR. RODRIGUEZ: Objection, scope.

You can answer.

A. Would I consider that often? So that's 5 percent, so that's another thing, okay. So high schoolers is a large population. So if you have say 10 million, let's say 1 million high schoolers, so 5 percent of that is, what, that would be 5,000, right? That would be 5,000. And then from that, yeah, that is -- so that quantity that is often.

Q. I think it would be 50,000.

A. 50,000 anyway, so that would be often in terms of the number, okay. But in rate wise, again, 5 percent, I don't know where to cut the line. But I

can tell you 2 percent or 3 percent is just not by any common sense would be viewed as common -- as often.

Q. Do you know what the rate of attempted or completed surgical treatment or autocastration is among non-transgender adults?

A. I do not, no.

Q. All right. Looking at Assertion 12, on the fourth line you say that: The WPATH study only provided qualitative studies, not any formal statistical meta-analysis.

Can qualitative evidence be useful in medicine?

MR. RODRIGUEZ: Objection, scope.

You can answer.

A. Of course it can. Of course they can be useful. But, again, this is -- what I wrote here is just a pure statement. It's -- of course qualitative would be better, because they provide -- they quantify things. I didn't say this -- their qualitative is not valuable. I'm not saying that.

Q. Okay. And then moving forward to the top of page 24, you are talking about other 9 studies. You say: The methodological problems include retrospective cross-sectional studies.

Is a retrospective cross-sectional study a

methodological problem?

A. Yes, I mean, again, as I said, retrospective cross-sectional means that there's no baseline measure of the outcome of the low quality, because it cannot control -- because it's subject to severe confounding bias, yes. So that is a problem. That is of low quality. And so the methodology did include that.

So it's one of the many weaknesses those studies are subject to.

Q. Do you disagree that researchers -- in looking at Ettner's assertion, do you disagree that researchers concluded that gender-affirming surgery positively affects well being, sexuality and quality of life in general?

A. As I said, that's not my opinion.

My opinion is that based on what they cited, the reference they cited, that those references they cited do not provide consistent or rigorous support for their statement.

In other words, if I'm a researcher, I look at those references. I would not make this statement, because I feel that the evidence is not strong enough.

Q. But you're not providing an opinion on whether the researchers conclude -- made that

conclusion?

A. Well, some of the researchers themselves said that they have called for -- again, they've called for this literature review. They called for better studies, better designs, and acknowledge the low quality of the current studies. So I stop there.

Q. So are you providing an opinion on whether the researchers concluded that gender-affirming surgery positively affects well-being, sexuality and quality of life in general?

MR. RODRIGUEZ: Asked and answered and scope. You can answer.

A. No, I didn't provide an opinion on that. I provided opinion on the quality of the study decided, and whether those studies that -- those studies would support the assertions they make.

Q. And so you are also not providing an opinion on whether gender affirming surgery does positively affect well-being, sexuality and quality of life in general?

MR. RODRIGUEZ: Scope, asked and answered. Go ahead.

A. Again, it's all of my scope, but as I repeated saying that, if I'm a researcher, and if I'm a researcher, and then I look at those studies, look at

those studies and decided I would not go to make that statement or those caveats, okay. Or I would acknowledge those assertions, or I would acknowledge the current state of the studies in this field do not provide consistent or rigorous conclusions and whether that equivalent to what you just said. That's not my -- that's a different question.

Q. Are you aware that the American Medical Association, the Endocrine Society and the American Psychological Association also put surgery in accordance with the WPATH standards of care as medically necessary treatments for individuals with severe gender dysphoria?

MR. RODRIGUEZ: Objection, scope, medical opinion. You can answer.

A. I'm not aware of that, because that's not my expertise.

Q. Okay. Do you think that they are wrong to do so, given your view that there is no rigorous and consistent statistical evidence on the benefits of sexual reassignment surgery?

MR. RODRIGUEZ: Objection, mischaracterization of testimony, scope and medical opinion. You can answer.

