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14 *Attorneys for Defendant*

15 **IN THE UNITED STATES DISTRICT COURT**
16 **FOR THE DISTRICT OF ARIZONA**

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

22 Plaintiffs,

23 vs.

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

27 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

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

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

19 **Plaintiff D.H.**: According to the Complaint, D.H. had “significant psychological
 20 distress at an early age, including severe anxiety and suicidal ideation” and was placed “in
 21 a psychiatric treatment facility on several occasions.” (Doc. 1, ¶6) As a young child, D.H.
 22 “began exhibiting signs of significant psychological distress including depression,
 23 prolonged crying episodes, anxiety, and insomnia.” (*Id.*, ¶69) At the age of 11, D.H. had
 24 “other stressors D.H. was trying to navigate” (beyond any stress related to gender
 25 identity), which caused him to start losing his hair. D.H. was hospitalized, including in
 26 intensive psychiatric care, four times beginning at age 11 for depression and suicidal
 27
 28

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

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

12 **Plaintiff John Doe:** In his early years, “John’s biological parents were unable to
 13 care for him and provide a stable home environment.” (Doc. 4-1, ¶5) John’s guardian is
 14 his grandmother. (Doc. 1, ¶89) John has been diagnosed with PTSD: “chronic post-
 15 traumatic stress disorder stemming from early-life attachment trauma.” (Doc. 4-2, ¶11).
 16 The term “early-life attachment trauma” means John suffered abuse or neglect at a young
 17 age. Laidlaw Decl. at ¶16. John has been depressed, suffered from anxiety, engaged in
 18 self-harm through cutting and burning,³ distanced from friends and family, lost interest in
 19 activities, and lost significant weight in a short period of time because of limited food
 20 intake. John also contemplated suicide. (Doc. 4, ¶5) According to John’s clinical therapist,
 21 Mischa Cohen-Peck, John continues to suffer from PTSD. She notes he is currently
 22
 23

24 ¹ D.H. was in intensive in-patient psychiatric care for severe anxiety and suicidal ideation
 25 beginning in 2014. There is no indication gender dysphoria was being evaluated,
 26 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.

27 ² The Declaration of Tamar Reed does not specify the nature of the “prior trauma.”

28 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

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.

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

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

24 Gender dysphoria is the only psychiatric condition to be treated by surgery. Levine
25 Decl. at ¶¶21-22. But quality studies showing that chest reconstruction surgery is safe,
26 effective, and optimal for treating minors with gender dysphoria do not exist; also, there is
27

28 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

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.

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.

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

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

16 In light of these facts, the cases Plaintiffs cite provide little support for a
 17 preliminary injunction. *Bowen v. City of New York*, 476 U.S. 467, 484 (1986) was a
 18 lawsuit brought by New York and eight disabled individuals who alleged the Social
 19 Security Administration was denying benefits based upon an unwritten policy that was
 20 contrary to published regulations. *Id.* at 473–74. The injunction at issue was not a
 21 preliminary injunction (the court’s decision followed a seven-day trial) but rather the court
 22 entered an order requiring the agency to “reopen the decisions denying or terminating
 23 benefits, and to redetermine eligibility.” *Id.* at 476. Nor were the *Bowen* plaintiffs seeking
 24 a mandatory injunction. As the court noted, the plaintiffs “neither sought nor were
 25 awarded benefits in the District Court, but rather challenged the Secretary’s failure to
 26 follow the applicable regulations.” *Id.* at 483. And finally, it should be noted the district
 27 court’s finding of irreparable harm was not challenged on appeal. *Id.* at 484. Further,
 28

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

14 Plaintiffs' remaining cases are also not dispositive. In *Chalk v. U.S. Dist. Court*
15 *Cent. Dist. of Cal.*, 840 F.2d 701 (9th Cir. 1988), a teacher diagnosed with AIDS brought
16 a claim under the Rehabilitation Act. The 9th Circuit found irreparable harm because the
17 Rehabilitation Act allows the recovery of emotional distress damages (*Id.* at 710) and
18 because, given the lethality of AIDS at the time, Chalk did not have time to wait for trial:
19 "Presently Chalk is fully qualified and able to return to work; but his ability to do so will
20 surely be affected in time. A delay, even if only a few months, pending trial represents
21 precious, productive time irretrievably lost to him." *Id.* Neither factor is present in this
22 case. And finally, Plaintiffs' reliance on *Whitaker v. Kenosha*, 858 F.3d 1034 (7th Cir.
23 2017) is misplaced for the simple reason that in *Whitaker*, the requested remedy was not
24 an expensive, irreversible surgery of questionable value for two minors who have not
25 established the ability to provide informed consent, but simply the ability to use a school
26 restroom of the transgender student's choosing. *Id.* at 1042.

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

11 **c. Likelihood of success on the merits**

12 *1. Plaintiffs fail to demonstrate the challenged rule violates EPSDT*

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

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

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

7 Although EPSDT coverage is broad, it is not unlimited. The 9th Circuit has stated,
 8 "[u]nder § 1396d(r)(5), states must cover every type of health care or service necessary
 9 for EPSDT corrective or ameliorative purposes that is allowable under § 1396d(a)", but
 10 the court immediately noted, "[t]his is subject to certain limits; for example, a state need
 11 not pay for experimental medical procedures." *Katie A., ex rel. Ludin v. Los Angeles Cty.*,
 12 481 F.3d 1150, 1154, n.10 (9th Cir. 2007). Medicaid does not require states to cover every
 13 service, especially services that have yet to be demonstrated to be safe and effective.
 14 States may limit the amount, duration, and scope of the services they cover. 42 U.S.C. §
 15 1396d(a). States are required to limit utilization of services. 42 U.S.C. § 1396a(a)(30)(A)
 16 (state plans must "provide such methods and procedures relating to the utilization of, and
 17 the payment for, care and services available under the plan ... as may be necessary to
 18 safeguard against unnecessary utilization of such care and services"); *Rush v. Parham*,
 19 625 F.2d 1150, 1156 (5th Cir. 1980) ("Georgia's definition of medically necessary
 20 services can reasonably exclude experimental treatment" when confronted with plaintiff's
 21 complaint that Georgia refused to pay for "transsexual surgery" prescribed by doctor);
 22 *Miller v. Whitburn*, 10 F.3d 1315, 1321 (7th Cir. 1993). As noted above and in the
 23 attached declarations, there is reason to question the "broad consensus" Plaintiffs allege as
 24 to its safety and efficacy. (Doc. 3, at 8) "Medicaid was not designed to fund risky,
 25 unproven procedures, but to provide the largest number of necessary medical services to
 26 the greatest number of needy people." *Ellis v. Patterson*, 859 F.2d 52, 55 (8th Cir. 1988).
 27 "It may be that, pursuant to a generally applicable funding restriction or utilization control
 28

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

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

9
10 *2. Plaintiffs fail to demonstrate violation of comparability requirement*

11 42 U.S.C. § 1396a(a)(10)(B)(i) provides “the medical assistance made available to
12 any individual described in subparagraph (A)--(i) shall not be less in amount, duration, or
13 scope than the medical assistance made available to any other such individual.” The
14 exclusion does not violate this requirement. First, the exclusion applies to all transgender
15 persons alike. Second, the rule requires comparable services for individuals with
16 comparable needs. “[N]eed is the only basis upon which distinctions between recipients
17 can be made without violating the comparability requirement.” *V.L. v. Wagner*, 669 F.
18 Supp. 2d 1106, 1117 (N.D.Cal. 2009). As noted in the declarations of Drs. Laidlaw and
19 Levine, the needs for relief from gender dysphoria are unique – they are not the same as
20 the needs of a person who seeks reconstruction after a mastectomy. This is particularly
21 true as to children. Nor does AHCCCS “arbitrarily deny or reduce the amount, duration,
22 or scope of a required service . . . to an otherwise eligible beneficiary solely because of the
23 diagnosis, type of illness, or condition.” 42 C.F.R. § 440.230(c). Plaintiffs argue
24 AHCCCS is denying “comparable services for individuals with comparable needs,” but
25 this begs the question whether reconstruction following a mastectomy is based on the
26 same needs as chest reconstruction to treat a child’s gender dysphoria.

