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IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF ARIZONA

D.H., by and through his mother, Janice Hennessy-Waller; and John Doe, by and through his guardian and next friend, Susan Doe, on behalf of themselves and all others similarly situated,

Plaintiffs,

vs.

Jami Snyder, Director of the Arizona Health Care Cost Containment System, in her official capacity,

Defendant.

Case No. 4:20-cv-00335-SHR

DEFENDANT'S OPPOSITION TO PLAINTIFFS' MOTION FOR PRELIMINARY INJUNCTION

(Assigned to the Honorable Scott H. Rash)

Defendant Jami Snyder, Director of the Arizona Health Care Cost Containment System ("AHCCCS"), submits this Opposition to Plaintiffs' Motion for Preliminary Injunction. (Doc. 3) D.H. and John Doe - minors with gender dysphoria - are demanding that AHCCCS, Arizona's Medicaid program, provide them coverage for gender reassignment surgery – specifically, chest reconstruction surgery. But Plaintiffs have not established this irreversible, expensive surgery is legally required or medically appropriate or effective for children generally or for themselves in particular; nor have they established their own ability to provide informed consent. Also, the relief sought would effectively decide the case at this point, as it would result in all the relief Plaintiffs seek in this case, and this is a highly disfavored result. Plaintiffs fail to meet the exceedingly high standards required for a mandatory injunction. Thus, the Court should deny the motion.

I. BACKGROUND

a. Plaintiffs D.H. and John Doe

Plaintiffs are minors - D.H. is 17 years old, and John Doe is 15 years old. (Doc. 1, ¶¶1, 21-22) Plaintiffs allege they are enrolled in AHCCCS "due to [their] family's limited income." (*Id.*) Plaintiffs have been diagnosed with gender dysphoria; they were identified as female at birth, but have since transitioned to live as male. (*Id.* ¶5) Plaintiffs seek "declaratory and injunctive relief to enjoin Arizona from continuing to deny them medically necessary treatment" – specifically, chest reconstruction surgery (permanent removal of breasts with chest wall reconstruction surgery). (Doc. 1, ¶¶1, 4, 17; Doc. 5-4, ¶35). The motion seeks to "enjoin Defendant from further enforcement of the regulation and order AHCCCS to cover male chest reconstruction surgery for D.H. and John," which they claim is "medically necessary." (Doc. 3, p.2; Doc. 1, ¶¶1, 17)

Plaintiffs' claims are based on Arizona Administrative Code ("A.A.C.") R9-22-205-B.4, which contains several AHCCCS coverage exclusions, including for: "(a) Infertility services, reversal of surgically induced infertility (sterilization), and gender reassignment surgeries; (b) Pregnancy termination counseling services; (c) Pregnancy

terminations, unless required by state or federal law; (d) Services or items furnished solely for cosmetic purposes; and (e) Hysterectomies unless determined medically necessary." While "gender reassignment surgeries" are excluded from coverage, other services for the treatment of gender dysphoria - hormone treatments and behavioral health/counseling - are not excluded. *Id*. D.H. claims prior authorization for chest reconstruction surgery was denied because of the exclusion, but the Complaint does not allege John sought prior authorization. (Doc. 1, ¶9)

Plaintiffs filed nine declarations (five from healthcare providers) in support of the motion. Plaintiffs gave their providers their medical records for review. *See, e.g.,* Declaration of Dr. Andrew Cronyn (Doc. 5-3, ¶5) Expert Declaration of Aron Janssen, M.D. (Doc. 5-4, ¶19); Expert Declaration of Loren Schechter, M.D. (Doc. 5-5, ¶18) And Plaintiffs argue relief should be granted because chest reconstruction surgery is "medically necessary" for them. For this reason, and in order to respond to the motion, Defendant requested Plaintiffs produce the medical records their providers/experts reviewed, explaining (1) the documents are relevant, (2) the prior authorization process requires AHCCCS to review relevant medical records, and (3) AHCCCS would hold the documents confidential. But Plaintiffs have obstinately refused to disclose any of these relevant medical records to Defendant.

Plaintiff D.H.: According to the Complaint, D.H. had "significant psychological distress at an early age, including severe anxiety and suicidal ideation" and was placed "in a psychiatric treatment facility on several occasions." (Doc. 1, ¶6) As a young child, D.H. "began exhibiting signs of significant psychological distress including depression, prolonged crying episodes, anxiety, and insomnia." (*Id*., ¶69) At the age of 11, D.H. had "other stressors D.H. was trying to navigate" (beyond any stress related to gender identity), which caused him to start losing his hair. D.H. was hospitalized, including in intensive psychiatric care, four times beginning at age 11 for depression and suicidal

ideation.[1] (Doc. 5-1, ¶¶5, 12; Doc. 1, ¶¶70, 78, 84) D.H. has a history of pervasive anxiety, chronic suicidal ideations and attempts, and related self-harm issues (including cutting, burning and hair pulling). (Doc. 5-2, ¶6) In addition, D.H. currently has "anxiety and psychological distress caused by prior trauma."[2] (*Id.* ¶13) Also, D.H. has a history of "oppositional disorder" (*Id.* ¶8), which the Diagnostic and Statistical Manual of Mental Disorders, 5th Edition ("DSM-5") defines as "a frequent and persistent pattern of angry/irritable mood, argumentative/defiant behavior, or vindictiveness."

At 13, D.H. informed his mother he is transgender and began seeing a therapist, Tamar Reed, who "recommended that D.H. begin to transition to living as male;" D.H. then began to socially transition to male and started hormone-replacement therapy (testosterone) that D.H. alleges "masculinize[d] his body." (Doc. 1, ¶¶7, 75, 79, 80)

Plaintiff John Doe: In his early years, "John's biological parents were unable to care for him and provide a stable home environment." (Doc. 4-1, ¶5) John's guardian is his grandmother. (Doc. 1, ¶89) John has been diagnosed with PTSD: "chronic post-traumatic stress disorder stemming from early-life attachment trauma." (Doc. 4-2, ¶11). The term "early-life attachment trauma" means John suffered abuse or neglect at a young age. Laidlaw Decl. at ¶16. John has been depressed, suffered from anxiety, engaged in self-harm through cutting and burning,[3] distanced from friends and family, lost interest in activities, and lost significant weight in a short period of time because of limited food intake. John also contemplated suicide. (Doc. 4, ¶5) According to John's clinical therapist, Mischa Cohen-Peck, John continues to suffer from PTSD. She notes he is currently

[1] D.H. was in intensive in-patient psychiatric care for severe anxiety and suicidal ideation beginning in 2014. There is no indication gender dysphoria was being evaluated, discussed, or addressed at this time. It was not until two years later (in 2016) that D.H. disclosed to another person that he was transgender. (Doc. 5-1, ¶¶5,7); Expert Declaration of Dr. Michael Laidlaw, M.D., Exhibit A ("Laidlaw Decl.") at ¶15.

[2] The Declaration of Tamar Reed does not specify the nature of the "prior trauma."

[3] Both D.H. and John have engaged in non-suicidal self-injury, which is associated with multiple types of psychiatric disorders (e.g., PTSD, depression, anxiety, and obsessive-compulsive, borderline personality, and eating disorders). Laidlaw Decl. at ¶19.

involved in "treatment of the trauma underlying his PTSD." (Doc. 4-2, ¶20) Thus, John has not been successfully treated for the trauma underlying his PTSD.[4]

At about age 11, John began to socially transition to male. (Doc. 1, ¶¶10-11) At 13, John began visiting a gender support program and then began hormone-replacement therapy (testosterone) and medicine to stop John's menstrual cycle. (*Id.* ¶¶96-97)

b. Treatment Standards

There are no laboratory, imaging, or other objective tests to predict whether children with gender dysphoria will outgrow the condition; a large majority of children with gender dysphoria outgrow the condition by adulthood. Expert Declaration of Dr. Stephen B. Levine, M.D. (Exhibit B) ("Levine Decl."), at ¶¶28, 56, 58-60; Laidlaw Decl. at ¶¶22, 40. Treatment interventions on behalf of children diagnosed with gender dysphoria must be held to the same scientific standards as other medical treatments; they must be optimal, efficacious, and safe, and any treatment that alters biological development in children should be used with extreme caution.[5] Laidlaw Decl. at ¶ 12.

A high percentage of children diagnosed with gender dysphoria have depression, anxiety, or other mental health disorders, and many had their first contact with psychiatric services for reasons other than gender identity issues. Laidlaw Decl. at ¶¶13, 23; Levine Decl. at ¶55 and n.7.[6] Both D.H. and John have a significant and lengthy history of significant psychiatric issues separate and apart from gender dysphoria. Laidlaw Decl. at ¶¶13-19. In addition, they have both been prescribed hormone-replacement therapy (i.e., testosterone). A typical dose of hormone-replacement therapy is very high (6 to 100 times

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[4] In addition, John describes "being detached" from his body. (Doc. 4-2, ¶12) One psychiatric disorder, dissociative identity disorder (often associated with traumatic events and/or physical or sexual abuse in childhood) causes people's bodies to feel different (like the opposite gender); also, suicide attempts and self-injurious behavior are common among people with this disorder. Laidlaw Decl. at ¶18.

[5] Indeed, Dr. Levine explains the "affirmation therapy" model for treating gender dysphoria disregards the principles of child development and family dynamics, and is not supported by science. Levine Decl. at ¶¶36-42, 61-67.

[6] Certain groups of children have an increased prevalence and incidence of trans identities, including children who are minorities, have mental developmental disabilities, are in foster homes or adopted, have a prior history of psychiatric illness, and adolescent girls. Levine Decl. at ¶19.

higher than the typical natal female body); significantly, high doses of testosterone predispose individuals towards mood disorders, psychosis, and psychiatric disorders, and thus hormone treatments can exacerbate a patient's underlying psychiatric problems. Laidlaw Decl. at ¶20. Plaintiffs claim they first felt better after the hormones, but later felt worse. It is likely they originally felt better because of the side effect of euphoria from high doses of testosterone; it is likely they later felt worse because (1) the high dose ultimately exacerbated their mental health issues, or (2) their underlying psychiatric issues were never actually resolved (or both). Laidlaw Decl. at ¶21.

A child's psychological disorders should be thoroughly treated before considering gender reassignment surgery, but there is insufficient evidence D.H. and John's psychiatric issues have been thoroughly evaluated and treated by a qualified psychiatrist/psychologist. Laidlaw Decl. at ¶23; Levine Decl. at ¶¶23, 27-35. In addition, there is nothing in the record to establish Plaintiffs (1) have been adequately treated or received medication to treat their psychological issues; (2) have had a thorough psychiatric evaluation; and (3) do not have a history of substance use/abuse (as is common in individuals with these types of disorders). Laidlaw Decl. at ¶¶23-25. This is all relevant as to whether two minors can provide informed consent for an irreversible surgery. Laidlaw Decl. at ¶¶25, 29; Levine Decl. at ¶¶105-118. If a patient later regrets the decision and decides to resume living as their natal sex (female), the patient will not be able to breastfeed a child. And like any surgery, it can result in damage to the nerves, trouble healing, scarring, and infections. Laidlaw Decl. at ¶¶26, 28; Levine Decl. at ¶90. Also, a final assessment (in-person exam) has not even been conducted on Plaintiffs to determine suitability for surgery.[7] Laidlaw Decl. at ¶27; Doc. 5-5, ¶45.

Gender dysphoria is the only psychiatric condition to be treated by surgery. Levine Decl. at ¶¶21-22. But quality studies showing that chest reconstruction surgery is safe, effective, and optimal for treating minors with gender dysphoria do not exist; also, there is

[7] Hennessy-Waller's declaration claims a plastic surgeon indicated D.H. was "a good candidate" for surgery, but there are no records or evidence of an in-person exam.

evidence that questions the long-term effectiveness of gender reassignment surgery.[8] Laidlaw Decl. at ¶¶30-38; Levine Decl. at ¶¶69-82, 96-98, 113-114. Indeed, the Centers for Medicare and Medicaid Services has found "inconclusive" clinical evidence regarding gender reassignment surgery. Laidlaw Decl. at ¶36. There are no tests to predict whether a young person will outgrow the gender dysphoria; and the under 21 age group is still undergoing brain development and are immature with respect to intellect, emotion, judgment, and self-control. Thus, there is a significant chance a young person may later regret removing an organ that cannot be replaced. Laidlaw Decl., at ¶40; Levine Decl., at ¶¶99-104. Plaintiffs have not established that an irreversible chest reconstruction surgery is safe, medically necessary, or effective to treat their gender dysphoria, or that they have the ability to provide informed consent for an irreversible surgery of this nature. Laidlaw Decl. at ¶¶12, 39-40; Levine Decl. at ¶¶14, 18, 69-82, 96-98, 113-114.

II. LEGAL ARGUMENT

a. Requirements to obtain a preliminary injunction

A preliminary injunction is extraordinary and drastic relief that a court may grant only in limited circumstances and after the moving party meets exacting requirements. "A plaintiff seeking a preliminary injunction must establish that he is likely to succeed on the

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[8] Plaintiffs cite the World Professional Association for Transgender Health's (WPATH) "Standards of Care for the Health of Transsexual, Transgender, and Gender Non-Conforming People" (7th ed., 2011) ("SOC"). But as Drs. Laidlaw and Levine note, (1) WPATH's SOC were prepared within an organization whose mission includes advocacy, (2) there are limitations on the SOC that have been caused by a lack of rigorous research in the field, (3) the SOC does not capture the clinical experiences of many in the medical profession, (4) because the latest SOC deleted the requirement for therapy, facilities are allowing patients to be counseled to transition by individuals with masters rather than medical or PhD clinical psychology degrees, and (5) there are serious questions about WPATH's scientific process; for example, unlike other organization's guidelines, WPATH does not have a grading system for the strength of their recommendations or quality of evidence. Levine Decl., at ¶¶43-51; Laidlaw Decl., at ¶33. Nonetheless, even under the SOC (p.59), the criteria for chest surgery are (1) the patient has "[c]apacity to make a fully informed decision and to give consent for treatment;" and (2) "If significant medical or mental health concerns are present, they must be reasonably well-controlled." Plaintiffs have not established they have capacity to provide informed consent or their other conditions have been reasonably well-controlled. Laidlaw Decl., at ¶¶14-21, 23-25, 29. For example, D.H. has ongoing anxiety and psychological distress from prior trauma; John is currently in treatment for trauma underlying his PTSD. (Doc. 4-2, ¶20; Doc. 5-2, ¶13)

merits, likely to suffer irreparable harm in the absence of preliminary relief, that the balance of equities tips in his favor, and that an injunction is in the public interest." *Monarch Content Mgmt. v. Ariz. Dep't of Gaming,* 971 F.3d 1021, 1027 (9th Cir. 2020) (citing *Winter v. Nat. Res. Def. Council,* 555 U.S. 7, 20 (2008)). The Supreme Court has emphasized a moving party must clearly prove each of these elements: "It frequently is observed that a preliminary injunction is an extraordinary and drastic remedy, one that should not be granted unless the movant, *by a clear showing*, carries the burden of persuasion." *Mazurek v. Armstrong*, 520 U.S. 968, 972 (1997) (quoting 11A *C. Wright, A. Miller, & M. Kane, Federal Prac. & Proc.* § 2948, pp. 129–130 (2d ed.1995) (emphasis in *Mazurek*; footnotes omitted)). This is particularly true in cases, like this one, where the moving party seeks a "mandatory" rather than a "prohibitory" injunction. Mandatory injunctions require a party to "take action"[9] and are "particularly disfavored" by courts. *Marlyn Nutraceuticals v. Mucos Pharm.,* 571 F.3d 873, 878–79 (9th Cir. 2009). Mandatory injunctions are "subject to heightened scrutiny and should not be issued unless the facts and law clearly favor the moving party." *Dahl v. HEM Pharm,* 7 F.3d 1399, 1403 (9th Cir.1993); *Marlyn,* 571 F.3d at 878–79. In *Anderson v. United States,* 612 F.2d 1112, 1115 (9th Cir. 1979) the Ninth Circuit described this "heightened scrutiny" as follows:

> Courts are more reluctant to grant a mandatory injunction than a prohibitory one and . . . generally an injunction will not lie except in prohibitory form. Such mandatory injunctions, however, are not granted unless extreme or very serious damage will result and **are not issued in doubtful cases** or where the injury complained of is capable of compensation in damages.

(Emphasis added.) This language was repeated in *Marlyn* (vacating a mandatory injunction). Plaintiffs' motion should be denied because there is more than a little doubt that Plaintiffs in this case are likely to succeed on the merits or suffer irreparable harm in the absence of a preliminary injunction.

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[9] Among other things, Plaintiffs would have this Court enter an order that AHCCCS "shall provide coverage for Plaintiffs' male chest reconstruction surgeries, consistent with all other requirements of federal law." (Doc. 3-1 at p. 1)

b. Plaintiffs have not established irreparable harm

Plaintiffs argue if the Court does not grant a preliminary injunction, they will suffer medical harm. The principal source of this harm is the binding that each Plaintiff wears to disguise their breasts. But a careful review of the facts presented demonstrates why there is no medical emergency that warrants immediate relief. The DSM-5 (p. 451) defines gender dysphoria as "distress that may accompany the incongruence between one's experienced or expressed gender and one's assigned gender." In the context of a preliminary injunction, the Court must consider whether this "distress" amounts to irreparable harm. Another important aspect of gender dysphoria in the context of this case is that, more often than not, gender dysphoria in children does not persist into adulthood. The DSM-5 (p. 455) says: "Rates of persistence of gender dysphoria from childhood into adolescence or adulthood vary. In natal males, persistence has ranged from 2.2% to 30%. In natal females, persistence has ranged from 12% to 50%." Dr. Laidlaw agrees, noting "[t]here are no laboratory, imaging, or other objective tests to predict whether children with gender dysphoria will outgrow the condition." Laidlaw Decl. at ¶22. Thus, the distress Plaintiffs currently experience may very well dissipate over time, which argues in favor of the Court adopting a deliberate rather than emergency pace here.

Dr. Laidlaw points to another concern related to the Plaintiffs in this case. Both suffer from other significant psychological disorders which pre-date their gender dysphoria. As Dr. Laidlaw notes, this history of psychiatric disorders calls into question the ability of these minors to provide true informed consent: "I have significant concerns about the ability of two minors with histories of significant underlying psychiatric issues, separate and apart from gender dysphoria, to provide informed consent to undergo an irreversible sex reassignment surgery." Laidlaw Decl. at ¶29. Our country does not allow children under 18 to vote. In Arizona, children under 16 cannot drive. Yet Plaintiffs would require the state to approve irreversible surgery for even younger children.