A. As I said, the treatment recommendations

IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF NORTH CAROLINA
CHARLOTTE DIVISION

Civil Action No. 3:22-cv-0191

KANAUTICA ZAYRE-BROWN,)
)
Plaintiff,)
)
v.)
)
THE NORTH CAROLINA)
DEPARTMENT OF PUBLIC)
SAFETY, et al.,)
)
Defendants.)
)

30(b)(6) DEPOSITION OF ARTHUR CAMPBELL, M.D.
THE NORTH CAROLINA DEPARTMENT OF PUBLIC SAFETY

(Taken by plaintiff.)

Raleigh, North Carolina

April 18, 2023, 9:30 a.m.

Reported By:
SUSAN GALLAGHER, CA CSR, CVR-CM

through memorandums of agreement and other methods to make sure that the offenders can receive the care that they need, and that's the full spectrum. There is nothing that's excluded or not included in it that.

Q Okay. Does DPS require that the healthcare decisions regarding individuals based on their own individualized circumstances?

A Yes, ma'am.

Q Do decisions for each individual to be based on individual determinations?

A Yes, ma'am.

Q Does DPS permit DPS healthcare providers' personal views to factor into the delivery of health and wellness services to people in custody?

A No, ma'am.

Q Does DPS permit DPS healthcare providers' political views to factor into the delivery of health services to people in their custody?

A No, ma'am.

Q I now want to have marked as Exhibit 3 a policy entitled "Health and Wellness Services Organization."

(Exhibit 3 marked for identification.)

BY MS. MAFFETORE:

Q Do you recognize this policy?

A Yes, ma'am.

Q And what is this policy, broadly speaking?

A So this talks about the overarching philosophy and the structure and authorities within -- they call it health and wellness here. That's since changed since we're the Department of Adult Corrections. So the new name for this is the Division of Comprehensive Health Services, but essentially the same policy carries forward.

Q And when would the policy have shifted title?

A When DPS made the transition to DAC, which was in the past 60 days, roughly.

Q Okay. And you've seen this policy before today; correct?

A Yes, ma'am.

Q Who at DPS is responsible for drafting this policy?

A So this would be -- under the current structure will be the deputy secretary for Comprehensive Health Services.

Q Okay. And under the previous structure?

A It would have been the director of Health and Wellness.

Q So is that or was that at the time Gary Junker?

A It was and still is.

Q Does Gary Junker have a -- his title is

slightly different now; is that correct?

A Correct. He's now the deputy secretary.

Q Did you have any involvement in drafting this policy?

A No, ma'am.

Q Have you ever been asked to contribute to any revisions of the policy?

A No, ma'am.

Q If you could please look at page 1 of this exhibit, Section 2C at the bottom, do you see a portion that says, "In support of DOP's mission statement, health and wellness professionals shall promote excellence, provide community-consistent cost effective quality healthcare throughout our system."

Did I read that accurately?

A Yes, ma'am.

Q What does DOP mean by "community consistent healthcare"?

A So, again, they -- well, we are expected to provide our services that are consistent with standards of care or community practice. So there is a little bit of a distinction between what's the standard of care as opposed to following clinical practice guidelines, but that's the consistency there. So we need to be consistent with what the community is doing.

In other words, offenders should receive the exact same care they would get if they were on the outside.

Q Okay. You mentioned just now some distinction between standards of care and clinical guidelines. Could you elaborate on that?

A Sure. Standard of care is, quite frankly, more of a legal term than a medical term. So in the medical community, what we rely on and what the vast majority of all of the professional medical societies publish are clinical practice guidelines. They don't call them standard of care, per se.

So the best medical definition of standard of care would be the diagnostic or treatment procedures that a clinician should follow in treating a particular patient, illness, or a particular clinical circumstance. Legally it has a little bit different twist, and my interpretation of a legal definition of that would be that it's, how would the average the prudent provider provide care for that specific patient in those circumstances, or how would a similarly qualified and trained clinician provide care for a particular patient in those exact clinical circumstances.

Q Okay. Now, when you say that folks that are incarcerated should receive the same care in prison as

if they were in the community, what community are you looking to to determine what constitutes community consistent healthcare?

A So in the broad context, it's outside the prison.

Q So would that be nationwide?