27 *3. Plaintiffs fail to demonstrate a violation of §1557 of the ACA*
28

1 The exclusion does not violate the Affordable Care Act (“ACA”), which prohibits
 2 discrimination “on the basis of sex.” 42 U.S.C. §18116(a) (incorporating 20 U.S.C.
 3 §1681(a)). The federal rules implementing §1557 were amended effective Aug. 18, 2020
 4 with the intent that “each State may balance for itself the various sensitive considerations
 5 relating to medical judgment and gender identity, within the limits of applicable Federal
 6 statutes (which are to be read according to their plain meaning).” *Fed. Reg.*, Vol. 85, No.
 7 119 at 37162 (June 24, 2020). Further, “[t]he Department does not and need not take a
 8 definitive view on any of the medical questions raised in these comments about treatments
 9 for gender dysphoria. The question is whether Title IX and Section 1557 require
 10 healthcare professionals, as a matter of nondiscrimination, to perform such procedures or
 11 provide such treatments. The answer is they do not.” *Id.* at 37188 (emphasis in original).
 12 Also, a “medical provider may rightly judge a hysterectomy due to the presence of
 13 malignant tumors to be different in kind from the removal of properly functioning and
 14 healthy reproductive tissue for psychological reasons, even if the instruments used are
 15 identical.” *Id.* at 37187.¹⁰ The new rule supports the ability of a state to exclude chest
 16 reconstruction for gender dysphoria while covering it to treat a mastectomy.

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

25
 26 ¹⁰ The new rules were challenged, and the E.D.N.Y issued a preliminary injunction against
 27 the Department’s repeal of its prior rules (*Walker v. Azar*, 2020 WL 4749859, at *10
 28 (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

1 The Equal Protection Clause (U.S. Const. Amend. XIV, §1) states, “[n]o State
 2 shall . . . deny to any person within its jurisdiction the equal protection of the laws.” This
 3 provision “does not forbid classifications. It simply keeps governmental decisionmakers
 4 from treating differently persons who are in all relevant respects alike.” *Nordlinger v.*
 5 *Hahn*, 505 U.S. 1, 10 (1992). A “classification neither involving fundamental rights nor
 6 proceeding along suspect lines is accorded a strong presumption of validity”; such a
 7 provision is subject to rational basis review. *Heller v. Doe*, 509 U.S. 312, 319-21 (1993);
 8 *McGowan v. State of Md.*, 366 U.S. 420, 425-26 (1961) (“State legislatures are presumed
 9 to have acted within their constitutional power despite the fact that, in practice, their laws
 10 result in some inequality. A statutory discrimination will not be set aside if any state of
 11 facts reasonably may be conceived to justify it.”). Multiple courts have applied rational
 12 basis to classifications based on transgender status. *Druley v. Patton*, 601 F.App’x 632,
 13 635 (10th Cir. 2015); *Murillo v. Parkinson*, 2015 WL 3791450, *12 (C.D. Cal. 2015);
 14 *Kaeo–Tomaselli v. Butts*, 2013 WL 399184, *5 (D. Haw. 2013); *Jamison v. Davue*, 2012
 15 WL 996383, *4 (E.D.Cal. 2012); *Brainburg v. Coalinga State Hosp.*, 2012 WL 3911910,
 16 *8 (E.D. Cal. 2012); *Stevens v. Williams*, 2008 WL 916991, *13 (D. Or. 2008); *Johnston*
 17 *v. Univ. of Pittsburgh*, 97 F. Supp. 3d 657, 668 (W.D. Pa. 2015).

18 Plaintiffs have not cited any U.S. Supreme Court case that changes the rational
 19 basis standard for claims brought by transgender individuals. While Plaintiffs cite
 20 *Bostock*, that case involved statutory interpretation of Title VII – it did not (i) involve an
 21 equal protection claim, (ii) hold transgender persons constitute a suspect or quasi-suspect
 22 class for equal protection claims, or (iii) create a new protected class for transgender
 23 persons. *See Bollfrass v. City of Phoenix*, 2020 WL 4284370, at *1 (D. Ariz. 2020)
 24 (declining to reconsider equal protection claim after *Bostock* which “involved a matter of
 25 statutory interpretation”). *Bostock* does not support heightened review here. In addition,
 26 Plaintiffs’ cases from other jurisdictions (i) are not precedent for this Court, (ii) are
 27 inapposite, (iii) did not mandate coverage of gender reassignment surgery for children,
 28

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

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

18 **d. Balance of equities**

19 Based on the record, Plaintiffs have failed to establish that chest reconstruction
 20 surgery is safe, effective, and urgent for them. Balanced against this is the well-
 21 established caution courts exercise in granting mandatory injunctive relief, particularly
 22 relief that involves an irreversible surgery for children. In addition, AHCCCS has a
 23 significant interest in not providing expensive services that have not been shown to be
 24

25 ¹¹ Plaintiffs again rely on the denial of a motion to dismiss in *Toomey*. That order not only
 26 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.

27 ¹² Rational basis review applies, *supra*. But even if intermediate scrutiny applies, Plaintiffs
 28 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).

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

5 **III. CONCLUSION**

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

8 RESPECTFULLY SUBMITTED this 28th day of September, 2020.

9
10 **BURNSBARTON PLC**

11
12 By /s/ Kathryn Hackett King

13 David T. Barton
14 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

1 2004. I also completed a fellowship in endocrinology, diabetes and metabolism at Los
2 Angeles County/University of Southern California Medical Center in 2006.

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

9
10 4. The information provided regarding my professional background are
11 detailed in my curriculum vitae. A true and correct copy of my curriculum vitae is
12 attached as Exhibit A.

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

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

23
24 7. If called to testify in this matter, I would testify truthfully and based on my
25 expert opinion. The opinions and conclusions I express herein are based on a reasonable
26 degree of scientific certainty.

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

5
6 9. My opinions contained in this report are based on: (1) my clinical
7 experience as an endocrinologist; (2) my clinical experience evaluating individuals who
8 have or have had gender incongruence and/or gender dysphoria; (3) my knowledge of
9 research and studies regarding the treatment of gender dysphoria, including for minors;
10 and (4) my review of the various declarations submitted by Plaintiffs D.H. and John Doe
11 in the present lawsuit, *D.H. and John Doe v. Snyder*, Case No. 4:20-cv-00335-SHR
12 (pending in the U.S. District Court for the District of Arizona).

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

19
20 11. In my professional opinion, treatment interventions on behalf of children
21 diagnosed with gender dysphoria must be held to the same scientific standards as other
22 medical treatments. These interventions must be optimal, efficacious, and safe. Any
23 treatment which alters biological development in children should be used with extreme
24 caution.

25 12. Based on the materials I have reviewed and in my professional opinion,
26 there is an insufficient clinical basis to conclude that either D.H. or John Doe will suffer
27 imminent, irreparable harm if they do not receive bilateral mastectomy with chest wall
28

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

4
5 13. A high percentage of children diagnosed with gender dysphoria have
6 depression, anxiety, or other mental health disorders separate and apart from gender
7 dysphoria. *See infra* ¶23. According to the declarations I reviewed, both D.H. and John
8 Doe have a significant and lengthy history of psychiatric issues separate and apart from
9 gender dysphoria.

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

20 15. According to the declaration of Janice Hennessy-Waller, D.H. was in
21 intensive in-patient psychiatric care for severe anxiety and suicidal ideation beginning in
22 2014. There is no indication gender dysphoria was being evaluated, discussed, or
23 addressed at this time. It was not until two years later (in 2016) that D.H. identified as
24 transgender to another person (D.H.’s mom).

25 16. According to the declaration of Susan Doe, John Doe’s biological parents
26 were unable to care for John Doe and provide John Doe with a stable home environment.
27 According to the declaration of Mischa Cohen Peck, John Doe was diagnosed with post-
28

1 traumatic stress disorder (“PTSD”) stemming from early-life attachment trauma.

2 Although not defined in the declarations, the term “early-life attachment trauma” indicates
3 that John Doe likely suffered abuse or neglect at a young age.

4
5 17. According to John Doe’s declaration, John Doe has been depressed, suffered
6 from anxiety, engaged in self-harm through cutting and burning, distanced from friends
7 and family, lost interest in activities, and lost a significant amount of weight in a very
8 short period of time because of limited food intake. John Doe also contemplated suicide.