D.H.: D.H., who is 17 years, first came out as transgender in about 2016. (Doc. 5-2, ¶¶5-6) According to Dr. Cronyn, he has been binding for five years now. (Doc. 5-3, ¶26) Despite this lengthy period of binding, D.H. has not reported any of the skin conditions Plaintiffs argue could develop into more serious medical issues. (*Id*. ¶26) Similarly, the back pain that DH complains of is relieved by stretching and removing the binder. (*Id*. ¶¶19-20) And although Dr. Cronyn opines that continued use of the binder "will exacerbate the symptoms of his asthma" that exacerbation has apparently not occurred to date. (*Id*. ¶23).

John Doe: John is 15 years old. John has suffered from "chronic post-traumatic stress disorder from early life attachment disorder." (Doc. 4-2, ¶11) Long-standing and pre-existent conditions should be addressed *before* irreversible surgical procedures are employed. Laidlaw Decl. at ¶¶11-29; Levine Decl. at ¶¶30-35, 75, 111-112. The Court should also note John's therapist is the only medical professional to provide a declaration in support of his need for surgery. Plaintiffs provide no declaration from a medical doctor who has actually treated John to support immediate and irreversible surgery for John.

In light of these facts, the cases Plaintiffs cite provide little support for a preliminary injunction. *Bowen v. City of New York*, 476 U.S. 467, 484 (1986) was a lawsuit brought by New York and eight disabled individuals who alleged the Social Security Administration was denying benefits based upon an unwritten policy that was contrary to published regulations. *Id.* at 473–74. The injunction at issue was not a preliminary injunction (the court's decision followed a seven-day trial) but rather the court entered an order requiring the agency to "reopen the decisions denying or terminating benefits, and to redetermine eligibility." *Id.* at 476. Nor were the *Bowen* plaintiffs seeking a mandatory injunction. As the court noted, the plaintiffs "neither sought nor were awarded benefits in the District Court, but rather challenged the Secretary's failure to follow the applicable regulations." *Id.* at 483. And finally, it should be noted the district court's finding of irreparable harm was not challenged on appeal. *Id.* at 484. Further,

Edmo v. Corizon, 935 F.3d 757 (9th Cir. 2019) was an 8th Amendment claim brought by a prisoner. The court's decision was issued only after the court allowed the parties four months of factual and expert discovery followed by a three-day evidentiary hearing. *Id.* at 775. This process allowed the court to make an evidentiary finding of irreparable harm based upon "Edmo's severe, ongoing psychological distress and the high risk of self-castration and suicide she faces absent surgery." *Id.* at 797. The importance of an evidentiary hearing was emphasized in *Thomas v. Cty. of Los Angeles*, 978 F.2d 504 (9th Cir. 1992), as amended (Feb. 12, 1993). *Thomas* was a Section 1983 class action by Black and Hispanic residents who alleged deputy sheriffs were utilizing terrorist-type tactics to cause them irreparable physical and emotional injuries. *Id.* at 511. Importantly, the 9th Circuit vacated the preliminary injunction entered by the District Court because "[b]efore issuing its preliminary injunction, the district court did not conduct evidentiary proceedings to resolve any of the disputed matters." *Id.* at 509.

Plaintiffs' remaining cases are also not dispositive. In *Chalk v. U.S. Dist. Court Cent. Dist. of Cal.*, 840 F.2d 701 (9th Cir. 1988), a teacher diagnosed with AIDS brought a claim under the Rehabilitation Act. The 9th Circuit found irreparable harm because the Rehabilitation Act allows the recovery of emotional distress damages (*Id.* at 710) and because, given the lethality of AIDS at the time, Chalk did not have time to wait for trial: "Presently Chalk is fully qualified and able to return to work; but his ability to do so will surely be affected in time. A delay, even if only a few months, pending trial represents precious, productive time irretrievably lost to him." *Id.* Neither factor is present in this case. And finally, Plaintiffs' reliance on *Whitaker v. Kenosha,* 858 F.3d 1034 (7th Cir. 2017) is misplaced for the simple reason that in *Whitaker*, the requested remedy was not an expensive, irreversible surgery of questionable value for two minors who have not established the ability to provide informed consent, but simply the ability to use a school restroom of the transgender student's choosing. *Id.* at 1042.

Plaintiffs contend the deprivation of constitutional rights constitutes irreparable injury. But they first have to prove a deprivation of their constitutional rights; as demonstrated in section II(c)(4) there is significant doubt whether Plaintiffs have a constitutional right to have AHCCCS pay for this surgery. This case is not like *Melendres v. Arpaio*, 695 F.3d 990 (9th Cir. 2012) in which Latino drivers were stopped just because of their race. Nor is it similar to *Edmo,* in which discovery and a lengthy evidentiary hearing demonstrated that a prisoner's 8th Amendment rights had been violated. Here, the Court must grapple with the difficult question of whether AHCCCS should be required to provide medically questionable, irreversible surgeries to children. That complex and difficult question cannot be resolved on the record before this Court. Laidlaw Decl. at ¶12.

c. Likelihood of success on the merits

1. Plaintiffs fail to demonstrate the challenged rule violates EPSDT

AHCCCS does not discriminate against its transgender members or exclude gender dysphoria treatment - for example, AHCCCS covers medically necessary hormone treatments and mental health counseling. The challenged rule merely draws the line at gender reconstruction surgery. As set forth above and in the declarations of Drs. Laidlaw and Levine, there is legitimate debate about whether such surgery should be covered, particularly for children. The question is: Does such surgery correct or ameliorate the underlying conditions of persons, particularly children, who seek such surgeries?

We do not know Plaintiffs' circumstances beyond what they allege in their Complaint, motion, and attached declarations. EPSDT covers treatment of defects, illnesses, or conditions that are "discovered by the [EPSDT] screening services," not simply asserted in expert declarations. 42 U.S.C. § 1396d(r)(5). Plaintiffs have been unwilling to produce the medical records upon which their expert declarations rely, and even their own declarations disclose Plaintiffs have not been finally assessed for suitability for surgery by the surgeon who would perform the procedures. (Doc. 5-5, ¶45)

D.H. alleges he sought chest reconstruction surgery from AHCCCS in 2019, and appealed the denial to his health plan but no further. (Doc. 5-1, ¶¶14-15) Apparently, D.H.'s next step was to seek not the review afforded by state law, but this Court's intervention instead. John does not allege he ever sought AHCCCS coverage of chest reconstruction surgery. Even interpreting the Complaint as a "request" for such authorizations, neither has yet demonstrated medical necessity for the service.

Although EPSDT coverage is broad, it is not unlimited. The 9th Circuit has stated, "[u]nder § 1396d(r)(5), states must cover every type of health care or service necessary for EPSDT corrective or ameliorative purposes that is allowable under § 1396d(a)", but the court immediately noted, "[t]his is subject to certain limits; for example, a state need not pay for experimental medical procedures." *Katie A., ex rel. Ludin v. Los Angeles Cty.*, 481 F.3d 1150, 1154, n.10 (9th Cir. 2007). Medicaid does not require states to cover every service, especially services that have yet to be demonstrated to be safe and effective. States may limit the amount, duration, and scope of the services they cover. 42 U.S.C. § 1396d(a). States are required to limit utilization of services. 42 U.S.C. § 1396a(a)(30)(A) (state plans must "provide such methods and procedures relating to the utilization of, and the payment for, care and services available under the plan ... as may be necessary to safeguard against unnecessary utilization of such care and services"); *Rush v. Parham,* 625 F.2d 1150, 1156 (5th Cir. 1980) ("Georgia's definition of medically necessary services can reasonably exclude experimental treatment" when confronted with plaintiff's complaint that Georgia refused to pay for "transsexual surgery" prescribed by doctor); *Miller v. Whitburn,* 10 F.3d 1315, 1321 (7th Cir. 1993). As noted above and in the attached declarations, there is reason to question the "broad consensus" Plaintiffs allege as to its safety and efficacy. (Doc. 3, at 8) "Medicaid was not designed to fund risky, unproven procedures, but to provide the largest number of necessary medical services to the greatest number of needy people." *Ellis v. Patterson*, 859 F.2d 52, 55 (8th Cir. 1988). "It may be that, pursuant to a generally applicable funding restriction or utilization control

procedure, a participating state could deny coverage for a service deemed medically necessary in a particular case." *Hern v. Beye*, 57 F.3d 906, 911 (10th Cir. 1995).

Further, while EPSDT is a mandatory set of services under Medicaid that is covered by AHCCCS, the services that correct or ameliorate a child's condition are not specifically listed. Defendant has not located any decision, nor have Plaintiffs cited one, that has found gender reassignment surgery to be recognized as an EPSDT requirement. Thus, it is not improper to exclude coverage for a service that continues to be the subject of legitimate debate as to its safety and efficacy.

2. Plaintiffs fail to demonstrate violation of comparability requirement

42 U.S.C. § 1396a(a)(10)(B)(i) provides "the medical assistance made available to any individual described in subparagraph (A)--(i) shall not be less in amount, duration, or scope than the medical assistance made available to any other such individual." The exclusion does not violate this requirement. First, the exclusion applies to all transgender persons alike. Second, the rule requires comparable services for individuals with comparable needs. "[N]eed is the only basis upon which distinctions between recipients can be made without violating the comparability requirement." *V.L. v. Wagner*, 669 F. Supp. 2d 1106, 1117 (N.D.Cal. 2009). As noted in the declarations of Drs. Laidlaw and Levine, the needs for relief from gender dysphoria are unique – they are not the same as the needs of a person who seeks reconstruction after a mastectomy. This is particularly true as to children. Nor does AHCCCS "arbitrarily deny or reduce the amount, duration, or scope of a required service . . . to an otherwise eligible beneficiary solely because of the diagnosis, type of illness, or condition." 42 C.F.R. § 440.230(c). Plaintiffs argue AHCCCS is denying "comparable services for individuals with comparable needs," but this begs the question whether reconstruction following a mastectomy is based on the same needs as chest reconstruction to treat a child's gender dysphoria.

3. Plaintiffs fail to demonstrate a violation of §1557 of the ACA

The exclusion does not violate the Affordable Care Act ("ACA"), which prohibits discrimination "on the basis of sex." 42 U.S.C. §18116(a) (incorporating 20 U.S.C. §1681(a)). The federal rules implementing §1557 were amended effective Aug. 18, 2020 with the intent that "each State may balance for itself the various sensitive considerations relating to medical judgment and gender identity, within the limits of applicable Federal statutes (which are to be read according to their plain meaning)." *Fed. Reg.,* Vol. 85, No. 119 at 37162 (June 24, 2020). Further, "[t]he Department does not and need not take a definitive view on any of the medical questions raised in these comments about treatments for gender dysphoria. The question is whether Title IX and Section 1557 require healthcare professionals, *as a matter of nondiscrimination*, to perform such procedures or provide such treatments. The answer is they do not." *Id.* at 37188 (emphasis in original). Also, a "medical provider may rightly judge a hysterectomy due to the presence of malignant tumors to be different in kind from the removal of properly functioning and healthy reproductive tissue for psychological reasons, even if the instruments used are identical." *Id.* at 37187.[10] The new rule supports the ability of a state to exclude chest reconstruction for gender dysphoria while covering it to treat a mastectomy.

Plaintiffs allege the exclusion discriminates against them because they are transgender, relying on *Bostock v. Clayton Cty., Georgia*, 140 S. Ct. 1731 (2020). But *Bostock* is not dispositive. In *Bostock*, the Court held "[a]n employer who fires an employee for being … transgender" has violated Title VII, relying on the traditional meaning of "sex" as "biological distinctions between male and female." *Id.* at 1737, 1739. *Bostock* restated the long-standing principle that Title VII protects employees from discrimination if they are treated differently because of their sex. *Id.* at 1741-42. As Justices Alito and Thomas explained in their dissent there are still unsettled areas of law:

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[10] The new rules were challenged, and the E.D.N.Y issued a preliminary injunction against the Department's repeal of its prior rules (*Walker v. Azar*, 2020 WL 4749859, at *10 (E.D.N.Y. Aug. 17, 2020)), but there is not any current affirmative requirement for coverage of gender reassignment surgery.

After *Bostock*, "healthcare benefits may emerge as an intense battleground under the Court's ruling." *Id*. at 1781 (Alito, J.). *Bostock* did not mandate anything with respect to coverage for transgender individuals under the ACA, and no court has determined *Bostock's* impact on health coverage. AHCCCS's exclusion for "gender reassignment surgeries" applies to all members, regardless of sex (it applies to males transitioning to female, and vice versa). Thus, it is not discrimination "on the basis of sex."

Plaintiffs also rely on the denial of a motion to dismiss in *Toomey v. Arizona*, 2019 WL 7172144 (D.Ariz. 2019). But a motion to dismiss evaluates whether a plaintiff has stated a claim "that is plausible on its face," accepting all allegations and reasonable inferences as true, *see Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). This stands in sharp contrast to a motion for preliminary injunction, which evaluates, under exacting standards, whether a claim is *clearly* likely to succeed on the merits based on the evidence presented.

Plaintiffs' other cases are from outside this jurisdiction (not precedent for this Court), and they are inapposite. None required a plan to provide coverage of gender reassignment surgeries for children or addressed a facially neutral policy regarding one specific category of services. *Prescott v. Rady*, 265 F.Supp.3d 1090, 1099 (S.D.Cal. 2017) (staff "continuously referr[ed] to him with female pronouns, despite knowing that he was a transgender boy" and "refused to treat Kyler as a boy"); *Flack v. Wisc. Dep't of Health,* 395 F.Supp.3d 1001 (W.D. Wis. 2019) (involved adult plaintiffs, and the plan contained a broad exclusion for transition coverage - not just surgery); *Boyden v. Conlin,* 341 F.Supp.3d 979 (W.D. Wis. 2018) (involved adult plaintiffs, and coverage excluded all services associated with gender reassignment); *Glenn v. Brumby,* 663 F.3d 1312 (11th Cir. 2011) (employment termination of plaintiff). Here, coverage is provided for hormone treatments and mental health counseling; thus, there is no discrimination against transgender persons or the elimination of coverage for all gender transition treatment. Plaintiffs have failed to establish their high burden.

4. Plaintiffs fail to establish an equal protection violation

The Equal Protection Clause (U.S. Const. Amend. XIV, §1) states, "[n]o State shall . . . deny to any person within its jurisdiction the equal protection of the laws." This provision "does not forbid classifications. It simply keeps governmental decisionmakers from treating differently persons who are in all relevant respects alike." *Nordlinger v. Hahn*, 505 U.S. 1, 10 (1992). A "classification neither involving fundamental rights nor proceeding along suspect lines is accorded a strong presumption of validity"; such a provision is subject to rational basis review. *Heller v. Doe*, 509 U.S. 312, 319-21 (1993); *McGowan v. State of Md.*, 366 U.S. 420, 425-26 (1961) ("State legislatures are presumed to have acted within their constitutional power despite the fact that, in practice, their laws result in some inequality. A statutory discrimination will not be set aside if any state of facts reasonably may be conceived to justify it."). Multiple courts have applied rational basis to classifications based on transgender status. *Druley v. Patton*, 601 F.App'x 632, 635 (10th Cir. 2015); *Murillo v. Parkinson*, 2015 WL 3791450, *12 (C.D. Cal. 2015); *Kaeo–Tomaselli v. Butts*, 2013 WL 399184, *5 (D. Haw. 2013); *Jamison v. Davue*, 2012 WL 996383, *4 (E.D.Cal. 2012); *Brainburg v. Coalinga State Hosp.*, 2012 WL 3911910, *8 (E.D. Cal. 2012); *Stevens v. Williams*, 2008 WL 916991, *13 (D. Or. 2008); *Johnston v. Univ. of Pittsburgh*, 97 F. Supp. 3d 657, 668 (W.D. Pa. 2015).

Plaintiffs have not cited any U.S. Supreme Court case that changes the rational basis standard for claims brought by transgender individuals. While Plaintiffs cite *Bostock*, that case involved statutory interpretation of Title VII – it did not (i) involve an equal protection claim, (ii) hold transgender persons constitute a suspect or quasi-suspect class for equal protection claims, or (iii) create a new protected class for transgender persons. *See Bollfrass v. City of Phoenix*, 2020 WL 4284370, at *1 (D. Ariz. 2020) (declining to reconsider equal protection claim after *Bostock* which "involved a matter of statutory interpretation"). *Bostock* does not support heightened review here. In addition, Plaintiffs' cases from other jurisdictions (i) are not precedent for this Court, (ii) are inapposite, (iii) did not mandate coverage of gender reassignment surgery for children,

and (iv) did not address a facially neutral policy regarding one specific category of services. *F.V. v. Barron*, 286 F.Supp.3d 1131 (D.Id. 2018) (policy categorically denied transgender people from changing sex on birth certificates); *Norsworthy v. Beard*, 87 F. Supp. 3d 1104 (N.D.Cal. 2015) (denying motion to dismiss on claims involving 8th Amendment and deliberate indifference to medical needs of prison inmate); *Whitaker*, 858 F.3d 1034 (plaintiff had to complete surgical transition to access boys restroom); *Glenn* (*supra*); *Smith v. City of Salem,* 378 F.3d 566 (6th Cir. 2004) (employee suspension).[11]

Under rational basis review, Plaintiffs simply cannot overcome the "strong presumption of validity" of the exclusion. Here, there are "plausible reasons for [the state] action," and thus the "inquiry is at an end." *U.S. Railroad Retirement Bd. v. Fritz*, 449 U.S. 166, 179 (1980). The government has a legitimate interest in not providing an expensive, irreversible surgery of questionable value for minors, including Plaintiffs who have a history of underlying unresolved psychiatric conditions and have not established the ability to provide informed consent.[12] In addition, there is no evidence the exclusion was motivated by animosity towards a protected class. The Court should apply the presumption of validity because there is a "plausible reason" supporting the classification and it is rationally related to a legitimate government interest.

d. Balance of equities

Based on the record, Plaintiffs have failed to establish that chest reconstruction surgery is safe, effective, and urgent for them. Balanced against this is the well-established caution courts exercise in granting mandatory injunctive relief, particularly relief that involves an irreversible surgery for children. In addition, AHCCCS has a significant interest in not providing expensive services that have not been shown to be

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[11] Plaintiffs again rely on the denial of a motion to dismiss in *Toomey*. That order not only involved a completely different standard (motion to dismiss), but *Toomey* also does not involve minor plaintiffs with the medical history and background of Plaintiffs in this case.
[12] Rational basis review applies, *supra*. But even if intermediate scrutiny applies, Plaintiffs still cannot obtain a preliminary injunction because the classification is substantially related to this important government interest. *See U.S. v. Virginia*, 518 U.S. 515 (1996).

medically necessary, particularly irreversible surgeries on minors that carry significant risks, and for which there is questionable scientific evidence about its effectiveness and long-term benefits for children. Plaintiffs have failed to demonstrate that the balance of equities is in their favor.