A Well, not specifically because, again, states have -- for instance, you know, Medicaid is a state-run program. So states have variations in what their individual state provides and covers. Within the context of medical care though, the care should be the same. You know, if it is truly standard of care, it's going to be fairly consistent across the country.

Q Okay. So if I'm understanding your testimony correctly, in certain circumstances the community against which you're judging would be the state, but generally speaking it is nationwide?

A Correct.

Q Okay. Where does the definition or the explanation you just described, "community consistent healthcare," come from?

A I don't know what the origins of that is.

Q How did you come to be familiar with that?

A Again, by reading these policies and understanding what the department's policy is and how

we are supposed to take care of these offenders. That's where I became aware of what that standard is.

Q Does DPS provide training to its health services staff members regarding the meaning of community consistent care?

A I don't know if there's any specific training for that. You obviously review policies and procedures, and you have orientation when you arrive at the organization, and that's part of that, but I don't know if there's a specific training dedicated to this particular aspect of that.

Q Okay. From your understanding or from DPS's understanding, is medically necessary care the same as community consistent care?

A Generally, yes.

Q You said "generally, yes." Are there circumstances when that is not the case?

A Well, I think the difference would be in the community, individuals can pay for care that may be elective. Whereas, in the prison, we are responsible for providing that care.

Q I'm not sure I understand -- I'm not sure I understand that answer. So that's a situation where medically necessary care and community consistent care would not be similar is where elective procedures are

involved?

A Well, not just elective, but individuals in the community may not have, for instance, insurance. So it's different here. We cover these individuals for the care that's provided in the prison.

Q Okay. How does DPS define "medical necessity"?

A That's a big answer. So in its simplest terms, when you look at medical necessity, it's probably best defined as a procedure that is reasonable and appropriate for a particular individual, really, to either protect their life, to prevent significant disability or illness, or to prevent significant pain and suffering. That is a very broad definition of medical necessity, and quite honestly, it's been through a lot of subjectivity, and so within prisons we need to be a little more deliberate in how we define that.

So what we need to be sure in prisons is that every officer that has a similar clinical circumstances that has a case submitted for review or a clinical condition, it's evaluated in the exact same way as objectively as possible as any other offender in the prison, and that's for any medical condition that they may see.

In my interpretation of medical necessity, in

order to get after that and to be able to come up with a more clear understanding of what that means, you have look at what factors would you see with medical necessity that could be attributed to that, and there's really three broad ones, I think, that fall under that category.

First is a risk-benefit analysis. Second is standard of care, and third is evidence based medicine, and I can certainly talk in more detail about each of those.

So as we look at a particular case or circumstance, those are the broad criteria we need to use to evaluate that. With risk-benefit analysis, it's important to note that this is by far the most critical piece of that evaluation. What that means is that you have to look at that particular patient and those particular circumstances and their clinical condition, and you need to determine whether the proposed treatment, what would be the impact if you were to not perform that procedure as opposed to performing the procedure for the offender. So you balance the risk of performing the procedure versus the potential risk of not performing that procedure, and what is the outcome of that, and that involves, again, a very individualized review of that particular patient and

those particular circumstances, and I think one of the things about that balance is that you cannot perform analysis without doing that individualized review of that case, and that's to your other question you asked about, that individualized review. So we do that.

So, for instance, if a procedure is proposed and you know the potential treatment for that, you look at that particular patient, those circumstances, and determine whether that procedure is appropriate and it's going to do those things I mentioned. Is it going to protect their life? Is it going to prevent significant illness or disability, and is it going to prevent significant pain and suffering? And that's how you do that risk-benefit analysis.

Q So I just have one follow-up regarding preventing significant pain and suffering. Is your understanding that emotional pain and suffering is also relevant to whether or not something is medically necessary?

A Yes, ma'am.

Q Psychological pain and suffering?

A Yes, ma'am.

Q And I believe a moment ago when you started explaining this to me, you said, "at least in my view," and I just want to be clear we're in the 30(b)(6)

portion of your deposition so I'm asking for DPS's position. Is your understanding that everything you just explained to me is DPS's position?