9 18. According to the declaration of Mischa Cohen Peck, John Doe has not been
10 successfully treated for the trauma underlying John Doe’s PTSD. In addition, John Doe
11 describes “being detached” from John Doe’s own body.¹

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

20 ¹ Although I did not review or have access to John Doe’s medical records, I note there is
21 one psychiatric disorder, dissociative identity disorder, which the American Psychiatric
22 Association describes as follows: “People with dissociative identity disorder may feel that
23 they have suddenly become observers of their own speech and actions, or their bodies may
24 feel different (e.g., like a small child, like the opposite gender, huge and muscular).”
25 Further, (1) “Dissociative identity disorder is associated with overwhelming experiences,
26 traumatic events and/or abuse that occurred in childhood”; (2) “People who have
27 experienced physical and sexual abuse in childhood are at increased risk of dissociative
28 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](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-Dysphoria/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

1 300 and 1000 mg/week of any AAS) and high use (more than 1000 mg/week of any AAS)
2 have demonstrated that 23% of subjects using these doses of steroids met the DSM-III-R
3 criteria for a major mood syndrome (mania, hypomania, and major depression) and that
4 3.4%–12% developed psychotic symptoms.” Hall, Hall & Chapman, “Psychiatric
5 Complications of Anabolic Steroid Abuse,” *Psychosomatics* 46:4 (July-August 2005).
6 Thus, hormone treatments can exacerbate any underlying psychiatric problems of a child,
7 including D.H. and John Doe.

8
9 21. According to several of the declarations, D.H. and John Doe originally felt
10 better after receiving the hormones, but then subsequently felt worse. In my professional
11 opinion, it is likely D.H. and John Doe originally felt better because of the side effect of
12 euphoria elicited by high doses of testosterone, as noted above. It is also likely D.H. and
13 John Doe may have later started feeling worse because either (1) the high dose of
14 testosterone ultimately exacerbated their mental health issues, or (2) their underlying
15 psychiatric issues, separate from the gender dysphoria, were never actually resolved (or a
16 combination of the two).

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

24 23. A key study from Finland indicated that 68% of children with gender
25 dysphoria had already been to psychiatric care for reasons other than gender identity
26 issues. Kaltiala-Heino, Sumia, Työläjäarvi, & Lindberg, “Two years of gender identity
27 service for minors: overrepresentation of natal girls with severe problems in adolescent
28

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

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

3
4 26. Depression, if not properly treated before surgery, may result in an increase
5 in morbidity and mortality post-surgery: “Several studies reported increased rate of
6 postoperative infections in patients suffering from depression.” With respect to
7 depression treatment for patients before major surgery, where it is “[n]on-alleviated, it
8 may predict increased morbidity and mortality after the operation. It may be associated
9 with greater postoperative pain, higher incidence of postoperative infections, progression
10 of malignant tumors, poor health-related quality of life as well as other complications.”
11 Ghoneim & O’Hara, “Depression and Postoperative complications: an overview,” *BMC*
12 *Surg.* 2016; 16:5 (Feb. 2, 2016).

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

23 28. A mastectomy surgery is irreversible. If a patient later regrets the decision
24 and decides to resume living as their natal sex (female), she will not be able to ever
25 breastfeed a child, because her functional organs have been removed and can never be
26 replaced. Possible complications of this procedure (bilateral mastectomy with chest wall
27
28

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

3
4 29. I have significant concerns about the ability of two minors with histories of
5 significant underlying psychiatric issues, separate and apart from gender dysphoria, to
6 provide informed consent to undergo an irreversible sex reassignment surgery.

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

15 31. In the Endocrine Society’s guidelines, the quality of evidence for the
16 treatment of adolescents is rated “very low-quality evidence” and “low quality evidence.”
17 (p. 3871-72).

18 32. “The Endocrine Society has published revised clinical guidelines in 2017 on
19 the treatment of gender dysphoric persons including adolescents (Hembree et al. 2017).
20 The quality of evidence for [puberty blocking agents] is noted to be low. In fact, all of the
21 evidence in the guidelines with regard to treating children/adolescents by [gender
22 affirmative therapy] is low to very low because of the absence of proper studies.”
23

24 ² The Endocrine Society guidelines (p.3380) note “in some forms of [gender
25 dysphoria]/gender incongruence, psychological interventions may be useful and
26 sufficient,” before ever needing to proceed with medicalized treatments. Further, the
27 guidelines (p. 3894) note “some transgender male adolescents” may “consider
28 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.

1 Laidlaw, Cretella & Donovan, “The Right to Best Care for Children Does Not Include the
2 Right to Medical Transition,” *The American Journal of Bioethics*, 19:2, 75-77 (Feb. 20,
3 2019). Unlike other recommendations for adolescent transition, the Endocrine Society’s
4 guidelines do not include any grading of the quality of evidence specifically for
5 adolescent mastectomy.

6
7 33. The declarations of Dr. Aron Janssen and Dr. Loren Schechter cite to the
8 World Professional Association for Transgender Health’s (“WPATH”) “Standards of Care
9 for the Health of Transsexual, Transgender, and Gender Non-Conforming People.”
10 According to their declarations, Dr. Janssen is a member of WPATH, Dr. Schechter is on
11 the Board of Directors of WPATH, and both have been contributing authors to WPATH’s
12 “Standards of Care.” WPATH’s “Standards of Care” were prepared within their advocacy
13 organization and are purported to be a “professional consensus about the psychiatric,
14 psychological, medical, and surgical management of gender dysphoria.” However, the
15 “professional consensus” exists only within the confines of its organization. Furthermore,
16 their “Standards of Care,” unlike the Endocrine Society’s guidelines, do not have a
17 grading system for either the strength of their recommendations or the quality of the
18 evidence presented.

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

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

5
6 35. There is also evidence that questions the long-term effectiveness of gender
7 reassignment surgery. A Swedish study in 2011 (Dhejne, et al., “Long-Term Follow-
8 Up of Transsexual Persons Undergoing Sex Reassignment Surgery: Cohort
9 Study in Sweden,” *PLoS One*, vol. 6, issue 2 (Feb. 22, 2011)) examined data over
10 a 30-year period. The Dhejne team made extensive use of numerous Swedish registries
11 and examined data from 324 patients in Sweden over 30 years who underwent sex
12 reassignment surgery. They used population controls matched by birth year, birth sex, and
13 reassigned sex. When followed out beyond ten years, the sex-reassigned group had
14 nineteen times the rate of completed suicides and nearly three times the rate of all-
15 cause mortality and inpatient psychiatric care compared to the general population.

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

23 37. Hayes Directories, Inc. is an internationally recognized research and
24 consulting firm dedicated to promoting better health outcomes by assessing quality
25 evidence. In 2014, the Hayes Directory conducted a comprehensive review and evaluation
26 of the scientific literature regarding the treatment of gender dysphoria in adults and
27 children. It concluded the practice of using hormones and sex reassignment surgery to
28

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

6
7 38. Recently, a major correction was issued by the American Journal of
8 Psychiatry. The editors of an October 2019 study, titled “Reduction in mental health
9 treatment utilization among transgender individuals after gender-affirming surgeries: a
10 total population study” (Bränström study) retracted their original primary conclusion. The
11 Bränström team reanalyzed the data and the results demonstrated “no advantage to
12 [gender reassignment] surgery” for their three endpoints in the subject population
13 (prescriptions for antidepressants and anti-anxiety medications, healthcare visits for mood
14 or anxiety disorders, and post-suicide attempt hospitalizations). Specifically, the
15 correction stated, “the results demonstrated no advantage of surgery in relation to
16 subsequent mood or anxiety disorder-related health care visits or prescriptions or
17 hospitalizations following suicide attempts in that comparison. Given that the study used
18 neither a prospective cohort design nor a randomized controlled trial design, the
19 conclusion that ‘the longitudinal association between gender-affirming surgery and lower
20 use of mental health treatment lends support to the decision to provide gender-affirming
21 surgeries to transgender individuals who seek them’ is too strong.” “Correction to
22 Bränström and Pachankis,” *Am J Psychiatry*, 177:8 (Aug. 2020).

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

25 40. Based on the studies and research cited above, in my professional opinion
26 there is insufficient quality of evidence at this time demonstrating the benefit of bilateral
27 mastectomy with chest wall recontouring surgery on individuals diagnosed with gender
28

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

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

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

13
14 
15 Michael K. Laidlaw, M.D.
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EXHIBIT A

Michael K. Laidlaw, M.D.