III. CONCLUSION

Plaintiffs cannot meet the exceedingly high standards required for a mandatory injunction. Thus, Defendant requests the Court deny Plaintiffs' motion.

RESPECTFULLY SUBMITTED this 28th day of September, 2020.

BURNSBARTON PLC

By *__/s/ Kathryn Hackett King__*

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CERTIFICATE OF SERVICE

I hereby certifies that on September 28, 2020, I electronically transmitted the foregoing document, using the ECF System for filing and transmittal of a Notice of Electronic Filing and to ECF registrants and e-mailed a copy of the foregoing to the following:

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IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF ARIZONA

D.H., by and through his mother, Janice Hennessy-Waller; and John Doe, by and through his guardian and next friend, Susan Doe, on behalf of themselves and all others similarly situated,

Plaintiffs,

vs.

Jami Snyder, Director of the Arizona Health Care Cost Containment System, in her official capacity,

Defendant.

Case No. 4:20-cv-00335-SHR

EXPERT DECLARATION OF MICHAEL K. LAIDLAW, M.D.

(Assigned to the Honorable Scott H. Rash)

I, Michael K. Laidlaw, M.D., hereby declare as follows:

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

2. I am a board-certified endocrinologist. I received my medical degree from the University of Southern California in 2001. I completed my residency in internal medicine at Los Angeles County/University of Southern California Medical Center in

2004. I also completed a fellowship in endocrinology, diabetes and metabolism at Los Angeles County/University of Southern California Medical Center in 2006.

3. I have been board certified by (1) the National Board of Physicians and Surgeons for Endocrinology, Diabetes & Metabolism, (2) the National Board of Physicians and Surgeons for Internal Medicine, (3) the American Board of Internal Medicine for Internal Medicine, and (4) the American Board of Internal Medicine for Endocrinology, Diabetes, and Metabolism.

4. The information provided regarding my professional background are detailed in my curriculum vitae. A true and correct copy of my curriculum vitae is attached as Exhibit A.

5. In my clinical practice as an endocrinologist, I evaluate and treat patients with hormonal and/or gland issues. Hormone and gland disorders can cause or be associated with psychiatric symptoms, such as depression, anxiety, and other psychiatric symptoms. Therefore, I frequently assess and treat patients demonstrating psychiatric symptoms and determine whether their psychiatric symptoms are being caused by a hormonal issue, gland issue, or something else.

6. I have been retained by Defendant in the above-captioned lawsuit to provide an expert opinion on (1) the standards of care for treating minors diagnosed with gender dysphoria, including considerations of various proposed treatments, and (2) the appropriateness of D.H. and John Doe receiving bilateral mastectomy surgery at this time.

7. If called to testify in this matter, I would testify truthfully and based on my expert opinion. The opinions and conclusions I express herein are based on a reasonable degree of scientific certainty.

8. I am being compensated at an hourly rate of $367 per hour plus expenses for my time spent preparing this declaration, and to prepare for and provide testimony in this matter. My compensation does not depend on the outcome of this litigation, the opinions I express, or the testimony I may provide.

9. My opinions contained in this report are based on: (1) my clinical experience as an endocrinologist; (2) my clinical experience evaluating individuals who have or have had gender incongruence and/or gender dysphoria; (3) my knowledge of research and studies regarding the treatment of gender dysphoria, including for minors; and (4) my review of the various declarations submitted by Plaintiffs D.H. and John Doe in the present lawsuit, *D.H. and John Doe v. Snyder*, Case No. 4:20-cv-00335-SHR (pending in the U.S. District Court for the District of Arizona).

10. I was provided with and reviewed the following case-specific materials: (1) the declarations of D.H. and John Doe, and their respective guardians Janice Hennessy-Waller and Susan Doe; (2) the declarations of D.H.'s and John Doe's respective treating providers, Tamar Reed, LPC, Dr. Andrew Cronyn, M.D., and Dr. Mischa Cohen Peck, PhD; and (3) the expert declarations of Dr. Aron Janssen, M.D. and Dr. Loren S. Schechter, M.D.

11. In my professional opinion, treatment interventions on behalf of children diagnosed with gender dysphoria must be held to the same scientific standards as other medical treatments. These interventions must be optimal, efficacious, and safe. Any treatment which alters biological development in children should be used with extreme caution.

12. Based on the materials I have reviewed and in my professional opinion, there is an insufficient clinical basis to conclude that either D.H. or John Doe will suffer imminent, irreparable harm if they do not receive bilateral mastectomy with chest wall

recontouring surgery prior to the conclusion of this case. To the contrary, in my professional opinion, this irreversible surgery should not be performed on minors D.H. and John Doe. I reach this opinion for the following reasons.

13. A high percentage of children diagnosed with gender dysphoria have depression, anxiety, or other mental health disorders separate and apart from gender dysphoria. *See infra* ¶23. According to the declarations I reviewed, both D.H. and John Doe have a significant and lengthy history of psychiatric issues separate and apart from gender dysphoria.

14. According to the declarations of Janice Hennessy-Waller and Tamar Reed, D.H. has been hospitalized, including in intensive psychiatric care, four times since age 11 for treatment of significant psychological distress, including severe anxiety and suicidal ideation. D.H. has a history of pervasive anxiety, chronic suicidal ideations and attempts, and related self-harm issues (including cutting, burning and hair pulling). D.H. also has oppositional defiant disorder, which the Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition ("DSM-5") defines as "a frequent and persistent pattern of angry/irritable mood, argumentative/defiant behavior, or vindictiveness." In addition, the declaration of Tamar Reed states that D.H. currently has "anxiety and psychological distress caused by prior trauma."

15. According to the declaration of Janice Hennessy-Waller, D.H. was in intensive in-patient psychiatric care for severe anxiety and suicidal ideation beginning in 2014. There is no indication gender dysphoria was being evaluated, discussed, or addressed at this time. It was not until two years later (in 2016) that D.H. identified as transgender to another person (D.H.'s mom).

16. According to the declaration of Susan Doe, John Doe's biological parents were unable to care for John Doe and provide John Doe with a stable home environment. According to the declaration of Mischa Cohen Peck, John Doe was diagnosed with post-

traumatic stress disorder ("PTSD") stemming from early-life attachment trauma. Although not defined in the declarations, the term "early-life attachment trauma" indicates that John Doe likely suffered abuse or neglect at a young age.

17. According to John Doe's declaration, John Doe has been depressed, suffered from anxiety, engaged in self-harm through cutting and burning, distanced from friends and family, lost interest in activities, and lost a significant amount of weight in a very short period of time because of limited food intake. John Doe also contemplated suicide.

18. According to the declaration of Mischa Cohen Peck, John Doe has not been successfully treated for the trauma underlying John Doe's PTSD. In addition, John Doe describes "being detached" from John Doe's own body.[1]

19. According to several of the declarations that I reviewed, both D.H. and John Doe have engaged in non-suicidal self-injury ("NSSI"), which is associated with multiple types of psychiatric disorders. As one article has noted, "[t]he age onset of NSSI most often occurs in early adolescence, between 12 and 14 years (Nock et al., 2006; Muehlenkamp and Gutierrez, 2007; Cerutti et al., 2011), but findings have also reported NSSI behavior in children under the age of 12 (Barrocas et al., 2012). The most common method was self-cutting (over 70%) followed by head banging, scratching, hitting and

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[1] Although I did not review or have access to John Doe's medical records, I note there is one psychiatric disorder, dissociative identity disorder, which the American Psychiatric Association describes as follows: "People with dissociative identity disorder may feel that they have suddenly become observers of their own speech and actions, or their bodies may feel different (e.g., like a small child, like the opposite gender, huge and muscular)." Further, (1) "Dissociative identity disorder is associated with overwhelming experiences, traumatic events and/or abuse that occurred in childhood"; (2) "People who have experienced physical and sexual abuse in childhood are at increased risk of dissociative identity disorder. The vast majority of people who develop dissociative disorders have experienced repetitive, overwhelming trauma in childhood. Among people with dissociative identity disorder in the United States, Canada and Europe, about 90 percent had been the victims of childhood abuse and neglect"; and (3) "Suicide attempts and other self-injurious behavior are common among people with dissociative identity disorder. More than 70 percent of outpatients with dissociative identity disorder have attempted suicide." *See* American Psychiatric Association, "What Are Dissociative Disorders?" (Aug. 2018), at https://www.psychiatry.org/patients-families/dissociative-disorders/what-are-dissociative-disorders (last visited Sept. 22, 2020). This issue should be fully explored by a psychiatrist for John Doe.

burning (Briere and Gil, 1998; Laye-Gindhu and Schonert-Reichl, 2005; Gratz, 2006; Whitlock et al., 2006)." Further, "[s]elf injury has long been linked to other disorders as well, including post-traumatic stress disorder (Briere and Gil, 1998; Bolognini et al., 2003), depressive disorders (Darche, 1990), obsessive-compulsive disorder (Bolognini et al., 2003), anxiety disorder (Darche, 1990; Simeon and Favazza, 2001), borderline personality disorder (BPD) (Klonsky et al., 2003; Nock et al., 2006), and eating disorder (Iannaccone et al., 2013)." Cipriano, Cella, & Cotrufo, "Nonsuicidal Self-injury: A Systematic Review," *Front Psychol.* 2017; 8: 1946 (Nov. 8, 2017). The link between self-injury and these psychiatric disorders warrant a full evaluation by a clinical psychiatrist and psychologist for John Doe and D.H.

20. According to several of the declarations, D.H. and John Doe have both been prescribed hormone-replacement therapy (i.e., testosterone) to develop a more masculine appearance. A typical dose of hormone-replacement for female-to-male transition is a high dose. Normal female testosterone levels are 10-50 ng/dL. The Endocrine Society Clinical Guidelines advise bringing these to 300-1000 ng/dL, which are values typically found with androgen-secreting tumors. *See* Laidlaw, Van Meter, Hruz, Van Mol, & Malone, "Letter to the Editor: Endocrine Treatment of Gender-Dsyphoria/Gender-Incongruent Persons: An Endocrine Society Clinical Practice Guideline," *J Clin Endocrinol Metab*, 104(3) (March 2019). This is 6 to 100 times higher than the natal female body typically contains. According to research, high doses of testosterone have been shown to predispose individuals towards mood disorders, psychosis, and psychiatric disorders. The "most prominent psychiatric features associated with AAS [anabolic-androgenic steroids, i.e. testosterone] abuse are manic-like presentations defined by irritability, aggressiveness, euphoria, grandiose beliefs, hyperactivity, and reckless or dangerous behavior. Other psychiatric presentations include the development of acute psychoses, exacerbation of tics and depression, and the development of acute confusional/delirious states." Moreover, "[s]tudies . . . of medium steroid use (between

300 and 1000 mg/week of any AAS) and high use (more than 1000 mg/week of any AAS) have demonstrated that 23% of subjects using these doses of steroids met the DSM-III-R criteria for a major mood syndrome (mania, hypomania, and major depression) and that 3.4%–12% developed psychotic symptoms." Hall, Hall & Chapman, "Psychiatric Complications of Anabolic Steroid Abuse," *Psychosomatics* 46:4 (July-August 2005). Thus, hormone treatments can exacerbate any underlying psychiatric problems of a child, including D.H. and John Doe.

21. According to several of the declarations, D.H. and John Doe originally felt better after receiving the hormones, but then subsequently felt worse. In my professional opinion, it is likely D.H. and John Doe originally felt better because of the side effect of euphoria elicited by high doses of testosterone, as noted above. It is also likely D.H. and John Doe may have later started feeling worse because either (1) the high dose of testosterone ultimately exacerbated their mental health issues, or (2) their underlying psychiatric issues, separate from the gender dysphoria, were never actually resolved (or a combination of the two).

22. There are no laboratory, imaging, or other objective tests to predict whether children with gender dysphoria will outgrow the condition. "Children with [gender dysphoria] will outgrow this condition in 61% to 98% of cases by adulthood. There is currently no way to predict who will desist and who will remain dysphoric." Laidlaw, Van Meter, Hruz, Van Mol, & Malone, "Letter to the Editor: Endocrine Treatment of Gender-Dsyphoria/Gender-Incongruent Persons: An Endocrine Society Clinical Practice Guideline," *J Clin Endocrinol Metab*, 104(3) (March 2019).

23. A key study from Finland indicated that 68% of children with gender dysphoria had already been to psychiatric care for reasons other than gender identity issues. Kaltiala-Heino, Sumia, Työläjärvi, & Lindberg, "Two years of gender identity service for minors: overrepresentation of natal girls with severe problems in adolescent

development," *Child & Adolescent Psychiatry & Mental Health* (2015) 9:9 ("Of the applicants, 68% (32/47) had had their first contact with psychiatric services due to other reasons than gender identity issues"; in addition, "[s]eventy-five per cent of the applicants (35/47) had been or were currently undergoing child and adolescent psychiatric treatment for reasons other than gender dysphoria when they sought referral to [sex reassignment] assessment"). Therefore, in my professional opinion, a child's psychological disorders should be thoroughly treated first before considering hormone therapy or gender reassignment surgery. Based on the declarations I reviewed, there is insufficient evidence to establish that D.H.'s and John Doe's psychiatric issues have been thoroughly evaluated and adequately treated by a qualified psychiatrist or clinical psychologist.

24. In addition to the information identified above, the declarations do not contain pertinent historical information regarding whether or not D.H. or John Doe are (or have been) on any psychiatric or other medication or have been provided other adequate treatments to treat any of their significant psychological issues.

25. The declarations are also missing pertinent history as to whether or not D.H. or John Doe have had any history of substance use or abuse. Many individuals with the disorders identified above may also have a history of substance abuse. The National Institutes of Health recommends that "people entering treatment either for a substance use disorder or for another mental disorder should be assessed for the co-occurrence of the other condition." Additionally, "as many as 6 in 10 people with an illicit substance use disorder also suffer from another mental illness." National Institute on Drug Abuse, "Principles of Drug Addiction Treatment: A Research-Based Guide" (3rd ed.) (Jan. 2018), located at https://www.drugabuse.gov/publications/principles-drug-addiction-treatment-research-based-guide-third-edition/frequently-asked-questions/how-do-other-mental-disorders-coexisting-drug-addiction (last accessed Sept. 25, 2020). A history of substance use or abuse would be important to clarify as substance use or abuse could impair

judgment with respect to informed consent for a procedure. Thus, it should be thoroughly examined and ruled out before any irreversible surgery is performed.

26. Depression, if not properly treated before surgery, may result in an increase in morbidity and mortality post-surgery: "Several studies reported increased rate of postoperative infections in patients suffering from depression." With respect to depression treatment for patients before major surgery, where it is "[n]on-alleviated, it may predict increased morbidity and mortality after the operation. It may be associated with greater postoperative pain, higher incidence of postoperative infections, progression of malignant tumors, poor health-related quality of life as well as other complications." Ghoneim & O'Hara, "Depression and Postoperative complications: an overview," *BMC Surg*. 2016; 16:5 (Feb. 2, 2016).

27. As Dr. Loren Schechter (plastic surgeon) confirms in her declaration (p. 16, ¶ 45) "[t]o make a final assessment of D.H.'s and John Doe's suitability for surgery, I would need to perform an in-person exam." Dr. Schechter acknowledges that before any individual can be determined suitable for surgery, a final assessment which requires an in-person exam, is required. But Dr. Schechter confirms he has not conducted a final assessment of John Doe and D.H.'s suitability for surgery. None of the other declarations indicate a final assessment or physical examination has been conducted on either D.H. or John Doe. As Dr. Schecther notes, a final assessment is necessary to assess skin elasticity and also to rule out any pathology, such as breast masses, lumps, and nipple retraction. A full work up for John Doe and D.H. has not been completed.

28. A mastectomy surgery is irreversible. If a patient later regrets the decision and decides to resume living as their natal sex (female), she will not be able to ever breastfeed a child, because her functional organs have been removed and can never be replaced. Possible complications of this procedure (bilateral mastectomy with chest wall

contouring) include loss of normal sensation of the nipples, problems with wound healing, pain, adverse scarring, and infections.

29. I have significant concerns about the ability of two minors with histories of significant underlying psychiatric issues, separate and apart from gender dysphoria, to provide informed consent to undergo an irreversible sex reassignment surgery.

30. While the Endocrine Society has issued "Endocrine Treatment of Gender-Dysphoric/Gender-Incongruent Persons: An Endocrine Society Clinical Practice Guideline," these are only "guidelines." The Endocrine Society's guidelines specifically note the "guidelines cannot guarantee any specific outcome, nor do they establish a standard of care." Wylie C. Hembree, et al., "Endocrine Treatment of Gender-Dysphoric/Gender-Incongruent Persons: An Endocrine Society Clinical Practice Guideline," *The Journal of Clinical Endocrinology & Metabolism*, Volume 102, Issue 11 (Nov. 1, 2017).[2]

31. In the Endocrine Society's guidelines, the quality of evidence for the treatment of adolescents is rated "very low-quality evidence" and "low quality evidence." (p. 3871-72).

32. "The Endocrine Society has published revised clinical guidelines in 2017 on the treatment of gender dysphoric persons including adolescents (Hembree et al. 2017). The quality of evidence for [puberty blocking agents] is noted to be low. In fact, all of the evidence in the guidelines with regard to treating children/adolescents by [gender affirmative therapy] is low to very low because of the absence of proper studies."

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[2] The Endocrine Society guidelines (p.3380) note "in some forms of [gender dysphoria]/gender incongruence, psychological interventions may be useful and sufficient," before ever needing to proceed with medicalized treatments. Further, the guidelines (p. 3894) note "some transgender male adolescents" may "consider mastectomy 2 years after they begin androgen [testosterone] therapy." But according to John Doe's declaration, John Doe began hormone replacement therapy in June 2019; thus, John Doe has not been on hormone therapy for two years.