A No. So I think that DPS does not have a medical necessity definition, per se, or DAC.

Q So where did the definition of medical necessity as you just explained to me come from?

A Well, I'm thought you were asking my opinion of that. I probably should have not answered that, but that's --

MR. RODRIGUEZ: It was asked in the context of the 30(b)(6), and your response was in the context of your understanding of that as the representative, and then I think you clarified that it is not written in a policy, a departmental policy.

THE WITNESS: Correct.

BY MS. MAFFETORE:

Q And that's your understanding. So is that the definition that you use acting as medical director for DPS, what you just explained to me?

A The medical necessity for DPS would be what I described initially, the generally accepted medical definition of medical necessity. So that first thing I told you where it's basically those things that prevent death, significant illness, and disability. That is

the accepted standard, really, everywhere for what medical necessity is.

Q So you mentioned certain factors that are taken into account regarding medical necessity. Does DPS ever take into consideration the cost of a procedure when it's considering medical necessity?

A No.

Q How about security?

A Security is always considered in every context in our setting.

Q So it's considered a medical necessity determination?

A It's not a medical necessity determination, no, but security's always a determination.

Q Okay. How about logistics?

A Again, not for medical necessity, if that's what you're asking.

Q What about the ability to provide postoperative care?

A Again, not for medical necessity.

Q Is your interpretation as medical director on behalf of DPS of medical necessity the same for all DPS decisions about the provision of, for example, mental health care?

MR. RODRIGUEZ: Object to speculation.

You can answer.

THE WITNESS: It's universal when it relates to health care, regardless of the type of healthcare.

BY MS. MAFFETORE:

Q So also all medical care, all sorts of care?

MR. RODRIGUEZ: Same objection. Speculation.

You can answer.

THE WITNESS: Yes.

BY MS. MAFFETORE:

Q And in evaluating the request from someone in DPS custody for healthcare services, is there any kind of care where DPS would consider an individual's legal history in making a medical necessity determination?

A No, ma'am.

Q Is there any situation where DPS would consider an individual's criminal record in making a medical necessity determination?

A No, ma'am.

Q Is there any instance where DPS would consider an individual's disciplinary history or history of interactions in a medical necessity determination?

A No, ma'am.

Q If you to turn to page 2 of Exhibit 3, if you'll look at Section 2G5, it states there that "one of the goals of health and wellness is to engage in

sound healthcare practices that meet an acceptable standard of care"; correct?

A Correct.

Q So I think that you started to get into this when you were talking about medical necessity, but if you could get into it now, what constitutes an acceptable standard of care according to DPS?

A So, again, within DPS we rely on the same things I mentioned, which are clinical practice guidelines, and that is across the board what we rely on for standard of care.

Q What are the sources of those clinical practice guidelines?

A They will vary. It can be from the individual professional medical associations and societies. We often develop our own clinical practice guidelines specific for our individual setting. Each one of those references the pertinent medical society clinical practice guidelines, and we'll adapt those as needed for the prison environment.

Q Are there any circumstances where DPS would not look to individual medical associations and societies for clinical guidelines?

MR. RODRIGUEZ WITNESS: Object to speculation.

You can answer.

THE WITNESS: No, ma'am.

BY MS. MAFFETORE:

Q Okay. So on the same page of this exhibit, Section 2H, it states that "the provision of treatment regarding clinical decisions that involve health and wellness providers are the sole responsibility of the managing health and wellness practitioner and are not reversed by non-clinicians."

Did I read that correctly?

A Yes, ma'am.

Q What does DPS mean by this?

A So it means that medical decisions are made by medical authorities within the prison.

Q Okay. How does DPS define "clinician"?

A It is a licensed independent provider. So it's a provider who is credentialed to practice within our healthcare system.

Q So you said is a licensed health provider. What degrees of licensure does that encompass?

A So it can be family nurse practitioners, physician assistants, and physicians.

Q Anyone else?

A No.

Q Would a mental health care provider be considered a clinician?

A Yes.

Q And at what levels of medical health -- or mental health licensure would be considered a clinician?