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Rocklin, CA 95677
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docdrlaidlaw@gmail.com

EMPLOYMENT

2006-Present	Michael K Laidlaw, MD Inc. Private Practice – Endocrinology, Diabetes, and Metabolism. Rocklin, CA
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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	<u>Publication</u> – 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	<u>Publication</u> – VanMol A, Laidlaw MK, Grossman M, McHugh P.. "Gender-affirmation surgery conclusion lacks evidence (letter)". Am J Psychiatry 2020; 177:765–766.
2020	<u>Publication</u> – 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	<u>Expert Witness Affidavit</u> – 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	<u>Publication</u> – 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	<u>Brief of Amicus Curiae</u> – 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	<u>Publication</u> – 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	<u>Publication</u> – Laidlaw MK. "The Gender Identity Phantom". gdworkinggroup.org, 24 Oct 2018. http://gdworkinggroup.org/2018/10/24/the-gender-identity-phantom/
2018	<u>Publication</u> – 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	<u>Abstract</u> – Poster presentation Jun 2013. Endocrine Society Annual Meeting. A 12 Step Program for the Treatment of Type 2 Diabetes and Obesity.
2011	<u>Abstract</u> – 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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12 david@burnsbarton.com
13 kate@burnsbarton.com

14 *Attorneys for Defendant*

15
16 **IN THE UNITED STATES DISTRICT COURT**
17 **FOR THE DISTRICT OF ARIZONA**
18

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

24 Plaintiffs,

25 vs.

26 Jami Snyder, Director of the Arizona Health
27 Care Cost Containment System, in her
28 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)

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

2 1. I am over the age of eighteen and submit this expert declaration based on
3 my personal knowledge and experience.
4

5 2. I am a Clinical Professor of Psychiatry at Case Western Reserve University
6 School of Medicine, and maintain an active private clinical practice. I received my M.D.
7 from Case Western Reserve University in 1967, and completed a psychiatric residency at
8 the University Hospitals of Cleveland in 1973. I became an Assistant Professor of
9 Psychiatry at Case Western in 1973, and became a Full Professor in 1985.
10

11 3. Since July 1973 my specialties have included psychological problems and
12 conditions relating to sexuality and sexual relations, therapies for sexual problems, and
13 the relationship between love and intimate relationships and wider mental health. I am a
14 Distinguished Life Fellow of the American Psychiatric Association.
15

16 4. I have served as a book and manuscript reviewer for numerous professional
17 publications. I have been the Senior Editor of the first (2003), second (2010) and third
18 (2016) editions of the *Handbook of Clinical Sexuality for Mental Health Professionals*. In
19 addition to five other solo-authored books, I have authored *Psychotherapeutic*
20 *Approaches to Sexual Problems*, published in 2020; it has a chapter titled "The Gender
21 Revolution."
22

23 5. I first encountered a patient suffering what we would now call gender
24 dysphoria in July 1973. In 1974, I founded the Case Western Reserve University Gender
25 Identity Clinic, and have served as Co-Director of that clinic since that time. Across the
26 years, our Clinic treated hundreds of patients who were experiencing a transgender
27
28

1 identity. An occasional child was seen during this era. I was the primary psychiatric
2 caregiver for several dozen of our patients and supervisor of the work of other therapists.
3
4 I was an early member of the Harry Benjamin International Gender Dysphoria
5 Association (later known as WPATH) and served as the Chairman of the Standards of
6 Care Committee that developed the 5th version of its Standards of Care. In 1993 the
7 Gender Identity Clinic was renamed, moved to a new location, and became independent
8 of Case Western Reserve University. I continue to serve as Co-Director.
9

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

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

17 8. If called to testify in this matter, I would testify truthfully and based on
18 my expert opinion. The opinions and conclusions I express herein are based on a
19 reasonable degree of medical and scientific certainty.
20

21 9. In this declaration, I offer, explain, and identify my opinions and the
22 bases for my opinions in this matter. Each of the opinions set forth herein is based on
23 my professional expertise and experience as described above and I hold each of the
24 opinions set forth herein to a reasonable degree of certainty within my field. The facts
25 upon which I rely are the type of facts reasonably relied upon by experts within my
26 field.
27
28

1 10. I am being compensated at an hourly rate of \$375 per hour plus expenses
2 for my time spent preparing this declaration. My rate to prepare for and provide
3 testimony is \$500 per hour plus expenses. My compensation does not depend on the
4 outcome of this litigation, the opinions I express, or the testimony I may provide.
5

6 **I. BACKGROUND ON THE FIELD**

7 **A. The biological base-line of sex**

8 11. The sex of a human individual at its core structures the individual's
9 biological reproductive capabilities—to produce ova and bear children as a mother, or
10 to produce semen and beget children as a father. Sex determination occurs at the
11 instant of conception, depending on whether a sperm's X or Y chromosome fertilizes
12 the egg. Medical technology can be used to determine a fetus's sex before birth. It is
13 thus not literally correct to assert that doctors "assign" the sex of a child at birth;
14 anyone can identify the sex of an infant by genital inspection. What the general public
15 may not understand, however, is that every nucleated cell of an individual's body is
16 chromosomally identifiably male or female—XY or XX.
17

18 12. The self-perceived gender of a child, in contrast, arises in part from how
19 others label the infant: "I love you, son (daughter)." This designation occurs thousands
20 of times in the first two years of life when a child begins to show awareness of the two
21 possibilities. As acceptance of the designated gender corresponding to the child's sex is
22 the outcome in >99% of children everywhere, anomalous gender identity formation
23 begs for understanding. Is it biologically shaped? Is it biologically determined? Is it the
24 product of how the child was privately regarded and treated? Does it stem from
25
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1 trauma-based rejection of maleness or femaleness, and if so flowing from what
2 trauma? Is it a symptom of another, as of yet unrevealed emotional disturbance? Does
3 it derive from a child's (mis)understanding of future possibilities of maleness or
4 femaleness? The answers to these relevant questions are not scientifically known.
5

6 13. Under the influence of hormones secreted by the testes or ovaries,
7 numerous additional sex-specific differences between male and female bodies
8 continuously develop post-natally, culminating in the dramatic maturation of the
9 primary and secondary sex characteristics with puberty. These include differences in
10 hormone levels, height, weight, bone mass, shape and development, internal organ size,
11 musculature, body fat levels and distribution, and hair patterns, as well as physiological
12 differences such as menstruation. These are genetically programmed biological
13 consequences of sex that also serve to influence the consolidation of gender identity
14 during and after puberty.
15

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

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 disabilities⁴ 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

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.

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

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

5 20. Discussions about appropriate responses by mental health professionals
6 (“MHPs”) to actual or sub-threshold gender dysphoria are complicated by the fact that
7 various speakers and advocates (or a single speaker at different times) view
8 transgenderism through at least three very different paradigms, often without being
9 aware of, or at least without acknowledging, the distinctions.
10

11 21. Gender dysphoria is **conceptualized and described by some**
12 **professionals and laypersons as though it were a serious, physical medical illness**
13 **that causes suffering**, comparable, for example, to prostate cancer, a disease that is
14 curable before it spreads. Within this paradigm, whatever is causing distress associated
15 with gender dysphoria—whether secondary sex characteristics such as facial hair, nose
16 and jaw shape, presence or absence of breasts, or the primary anatomical sex organs of
17 testes, ovaries, penis, or vagina—should be removed to alleviate the illness. The
18 promise of these interventions is the cure of the gender dysphoria.
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23 ⁷ L. Edwards-Leeper et al. (2017), *Psychological Profile of the First Sample of Transgender Youth Presenting for*
24 *Medical Intervention in a U.S. Pediatric Gender Center*, PSYCHOLOGY OF SEXUAL ORIENTATION AND
25 GENDER DIVERSITY, 4(3) 374 at 375 (“Psychological Profile”); R. Kaltiala-Heino et al. (2015), *Two Years of*
26 *Gender Identity Service for Minors: Overrepresentation of Natal Girls with Severe Problems in Adolescent*
27 *Development*, CHILD & ADOLESCENT PSYCHIATRY & MENTAL HEALTH 9(9) 1 at 5. (In 2015 Finland gender
28 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.”).