Laidlaw, Cretella & Donovan, "The Right to Best Care for Children Does Not Include the Right to Medical Transition," *The American Journal of Bioethics*, 19:2, 75-77 (Feb. 20, 2019). Unlike other recommendations for adolescent transition, the Endocrine Society's guidelines do not include any grading of the quality of evidence specifically for adolescent mastectomy.

33. The declarations of Dr. Aron Janssen and Dr. Loren Schechter cite to the World Professional Association for Transgender Health's ("WPATH") "Standards of Care for the Health of Transsexual, Transgender, and Gender Non-Conforming People." According to their declarations, Dr. Janssen is a member of WPATH, Dr. Schechter is on the Board of Directors of WPATH, and both have been contributing authors to WPATH's "Standards of Care." WPATH's "Standards of Care" were prepared within their advocacy organization and are purported to be a "professional consensus about the psychiatric, psychological, medical, and surgical management of gender dysphoria." However, the "professional consensus" exists only within the confines of its organization. Furthermore, their "Standards of Care," unlike the Endocrine Society's guidelines, do not have a grading system for either the strength of their recommendations or the quality of the evidence presented.

34. Good quality studies specifically showing that mastectomy surgery is safe, effective, and optimal for treating minors with gender dysphoria do not exist. The declaration of Dr. Loren Schechter refers to the article *Chest Reconstruction and Chest Dysphoria in Transmasculine Minors and Young Adults Comparisons of Nonsurgical and Postsurgical Cohorts*, 172 JAMA Pediatrics 431, 434 (2018), and quotes the conclusion that "Chest dysphoria was high among presurgical transmasculine youth, and surgical intervention positively affected both minors and young adults." However, there are a number of problems with this study. First, the term "chest dysphoria" is a creation of the study authors and is not found as a diagnosis or even referenced in the DSM-5. Second the "chest dysphoria scale" is a measuring tool created by the authors, but which the authors

state "is not yet validated." (p. 435) Third, the mastectomies were performed on girls as young as 13 and 14 years old and who thereby lacked the maturity and capacity of good judgement for truly informed consent for this life altering procedure. For this reason, in my professional opinion, the research and surgeries performed were flawed and unethical.

35. There is also evidence that questions the long-term effectiveness of gender reassignment surgery. A Swedish study in 2011 (Dhejne, et al., "Long-Term Follow-Up of Transsexual Persons Undergoing Sex Reassignment Surgery: Cohort Study in Sweden," *PLoS One,* vol. 6, issue 2 (Feb. 22, 2011)) examined data over a 30-year period. The Dhejne team made extensive use of numerous Swedish registries and examined data from 324 patients in Sweden over 30 years who underwent sex reassignment surgery. They used population controls matched by birth year, birth sex, and reassigned sex. When followed out beyond ten years, the sex-reassigned group had nineteen times the rate of completed suicides and nearly three times the rate of all-cause mortality and inpatient psychiatric care compared to the general population.

36. The Centers for Medicare and Medicaid Services ("CMS") has found "inconclusive" clinical evidence regarding gender reassignment surgery. Specifically, the CMS Decision Memo for Gender Dysphoria and Gender Reassignment Surgery (CAG-00446N) (June 19, 2019) states: "The Centers for Medicare & Medicaid Services (CMS) is not issuing a National Coverage Determination (NCD) at this time on gender reassignment surgery for Medicare beneficiaries with gender dysphoria because the clinical evidence is inconclusive for the Medicare population."

37. Hayes Directories, Inc. is an internationally recognized research and consulting firm dedicated to promoting better health outcomes by assessing quality evidence. In 2014, the Hayes Directory conducted a comprehensive review and evaluation of the scientific literature regarding the treatment of gender dysphoria in adults and children. It concluded the practice of using hormones and sex reassignment surgery to

treat gender dysphoria is based on "very low" quality of evidence. For sex reassignment surgery ("SRS") to treat gender dysphoria in adolescents, it received a Hayes Rating of D2 (which is "insufficient evidence"): "This rating reflects the paucity of data of SRS in adolescents." "Sex Reassignment Surgery for the Treatment of Gender Dysphoria," *Hayes Medical Technology Directory*, p. 3-4 (May 15, 2014).

38. Recently, a major correction was issued by the American Journal of Psychiatry. The editors of an October 2019 study, titled "Reduction in mental health treatment utilization among transgender individuals after gender-affirming surgeries: a total population study" (Bränström study) retracted their original primary conclusion. The Bränström team reanalyzed the data and the results demonstrated "no advantage to [gender reassignment] surgery" for their three endpoints in the subject population (prescriptions for antidepressants and anti-anxiety medications, healthcare visits for mood or anxiety disorders, and post-suicide attempt hospitalizations). Specifically, the correction stated, "the results demonstrated no advantage of surgery in relation to subsequent mood or anxiety disorder-related health care visits or prescriptions or hospitalizations following suicide attempts in that comparison. Given that the study used neither a prospective cohort design nor a randomized controlled trial design, the conclusion that 'the longitudinal association between gender-affirming surgery and lower use of mental health treatment lends support to the decision to provide gender-affirming surgeries to transgender individuals who seek them' is too strong." "Correction to Bränström and Pachankis," *Am J Psychiatry*, 177:8 (Aug. 2020).

39. For these reasons, in my professional opinion, an irreversible chest reconstruction surgery should not be performed on minors D.H. and John Doe.

40. Based on the studies and research cited above, in my professional opinion there is insufficient quality of evidence at this time demonstrating the benefit of bilateral mastectomy with chest wall recontouring surgery on individuals diagnosed with gender

dysphoria in any age group. For those under 21, there is an additional reason to avoid irreversible procedures: there are no laboratory, imaging, or other objective tests to predict whether a young person with gender dysphoria will outgrow this condition. Because this age group is still undergoing brain development and as such they are immature with respect to intellect, emotion, judgment, and self-control, in my professional opinion this means there is a significant chance that a young person may later regret removing an organ that cannot be replaced. Thus, in my professional opinion, it is never appropriate to provide bilateral mastectomy with chest wall recontouring surgery on individuals diagnosed with gender dysphoria - particularly those under the age of 21.

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

Executed this 27th day of September, 2020 at Rocklin, California.

Michael K. Laidlaw M.D.

Michael K. Laidlaw, M.D.

EXHIBIT A

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EMPLOYMENT

2006-Present	Michael K Laidlaw, MD Inc. Private Practice – Endocrinology, Diabetes, and Metabolism. Rocklin, CA

EDUCATION

2004-2006	Endocrinology and Metabolism Fellowship - Los Angeles County/University of Southern California Keck School of Medicine
2001-2004	Internal Medicine Residency - Los Angeles County/University of Southern California Keck School of Medicine
1997-2001	University of Southern California Keck School of Medicine Doctor of Medicine Degree May 2001
1990-1997	San Jose State University Bachelor of Science Degree in Biology with a concentration in Molecular Biology, Cum Laude

LICENSURE

National Board of Physicians and Surgeons - Endocrinology, Diabetes, & Metabolism 2018-2022
National Board of Physicians and Surgeons - Internal Medicine 2018-2022
Diplomate in Endocrinology, Diabetes, and Metabolism – American Board of Internal Medicine - Certified 2006
Diplomate in Internal Medicine - American Board of Internal Medicine - Certified 2005
California Medical License – Physician and Surgeon: # A81060: Nov 6, 2002. Exp 5/31/2022.
Certification in Diagnostic Thyroid Ultrasound and Biopsy – AACE 2005

PROFESSIONAL AFFILIATIONS

Endocrine Society 2006-2020

HONORS AND RECOGNITION

2010	Endocrine Society Harold Vigersky Practicing Physician Travel Award
2004-2005	Vice President - Joint Council of Interns and Residents
2002-2004	Council Member – Joint Council of Interns and Residents
1996, 1997	Dean's Scholar, San Jose State University
1995	Golden Key National Honor Society

RESEARCH & PUBLICATIONS

2020	Publication – Van Mol A, Laidlaw MK, Grossman M, McHugh P. "Correction: Transgender Surgery Provides No Mental Health Benefit." Public Discourse, 13 Sep 2020. https://www.thepublicdiscourse.com/2020/09/71296/
2020	Publication – VanMol A, Laidlaw MK, Grossman M, McHugh P.. "Gender-affirmation surgery conclusion lacks evidence (letter)". Am J Psychiatry 2020; 177:765–766.
2020	Publication – Laidlaw MK. "The Pediatric Endocrine Society's Statement on Puberty Blockers Isn't Just Deceptive. It's Dangerous." Public Discourse. 13 Jan 2020. https://www.thepublicdiscourse.com/2020/01/59422/
2019	Expert Witness Affidavit – Laidlaw MK. Court of Appeal File No. CA45940, Vancouver Registry. B.C. Supreme Court File No. E190334, between A.B. Respondent/Claimant, and C.D. Appellant/Respondent, and E.F. Respondent/Respondent. 24 Jun 2019.
2019	Publication – Laidlaw MK, Cretella M, Donovan K. "The Right to Best Care for Children Does Not Include the Right to Medical Transition". The American Journal of Bioethics. Volume 19. Published online 20 Feb 2019. 75-77. https://doi.org/10.1080/15265161.2018.1557288
2018	Brief of Amicus Curiae – Alliance Defending Freedom, Campbell, James A., Grossman, Miriam, Laidlaw, Michael K., McCaleb, Gary S., Van Meter, Quentin L., Van Mol, Andre. Brief of Amicus Curiae. United States Court of Appeals for the Eleventh Circuit. Drew Adams, Plaintiff-Appellee, v. School Board of St. Johns County, Florida, Defendant-Appellant. 12/27/2018.
2018	Publication – Laidlaw MK, Van Meter QL, Hruz PW, Van Mol A, Malone WJ. Letter to the Editor: "Endocrine Treatment of Gender-Dysphoric/Gender-Incongruent Persons: An Endocrine Society Clinical Practice Guideline." The Journal of Clinical Endocrinology & Metabolism, Volume 104, Issue 3, 1 March 2019, Pages 686–687, https://doi.org/10.1210/jc.2018-01925 (first published on-line 11/2018)
2018	Publication – Laidlaw MK. "The Gender Identity Phantom". gdworkinggroup.org, 24 Oct 2018. http://gdworkinggroup.org/2018/10/24/the-gender-identity-phantom/
2018	Publication – Laidlaw MK. "Gender Dysphoria and Children: An Endocrinologist's Evaluation of 'I am Jazz'". Public Discourse, 5 Apr 2018. https://www.thepublicdiscourse.com/2018/04/21220/
2013	Abstract – Poster presentation Jun 2013. Endocrine Society Annual Meeting. A 12 Step Program for the Treatment of Type 2 Diabetes and Obesity.
2011	Abstract – Poster presentation Nov 2011. Journal of Diabetes Science and

	Technology. A Video Game Teaching Tool for the Prevention of Type 2 Diabetes and Obesity in Children and Young Adults.
2011	Abstract – Journal of Diabetes Science and Technology. A Web-Based Clinical Software Tool to Assist in Meeting Diabetes Guidelines and Documenting Patient Encounters.
2008	Abstract - Accepted to Endocrine Society Annual Meeting 2008. Hypercalcemia with an elevated 1,25 dihydroxy-Vitamin D level and low PTH due to granulomatous disease.
2005-2006	Clinical Research - University of Southern California – Utility of Thyroid Ultrasound in the Detection of Thyroid Cancer. Study involving the use of color flow/power doppler ultrasound and ultrasound guided biopsy to detect the recurrence of thyroid cancer in patients with total thyroidectomies.
2002-2005	Clinical Research - University of Southern California - Determining the Role of Magnesium in Osteoporosis. Study involved collecting and analyzing patient data related to patient characteristics, laboratory results, bone mineral density exams, nutrition analysis, and genetic analysis in order to determine a link between magnesium deficiency and osteoporosis.
1996	Research Assistant - San Jose State University - Role of the suprachiasmatic nucleus pacemaker in antelope ground squirrels.
1995-1996	Research Assistant - San Jose State University/NASA. Acoustic tolerance test and paste diet study for space shuttle rats.

PERSONAL

Languages: Conversational Spanish, French
Tutor: Biochemistry, computer science, High School mentor
Computers: Ruby, Rails, Javascript, C++, C, Java, and HTML programming

EXHIBIT B

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Attorneys for Defendant

IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF ARIZONA

D.H., by and through his mother, Janice Hennessy-Waller; and John Doe, by and through his guardian and next friend, Susan Doe, on behalf of themselves and all others similarly situated,

Plaintiffs,

vs.

Jami Snyder, Director of the Arizona Health Care Cost Containment System, in her official capacity,

Defendant.

Case No. 4:20-cv-00335-SHR

EXPERT DECLARATION OF DR. STEPHEN B. LEVINE, M.D.

(Assigned to the Honorable Scott H. Rash)

I, Stephen B. Levine, M.D., hereby declare as follows:

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

2. I am a Clinical Professor of Psychiatry at Case Western Reserve University School of Medicine, and maintain an active private clinical practice. I received my M.D. from Case Western Reserve University in 1967, and completed a psychiatric residency at the University Hospitals of Cleveland in 1973. I became an Assistant Professor of Psychiatry at Case Western in 1973, and became a Full Professor in 1985.

3. Since July 1973 my specialties have included psychological problems and conditions relating to sexuality and sexual relations, therapies for sexual problems, and the relationship between love and intimate relationships and wider mental health. I am a Distinguished Life Fellow of the American Psychiatric Association.

4. I have served as a book and manuscript reviewer for numerous professional publications. I have been the Senior Editor of the first (2003), second (2010) and third (2016) editions of the *Handbook of Clinical Sexuality for Mental Health Professionals*. In addition to five other solo-authored books, I have authored *Psychotherapeutic Approaches to Sexual Problems*, published in 2020; it has a chapter titled "The Gender Revolution."

5. I first encountered a patient suffering what we would now call gender dysphoria in July 1973. In 1974, I founded the Case Western Reserve University Gender Identity Clinic, and have served as Co-Director of that clinic since that time. Across the years, our Clinic treated hundreds of patients who were experiencing a transgender

identity. An occasional child was seen during this era. I was the primary psychiatric caregiver for several dozen of our patients and supervisor of the work of other therapists. I was an early member of the Harry Benjamin International Gender Dysphoria Association (later known as WPATH) and served as the Chairman of the Standards of Care Committee that developed the 5th version of its Standards of Care. In 1993 the Gender Identity Clinic was renamed, moved to a new location, and became independent of Case Western Reserve University. I continue to serve as Co-Director.

6. A review of my professional experience, publications, and awards as well as identification of cases in which I have provided expert testimony within the last 13 years, is provided in my CV, a copy of which is attached hereto as Exhibit A.

7. I have been retained by Defendant in the above-captioned lawsuit to provide an expert opinion on the standards of care for treating adolescents diagnosed with gender dysphoria.

8. If called to testify in this matter, I would testify truthfully and based on my expert opinion. The opinions and conclusions I express herein are based on a reasonable degree of medical and scientific certainty.

9. In this declaration, I offer, explain, and identify my opinions and the bases for my opinions in this matter. Each of the opinions set forth herein is based on my professional expertise and experience as described above and I hold each of the opinions set forth herein to a reasonable degree of certainty within my field. The facts upon which I rely are the type of facts reasonably relied upon by experts within my field.

10. I am being compensated at an hourly rate of $375 per hour plus expenses for my time spent preparing this declaration. My rate to prepare for and provide testimony is $500 per hour plus expenses. My compensation does not depend on the outcome of this litigation, the opinions I express, or the testimony I may provide.

I. BACKGROUND ON THE FIELD

A. The biological base-line of sex

11. The sex of a human individual at its core structures the individual's biological reproductive capabilities—to produce ova and bear children as a mother, or to produce semen and beget children as a father. Sex determination occurs at the instant of conception, depending on whether a sperm's X or Y chromosome fertilizes the egg. Medical technology can be used to determine a fetus's sex before birth. It is thus not literally correct to assert that doctors "assign" the sex of a child at birth; anyone can identify the sex of an infant by genital inspection. What the general public may not understand, however, is that every nucleated cell of an individual's body is chromosomally identifiably male or female—XY or XX.

12. The self-perceived gender of a child, in contrast, arises in part from how others label the infant: "I love you, son (daughter)." This designation occurs thousands of times in the first two years of life when a child begins to show awareness of the two possibilities. As acceptance of the designated gender corresponding to the child's sex is the outcome in >99% of children everywhere, anomalous gender identity formation begs for understanding. Is it biologically shaped? Is it biologically determined? Is it the product of how the child was privately regarded and treated? Does it stem from

trauma-based rejection of maleness or femaleness, and if so flowing from what trauma? Is it a symptom of another, as of yet unrevealed emotional disturbance? Does it derive from a child's (mis)understanding of future possibilities of maleness or femaleness? The answers to these relevant questions are not scientifically known.

13. Under the influence of hormones secreted by the testes or ovaries, numerous additional sex-specific differences between male and female bodies continuously develop post-natally, culminating in the dramatic maturation of the primary and secondary sex characteristics with puberty. These include differences in hormone levels, height, weight, bone mass, shape and development, internal organ size, musculature, body fat levels and distribution, and hair patterns, as well as physiological differences such as menstruation. These are genetically programmed biological consequences of sex that also serve to influence the consolidation of gender identity during and after puberty.

14. Despite the increasing ability of hormones and various surgical procedures to reconfigure some male bodies to visually pass as female, or vice versa, the biology of the person remains as defined by his (XY) or her (XX) chromosomes, including cellular, anatomic, and physiologic characteristics and the particular disease vulnerabilities associated with that chromosomally-defined sex. For instance, the XX (genetically female) individual who takes testosterone to stimulate certain male secondary sex characteristics will nevertheless remain unable to produce sperm and father children. Contrary to assertions and hopes that medicine and society can fulfill the aspiration of the trans individual to become "a complete man" or "a complete

woman," this is not biologically attainable.[1] It is possible for some adolescents and adults to pass unnoticed as the opposite gender that they aspire to be—but with limitations, costs, and risks, as I detail later.

B. Definition and diagnosis of gender dysphoria

15. Specialists have used a variety of terms over time, with somewhat shifting definitions, to identify and speak about a distressing incongruence between an individual's sex as determined by their chromosomes and their thousands of contained genes, and the gender with which they eventually subjectively identify or to which they aspire. Today's American Psychiatric Association *Diagnostic and Statistical Manual of Mental Disorders* ("DSM-5") employs the term Gender Dysphoria and defines it with separate sets of criteria for adolescents and adults on the one hand, and children on the other.