A Licensed clinical social workers, psychologists, obviously psychiatrists are physicians, but they all fall in that same spectrum.

Q Does DP's definition of clinician have anything to do with the degree of patient contact a medical provider or mental health care provider has?

A No. They're licensed or credentialed based on their qualifications.

Q Okay. So if somebody holds a licensure within DPS but is in a position where they do not see patients at all, that person is still considered a clinician based on DPS's definition of clinician?

A Yes, ma'am.

Q Who, if anyone within Health and Wellness Services, would not be considered a clinician by DPS?

A So the registered nurses, the LPNs, the certified nursing assistant, the certified medical assistants. There are lots of administrative staff, both budgetary and accounting. The section is very large and includes not only clinical folks, but clinical support folks as well. There's respiratory

therapists. There's a lot of folks that are not considered credential providers.

Q Is there anyone outside of health and wellness who would be considered a clinician by DPS?

A No.

Q According to DPS, why shouldn't medical decisions be reversed by non-clinicians?

MR. RODRIGUEZ: Object to speculation.

You can answer.

THE WITNESS: Again, the only folks trained and qualified to make those medical decisions and recommendations are medical providers.

BY MS. MAFFETORE:

Q Are there any circumstances when DPS considers it appropriate for decisions to be reversed by non-clinicians?

MR. RODRIGUEZ: Objection to speculation.

You can answer.

THE WITNESS: Not that I'm aware of, no.

BY MS. MAFFETORE:

Q If you could turn to page 5 of this exhibit and look with me to Section -- you can't see a 3 on this page, but it's 3H. That section states, "Medical services are provided under the direction of the medical director/chief medical officer who maintains

responsibility for the quality of medical services provided to offenders."

Did I read that correctly?

A Yes, ma'am.

Q The medical director/chief medical officer referred to in this policy is currently you; correct?

A Yes, ma'am.

Q Still on page 5, still under H, Section 1 states that "services are provided in accordance with a professionally identified evidence-based clinical decision support resource."

Did I read that correctly?

A Yes, ma'am.

Q What is a clinical support -- clinical decision support resource?

A So it references, again, back to what I told you, the clinical practice guidelines, the pertinent medical societies, all of those entities provide input into what's ultimately our clinical practice guidelines, the way we practice medicine within the prisons.

Q So are there different resources based on different conditions?

A I'm not sure I understand the question. I think that any pertinent medical literature is going to

be appropriate to be considered when you're considering medical problems. So whether that's using resources such as UpToDate or whether it's relying on, you know, medical societies and those things.

Q Okay. So just to clarify on my end, a clinical decision support resource is not something that DPS drafts, essentially, to provide to clinicians as a resource?

A No, ma'am.

Q Okay. My understanding of your testimony is that the, sort of, wide variety of sources related to specific conditions, documents from medical societies, various research, all of that is considered by DPS to be a clinical decision support resource. Am I understanding correctly?

A Yes, ma'am.

Q In H-1, when DPS says "professionally identified," by whom?

A So, again, I think it goes back to what I said, is that you rely on medical societies and organizations that are recognized. So in other words, they're well recognized entities in the medical community.

Q Is anybody within DPS Health and Wellness Services responsible for vetting which sources are credible enough to be utilized as a clinical decision

support resource?

A No, ma'am. I think that the reason they're licensed as providers is we expect them to conduct that analysis as they would in accordance with their credentials.

Q So what materials can be relied upon is left up to the discretion of the individual provider?

A Correct, assuming it doesn't violate any policies and procedures within the department.

Q How would the department know if the selection of resources to rely on violated the policies of the department?

A Probably would not know until, you know -- I can't even think of an example where that would be the case, but -- yeah. I can't think of an example right now.

Q And that same section that we're looking at, what does DPS mean by "evidence based"?

A So, again, that's critical. What you want to show is that the research that you're relying on, the decisions you make in developing clinical practice guidelines, are on based on the best available research that has been evaluated over time longitudinally, that's been studied very frequently and reproducible across, you know, the medical community.

Q How do you determine if a resource meets the criteria that you just described?