1 22. It should be noted, however, that gender dysphoria is a psychiatric
2 rather than a medical diagnosis. Since its inception in DSM-III, it has always and
3 only been specified in the psychiatric DSM manuals. Notably, gender dysphoria is
4 the only psychiatric condition to be treated by surgery, even though no endocrine or
5 surgical intervention package corrects any identified biological abnormality. (Levine,
6 *Reflections*, at 240.)
7

8
9 23. Gender dysphoria is alternatively **conceptualized in developmental**
10 **terms**, as an adaptation to a psychological problem that was first manifested as a failure
11 to establish a comfortable conventional sense of self in early childhood. This paradigm
12 starts from the premise that all human lives are influenced by past processes and events.
13 Trans lives are not exceptions to this axiom. (Levine, *Reflections*, at 238.) MHPs who
14 think of gender dysphoria through this paradigm may work both to identify and address
15 causes of the basic problem of the deeply uncomfortable self, and also to ameliorate
16 suffering when the underlying problem cannot be solved. They work with the patient
17 and (ideally) family to inquire what forces may have led to the trans person repudiating
18 the gender associated with his sex. The developmental paradigm is mindful of
19 temperamental, parental bonding, psychological, sexual, and physical trauma
20 influences, and the fact that young children work out their psychological issues through
21 fantasy and play.
22
23
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25 24. In addition, the developmental paradigm recognizes that, with the
26 important exception of genetic sex, essentially all aspects of an individual's
27 multifaceted identity evolve—often markedly—across the individual's lifetime.
28

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

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

27
28 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).

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

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

12 **E. Four competing models of therapy**

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

21 **(1) The "watchful waiting" therapy model**

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

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

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

21 33. As I note above, many gender-nonconforming children and adolescents
22 in recent years derive from minority and vulnerable groups who have reasons to feel
23 isolated and have an uncomfortable sense of self. A trans identity may be a hopeful
24 attempt to redefine the self in a manner that increases their comfort and decreases their
25

27
28 ⁹ S. Levine (2017), *Transitioning Back to Maleness*, ARCH. OF SEXUAL BEHAVIOR at 7, DOI: 10.1007/s10508-017-1136-9 (“*Transitioning*”).

1 anxiety. The clinician who uses traditional methods of psychotherapy may not focus on
2 their gender identity, but instead work to help them to address the actual sources of
3 their discomfort. Success in this effort may remove or reduce the desire for a redefined
4 identity. This often involves a focus on disruptions in their attachment to parents in
5 vulnerable children, for instance, those in the foster care system.
6

7 34. Because “watchful waiting” can include treatment of accompanying
8 psychological co-morbidities, and the psychotherapist who hopes to relieve gender
9 dysphoria may focus on potentially causal sources of psychological distress rather than
10 on the gender dysphoria itself, there is no sharp line between “watchful waiting” and
11 the psychotherapy model in the case of prepubescent children.
12

13 35. To my knowledge, there is no evidence beyond anecdotal reports that
14 psychotherapy can enable a return to male identification for genetically male boys,
15 adolescents, and men, or return to female identification for genetically female girls,
16 adolescents and women. On the other hand, anecdotal evidence of such outcomes does
17 exist; I and other clinicians have witnessed reinvestment in the patient’s biological sex
18 in some individual patients who are undergoing psychotherapy. The Internet contains
19 many such reports, and I have published a paper recently on a patient who sought my
20 therapeutic assistance to reclaim his male gender identity after 30 years living as a
21 woman and is in fact living as a man today. (Levine, *Transitioning*, at 1.) I have seen
22 children desist even before puberty in response to thoughtful parental interactions and
23 a few meetings of the child with a therapist.
24
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27 **(3) The affirmation therapy model (model #4)**
28

1 36. While it is widely agreed that the therapist should not directly challenge a
2 claimed transgender identity in a child, some advocates and practitioners go much
3 further, and promote and recommend that any expression of transgender identity should
4 be immediately accepted as decisive, and thoroughly affirmed by means of consistent
5 use of clothing, toys, pronouns, etc. associated with transgender identity. These
6 advocates treat any question about the causes of the child's transgender identification
7 as inappropriate, and assume that observed psychological co-morbidities in the children
8 or their families are unrelated or will get better with transition, and need not be
9 addressed by the MHP who is providing supportive guidance concerning the child's
10 gender identity.
11

12 37. Some advocates, indeed, assert that unquestioning affirmation of any
13 claim of transgender identity in children is essential, and that the child will otherwise
14 face a high risk of suicide or severe psychological damage. I address claims about
15 suicide and health outcomes in Section IV below.
16

17 38. Some advocates also assert that this "affirmation therapy" model is
18 accepted and agreed with by the overwhelming majority of mental health professionals.
19 However, one respected academic in the field has recently written that, on the contrary,
20 "almost all clinics and professional associations in the world" do not use "gender
21 affirmation" for prepubescent children and instead "delay any transitions after the onset
22 of puberty."¹⁰ The National Health Service in the United Kingdom announced on
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28 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.

1 September 22, 2020 that they were undertaking a thorough review of how children and
2 adolescents with atypical gender identities are being treated in England. This indicates
3 a great deal of doubt about the wisdom of rapid affirmative care.
4

5 39. Even the Standards of Care published by WPATH, an organization which
6 in general leans strongly towards affirmation in the case of adults, does not specify
7 affirmation of transgender identity as the indicated therapeutic response for young
8 children, but rather calls for a careful process of discernment and decision specific to
9 each child by the family in consultation with the mental health professional.
10

11 40. Further, the DSM-5 added—for both children and adolescents—a
12 requirement that a sense of incongruence between biological and felt gender must last
13 at least six months as a precondition for a diagnosis of gender dysphoria, precisely
14 because of the risk of “transitory” symptoms and “hasty” diagnosis that might lead to
15 “inappropriate” treatments.¹¹
16

17 41. I do not know what proportion of practitioners are using which model.
18 However, in my opinion, in the case of young children, prompt and thorough
19 affirmation of a transgender identity disregards the principles of child development
20 and family dynamics, and is not supported by science. Rather, the MHP must focus
21 attention on the child’s underlying internal and familial issues. Ongoing relationships
22 between the MHP and the parents and the MHP and the child are vital to help the
23 parents, child, other family members, and the MHP to understand over time the issues
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27 ¹¹ K. Zucker (2015), *The DSM-5 Diagnostic Criteria for Gender Dysphoria*, in C. Trombetta et al. (eds.),
28 MANAGEMENT OF GENDER DYSPHORIA: A MULTIDISCIPLINARY APPROACH, DOI 10.1007/978-88-470-
5696-1_4 (Springer-Verlag Italia 2015).

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

2 42. Likewise, since the child's sense of gender develops in interaction with
3 his parents and their own gender roles and relationships, the responsible MHP will
4 almost certainly need to delve into family and marital dynamics.
5

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

7 43. In almost any discussion of the diagnosis and care of patients suffering
8 gender dysphoria or exhibiting transgender characteristics, the World Professional
9 Association for Transgender Health (WPATH) and the Standards of Care that that
10 organization publishes will be mentioned. Accordingly, I provide some context
11 concerning that private organization.
12

13 44. I was a member of the Harry Benjamin International Gender
14 Dysphoria Association from 1974 until 2001. From 1997 through 1998, I served as
15 the Chairman of the eight-person International Standards of Care Committee that
16 issued the fifth version of the Standards of Care. I resigned my membership in 2002
17 due to my regretful conclusion that the organization and its recommendations had
18 become dominated by politics and ideology, rather than by scientific process, as it
19 was years earlier. In approximately 2007, the Henry Benjamin International Gender
20 Dysphoria Association changed its name to the World Professional Association for
21 Transgender Health.
22
23

24 45. WPATH is a voluntary membership organization. Since at least 2002,
25 attendance at its biennial meetings has been open to trans individuals who are not
26 licensed professionals. While this ensures taking patients' needs into consideration, it
27
28

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

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

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

17 48. In recent years, WPATH has fully adopted some mix of the medical and
18 civil rights paradigms. It has downgraded the role of counseling or psychotherapy as a
19 requirement for these life-changing processes. WPATH no longer considers
20 preoperative psychotherapy to be a requirement. It is important to WPATH that the
21 person has gender dysphoria; the pathway to the development of this state is not.
22 (Levine, *Reflections*, at 240.) The trans person is assumed to have thoughtfully
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1 considered his or her options before seeking hormones, for instance. Many have
2 wondered whether adolescents are developmentally capable of a prudent consideration
3 of the consequences of their decisions.
4