16. The criteria used in DSM-5 to identify Gender Dysphoria include a number of signs of discomfort with one's natal sex and vary somewhat depending on the age of the patient, but in all cases require "clinically significant distress or impairment in . . . important areas of functioning" such as social, school, or occupational settings.

17. When these criteria in children, (or adolescents, or adults) are not met, two other diagnoses may be given. These are: Other Specified Gender Dysphoria and Unspecified Gender Dysphoria. Specialists sometimes refer to children who do not meet criteria as being "subthreshold."

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[1] S. Levine (2018), *Informed Consent for Transgendered Patients*, J. OF SEX & MARITAL THERAPY, at 6, DOI: 10.1080/0092623X.2018.1518885 ("*Informed Consent*"); S. Levine (2016), *Reflections on the Legal Battles Over Prisoners with Gender Dysphoria*, J. AM. ACAD. PSYCHIATRY LAW 44, 236 at 238 ("*Reflections*").

18. Children who conclude that they are transgender are often unaware of a vast array of adaptive possibilities for how to live life as a man or a woman—possibilities that become increasingly apparent over time to both males and females. A boy or a girl who claims or expresses interest in pursuing a transgender identity often does so based on stereotypical notions of femaleness and maleness that are based on constrictive notions of what men and women can be.[2] A young child's—or even adolescent's—understanding of this topic is quite limited. Nor do they have the perspective that discomfort with the body and perceived social role is not new to civilization; what is new is the option to become a trans person.

C. Impact of gender dysphoria on minority and vulnerable groups

19. In considering the appropriate response to gender dysphoria, it is important to know that certain groups of children have an increased prevalence and incidence of trans identities. These include: minority children,[3] children with mental developmental disabilities[4] including children on the autistic spectrum (at a rate more than 7x the general population),[5] children residing in foster care homes, adopted children (at a rate more than 3x the general population),[6] children with a prior history of

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[2] S. Levine (2017), *Ethical Concerns About Emerging Treatment Paradigms for Gender Dysphoria*, J. OF SEX & MARITAL THERAPY at 7, DOI: 10.1080/0092623X.2017.1309482 ("*Ethical Concerns*").

[3] G. Rider et al. (2018), *Health and Care Utilization of Transgender/Gender Non-Conforming Youth: A Population Based Study*, PEDIATRICS at 4, DOI: 10.1542/peds.2017-1683. (In a large sample, non-white youth made up 41% of the set who claimed a transgender or gender-non conforming identity, but only 29% of the set who had a gender identity consistent with their sex.)

[4] D. Shumer & A. Tishelman (2015), *The Role of Assent in the Treatment of Transgender Adolescents*, INT. J. TRANSGENDERISM at 1, DOI: 10.1080/15532739.2015.1075929.

[5] D. Shumer et al. (2016), *Evaluation of Asperger Syndrome in Youth Presenting to a Gender Dysphoria Clinic*, LGBT HEALTH, 3(5) 387 at 387.

[6] D. Shumer et al. (2017), *Overrepresentation of Adopted Adolescents at a Hospital- Based Gender Dysphoria Clinic*, TRANSGENDER HEALTH Vol. 2(1) 76 at 77.

psychiatric illness,[7] and more recently adolescent girls (in a large recent study, at a rate more than 2x that of boys). (G. Rider at 4.)

D. Three competing conceptual models of gender dysphoria and transgender identity

20. Discussions about appropriate responses by mental health professionals ("MHPs") to actual or sub-threshold gender dysphoria are complicated by the fact that various speakers and advocates (or a single speaker at different times) view transgenderism through at least three very different paradigms, often without being aware of, or at least without acknowledging, the distinctions.

21. Gender dysphoria is **conceptualized and described by some professionals and laypersons as though it were a serious, physical medical illness that causes suffering,** comparable, for example, to prostate cancer, a disease that is curable before it spreads. Within this paradigm, whatever is causing distress associated with gender dysphoria—whether secondary sex characteristics such as facial hair, nose and jaw shape, presence or absence of breasts, or the primary anatomical sex organs of testes, ovaries, penis, or vagina—should be removed to alleviate the illness. The promise of these interventions is the cure of the gender dysphoria.

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[7] L. Edwards-Leeper et al. (2017), *Psychological Profile of the First Sample of Transgender Youth Presenting for Medical Intervention in a U.S. Pediatric Gender Center,* PSYCHOLOGY OF SEXUAL ORIENTATION AND GENDER DIVERSITY, 4(3) 374 at 375 ("*Psychological Profile*"); R. Kaltiala-Heino et al. (2015), *Two Years of Gender Identity Service for Minors: Overrepresentation of Natal Girls with Severe Problems in Adolescent Development*, CHILD & ADOLESCENT PSYCHIATRY & MENTAL HEALTH 9(9) 1 at 5. (In 2015 Finland gender identity service statistics, 75% of adolescents assessed "had been or were currently undergoing child and adolescent psychiatric treatment for reasons other than gender dysphoria."); L. Littman (2018), *Parent Reports of Adolescents & Young Adults Perceived to Show Signs of a Rapid Onset of Gender Dysphoria*, PLoS ONE 13(8): e0202330 at 13 (Parental survey concerning adolescents exhibiting Rapid Onset Gender Dysphoria reported that 62.5% of gender dysphoric adolescents had "a psychiatric disorder or neurodevelopmental disability preceding the onset of gender dysphoria.").

22. It should be noted, however, that gender dysphoria is a psychiatric rather than a medical diagnosis. Since its inception in DSM-III, it has always and only been specified in the psychiatric DSM manuals. Notably, gender dysphoria is the only psychiatric condition to be treated by surgery, even though no endocrine or surgical intervention package corrects any identified biological abnormality. (Levine, *Reflections,* at 240.)

23. Gender dysphoria is alternatively **conceptualized in developmental terms**, as an adaptation to a psychological problem that was first manifested as a failure to establish a comfortable conventional sense of self in early childhood. This paradigm starts from the premise that all human lives are influenced by past processes and events. Trans lives are not exceptions to this axiom. (Levine, *Reflections*, at 238.) MHPs who think of gender dysphoria through this paradigm may work both to identify and address causes of the basic problem of the deeply uncomfortable self, and also to ameliorate suffering when the underlying problem cannot be solved. They work with the patient and (ideally) family to inquire what forces may have led to the trans person repudiating the gender associated with his sex. The developmental paradigm is mindful of temperamental, parental bonding, psychological, sexual, and physical trauma influences, and the fact that young children work out their psychological issues through fantasy and play.

24. In addition, the developmental paradigm recognizes that, with the important exception of genetic sex, essentially all aspects of an individual's multifaceted identity evolve—often markedly—across the individual's lifetime.

(Levine, *Psychotherapeutic Approaches to Sexual Problems*, Chapter 6 "The Gender Revolution") This includes gender. While some advocates assert that a transgender identity is biologically caused, fixed from early life, and eternally present in an unchanging manner, this is not supported by science. Although numerous studies have been undertaken to attempt to demonstrate a distinctive physical brain structure associated with transgender identity, as of yet there is no evidence that these patients have any defining abnormality in brain structure that precedes the onset of gender dysphoria. The belief that gender dysphoria is the consequence of brain structure is challenged by the sudden increase in incidence of child and adolescent gender dysphoria over the last twenty years in North America and Europe. Meanwhile, multiple studies have documented rapid shifts in gender ratios of patients presenting for care with gender-related issues, pointing to cultural influences,[8] while a recent study documented "clustering" of new presentations in specific schools and among specific friend groups, pointing to social influences (Littman). Both of these findings strongly suggest cultural factors. From the beginning of epidemiological research into this arena, there have always been some countries, Poland and Australia, for example, where the sex ratios were reversed as compared to North America and Europe, again demonstrating a powerful effect of cultural influences.

25. In recent years, for adolescent patients, intense involvement with online transgender communities or "friends" is the rule rather than the exception, and the MHP

[8] Levine, *Ethical Concerns*, at 8 (*citing* M. Aitken, T. D. Steensma, et al. (2015), *Evidence for an Altered Sex Ratio in Clinic-Referred Adolescents with Gender Dysphoria*, J. OF SEXUAL MEDICINE 12(3) 756 at 756-63).

will also be alert to this as a potentially significant influence on the identity development of the patient.

26. The third paradigm through which gender dysphoria is alternatively conceptualized is from a **sexual minority rights perspective**. Under this paradigm, any response other than medical and societal affirmation and implementation of a patient's claim to "be" the opposite gender is a violation of the individual's civil right to self-expression. Any effort to ask "why" questions about the patient's condition, or to address underlying causes, is viewed as a violation of autonomy and civil rights. In the last few years, this paradigm has been successful in influencing public policy and the education of pediatricians, endocrinologists, public school officials, and many mental health professionals.

E. Four competing models of therapy

27. Because of the complexity of the human psyche and the difficulty of running controlled experiments in this area, substantial disagreements among professionals about the causes of psychological disorders, and about the appropriate therapeutic responses, are not unusual. When we add to this the very different paradigms for understanding transgender phenomena discussed above, it is not surprising that such disagreements also exist with regard to appropriate therapies for patients experiencing gender-related distress. I summarize below the leading approaches, and offer certain observations and opinions concerning them.

(1) The "watchful waiting" therapy model

28. I review below the uniform finding of follow-up studies that the large

majority of children who present with gender dysphoria will desist from desiring a transgender identity by adulthood if left untreated. (See infra ¶ 58.)

29. When a pre-adolescent child presents with gender dysphoria, a "watchful waiting" approach seeks to allow for the fluid nature of gender identity in children to naturally evolve— that is, take its course from forces within and surrounding the child. Watchful waiting has two versions:

a. Treating any other psychological co-morbidities—that is, other mental illnesses as defined by the DSM—that the child may exhibit (separation anxiety, bedwetting, attention deficit disorder, social anxiety, obsessive-compulsive disorder) without a focus on gender (model #1), and

b. No treatment at all for anything, but a regular follow-up appointment. This might be labeled a "hands off" approach (model #2).

(2) The psychotherapy model: Alleviate distress by identifying and addressing causes (model #3)

30. One of the foundational principles of psychotherapy has long been to work with a patient to identify the causes of observed psychological distress and then to address those causes as a means of alleviating the distress. The National Institute of Mental Health has promulgated the idea that 75% of adult psychopathology has its origins in childhood experience.

31. Many experienced practitioners in the field of gender dysphoria, including myself, have believed that it makes sense to employ these long-standing tools of psychotherapy for patients suffering gender dysphoria, asking the question as to what factors in the patient's life are the determinants of the patient's repudiation of his or her

natal sex. (Levine, *Ethical Concerns*, at 8.) I and others have reported success in alleviating distress in this way for some patients, whether or not the patient's sense of discomfort or incongruence with his or her natal sex entirely disappeared. Relieving accompanying psychological co-morbidities leaves the patient freer to consider the pros and cons of transition as he or she matures.

32. Among other things, the psychotherapist who is applying traditional methods of psychotherapy may help—for example—the male patient appreciate the wide range of masculine emotional and behavioral patterns as he grows older. He may discuss with his patient, for example, that one does not have to become a "woman" in order to be kind, compassionate, caring, noncompetitive, and devoted to others' feelings and needs.[9] Many biologically male trans individuals, from childhood to older ages, speak of their perceptions of femaleness as enabling them to discuss their feelings openly, whereas they perceive boys and men to be constrained from emotional expression within the family and larger culture. Men, of course, can be emotionally expressive, just as they can wear pink. Converse examples can be given for girls and women. These types of ideas regularly arise during psychotherapies.

33. As I note above, many gender-nonconforming children and adolescents in recent years derive from minority and vulnerable groups who have reasons to feel isolated and have an uncomfortable sense of self. A trans identity may be a hopeful attempt to redefine the self in a manner that increases their comfort and decreases their

[9] S. Levine (2017), *Transitioning Back to Maleness*, ARCH. OF SEXUAL BEHAVIOR at 7, DOI: 10.1007/s10508-017-1136-9) ("*Transitioning*").

anxiety. The clinician who uses traditional methods of psychotherapy may not focus on their gender identity, but instead work to help them to address the actual sources of their discomfort. Success in this effort may remove or reduce the desire for a redefined identity. This often involves a focus on disruptions in their attachment to parents in vulnerable children, for instance, those in the foster care system.

34. Because "watchful waiting" can include treatment of accompanying psychological co-morbidities, and the psychotherapist who hopes to relieve gender dysphoria may focus on potentially causal sources of psychological distress rather than on the gender dysphoria itself, there is no sharp line between "watchful waiting" and the psychotherapy model in the case of prepubescent children.

35. To my knowledge, there is no evidence beyond anecdotal reports that psychotherapy can enable a return to male identification for genetically male boys, adolescents, and men, or return to female identification for genetically female girls, adolescents and women. On the other hand, anecdotal evidence of such outcomes does exist; I and other clinicians have witnessed reinvestment in the patient's biological sex in some individual patients who are undergoing psychotherapy. The Internet contains many such reports, and I have published a paper recently on a patient who sought my therapeutic assistance to reclaim his male gender identity after 30 years living as a woman and is in fact living as a man today. (Levine, *Transitioning*, at 1.) I have seen children desist even before puberty in response to thoughtful parental interactions and a few meetings of the child with a therapist.

(3) The affirmation therapy model (model #4)

36. While it is widely agreed that the therapist should not directly challenge a claimed transgender identity in a child, some advocates and practitioners go much further, and promote and recommend that any expression of transgender identity should be immediately accepted as decisive, and thoroughly affirmed by means of consistent use of clothing, toys, pronouns, etc. associated with transgender identity. These advocates treat any question about the causes of the child's transgender identification as inappropriate, and assume that observed psychological co-morbidities in the children or their families are unrelated or will get better with transition, and need not be addressed by the MHP who is providing supportive guidance concerning the child's gender identity.

37. Some advocates, indeed, assert that unquestioning affirmation of any claim of transgender identity in children is essential, and that the child will otherwise face a high risk of suicide or severe psychological damage. I address claims about suicide and health outcomes in Section IV below.

38. Some advocates also assert that this "affirmation therapy" model is accepted and agreed with by the overwhelming majority of mental health professionals. However, one respected academic in the field has recently written that, on the contrary, "almost all clinics and professional associations in the world" do not use "gender affirmation" for prepubescent children and instead "delay any transitions after the onset of puberty."[10] The National Health Service in the United Kingdom announced on

[10] J. Cantor (2019), *Transgender and Gender Diverse Children and Adolescents: Fact- Checking of AAP Policy*, J. OF SEX & MARITAL THERAPY at 1, DOI: 10.1080.0092623X.2019.1698481.

September 22, 2020 that they were undertaking a thorough review of how children and adolescents with atypical gender identities are being treated in England. This indicates a great deal of doubt about the wisdom of rapid affirmative care.

39. Even the Standards of Care published by WPATH, an organization which in general leans strongly towards affirmation in the case of adults, does not specify affirmation of transgender identity as the indicated therapeutic response for young children, but rather calls for a careful process of discernment and decision specific to each child by the family in consultation with the mental health professional.

40. Further, the DSM-5 added—for both children and adolescents—a requirement that a sense of incongruence between biological and felt gender must last at least six months as a precondition for a diagnosis of gender dysphoria, precisely because of the risk of "transitory" symptoms and "hasty" diagnosis that might lead to "inappropriate" treatments.[11]

41. I do not know what proportion of practitioners are using which model. However, in my opinion, in the case of young children, prompt and thorough affirmation of a transgender identity disregards the principles of child development and family dynamics, and is not supported by science. Rather, the MHP must focus attention on the child's underlying internal and familial issues. Ongoing relationships between the MHP and the parents and the MHP and the child are vital to help the parents, child, other family members, and the MHP to understand over time the issues

[11] K. Zucker (2015), *The DSM-5 Diagnostic Criteria for Gender Dysphoria*, in C. Trombetta et al. (eds.), MANAGEMENT OF GENDER DYSPHORIA: A MULTIDISCIPLINARY APPROACH, DOI 10.1007/978-88-470-5696-1_4 (Springer-Verlag Italia 2015).

that need to be dealt with over time by each of them.

42. Likewise, since the child's sense of gender develops in interaction with his parents and their own gender roles and relationships, the responsible MHP will almost certainly need to delve into family and marital dynamics.

F. Understanding the WPATH and its "Standards of Care"

43. In almost any discussion of the diagnosis and care of patients suffering gender dysphoria or exhibiting transgender characteristics, the World Professional Association for Transgender Health (WPATH) and the Standards of Care that that organization publishes will be mentioned. Accordingly, I provide some context concerning that private organization.

44. I was a member of the Harry Benjamin International Gender Dysphoria Association from 1974 until 2001. From 1997 through 1998, I served as the Chairman of the eight-person International Standards of Care Committee that issued the fifth version of the Standards of Care. I resigned my membership in 2002 due to my regretful conclusion that the organization and its recommendations had become dominated by politics and ideology, rather than by scientific process, as it was years earlier. In approximately 2007, the Henry Benjamin International Gender Dysphoria Association changed its name to the World Professional Association for Transgender Health.

45. WPATH is a voluntary membership organization. Since at least 2002, attendance at its biennial meetings has been open to trans individuals who are not licensed professionals. While this ensures taking patients' needs into consideration, it

limits the ability for honest and scientific debate, and means that WPATH can no longer be considered a purely professional organization.

46. WPATH takes a decided view on issues as to which there is a wide range of opinion among professionals. WPATH explicitly views itself as not merely a scientific organization, but also as an advocacy organization. (Levine, *Reflections*, at 240.) WPATH is supportive to those who want sex reassignment surgery ("SRS"). Skepticism as to the benefits of SRS to patients, and strong alternate views, are not well tolerated in discussions within the organization. Such views have been known to be shouted down and effectively silenced by the large numbers of nonprofessional adults who attend the organization's biennial meetings.

47. The Standards of Care ("SOC") is the product of an enormous effort to be balanced, but it is not a politically neutral document. WPATH aspires to be both a scientific organization and an advocacy group for the transgendered. These aspirations sometimes conflict. The limitations of the Standards of Care, however, are not primarily political. They are caused by the lack of rigorous research in the field, which allows room for passionate convictions on how to care for the transgendered.

48. In recent years, WPATH has fully adopted some mix of the medical and civil rights paradigms. It has downgraded the role of counseling or psychotherapy as a requirement for these life-changing processes. WPATH no longer considers preoperative psychotherapy to be a requirement. It is important to WPATH that the person has gender dysphoria; the pathway to the development of this state is not. (Levine, *Reflections*, at 240.) The trans person is assumed to have thoughtfully

considered his or her options before seeking hormones, for instance. Many have wondered whether adolescents are developmentally capable of a prudent consideration of the consequences of their decisions.