A So, again, I think that you can look to the professional medical organizations that I talked about, and they're going to reference a lot of those, and I so I think you're already starting with reliable sources when you do your analysis.

Q So you generally consider those professional medical associations to be reliable?

A Yes, ma'am.

Q You can set that aside for now. Actually, I don't think we'll come back to that.

Does DPS facilitate surgery for those in its custody with outside specialists?

A Yes, ma'am.

Q How do DPS facilities typically coordinate the logistics of surgical procedures to be performed on those in custody that will be performed by outside specialists?

A The logistics?

Q Yes.

A So the logistics of -- so there's a referral that's made, just like happens anywhere else in the community. There's a -- the primary care provider will make a referral, in this case, to a surgical

it needs to be a DOT medication, direct observation therapy. So there are several examples where depending on the medication there may need to be some changes to how they are prescribed.

Q Are there specific conditions for which medication must always be approved through the physician review process?

A There is no conditions that I'm aware of. It's generally based on the medication itself.

Q Okay. Understood. Is there a difference in the approval process based on whether or not a condition is considered chronic versus acute?

A Not with the initial approval, but we do have what's called a MRTS system. So for a chronic condition, those medications are automatically refilled up to a period of time before that individual has a reevaluation.

Q Okay. How does DPS determine whether a condition is chronic?

A So we have designated what we consider to be chronic diseases or illnesses.

Q So those are designations that are standard and not specific to an individual?

A Correct. They're based on the condition.

Q Does DPS consider gender dysphoria chronic or

acute?

A It's a chronic condition, but not all transgender or gender dysphoric patients are on medications, obviously.

Q If somebody is on, for example, hormone therapy to treat their gender dysphoria, would that fall under the chronic and thus automatically renew, or would it -- or not?

A No. Because when you're treating someone for, in this case I assume for hormonal replacement, you need to monitor levels. So you don't want to automatically refill medications without checking the levels. So that will apply to a lot of conditions. Individuals that are on anticoagulants, if that anticoagulant requires surveillance, then that won't be an automatically refilled medication. It needs to be monitored accordingly.

Q So my understanding is if it's chronic, it's refilled automatically, but if it's not chronic, there essentially needs to be another UR in order for that person to continue on that medication if that's what's necessary?

A Generally, yes. Again, it depends on -- these are very medication-specific questions. So it's going to depend on whether there's -- thyroid's another

example. So if you're giving Synthroid to a patient, you need to monitor their TSH levels. So you don't want to just continue to refill that medication without monitoring that. So at each of those intervals, you'll need to enter a new prescription.

Q If DPS is unable to coordinate the monitoring that is necessary before a UR expires, does that medication continue in the interim?

MR. RODRIGUEZ: Objection to form.

You can answer.

THE WITNESS: So, again, that's going to be a clinical decision by the provider. So if a medication is about to run out and we haven't had labs or whatever surveillance is necessary performed, then that individual provider, the primary care provider, will need to make a decision, and it will be a risk-benefit analysis like we've talked about before, to determine whether we continue the current dose while we await those labs. If we hold the dose depending on the medication until we get the labs, if there's some clinical reason to believe that it's not an appropriate dose, then we can hold it. So, again, it's a very specific, individualized determination that's made.

BY MS. MAFFETORE:

Q If a UR for a specific medication has expired,

will a prisoner be able to receive that medication?

A Not once the order has expired, no.

Q Okay. So if a physician does not take some action on behalf of the prisoner before the UR expires, that prisoner just won't receive that medication while waiting for labs; is that right?

A I mean, theoretically that could happen. We also put some personal responsibility on the offenders as well to inform us that they need a refill of their medication. So there are fall backs.

Q If the medication is not a carry-on-person medication, how would the prisoner be able to tell whether or not their medication was about to expire?

A So they will know when their last prescription was, and they're informed what the duration of the prescription is when they receive the prescription. So they'll know they were prescribed 60 days, 90 days of their medication.

Q If somebody's given medication, it's not carry-on-person, they're given medication once every two weeks and it's administered to them and the UR order is for, for example, six months, is it still the responsibility of the offender to know when that prescription would expire and need to seek physician approval for a new prescription?