5 49. Most psychiatrists and psychologists who treat patients suffering
6 sufficiently severe distress from gender dysphoria to seek inpatient psychiatric care are
7 not members of WPATH. Many psychiatrists and psychologists who treat some patients
8 suffering gender dysphoria on an outpatient basis are not members of WPATH.
9

10 WPATH represents a self-selected subset of the mental health professions,
11 endocrinologists, and surgeons along with its many non-professional trans members; it
12 does not capture the clinical experiences of others. WPATH claims to speak for the
13 medical profession; however, it does not welcome skepticism and therefore, deviates
14 from the philosophical core of medical science.
15

16 50. For example, in 2010 the WPATH Board of Directors issued a
17 statement advocating that incongruence between sex and felt gender identity should
18 cease to be identified in the DSM as a pathology.¹² This position was debated but not
19 adopted by the (much larger) American Psychiatric Association, which maintained
20 the definitions and diagnoses of gender dysphoria as a pathology in the DSM-5
21 manual issued in 2013.
22

23 51. In my experience most current members of WPATH have little ongoing
24 experience with the mentally ill, and many trans care facilities are staffed by MHPs
25
26

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

1 who are not deeply experienced with recognizing and treating frequently associated
2 psychiatric co-morbidities. Because the 7th version of the WPATH SOC deleted the
3 requirement for therapy, trans care facilities that consider these Standards sufficient are
4 permitting patients to be counseled to transition by means of social presentation,
5 hormones, and surgery by individuals with masters rather than medical or PhD clinical
6 psychology degrees. As a result of the downgrading of the role of the psychiatric
7 assessment of patients, new “gender affirming” clinics have arisen in many urban
8 settings that quickly (sometimes within an hour’s time) recommend transition.
9
10 Concerned parents who came wanting to know what is going on in their children are
11 overwhelmed, and feel disoriented, fearful for the health and safety of their children,
12 and dependent on the professional.
13

14
15 **II. PATIENTS DIFFER WIDELY AND MUST BE CONSIDERED**
16 **INDIVIDUALLY.**

17 52. In my opinion, it is not possible to make a single, categorical statement
18 about the proper treatment of children presenting with gender dysphoria or other
19 gender-related issues. Indeed, a MHP cannot responsibly opine on the proper treatment
20 of a particular child presenting with gender dysphoria unless and until he or she has had
21 more than one working session with that child, and has taken a thorough developmental
22 history of the child’s gender-related issues (or has reviewed such a history prepared by
23 another MHP). This is so for multiple reasons.
24

25 53. There is no single pathway of development and outcomes governing
26 transgender identity, nor one that predominates over the large majority of cases.
27
28 Instead, as individuals grow up and age, depending on their differing psychological,

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

2 54. As to causes in children, details about the onset of gender dysphoria may
3 be found in an understanding of family relationship dynamics. In particular, the
4 relationship between the parents and each of the parents and the child, and each of the
5 siblings and the child should be well known by the MHP.
6

7 55. Further, a disturbingly large proportion of children who seek professional
8 care in connection with gender issues have a wider history of psychiatric co-
9 morbidities. (*See supra* n. 7.) A 2017 study from the Boston Children's Hospital
10 Gender Management Service program reported that: "Consistent with the data reported
11 from other sites, this investigation documented that 43.3% of patients presenting for
12 services had significant psychiatric history, with 37.1% having been prescribed
13 psychotropic medications, 20.6% with a history of self-injurious behavior, 9.3% with a
14 prior psychiatric hospitalization, and 9.3% with a history of suicide attempts." (L.
15 Edwards-Leeper, *Psychological Profile*, at 375.) It seems likely that an even higher
16 proportion will have had prior undiagnosed psychiatric conditions.
17
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19

20 56. As to outcomes, as I explain below, for pre-pubertal children, desistance
21 from transgender identification in favor of a gender corresponding to the child's sex,
22 during or within a few years of puberty, is a likely outcome absent intervention. (*Infra*
23 Section III.)
24

25 57. Because the causes, characteristics, social and relational context, and
26 likely future course of gender dysphoria vary widely from individual to individual, it is
27 essential that the MHP spend significant time with an individual patient over multiple
28

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

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

7 58. A distinctive and critical characteristic of juvenile gender dysphoria is
 8 that multiple studies from separate groups and at different times have reported that in
 9 the large majority of patients, absent a substantial intervention such as social transition
 10 and/or hormone therapy, gender dysphoria does *not* persist through puberty. A recent
 11 article reviewed all existing follow-up studies that the author could identify of children
 12 diagnosed with gender dysphoria (11 studies), and reported that “every follow-up study
 13 of GD children, without exception, found the same thing: By puberty, the majority of
 14 GD children ceased to want to transition.” (Cantor at 1.) Another author reviewed the
 15 existing studies and reported that in “prepubertal boys with gender discordance . . . the
 16 cross gender wishes usually fade over time and do not persist into adulthood, with only
 17 2.2% to 11.9% continuing to experience gender discordance.”¹³ A third summarized the
 18 existing data as showing that “Symptoms of GID at prepubertal ages decrease or
 19 disappear in a considerable percentage of children (estimates range from 80-95%).”¹⁴
 20
 21
 22

23 59. It is not yet known how to distinguish those children who will desist
 24 from that small minority whose trans identity will persist. (Levine, *Ethical*
 25

26 ¹³ S. Adelson & American Academy of Child & Adolescent Psychiatry (2012), *Practice Parameter on Gay, Lesbian,*
 27 *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”).

28 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

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.)

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

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."

1 63. Accordingly, I agree with a noted researcher in the field who has
2 written that social transition in children must be considered “a form of psychosocial
3 treatment.”²¹
4

5 64. So far as I am aware, no study yet reveals whether the life-course mental
6 and physical health outcomes for this relatively new class of “persisters” are more
7 similar to those of the general non-transgender population, or to the notably worse
8 outcomes exhibited by the transgender population generally.
9

10 65. However, I agree with Zucker who has written, “...we cannot rule out
11 the possibility that early successful treatment of childhood GID [Gender Identity
12 Disorder] will diminish the role of a continuation of GID into adulthood. If so,
13 successful treatment would also reduce the need for the long and difficult process of
14 sex reassignment which includes hormonal and surgical procedures with substantial
15 medical risks and complications.”²² By the same token, a therapeutic methodology for
16 children that *increases* the likelihood that the child will continue to identify as the
17 opposite gender into adulthood will *increase* the need for the long and potentially
18 problematic processes of hormonal and genital and cosmetic surgical procedures.
19
20

21 66. Not surprisingly, given these facts, encouraging social transition in
22 children remains controversial. Supporters of such transition acknowledge that
23 “Controversies among providers in the mental health and medical fields are
24 abundant . . . These include differing assumptions regarding . . . the age at which
25

26
27 ²¹ K. Zucker (2019), *Debate: Different Strokes for Different Folks*, CHILD & ADOLESCENT MENTAL HEALTH,
at 1, DOI: 10.1111/camh.12330 (“Debate”).

28 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.).

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

4
 5 67. In sum, therapy for young children that encourages transition cannot be
 6 considered to be neutral, but instead is an experimental procedure that has a high
 7 likelihood of changing the life path of the child, with highly unpredictable effects on
 8 mental and physical health, suicidality, and life expectancy. Claims that a civil right is
 9 at stake do not change the fact that what is proposed is a social and medical
 10 experiment. (Levine, *Reflections*, at 241.) Ethically, then, it should be undertaken only
 11 subject to standards, protocols, and reviews appropriate to such experimentation.
 12

13 **IV. THE AVAILABLE DATA DOES NOT SUPPORT THE**
 14 **CONTENTION THAT “AFFIRMATION” OF TRANSGENDER**
 15 **IDENTITY REDUCES SUICIDE OR RESULTS IN BETTER**
 16 **PHYSICAL OR MENTAL HEALTH OUTCOMES GENERALLY.**

17 68. I am aware that organizations including The Academy of Pediatrics and
 18 Parents, Families and Friends of Lesbians and Gays (PFLAG)) have published
 19 statements that suggest that all children who express a desire for a transgender identity
 20 should be promptly supported in that claimed identity. This position appears to rest on
 21 the belief—which is widely promulgated by certain advocacy organizations—that
 22 science has already established that prompt “affirmance” is best for all patients,
 23 including all children, who present indicia of transgender identity. As I discuss later
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28 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*”).