49. Most psychiatrists and psychologists who treat patients suffering sufficiently severe distress from gender dysphoria to seek inpatient psychiatric care are not members of WPATH. Many psychiatrists and psychologists who treat some patients suffering gender dysphoria on an outpatient basis are not members of WPATH. WPATH represents a self-selected subset of the mental health professions, endocrinologists, and surgeons along with its many non-professional trans members; it does not capture the clinical experiences of others. WPATH claims to speak for the medical profession; however, it does not welcome skepticism and therefore, deviates from the philosophical core of medical science.

50. For example, in 2010 the WPATH Board of Directors issued a statement advocating that incongruence between sex and felt gender identity should cease to be identified in the DSM as a pathology.[12] This position was debated but not adopted by the (much larger) American Psychiatric Association, which maintained the definitions and diagnoses of gender dysphoria as a pathology in the DSM-5 manual issued in 2013.

51. In my experience most current members of WPATH have little ongoing experience with the mentally ill, and many trans care facilities are staffed by MHPs

[12] WPATH *De-Psychopathologisation Statement* (May 26, 2010), available at wpath.org/policies (last accessed January 21, 2020).

who are not deeply experienced with recognizing and treating frequently associated psychiatric co-morbidities. Because the 7th version of the WPATH SOC deleted the requirement for therapy, trans care facilities that consider these Standards sufficient are permitting patients to be counseled to transition by means of social presentation, hormones, and surgery by individuals with masters rather than medical or PhD clinical psychology degrees. As a result of the downgrading of the role of the psychiatric assessment of patients, new "gender affirming" clinics have arisen in many urban settings that quickly (sometimes within an hour's time) recommend transition. Concerned parents who came wanting to know what is going on in their children are overwhelmed, and feel disoriented, fearful for the health and safety of their children, and dependent on the professional.

II. PATIENTS DIFFER WIDELY AND MUST BE CONSIDERED INDIVIDUALLY.

52. In my opinion, it is not possible to make a single, categorical statement about the proper treatment of children presenting with gender dysphoria or other gender-related issues. Indeed, a MHP cannot responsibly opine on the proper treatment of a particular child presenting with gender dysphoria unless and until he or she has had more than one working session with that child, and has taken a thorough developmental history of the child's gender-related issues (or has reviewed such a history prepared by another MHP). This is so for multiple reasons.

53. There is no single pathway of development and outcomes governing transgender identity, nor one that predominates over the large majority of cases. Instead, as individuals grow up and age, depending on their differing psychological,

social, familial, and life experiences, their outcomes differ widely.

54. As to causes in children, details about the onset of gender dysphoria may be found in an understanding of family relationship dynamics. In particular, the relationship between the parents and each of the parents and the child, and each of the siblings and the child should be well known by the MHP.

55. Further, a disturbingly large proportion of children who seek professional care in connection with gender issues have a wider history of psychiatric co-morbidities. (*See supra* n. 7.) A 2017 study from the Boston Children's Hospital Gender Management Service program reported that: "Consistent with the data reported from other sites, this investigation documented that 43.3% of patients presenting for services had significant psychiatric history, with 37.1% having been prescribed psychotropic medications, 20.6% with a history of self-injurious behavior, 9.3% with a prior psychiatric hospitalization, and 9.3% with a history of suicide attempts." (L. Edwards-Leeper, *Psychological Profile*, at 375.) It seems likely that an even higher proportion will have had prior undiagnosed psychiatric conditions.

56. As to outcomes, as I explain below, for pre-pubertal children, desistance from transgender identification in favor of a gender corresponding to the child's sex, during or within a few years of puberty, is a likely outcome absent intervention. (*Infra* Section III.)

57. Because the causes, characteristics, social and relational context, and likely future course of gender dysphoria vary widely from individual to individual, it is essential that the MHP spend significant time with an individual patient over multiple

sessions to take a careful developmental history, before attempting to decide on a course of therapy for that individual.

III. SOCIAL TRANSITION OF PRE-PUBERTAL CHILDREN IS A MAJOR, EXPERIMENTAL, AND CONTROVERSIAL INTERVENTION THAT SUBSTANTIALLY CHANGES OUTCOMES.

58. A distinctive and critical characteristic of juvenile gender dysphoria is that multiple studies from separate groups and at different times have reported that in the large majority of patients, absent a substantial intervention such as social transition and/or hormone therapy, gender dysphoria does *not* persist through puberty. A recent article reviewed all existing follow-up studies that the author could identify of children diagnosed with gender dysphoria (11 studies), and reported that "every follow-up study of GD children, without exception, found the same thing: By puberty, the majority of GD children ceased to want to transition." (Cantor at 1.) Another author reviewed the existing studies and reported that in "prepubertal boys with gender discordance . . . the cross gender wishes usually fade over time and do not persist into adulthood, with only 2.2% to 11.9% continuing to experience gender discordance."[13] A third summarized the existing data as showing that "Symptoms of GID at prepubertal ages decrease or disappear in a considerable percentage of children (estimates range from 80-95%)."[14]

59. It is not yet known how to distinguish those children who will desist from that small minority whose trans identity will persist. (Levine, *Ethical*

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[13] S. Adelson & American Academy of Child & Adolescent Psychiatry (2012), *Practice Parameter on Gay, Lesbian, or Bisexual Sexual Orientation, Gender Nonconformity, and Gender Discordance in Children and Adolescents*, J. AM. ACAD. CHILD ADOLESCENT PSYCHIATRY 51(9) 957 at, 963 ("*Practice Parameter*").

[14] P. T. Cohen-Kettenis, H. A. Delemarre-van de Waal et al. (2008), *The Treatment of Adolescent Transsexuals: Changing Insights*, J. SEXUAL MEDICINE 5(8) 1892 at 1895.

Concerns, at 9.)[15]

60. Desistance within a relatively short period may also be a common outcome for post-pubertal youths who exhibit recently described "rapid onset gender disorder." I observe an increasingly vocal online community of young women who have reclaimed a female identity after claiming a male gender identity at some point during their teen years. However, data on outcomes for this age group with and without therapeutic interventions are not yet available to my knowledge.

61. In contrast, there is now data that suggests that a therapy that encourages social transition dramatically changes outcomes. A prominent group of authors has written that "The gender identity affirmed during puberty appears to predict the gender identity that will persist into adulthood."[16] Similarly, a comparison of recent and older studies suggests that when an "affirming" methodology is used with children, a substantial proportion of children who would otherwise have desisted by adolescence—that is, achieved comfort identifying with their natal sex—instead persist in a transgender identity. (Zucker, *Myth of Persistence*, at 7.)[17]

62. Indeed, a review of multiple studies of children treated for gender

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[15] It is also apparent in the adolescent phenomenon of rapid onset of gender dysphoria following a gender normative childhood that childhood gender identity is not inherently stable in either direction.

[16] C. Guss et al. (2015), *Transgender and Gender Nonconforming Adolescent Care: Psychosocial and Medical Considerations*, CURR. OPIN. PEDIATR. 26(4) 421 at 421 ("TGN Adolescent Care").

[17] One study found that social transition by the child was found to be strongly correlated with persistence for natal boys, but not for girls. K. Zucker (2018), *The Myth of Persistence: Response to "A Critical Commentary on Follow-Up Studies & 'Desistance' Theories about Transgender & Gender Non-Conforming Children" by Temple Newhook et al.*, INT'L J. OF TRANSGENDERISM at 5, DOI: 10.1080/15532739.2018.1468293 ("Myth of Persistence") (citing T.D. Steensma, J.K. McGuire et al. (2013), *Factors Associated with Desistance & Persistence of Childhood Gender Dysphoria: A Qualitative Follow-up Study*, J. OF THE AM. ACAD. OF CHILD & ADOLESCENT PSYCHIATRY 52, 582.)

dysphoria across the last three decades found that early social transition to living as the opposite sex severely reduces the likelihood that the child will revert to identifying with the child's natal sex, at least in the case of boys. That is, while, as I review above, studies conducted before the widespread use of social transition for young children reported desistance rates in the range of 80-98%, a more recent study reported that fewer than 20% of boys who engaged in a partial or complete social transition before puberty had desisted when surveyed at age 15 or older. (Zucker, *Myth of Persistence*, at 7; Steensma (2013).)[18] Some vocal practitioners of prompt affirmation and social transition even claim that essentially *no* children who come to their clinics exhibiting gender dysphoria or cross-gender identification desist in that identification and return to a gender identity consistent with their biological sex.[19] This is a very large change as compared to the desistance rates documented apart from social transition. Some researchers who generally advocate prompt affirmation and social transition also acknowledge a causal connection between social transition and this change in outcomes.[20]

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[18] Only 2 (3.6%) of 56 of the male desisters observed by Steensma et al. had made a complete or partial transition prior to puberty, and of the twelve males who made a complete or partial transition prior to puberty, only two had desisted when surveyed at age 15 or older. Steensma (2013) at 584.

[19] *See, e.g.,* B. Ehrensaft (2015), *Listening and Learning from Gender-Nonconforming Children,* THE PSYCHOANALYTIC STUDY OF THE CHILD 68(1) 28 at 34: "In my own clinical practice . . . of those children who are carefully assessed as transgender and who are allowed to transition to their affirmed gender, we have no documentation of a child who has 'desisted' and asked to return to his or her assigned gender."

[20] *See* Guss, *TGN Adolescent Care*, at 2. "The gender identity affirmed during puberty appears to predict the gender identity that will persist into adulthood." "Youth with persistent TNG [transgender, nonbinary, or gender-nonconforming] identity into adulthood . . . are more likely to have experienced social transition, such as using a different name . . . which is stereotypically associated with another gender at some point during childhood."

63. Accordingly, I agree with a noted researcher in the field who has written that social transition in children must be considered "a form of psychosocial treatment."[21]

64. So far as I am aware, no study yet reveals whether the life-course mental and physical health outcomes for this relatively new class of "persisters" are more similar to those of the general non-transgender population, or to the notably worse outcomes exhibited by the transgender population generally.

65. However, I agree with Zucker who has written, "…we cannot rule out the possibility that early successful treatment of childhood GID [Gender Identity Disorder] will diminish the role of a continuation of GID into adulthood. If so, successful treatment would also reduce the need for the long and difficult process of sex reassignment which includes hormonal and surgical procedures with substantial medical risks and complications."[22] By the same token, a therapeutic methodology for children that *increases* the likelihood that the child will continue to identify as the opposite gender into adulthood will *increase* the need for the long and potentially problematic processes of hormonal and genital and cosmetic surgical procedures.

66. Not surprisingly, given these facts, encouraging social transition in children remains controversial. Supporters of such transition acknowledge that "Controversies among providers in the mental health and medical fields are abundant . . . These include differing assumptions regarding . . . the age at which

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[21] K. Zucker (2019), *Debate: Different Strokes for Different Folks*, CHILD & ADOLESCENT MENTAL HEALTH, at 1, DOI: 10.1111/camh.12330 ("*Debate*").

[22] Zucker, *Myth of Persistence*, at 8 (citing H. Meyer-Bahlburg (2002), *Gender Identity Disorder in Young Boys: A Parent- & Peer-Based Treatment Protocol*, CLINICAL CHILD PSYCHOLOGY & PSYCHIATRY 7, 360 at 362.).

children . . . should be encouraged or permitted to socially transition . . . These are complex and providers in the field continue to be at odds in their efforts to work in the best interests of the youth they serve."[23]

67. In sum, therapy for young children that encourages transition cannot be considered to be neutral, but instead is an experimental procedure that has a high likelihood of changing the life path of the child, with highly unpredictable effects on mental and physical health, suicidality, and life expectancy. Claims that a civil right is at stake do not change the fact that what is proposed is a social and medical experiment. (Levine, *Reflections,* at 241.) Ethically, then, it should be undertaken only subject to standards, protocols, and reviews appropriate to such experimentation.

IV. THE AVAILABLE DATA DOES NOT SUPPORT THE CONTENTION THAT "AFFIRMATION" OF TRANSGENDER IDENTITY REDUCES SUICIDE OR RESULTS IN BETTER PHYSICAL OR MENTAL HEALTH OUTCOMES GENERALLY.

68. I am aware that organizations including The Academy of Pediatrics and Parents, Families and Friends of Lesbians and Gays (PFLAG)) have published statements that suggest that all children who express a desire for a transgender identity should be promptly supported in that claimed identity. This position appears to rest on the belief—which is widely promulgated by certain advocacy organizations—that science has already established that prompt "affirmance" is best for all patients, including all children, who present indicia of transgender identity. As I discuss later

[23] A. Tishelman et al. (2015), *Serving Transgender Youth: Challenges, Dilemmas and Clinical Examples*, PROF. PSYCHOL. RES. PR. at 11, DOI: 10.1037/a0037490 ("*Serving TG Youth*").

below, this belief is scientifically incorrect, and ignores both what is known and what is unknown.

69. The knowledge-base concerning the causes and treatment of gender dysphoria has low scientific quality.

70. In evaluating claims of scientific or medical knowledge, it is important to understand that it is axiomatic in science that no knowledge is absolute, and to recognize the widely accepted hierarchy of reliability when it comes to "knowledge" about medical or psychiatric phenomena and treatments. Unfortunately, in this field opinion is too often confused with knowledge, rather than clearly locating what exactly is scientifically known. In order of increasing confidence, such "knowledge" may be based upon data comprising:

a. Expert opinion—it is perhaps surprising to educated laypersons that expert opinion standing alone is the lowest form of knowledge, the least likely to be proven correct in the future, and therefore does not garner as much respect from professionals as what follows.

b. A single case or series of cases (what could be called anecdotal evidence); (Levine, *Reflections*, at 239.)

c. A series of cases with a control group;

d. A cohort study;

e. A randomized double-blind clinical trial;

f. A review of multiple trials;

g. A meta-analysis of multiple trials that maximizes the number of patients treated despite their methodological differences to detect trends from larger data sets.

71. Prominent voices in the field have emphasized the severe lack of scientific knowledge in this field. The American Academy of Child and Adolescent Psychiatry has recognized that "Different clinical approaches have been advocated for childhood gender discordance. . . . There have been no randomized controlled trials of any treatment. . . . [T]he proposed benefits of treatment to eliminate gender discordance…must be carefully weighed against… possible deleterious effects." (Adelson et al., *Practice Parameter,* at 968–69.) Similarly, the American Psychological Association has stated, "…because no approach to working with [transgender and gender nonconforming] children has been adequately, empirically validated, consensus does not exist regarding best practice with pre-pubertal children."[24]

72. Critically, "there are no randomized control trials with regard to treatment of children with gender dysphoria." (Zucker, *Myth of Persistence,* at 8.) On numerous critical questions relating to cause, developmental path if untreated, and the effect of alternative treatments, the knowledge base remains primarily at the level of the practitioner's exposure to individual cases, or multiple individual

[24] American Psychological Association, *Guidelines for Psychological Practice with Transgender & Gender Nonconforming People* (2015), AM. PSYCHOLOGIST 70(9) 832 at 842.

cases. As a result, claims to certainty are not justifiable. (Levine, *Reflections*, at 239.)

73. Large gaps exist in the medical community's knowledge regarding the long-term effects of SRS and other gender identity disorder treatments in relation to their positive or negative correlation to suicidal ideation, attempts, and completion. What is known, however, is not encouraging.

74. With respect to suicide, individuals with gender dysphoria are well known to commit suicide or otherwise suffer increased mortality before and after not only social transition, but also before and after SRS. (Levine, *Reflections,* at 242.) For example, in the United States, the death rates of trans veterans are comparable to those with schizophrenia and bipolar diagnoses—20 years earlier than expected. These crude death rates include significantly elevated suicide rates. (Levine, *Ethical Concerns,* at 10.) Similarly, researchers in Sweden and Denmark have reported on almost all individuals who underwent sex-reassignment surgery over a 30-year period.[25] The Swedish follow-up study found a suicide rate in the post-SRS population 19.1 times greater than that of the controls; both studies demonstrated elevated mortality rates from medical and psychiatric conditions. (Levine, *Ethical Concerns,* at 10.)

75. Advocates of immediate and unquestioning affirmation of social

[25] C. Dhejne et al. (2011), *Long-Term Follow-Up of Transsexual Persons Undergoing Sex Reassignment Surgery: Cohort Study in Sweden*, PLOS ONE 6(2) e16885 ("*Long Term*"); R. K. Simonsen et al. (2016), *Long-Term Follow-Up of Individuals Undergoing Sex Reassignment Surgery: Psychiatric Morbidity & Mortality*, NORDIC J. OF PSYCHIATRY 70(4).

transition in children who indicate a desire for a transgender identity sometimes assert that any other course will result in a high risk of suicide in the affected children and young people. Contrary to these assertions, no studies show that affirmation of children (or anyone else) reduces suicide, prevents suicidal ideation, or improves long-term outcomes, as compared to either a "watchful waiting" or a psychotherapeutic model of response, as I have described above.[26]

76. I will also note that any discussion of suicide when considering younger children involves very long-range and very uncertain prediction. Suicide in pre-pubescent children is rare and the existing studies of gender identity issues in pre-pubescent children do not report significant incidents of suicide. The estimated suicide rate of trans adolescents is the same as teenagers who are in treatment for serious mental illness. What trans teenagers do demonstrate is more suicidal ideation and attempts (however serious) than other teenagers.[27]

77. In sum, claims that affirmation will reduce the risk of suicide for children are not based on science. Such claims overlook the lack of even short-term supporting data as well as the lack of studies of long-term outcomes resulting from the affirmation or lack of affirmation of transgender identity in children. It also overlooks the other tools that the profession does have for addressing depression and suicidal thoughts in a

[26] A recent article, J. Turban et al. (2020), *Puberty Suppression for Transgender Youth and Risk of Suicidal Ideation*, PEDIATRICS 145(2), DOI: 10.1542/peds.2019-1725 ("*Puberty Suppression*"), has been described in press reports as demonstrating that administration of puberty suppressing hormones to transgender adolescents reduces suicide or suicidal ideation. The paper itself does not make that claim, nor permit that conclusion.

[27] A. Perez-Brumer, J. K. Day et al. (2017), *Prevalence & Correlates of Suicidal Ideation Among Transgender Youth in Cal.: Findings from a Representative, Population-Based Sample of High Sch. Students*, J. AM. ACAD. CHILD ADOLESCENT PSYCHIATRY 56(9), 739 at 739.

patient once that risk is identified. (Levine, *Reflections*, at 242.)

78. A number of data sets have also indicated significant concerns about wider indicators of physical and mental health, including ongoing functional limitations;[28] substance abuse, depression, and psychiatric hospitalizations;[29] and increased cardiovascular disease, cancer, asthma, and COPD.[30] Worldwide estimates of HIV infection among transgendered individuals are up to 17-fold higher than the cisgender population. (Levine, *Informed Consent,* at 6.)

79. Meanwhile, no studies show that affirmation of pre-pubescent children leads to more positive outcomes (mental, physical, social, or romantic) by, e.g., age 25 or older than does "watchful waiting" or ordinary therapy. Because children's affirmation, social transition, and the use of puberty blockers for transgender children are a recent phenomenon, it could hardly be otherwise.

80. Thus, transition of any sort must be justified, if at all, as a life-enhancing measure, not a lifesaving measure. (Levine, *Reflections,* at 242.) In my opinion, this is an important fact that patients, parents, and even many MHPs fail to understand.

81. The long-term benefits of SRS on the mental health of individuals diagnosed with gender dysphoria are widely assumed to be positive, but in fact are scientifically and clinically unknown. Several studies (Turban et al, *JAMA Psychiatry*, 77(1) (2020); Turban et al, *Puberty Suppression* (*supra* n.26); Bränström & Pachankis

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[28] G. Zeluf, C. Dhejne et al. (2016), *Health, Disability and Quality of Life Among Trans People in Sweden—A Web-Based Survey*, BMC PUBLIC HEALTH 16(903), DOI: 10.1186/s12889- 016-3560-5.

[29] C. Dhejne, R. Van Vlerken et al. (2016), *Mental Health & Gender Dysphoria: A Review of the Literature*, INT'L REV. OF PSYCHIATRY 28(1) 44.

[30] C. Dragon, P. Guerino, et al. (2017), *Transgender Medicare Beneficiaries & Chronic Conditions: Exploring Fee-for-Service Claims Data*, LGBT HEALTH 4(6) 404, DOI: 10.1089/lgbt.2016.0208.

Am J Psychiatry, 177: 727-724 (2020)) have been undertaken because this uncertainty is now widely recognized among researchers. These studies either claimed positive mental health outcomes or that psychotherapy interventions had negative outcomes. Each has been been soundly criticized. Criticisms about the Bränström & Pachankis publication caused the editor of the journal to have the data reanalyzed by two new consultants who agreed that the authors' conclusions were invalid (*see* August 2020 issue of the *Am J Psychiatry*). Every person's life has multiple dimensions--vocational, educational, interpersonal, romantic, familial, mental health, physical health, substance dependence, etc. Previous studies of adjustment after SRS rested on the infrequency of regret for having undergone surgery. There is already much evidence that the long-term outcome of SRS is not favorable for many gender dysphoric individuals. Providing SRS to an adolescent further commits the young person to a pathway that is known to have innumerable challenges. Many of these adolescents who appear quite certain about what they need to be happier cannot envision the unique challenges they will face, let alone master these developmental challenges.

82. If trans male identified adolescents have their breasts removed, they will have a male appearing chest and female genitalia. This surgery will initially make them happy about their chest per se, but they still will experience gender dysphoria because of the presence of the female genitalia. This anatomic source of incongruence will continue to limit intimate dimensions of their life possibilities. Genital reconstruction of male appearing genitalia is unable to produce the normal functions of a penis. It is expensive, fraught with complications, and leaves a significant scarring of

a limb. Most trans males do not undergo this arduous procedure. This makes the incongruence a permanent feature. Bilateral mastectomies should not be construed as a curative intervention for gender dysphoria. It only eradicates the displeasure of having female breasts.

V. KNOWN, LIKELY, OR POSSIBLE DOWNSIDE RISKS ATTENDANT ON MOVING QUICKLY TO "AFFIRM" TRANSGENDER IDENTITY IN CHILDREN.

83. The multiple studies from different nations that have documented the increased vulnerability of the adult transgender population to substance abuse, mood and anxiety disorders, suicidal ideation, and other health problems warn that assisting the child down the road to becoming a transgender adult is a very serious decision, and stand as a reminder that a casual assumption that transition will improve the child's life is not justified based on numerous scientific snapshots of cohorts of trans adults and teenagers.

84. The possibility that steps along this pathway, while lessening the pain of gender dysphoria, could lead to additional sources of crippling emotional and psychological pain, are too often not considered by advocates of social transition and not considered at all by the trans child. (Levine, *Reflections,* at 243.)

85. I detail below several classes of predictable, likely, or possible harms to the patient associated with transitioning to live as a transgender individual.

A. Physical risks associated with transition

86. Sterilization. Obviously, SRS that removes testes, ovaries, or the uterus is

inevitably sterilizing. While by no means all transgender adults elect SRS, many patients do ultimately feel compelled to take this serious step in their effort to live fully as the opposite sex. More immediately, practitioners recognize that the administration of cross-sex hormones, which is often viewed as a less "radical" measure, and is now increasingly done to minors, creates at least a risk of irreversible sterility.[31] As a result, even when treating a child, the MHP, patient, and parents must consider loss of reproductive capacity—sterilization—to be one of the major risks of starting down the road. The risk that supporting social transition may put the child on a pathway that leads to intentional or unintentional permanent sterilization is particularly concerning given the disproportionate representation of minority and other vulnerable groups among children reporting a transgender or gender-nonconforming identity. (*See supra* ¶ 19.)

87. Loss of sexual response. Puberty-blockers prevent maturation of the sexual organs and response. Some and perhaps many transgender individuals who transitioned as children and thus did not go through puberty consistent with their sex face significantly diminished sexual response as they enter adulthood, and are unable ever to experience orgasm. To my knowledge, data quantifying this impact has not been published.

88. Other effects of hormone administration. While it is commonly said that the effects of puberty blockers are reversible after cessation, in fact controlled studies have

[31] *See* C. Guss et al., *TGN Adolescent Care* at 4 ("a side effect [of cross-sex hormones] may be infertility") and 5 ("cross-sex hormones . . . may have irreversible effects"); Tishelman et al., *Serving TG Youth* at 8 (Cross-sex hormones are "irreversible interventions" with "significant ramifications for fertility").

not been done of how completely this is true. However, it is well known that many effects of cross-sex hormones cannot be reversed should the patient later regret his transition. After puberty, the individual who wishes to live as the opposite sex will in most cases have to take cross-sex hormones for life.

89. The long-term health risks of this major alteration of hormonal levels have not yet been quantified in terms of exact risk.[32] However, a recent study found greatly elevated levels of strokes and other acute cardiovascular events among male-to-female transgender individuals taking estrogen. Those authors concluded, "it is critical to keep in mind that the risk for these cardiovascular events in this population must be weighed against the benefits of hormone treatment."[33] Another group of authors similarly noted that administration of cross-sex hormones creates "an additional risk of thromboembolic events"—i.e., blood clots (Guss et al., *T GNAdolescent Care* at 5), which are associated with strokes, heart attack, and lung and liver failure. Clinicians must distinguish the apparent short-term safety of hormones from likely or possible long-term consequences, and help the patient or parents understand these implications as well. The young patient may feel, "I don't care if I die young, just as long I get to live as a woman." The mature adult may take a different view.

90. Health risks inherent in complex surgery. Complications of surgery exist for each procedure,[34] and complications in surgery affecting the breasts and chest can

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[32] *See* Tishelman et al., *Serving TG Youth* at 6-7 (Long-term effect of cross-sex hormones "is an area where we currently have little research to guide us").

[33] D. Getahun et al. (2018), *Cross-Sex Hormones and Acute Cardiovascular Events in Transgender Persons: A Cohort Study*, ANNALS OF INTERNAL MEDICINE at 8, DOI:10.7326/M17- 2785.

[34] Levine, *Informed Consent*, at 5 (citing T. van de Grift, G. Pigot et al. (2017), *A Longitudinal Study of Motivations Before & Psychosexual Outcomes After Genital Gender- Confirming Surgery in Transmen*, J. SEXUAL MEDICINE

have significant anatomical and functional complications for the patient's quality of life. Genital surgeries carry even more significant short and long term complication risks.

91. Disease and mortality generally. The MHP, the patient, and in the case of a child the parent, must also be aware of the wide sweep of strongly negative health outcomes among transgender individuals, as I have detailed above.

B. Social risks associated with transition

92. Family and friendship relationships. Gender transition routinely leads to isolation from at least a significant portion of one's family in adulthood. In the case of a juvenile transition, this will be less dramatic while the child is young, but commonly increases over time. In adulthood, the friendships of transgender individuals tend to be confined to other transgender individuals (often "virtual" friends known only online) and a generally more limited set of others. (Levine, *Ethical Concerns,* at 5.)

93. Long term psychological and social impact of sterility. The life-long negative emotional impact of infertility on both men and women has been well studied. While this impact has not been studied specifically within the transgender population, the opportunity to be a parent is likely a human, emotional need, and so should be considered an important risk factor when considering gender transition for any patient. However, it is particularly difficult for parents of a young child to seriously contemplate that child's potential as a future parent and grandparent. This makes it all the more critical that the MHP spend substantial and repeated time with parents to help them see the implications of what they are considering.

14(12) 1621.).

94. Sexual-romantic risks associated with transition. After adolescence, transgender individuals can find the pool of individuals willing to develop a romantic and intimate relationship with them to be greatly diminished. (Levine, *Ethical Concerns*, at 5, 13).[35]

95. Social risks associated with delayed puberty. The social and psychological impact of remaining puerile for, e.g., three years while one's peers are undergoing puberty, and of undergoing puberty at a substantially older age, have not been systematically studied, although clinical mental health professionals often hear of distress and social awkwardness in those who naturally have a delayed onset of puberty. In my opinion, individuals in whom puberty is delayed multiple years are likely to suffer at least subtle negative psychosocial and self-confidence effects as they stand on the sidelines while their peers are developing the social relationships (and attendant painful social learning experiences) that come with adolescence. (Levine, *Informed Consent,* at 9.)

C. Mental health costs or risks

96. One would expect the negative physical and social impacts reviewed above to adversely affect the mental health of individuals who have transitioned.

97. In addition, individuals often pin excessive hope in transition, believing that transition will solve what are in fact ordinary social stresses associated with maturation, or mental health co-morbidities. Thus, transition can result in

[35] S. Levine, *Barriers to Loving: A Clinician's Perspective*, at 40 (Routledge, New York 2013).

deflection from mastering personal challenges at the appropriate time, or addressing conditions that require treatment.

98. Whatever the reason, transgender individuals including transgender youth certainly experience greatly increased rates of mental health problems. I have detailed this above with respect to adults living under a transgender identity. Indeed, Swedish researchers in a long- term study (up to 30 years since SRS, with a median time since SRS of > 10 years) concluded that individuals who have SRS should have postoperative lifelong psychiatric care. (Dhejne, *Long Term*, at 6-7.) With respect to youths a cohort study found that transgender youth had an elevated risk of depression (50.6% vs. 20.6%) and anxiety (26.7% vs. 10.0%); a higher risk of suicidal ideation (31.1% vs. 11.1%), suicide attempts (17.2% vs. 6.1%), and self-harm without lethal intent (16.7% vs. 4.4%) relative to the matched controls; and a significantly greater proportion of transgender youth accessed inpatient mental health care (22.8% vs. 11.1%) and outpatient mental health care (45.6% vs. 16.1%) services.[36]

D. Regret following transition is not an infrequent phenomenon.

99. The large numbers of children and young adults who have desisted as documented in both group and case studies each represent "regret" over the initial choice in some sense.

100. The phenomenon of desistance or regret experienced *later* than adolescence or young adulthood, or among older transgender individuals, has to my

[36] S. Reisner et al. (2015), *Mental Health of Transgender Youth in Care at an Adolescent Urban Community Health Center: A Matched Retrospective Cohort Study*, J. OF ADOLESCENT HEALTH 56(3) at 6, DOI:10.1016/j.jadohealth.2014.10.264; *see also supra* ¶ 19.

knowledge not been quantified or well studied. However, it is a real phenomenon. I myself have worked with multiple individuals who have abandoned trans female identity after living in that identity for years, and who would describe their experiences as "regret."

101. I have seen several Massachusetts inmates and trans individuals in the community abandon their [trans] female identity after several years. (Levine, *Reflections,* at 239.) In the gender clinic which I founded in 1974 and to this day, in a different location, continue to co-direct, we have seen many instances of individuals who claimed a transgender identity for a time, but ultimately changed their minds and reclaimed the gender identity congruent with their sex.

102. More dramatically, a surgical group prominently active in the SRS field has published a report on a series of seven male-to-female patients requesting surgery to transform their surgically constructed female genitalia back to their original male form.[37]

103. I noted above an increasingly visible online community of young women who have desisted after claiming a male gender identity at some point during their teen years. (*See supra* ¶ 60.) Given the rapid increase in the number of girls presenting to gender clinics within the last few years, the phenomena of regret and desistance by young women deserves careful attention and study by MHPs.

104. Thus, one cannot assert with any degree of certainty that once a

[37] Djordjevic et al. (2016), *Reversal Surgery in Regretful Male-to-Female Transsexuals After Sex Reassignment Surgery*, J. Sex Med. 13(6) 1000, DOI: 10.1016/j.jsxm.2016.02.173.

transgendered person, always a transgendered person, whether referring to a child, adolescent, or adult, male or female.

VI. MEDICAL ETHICS & INFORMED CONSENT

A. The obligation of the mental health professional to enable and obtain informed consent

105. I have reviewed above the knowledge and experience that, in my view, a mental health professional should have before undertaking the responsibility to counsel or treat a child who is experiencing gender dysphoria or transgender identification. The MHP who undertakes this type of responsibility must also be guided by the ethical principles that apply to all health care professionals. One of the oldest and most fundamental principles guiding medical and psychological care—part of the Hippocratic Oath—is that the physician must "first, do no harm." This states an ethical responsibility that cannot be delegated to the patient. Physicians themselves must weigh the risks of treatment against the harm of not treating. If the risks of treatment outweigh the benefits, ethics prohibit the treatment.

106. A distinct ethical responsibility of physicians, when a significant risk exists of adverse consequences to any procedure or therapy, is to ensure that the patient understands and is legally able to consent to the treatment, and does consent. To achieve informed consent, the MHP must do at least the following:

a. The MHP must reasonably inform himself regarding the particular situation of his patient;

b. The MHP must reasonably inform himself concerning the state of knowledge concerning relevant methodologies and outcomes;

c. The MHP must honestly inform the patient concerning not only the benefits of treatment, but also the risks and downsides of treatment, and alternative treatments;

d. The MHP must conclude that the patient (or the decision maker, such as parent or healthcare power of attorney) has comprehended what he or she has been told and possesses a cognitive capacity to make a decision based on an adequate understanding of his or her unique life circumstances.

107. Perfunctory "consent" is inadequate to fulfill the professional's ethical obligation to obtain informed consent. At the very least, a patient (or parent) considering the life-altering choice of transition should be helped or indeed required by their clinicians to grapple with four relevant questions:

a. "What benefits do you expect that the consolidation of this identity, gender transition, hormones, or surgery will provide?

b. "What do you understand of the social, educational, vocational, and psychological risks of this identity consolidation and gender role transition?

c. "What do you understand about the common and rare, short- and long-term medical and health risks of hormone and surgical interventions?

d. "What have you considered the nature of your life will be in 10 to 20 years?" (Levine, *Informed Consent,* at 3.)

108. The answers of the patient will enable the professional to make a judgment about how realistic he or she is being. For example, the biological boy who

envisions himself as a happy, attractive, socially accepted 21-year-old girl in future college years has probably not been adequately informed of—or has mentally blocked—hard data concerning the mental health and social wellbeing of the transgender population in their 20s, and is failing to consider the material risk that he, as a transgender individual, will not be perceived as attractive to either sex, and the impact that this may have on his future well-being.

109. Most commonly, meaningful engagement with difficult and painful questions such as those above requires a process that will consist of multiple discussions in a psychotherapeutic or counseling context, not merely "disclosure" of facts. In my experience, a too-rapid or too-eager attachment to some outcome is a red warning flag that the patient is not able to tolerate knowledge of the risks and alternative approaches.

110. In my experience, in the area of transgender therapy, rather than the type of information and engagement that I have described, even mental health professionals too often encourage or permit decisions based on a great deal of patient and professional blind optimism about the future. (Levine, *Ethical Concerns*, at 3-4.)

B. The interests of the patient, as well as necessary disclosures and consent, must be considered from a life course perspective.

111. The psychiatrist or psychologist treating a child must have in view not merely (or not even primarily) making the child "happy" now, but making him or her as healthy and happy as possible across the entire trajectory of life, to the extent that is predictable. Certainly, avoiding suicide is one important aspect of a "life course" analysis, and recognizes that "today" is not the only goal. But as I have reviewed

above, there is much more across the future decades of the patient's life that also needs to be taken into account.

112. Further, I do not believe that a patient can meaningfully be said to know what will make him "happy" over the long term, prior to receiving, understanding, and usually discussing the type of information that I have described above in connection with informed consent. With respect to children who are not equipped to understand, evaluate, and feel the life implications of such information, it is doubtful that there is any meaningful way in which they can be said to "know" what will make them happy over the long term. It is for similar reasons that parents ordinarily make a great many decisions, both large and small, for their young children.

C. Special concerns and ethical rules

113. When psychiatric or medical research is done on subjects the informed consent process is far more rigorous than in ordinary medical and psychiatric procedures. For example, in a recent study of an agent to assist women who are distressed by their lack of sexual desire that I was a part of, the Informed Consent document was 19 pages long.

114. The absence of long-term studies in the arena of childhood gender dysphoria or the more recently documented phenomenon of "rapid onset gender dysphoria" among adolescents means that therapeutic responses to these conditions are still at a primitive stage of development, and must be considered to be experimental, rendering adequately informed consent all the more essential, and all the more difficult to obtain. (Levine, *Reflections,* at 241.)

D. The inability of children to understand major life issues and risks complicates informed consent

115. Obviously, most children cannot give legally valid consent to a medical procedure.[38] This is not a mere legal technicality. Instead, it is a legal reflection of a reality of human development that is highly relevant to the ethical requirement of informed consent quite apart from law. The argument that the child is consenting to the transition by his happiness ignores the fact just described.