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

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

5 70. In evaluating claims of scientific or medical knowledge, it is
6 important to understand that it is axiomatic in science that no knowledge is
7 absolute, and to recognize the widely accepted hierarchy of reliability when it
8 comes to “knowledge” about medical or psychiatric phenomena and treatments.
9 Unfortunately, in this field opinion is too often confused with knowledge, rather
10 than clearly locating what exactly is scientifically known. In order of increasing
11 confidence, such “knowledge” may be based upon data comprising:
12
13
14

15 a. Expert opinion—it is perhaps surprising to educated laypersons that
16 expert opinion standing alone is the lowest form of knowledge, the least likely
17 to be proven correct in the future, and therefore does not garner as much respect
18 from professionals as what follows.
19

20 b. A single case or series of cases (what could be called anecdotal
21 evidence); (Levine, *Reflections*, at 239.)
22

23 c. A series of cases with a control group;

24 d. A cohort study;

25 e. A randomized double-blind clinical trial;

26 f. A review of multiple trials;
27
28

1
2 g. A meta-analysis of multiple trials that maximizes the number of
3 patients treated despite their methodological differences to detect trends
4 from larger data sets.
5

6 71. Prominent voices in the field have emphasized the severe lack of
7 scientific knowledge in this field. The American Academy of Child and Adolescent
8 Psychiatry has recognized that “Different clinical approaches have been advocated for
9 childhood gender discordance. . . . There have been no randomized controlled trials of
10 any treatment. . . . [T]he proposed benefits of treatment to eliminate gender
11 discordance...must be carefully weighed against... possible deleterious effects.”
12 (Adelson et al., *Practice Parameter*, at 968–69.) Similarly, the American Psychological
13 Association has stated, “...because no approach to working with [transgender and
14 gender nonconforming] children has been adequately, empirically validated, consensus
15 does not exist regarding best practice with pre-pubertal children.”²⁴
16
17

18 72. Critically, “there are no randomized control trials with regard to
19 treatment of children with gender dysphoria.” (Zucker, *Myth of Persistence*, at 8.)
20 On numerous critical questions relating to cause, developmental path if untreated,
21 and the effect of alternative treatments, the knowledge base remains primarily at
22 the level of the practitioner’s exposure to individual cases, or multiple individual
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24
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28 ²⁴ American Psychological Association, *Guidelines for Psychological Practice with Transgender & Gender Nonconforming People* (2015), AM. PSYCHOLOGIST 70(9) 832 at 842.

1 cases. As a result, claims to certainty are not justifiable. (Levine, *Reflections*, at
2 239.)

3
4 73. Large gaps exist in the medical community's knowledge regarding
5 the long-term effects of SRS and other gender identity disorder treatments in relation
6 to their positive or negative correlation to suicidal ideation, attempts, and completion.
7 What is known, however, is not encouraging.

8
9 74. With respect to suicide, individuals with gender dysphoria are well
10 known to commit suicide or otherwise suffer increased mortality before and after not
11 only social transition, but also before and after SRS. (Levine, *Reflections*, at 242.)
12 For example, in the United States, the death rates of trans veterans are comparable to
13 those with schizophrenia and bipolar diagnoses—20 years earlier than expected.
14 These crude death rates include significantly elevated suicide rates. (Levine, *Ethical*
15 *Concerns*, at 10.) Similarly, researchers in Sweden and Denmark have reported on
16 almost all individuals who underwent sex-reassignment surgery over a 30-year
17 period.²⁵ The Swedish follow-up study found a suicide rate in the post-SRS
18 population 19.1 times greater than that of the controls; both studies demonstrated
19 elevated mortality rates from medical and psychiatric conditions. (Levine, *Ethical*
20 *Concerns*, at 10.)

21
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23 75. Advocates of immediate and unquestioning affirmation of social
24
25
26

27 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).
28

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

7
 8 76. I will also note that any discussion of suicide when considering younger
 9 children involves very long-range and very uncertain prediction. Suicide in pre-
 10 pubescent children is rare and the existing studies of gender identity issues in pre-
 11 pubescent children do not report significant incidents of suicide. The estimated suicide
 12 rate of trans adolescents is the same as teenagers who are in treatment for serious
 13 mental illness. What trans teenagers do demonstrate is more suicidal ideation and
 14 attempts (however serious) than other teenagers.²⁷

15
 16 77. In sum, claims that affirmation will reduce the risk of suicide for children
 17 are not based on science. Such claims overlook the lack of even short-term supporting
 18 data as well as the lack of studies of long-term outcomes resulting from the affirmation
 19 or lack of affirmation of transgender identity in children. It also overlooks the other
 20 tools that the profession does have for addressing depression and suicidal thoughts in a
 21
 22
 23
 24

25 ²⁶ A recent article, J. Turban et al. (2020), *Puberty Suppression for Transgender Youth and Risk of Suicidal Ideation*,
 26 PEDIATRICS 145(2), DOI: 10.1542/peds.2019-1725 (“*Puberty Suppression*”), has been described in press reports as
 27 demonstrating that administration of puberty suppressing hormones to transgender adolescents reduces suicide or
 28 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.

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

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

8
9
10 79. Meanwhile, no studies show that affirmation of pre-pubescent children
11 leads to more positive outcomes (mental, physical, social, or romantic) by, e.g., age 25
12 or older than does “watchful waiting” or ordinary therapy. Because children’s
13 affirmation, social transition, and the use of puberty blockers for transgender children
14 are a recent phenomenon, it could hardly be otherwise.

15
16 80. Thus, transition of any sort must be justified, if at all, as a life-enhancing
17 measure, not a lifesaving measure. (Levine, *Reflections*, at 242.) In my opinion, this is
18 an important fact that patients, parents, and even many MHPs fail to understand.

19
20 81. The long-term benefits of SRS on the mental health of individuals
21 diagnosed with gender dysphoria are widely assumed to be positive, but in fact are
22 scientifically and clinically unknown. Several studies (Turban et al, *JAMA Psychiatry*,
23 77(1) (2020); Turban et al, *Puberty Suppression* (*supra* n.26); Bränström & Pachankis
24

25
26 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.

27 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.

28 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.

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

16
17
18
19
20 82. If trans male identified adolescents have their breasts removed, they will
21 have a male appearing chest and female genitalia. This surgery will initially make
22 them happy about their chest per se, but they still will experience gender dysphoria
23 because of the presence of the female genitalia. This anatomic source of incongruence
24 will continue to limit intimate dimensions of their life possibilities. Genital
25 reconstruction of male appearing genitalia is unable to produce the normal functions of
26 a penis. It is expensive, fraught with complications, and leaves a significant scarring of
27
28

1 a limb. Most trans males do not undergo this arduous procedure. This makes the
 2 incongruence a permanent feature. Bilateral mastectomies should not be construed as a
 3 curative intervention for gender dysphoria. It only eradicates the displeasure of having
 4 female breasts.
 5

6 **V. KNOWN, LIKELY, OR POSSIBLE DOWNSIDE RISKS ATTENDANT**
 7 **ON MOVING QUICKLY TO “AFFIRM” TRANSGENDER IDENTITY**
 8 **IN CHILDREN.**

9 83. The multiple studies from different nations that have documented the
 10 increased vulnerability of the adult transgender population to substance abuse, mood
 11 and anxiety disorders, suicidal ideation, and other health problems warn that assisting
 12 the child down the road to becoming a transgender adult is a very serious decision, and
 13 stand as a reminder that a casual assumption that transition will improve the child’s life
 14 is not justified based on numerous scientific snapshots of cohorts of trans adults and
 15 teenagers.
 16

17 84. The possibility that steps along this pathway, while lessening the pain of
 18 gender dysphoria, could lead to additional sources of crippling emotional and
 19 psychological pain, are too often not considered by advocates of social transition and
 20 not considered at all by the trans child. (Levine, *Reflections*, at 243.)
 21

22 85. I detail below several classes of predictable, likely, or possible
 23 harms to the patient associated with transitioning to live as a transgender
 24 individual.
 25

26 **A. Physical risks associated with transition**

27 86. Sterilization. Obviously, SRS that removes testes, ovaries, or the uterus is
 28

1 inevitably sterilizing. While by no means all transgender adults elect SRS, many
 2 patients do ultimately feel compelled to take this serious step in their effort to live fully
 3 as the opposite sex. More immediately, practitioners recognize that the administration
 4 of cross-sex hormones, which is often viewed as a less “radical” measure, and is now
 5 increasingly done to minors, creates at least a risk of irreversible sterility.³¹ As a result,
 6 even when treating a child, the MHP, patient, and parents must consider loss of
 7 reproductive capacity—sterilization—to be one of the major risks of starting down the
 8 road. The risk that supporting social transition may put the child on a pathway that
 9 leads to intentional or unintentional permanent sterilization is particularly concerning
 10 given the disproportionate representation of minority and other vulnerable groups
 11 among children reporting a transgender or gender-nonconforming identity. (*See supra* ¶
 12 19.)