116. Each age group poses different questions about risk comprehension. (Levine, *Informed Consent*, at 3.)

117. In my experience, when clinicians actually attempt to understand patients' motives for the repudiation of their natal gender, the developmental lack of sophistication underlying their reasons can become apparent. What must a 12-year-old, for example, understand about masculinity and femininity that enables the conviction that "I can never be happy in my body?" (Levine, *Ethical Concerns,* at 8.)

118. Similarly, one cannot expect a 17-year-old to grasp the complexity of married life with children when 38. One cannot expect a ten-year-old to understand the emotional growth that comes from a first long term love relationship including sexual behavior. One cannot expect a six-year-old to comprehend the changes in his psyche that may come about as the result of puberty.

[38] I recognize that in some States or under some circumstances "mature minors" may be legally empowered to grant consent to certain medical procedures.

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

Executed this 28th day of September, 2020 at Beachwood, Ohio.

Stephen B. Levine MD

Stephen B. Levine, M.D.

Declaration of Stephen B. Levine Sept 26

Final Audit Report 2020-09-28

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EXHIBIT A

Brief Introduction

Dr. Levine is Clinical Professor of Psychiatry at Case Western Reserve University School of Medicine. He is the solo author of four books, Sex Is Not Simple in 1989 (translated to German in 1992 and reissued in English in 1997 as Solving Common Sexual Problems); Sexual Life: A clinician's guide in 1992; Sexuality in Midlife in 1998 and Demystifying Love: Plain talk for the mental health professional in 2006; Barriers to Loving: A clinician's perspective in October 2013. He is the Senior Editor of the first (2003), second (2010) and third (2016) editions of the Handbook of Clinical Sexuality for Mental Health Professionals. Psychotherapeutic Approaches to Sexual Problems: An Essential Guide For Mental Health Professionals will be published in the fall 2019. He has been teaching, providing clinical care, and writing since 1973 and has generated original research, invited papers, commentaries, chapters, and book reviews. He has served as a journal manuscript and book prospectus reviewer for many years. He was co-director of the Center for Marital and Sexual Health/ Levine, Risen & Associates, Inc. in Beachwood, Ohio from 1992-2017. He and two colleagues received a lifetime achievement Masters and Johnson's Award from the Society for Sex Therapy and Research in March 2005.

Personal Information

Date of birth 1/14/42

Medical license no. Ohio 35-03-0234-L

Board Certification 6/76 American Board of Neurology and Psychiatry

Education

1963 BA Washington and Jefferson College

1967 MD Case Western Reserve University School of Medicine

1967-68 internship in Internal Medicine University Hospitals of Cleveland

1968-70 Research associate, National Institute of Arthritis and Metabolic Diseases, Epidemiology Field Studies Unit, Phoenix, Arizona, United States Public Health Service

1970-73 Psychiatric Residency, University Hospitals of Cleveland

1974-77 Robert Wood Johnson Foundation Clinical Scholar

Appointments at Case Western Reserve University School of Medicine

1973 - Assistant Professor of Psychiatry

1979 - Associate Professor

1982 - Tenure

1985 - Full Professor

1993 - Clinical Professor

Honors

Summa Cum Laude, Washington & Jefferson

Teaching Excellence Award - 1990 and 2010 (residency program)

Visiting Professorships:

- Stanford University-Pfizer Professorship program (3 days) - 1995
- St. Elizabeth's Hospital, Washington, DC - 1998
- St. Elizabeth's Hospital, Washington, DC - 2002

Named to America's Top Doctors consecutively since 2001

Invitations to present various Grand Rounds at Departments of Psychiatry and Continuing Education Lectures and Workshops

Masters and Johnson Lifetime Achievement Award from the Society of Sex Therapy and Research, April 2005 along with Candace Risen and Stanley Althof

2006 SSTAR Book Award for The Handbook of Clinical Sexuality for Mental Health Professionals: Exceptional Merit

2018 - Albert Marquis Lifetime Achievement Award from Marquis Who's Who. (exceling in one's field for at least twenty years)

Professional Societies

1971 - American Psychiatric Association; fellow

2005 - American Psychiatric Association - **Distinguished Life Fellow**

1973 - Cleveland Psychiatric Society

1973 - Cleveland Medical Library Association

- 1985 - Life Fellow
- 2003 - Distinguished Life Fellow

1974 - Society for Sex Therapy and Research

- 1987-89 - President

1983 - International Academy of Sex Research

1983 - Harry Benjamin International Gender Dysphoria Association

- 1997-98 - Chairman, Standards of Care Committee

1994-99 - Society for Scientific Study of Sex

Community Boards

1999-2002 - Case Western Reserve University Medical Alumni Association

1996-2001 - Bellefaire Jewish Children's Bureau

1999-2001 - Physicians' Advisory Committee, The Gathering Place (cancer rehabilitation)

Editorial Boards

1978-80 Book Review Editor Journal Sex and Marital Therapy

Manuscript Reviewer for:

- Archives of Sexual Behavior
- Annals of Internal Medicine
- British Journal of Obstetrics and Gynecology
- JAMA
- Diabetes Care
- American Journal of Psychiatry
- Maturitas
- Psychosomatic Medicine
- Sexuality and Disability
- Journal of Nervous and Mental Diseases
- Journal of Neuropsychiatry and Clinical Neurosciences
- Neurology
- Journal Sex and Marital Therapy
- Journal Sex Education and Therapy
- Social Behavior and Personality: an international journal (New Zealand)
- International Journal of Psychoanalysis
- International Journal of Transgenderism
- Journal of Urology
- Journal of Sexual Medicine
- Current Psychiatry
- International Journal of Impotence Research
- Postgraduate medical journal
- Academic Psychiatry

Prospectus Reviewer for:

- Guilford
- Oxford University Press

- Brunner/Routledge
- Routledge

Administrative Responsibilities

Co-director, Center for Marital and Sexual Health/ Levine, Risen & Associates, Inc. until June 30, 2017

Principal Investigator of approximately 70 separate studies involving pharmacological interventions for sexual dysfunction since 1989.

Co-leader of case conferences at DELRLLC.com

Recent Expert Witness Appearances

US District Court, Judge Mark L.Wolf's witness in Michelle Kosilek vs. Massachusetts Dept of Corrections et al. case (transsexual issue) in Boston 2007

Deposition in the Battista vs. Massachusetts Dept of Corrections case (transsexual issue) in Cleveland October 2009

Witness for Massachusetts Dept. of Corrections in their defense of a lawsuit brought by prisoner Katheena Soneeya. March 22, 2011 Deposition in Boston and October 2018 in Cleveland

Witness for State of Florida vs. Reyne Keohane July 2017

Expert testimony by deposition and at trial in *In the Interests of the Younger Children*, Dallas, TX, 2019.

Consultancy

Massachusetts Department of Corrections - evaluation of 12 transsexual prisoners and the development of a Gender Identity Disorders Program for the state prison system. Monthly consultation with the GID treatment team since February 2009 and the GID policy committee since February 2010

California Department of Corrections and Rehabilitation; 2012-2015; education, inmate evaluation, commentary on inmate circumstances, suggestions on future policies

Virginia Department of Corrections - evaluation of an inmate

New Jersey Department of Corrections - evaluation of an inmate

Idaho Department of Corrections - workshop 2016

Grant Support/Research Studies

TAP - studies of Apomorphine sublingual in treatment of erectile dysfunction

Pfizer - Sertraline for premature ejaculation

Pfizer - Viagra and depression; Viagra and female sexual dysfunction; Viagra as a treatment for SSRI-induced erectile dysfunction

NIH - Systemic lupus erythematosis and sexuality in women

Sihler Mental Health Foundation

- Program for Professionals
- Setting up of Center for Marital and Sexual Health
- Clomipramine and Premature ejaculation
- Follow-up study of clergy accused of sexual impropriety
- Establishment of services for women with breast cancer

Alza - controlled study of a novel SSRI for rapid ejaculation

Pfizer - Viagra and self-esteem

Pfizer - double-blind placebo control studies of a compound for premature ejaculation

Johnson & Johnson - controlled studies of Dapoxetine for rapid ejaculation

Proctor and Gamble - multiple studies to test testosterone patch for post menopausal sexual dysfunction for women on and off estrogen replacement

Lilly-Icos - study of Cialis for erectile dysfunction

VIVUS - study for premenopausal women with FSAD

Palatin Technologies - studies of bremelanotide in female sexual dysfunction—first intranasal then subcutaneous administration

Medtap - interview validation questionnaire studies

HRA - quantitative debriefing study for Female partners of men with premature ejaculation, Validation of a New Distress Measure for FSD,

Boehringer-Ingelheim - double blind and open label studies of a prosexual agent for hypoactive female sexual desire disorder

Biosante - studies of testosterone gel administration for post menopausal women with HSDD

J&J - a single-blind, multi-center, in home use study to evaluate sexual enhancement effects of a product in females.

UBC - Content validity study of an electronic FSEP-R and FSDS-DAO and usability of study PRO measures in premenopausal women with FSAD, HSDD or Mixed FSAD/HSDD

National registry trial for women with HSDD

Endoceutics - two studies of DHEA for vaginal atrophy and dryness in post menopausal women

Palatin - study of SQ Bremelanotide for HSDD and FSAD

Trimel - a double-blind, placebo controlled study for women with acquired female orgasmic disorder.

S1 Biopharma - a phase 1-B non-blinded study of safety, tolerability and efficacy of Lorexys in premenopausal women with HSDD

HRA - qualitative and cognitive interview study for men experiencing PE

Publications

A) Books

1) Pariser SR, Levine SB, McDowell M (eds.), Clinical Sexuality, Marcel Dekker, New York, 1985
2) Sex Is Not Simple, Ohio Psychological Publishing Company, 1988; Reissued in paperback as: Solving Common Sexual Problems: Toward a Problem Free Sexual Life, Jason Aronson, Livingston, NJ. 1997
3) Sexual Life: A Clinician's Guide. Plenum Publishing Corporation. New York, 1992
4) Sexuality in Midlife. Plenum Publishing Corporation. New York, 1998
5) Editor. Clinical Sexuality. Psychiatric Clinics of North America, March, 1995.
6) Editor, (Candace Risen and Stanley Althof, associate editors) Handbook of Clinical Sexuality for Mental Health Professionals. Routledge, New York, 2003
   (a) 2006 SSTAR Book Award: Exceptional Merit
7) Demystifying Love: Plain Talk For The Mental Health Professional. Routledge, New York, 2006
8) Senior editor, (Candace B. Risen and Stanley E. Althof, Associate editors), Handbook of Clinical Sexuality for Mental Health Professionals. 2nd edition Routledge, New York, 2010. See review by Pega Ren, JSex&Marital Therapy
9) Barriers to Loving: A Clinician's Perspective. Routledge, New York, 2014.
10) Senior editor Candace B. Risen and Stanley E. Althof, Associate editors), Handbook of Clinical Sexuality for Mental Health Professionals. 3rd edition Routledge, New York, 2016

B) Research and Invited Papers

(When his name is not listed in a citation, Dr. Levine is either the solo or the senior author)

1) Sampliner R. Parotid enlargement in Pima Indians. Annals of Internal Medicine 1970; 73:571-73
2) Confrontation and residency activism: A technique for assisting residency change: World Journal of Psychosynthesis 1974; 6: 23-26
3) Activism and confrontation: A technique to spur reform. Resident and Intern Consultant 173; 2
4) Medicine and Sexuality. Case Western Reserve Medical Alumni Bulletin 1974:37:9-11.

5) Some thoughts on the pathogenesis of premature ejaculation. J. Sex & Marital Therapy 1975; 1:326-334

6) Marital Sexual Dysfunction: Introductory Concepts. Annals of Internal Medicine 1976;84:448-453

7) Marital Sexual Dysfunction: Ejaculation Disturbances 1976; 84:575-579

8) Yost MA: Frequency of female sexual dysfunction in a gynecology clinic: An epidemiological approach. Archives of Sexual Behavior 1976;5:229-238

9) Engel IM, Resnick PJ, Levine SB: Use of programmed patients and videotape in teaching medical students to take a sexual history. Journal of Medical Education 1976;51:425-427

10) Marital Sexual Dysfunction: Erectile dysfunction. Annals of Internal Medicine 1976;85:342-350

11) Articles in Medical Aspects of Human Sexuality

    (a) Treating the single impotent male. 1976; 10:123, 137

    (b) Do men enjoy being caressed during foreplay as much as women do? 1977; 11:9

    (c) Do men like women to be sexually assertive? 1977;11:44

    (d) Absence of sexual desire in women: Do some women never experience sexual desire? Is this possibility genetically determined? 1977; 11:31

    (e) Barriers to the attainment of ejaculatory control. 1979; 13:32-56.

    (f) Commentary on sexual revenge.1979;13:19-21

    (g) Prosthesis for psychogenic impotence? 1979;13:7

    (h) Habits that infuriate mates. 1980;14:8-19

    (i) Greenberger-Englander, Levine SB. Is an enema an erotic equivalent?1981; 15:116

    (j) Ford AB, Levine SB. Sexual Behavior and the Chronically Ill Patients. 1982; 16:138-150

    (k) Preoccupation with wife's sexual behavior in previous marriage 1982; 16:172

    (l) Co-existing organic and psychological impotence. 1985;19:187-8

    (m) Althof SE, Turner LA, Kursh ED, Bodner D, Resnick MI, Risen CB. Benefits and Problems with Intracavernosal injections for the treatment of impotence. 1989;23(4):38-40

12) Male Sexual Problems. Resident and Staff Physician 1981:2:90-5

13) Female Sexual Problems. Resident and Staff Physician 1981:3:79-92

14) How can I determine whether a recent depression in a 40 year old married man is due to organic loss of erectile function or whether the depression is the source of the

dysfunction? Sexual Medicine Today 1977;1:13

15) Corradi RB, Resnick PJ Levine SB, Gold F. For chronic psychologic impotence: sex therapy or psychotherapy? I & II Roche Reports; 1977

16) Marital Sexual Dysfunction: Female dysfunctions 1977; 86:588-597

17) Current problems in the diagnosis and treatment of psychogenic impotence. Journal of Sex & Marital Therapy 1977; 3:177-186

18) Resnick PJ, Engel IM. Sexuality curriculum for gynecology residents. Journal of Medical Education 1978; 53:510-15

19) Agle DP. Effectiveness of sex therapy for chronic secondary psychological impotence Journal of Sex & Marital Therapy 1978; 4:235-258

20) DePalma RG, Levine SB, Feldman S. Preservation of erectile function after aortoiliac reconstruction. Archives of Surgery 1978; 113-958-962

21) Conceptual suggestions for outcome research in sex therapy Journal of Sex & Marital Therapy 1981; 6:102-108

22) Lothstein LM. Transsexualism or the gender dysphoria syndrome. Journal of Sex & Marital Therapy 1982; 7:85-113

23) Lothstein LM, Levine SB. Expressive psychotherapy with gender dysphoria patients Archives General Psychiatry 1981; 38:924-929

24) Stern RG Sexual function in cystic fibrosis. Chest 1982; 81:422-8

25) Shumaker R. Increasingly Ruth: Towards understanding sex reassignment surgery Archives of Sexual Behavior 1983; 12:247-61

26) Psychiatric diagnosis of patients requesting sex reassignment surgery. Journal of Sex & Marital Therapy 1980; 6:164-173

27) Problem solving in sexual medicine I. British Journal of Sexual Medicine 1982; 9:21-28

28) A modern perspective on nymphomania. Journal of Sex & Marital Therapy 1982; 8:316-324

29) Nymphomania. Female Patient 1982;7:47-54

30) Commentary on Beverly Mead's article: When your patient fears impotence. Patient Care 1982; 16:135-9

31) Relation of sexual problems to sexual enlightenment. Physician and Patient 1983 2:62

32) Clinical overview of impotence. Physician and Patient 1983; 8:52-55.

33) An analytical approach to problem-solving in sexual medicine: a clinical introduction to the psychological sexual dysfunctions. II. British Journal of Sexual Medicine

34) Coffman CB, Levine SB, Althof SE, Stern RG Sexual Adaptation among single young adults with cystic fibrosis. Chest 1984; 86:412-418

35) Althof SE, Coffman CB, Levine SB. The effects of coronary bypass in female sexual, psychological, and vocational adaptation. Journal of Sex & Marital Therapy 1984; 10:176-184

36) Letter to the editor: Follow-up on Increasingly Ruth. Archives of Sexual Behavior 1984; 13:287-9

37) Essay on the nature of sexual desire Journal of Sex & Marital Therapy 1984; 10:83-96

38) Introduction to the sexual consequences of hemophilia. Scandanavian Journal of Haemology 1984; 33:(supplement 40).75-

39) Agle DP, Heine P. Hemophila and Acquired Immune Deficiency Syndrome: Intimacy and Sexual Behavior. National Hemophilia Foundation; July, 1985

40) Turner LA, Althof SE, Levine SB, Bodner DR, Kursh ED, Resnick MI. External vacuum devices in the treatment of erectile dysfunction: a one-year study of sexual and psychosocial impact. Journal of Sex & Marital Therapy

41) Schein M, Zyzanski SJ, Levine SB, Medalie JH, Dickman RL, Alemagno SA. The frequency of sexual problems among family practice patients. Family Practice Research Journal 1988; 7:122-134

42) More on the nature of sexual desire. Journal of Sex & Marital Therapy 1987; 13:35-44

43) Waltz G, Risen CB, Levine SB. Antiandrogen treatment of male sex offenders. Health Matrix 1987; V.51-55.

44) Lets talk about sex. National Hemophilia Foundation January, 1988

45) Sexuality, Intimacy, and Hemophilia: questions and answers . National Hemophilia Foundation January, 1988

46) Prevalence of sexual problems. Journal Clinical Practice in Sexuality 1988;4:14-16.

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49) Sexual passion in mid-life. Journal of Clinical Practice in Sexuality 1991 6(8):13-19

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51) Althof SE, Turner LA, Risen CB, Bodner DR, Kursh ED, Resnick MI. Side effects of self-administration of intracavernosal injection of papaverine and phentolamine for treatment of impotence. Journal of Urology 1989; 141:54-7

52) Turner LA, Froman SL, Althof SE, Levine SB, Tobias TR, Kursh ED, Bodner DR. Intracavernous injection in the management of diabetic impotence. Journal of Sexual Education and Therapy 16(2):126-36, 1989

53) Is it time for sexual mental health centers? Journal of Sex & Marital Therapy 1989;

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