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

24 88. Other effects of hormone administration. While it is commonly said that the
 25 effects of puberty blockers are reversible after cessation, in fact controlled studies have
 26

27 ³¹ See C. Guss et al., *TGN Adolescent Care* at 4 (“a side effect [of cross-sex hormones] may be infertility”) and 5
 28 (“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”).

1 not been done of how completely this is true. However, it is well known that many effects
 2 of cross-sex hormones cannot be reversed should the patient later regret his transition.
 3 After puberty, the individual who wishes to live as the opposite sex will in most cases
 4 have to take cross-sex hormones for life.
 5

6 89. The long-term health risks of this major alteration of hormonal levels have
 7 not yet been quantified in terms of exact risk.³² However, a recent study found greatly
 8 elevated levels of strokes and other acute cardiovascular events among male-to-female
 9 transgender individuals taking estrogen. Those authors concluded, “it is critical to keep
 10 in mind that the risk for these cardiovascular events in this population must be weighed
 11 against the benefits of hormone treatment.”³³ Another group of authors similarly noted
 12 that administration of cross-sex hormones creates “an additional risk of thromboembolic
 13 events”—i.e., blood clots (Guss et al., *TGN Adolescent Care* at 5), which are associated
 14 with strokes, heart attack, and lung and liver failure. Clinicians must distinguish the
 15 apparent short-term safety of hormones from likely or possible long-term consequences,
 16 and help the patient or parents understand these implications as well. The young patient
 17 may feel, “I don’t care if I die young, just as long I get to live as a woman.” The mature
 18 adult may take a different view.
 19
 20
 21

22 90. Health risks inherent in complex surgery. Complications of surgery exist
 23 for each procedure,³⁴ and complications in surgery affecting the breasts and chest can
 24

25
 26 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”).

27 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.

28 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

1 have significant anatomical and functional complications for the patient's quality of life.

2 Genital surgeries carry even more significant short and long term complication risks.

3
4 91. Disease and mortality generally. The MHP, the patient, and in the case of a
5 child the parent, must also be aware of the wide sweep of strongly negative health outcomes
6 among transgender individuals, as I have detailed above.

7
8 **B. Social risks associated with transition**

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

16 93. Long term psychological and social impact of sterility. The life-long
17 negative emotional impact of infertility on both men and women has been well studied.
18 While this impact has not been studied specifically within the transgender population,
19 the opportunity to be a parent is likely a human, emotional need, and so should be
20 considered an important risk factor when considering gender transition for any patient.
21 However, it is particularly difficult for parents of a young child to seriously
22 contemplate that child's potential as a future parent and grandparent. This makes it all
23 the more critical that the MHP spend substantial and repeated time with parents to help
24 them see the implications of what they are considering.
25
26

27
28

14(12) 1621.).

1 94. Sexual-romantic risks associated with transition. After adolescence,
 2 transgender individuals can find the pool of individuals willing to develop a romantic and
 3 intimate relationship with them to be greatly diminished. (Levine, *Ethical Concerns*, at 5,
 4 13).³⁵

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

19 **C. Mental health costs or risks**

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

22 97. In addition, individuals often pin excessive hope in transition,
 23 believing that transition will solve what are in fact ordinary social stresses associated
 24 with maturation, or mental health co-morbidities. Thus, transition can result in
 25

26
 27
 28 ³⁵ S. Levine, *Barriers to Loving: A Clinician's Perspective*, at 40 (Routledge, New York 2013).

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

3
4 98. Whatever the reason, transgender individuals including transgender
5 youth certainly experience greatly increased rates of mental health problems. I have
6 detailed this above with respect to adults living under a transgender identity. Indeed,
7 Swedish researchers in a long- term study (up to 30 years since SRS, with a median
8 time since SRS of > 10 years) concluded that individuals who have SRS should have
9 postoperative lifelong psychiatric care. (Dhejne, *Long Term*, at 6-7.) With respect to
10 youths a cohort study found that transgender youth had an elevated risk of depression
11 (50.6% vs. 20.6%) and anxiety (26.7% vs. 10.0%); a higher risk of suicidal ideation
12 (31.1% vs. 11.1%), suicide attempts (17.2% vs. 6.1%), and self-harm without lethal
13 intent (16.7% vs. 4.4%) relative to the matched controls; and a significantly greater
14 proportion of transgender youth accessed inpatient mental health care (22.8% vs.
15 11.1%) and outpatient mental health care (45.6% vs. 16.1%) services.³⁶

16
17
18
19 **D. Regret following transition is not an infrequent phenomenon.**

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

23
24 100. The phenomenon of desistance or regret experienced *later* than
25 adolescence or young adulthood, or among older transgender individuals, has to my
26

27 ³⁶ S. Reisner et al. (2015), *Mental Health of Transgender Youth in Care at an Adolescent Urban Community Health*
28 *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.

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

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

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

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

24 104. Thus, one cannot assert with any degree of certainty that once a
25
26

27
28 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.

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

3
4 **VI. MEDICAL ETHICS & INFORMED CONSENT**

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

7 105. I have reviewed above the knowledge and experience that, in my view, a
8 mental health professional should have before undertaking the responsibility to counsel
9 or treat a child who is experiencing gender dysphoria or transgender identification. The
10 MHP who undertakes this type of responsibility must also be guided by the ethical
11 principles that apply to all health care professionals. One of the oldest and most
12 fundamental principles guiding medical and psychological care—part of the
13 Hippocratic Oath—is that the physician must “first, do no harm.” This states an ethical
14 responsibility that cannot be delegated to the patient. Physicians themselves must weigh
15 the risks of treatment against the harm of not treating. If the risks of treatment outweigh
16 the benefits, ethics prohibit the treatment.
17

18
19 106. A distinct ethical responsibility of physicians, when a significant risk
20 exists of adverse consequences to any procedure or therapy, is to ensure that the patient
21 understands and is legally able to consent to the treatment, and does consent. To
22 achieve informed consent, the MHP must do at least the following:
23

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

26 b. The MHP must reasonably inform himself concerning the state of
27 knowledge concerning relevant methodologies and outcomes;
28

1 c. The MHP must honestly inform the patient concerning not only the
2 benefits of treatment, but also the risks and downsides of treatment, and
3 alternative treatments;
4

5 d. The MHP must conclude that the patient (or the decision maker,
6 such as parent or healthcare power of attorney) has comprehended what he or
7 she has been told and possesses a cognitive capacity to make a decision based
8 on an adequate understanding of his or her unique life circumstances.
9

10 107. Perfunctory “consent” is inadequate to fulfill the professional’s ethical
11 obligation to obtain informed consent. At the very least, a patient (or parent)
12 considering the life-altering choice of transition should be helped or indeed required
13 by their clinicians to grapple with four relevant questions:
14

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

17 b. “What do you understand of the social, educational,
18 vocational, and psychological risks of this identity consolidation and
19 gender role transition?
20

21 c. “What do you understand about the common and rare, short- and
22 long-term medical and health risks of hormone and surgical interventions?
23

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

26 108. The answers of the patient will enable the professional to make a
27 judgment about how realistic he or she is being. For example, the biological boy who
28

1 envisions himself as a happy, attractive, socially accepted 21-year-old girl in future
2 college years has probably not been adequately informed of—or has mentally
3 blocked—hard data concerning the mental health and social wellbeing of the
4 transgender population in their 20s, and is failing to consider the material risk that he,
5 as a transgender individual, will not be perceived as attractive to either sex, and the
6 impact that this may have on his future well-being.
7

8 109. Most commonly, meaningful engagement with difficult and painful
9 questions such as those above requires a process that will consist of multiple
10 discussions in a psychotherapeutic or counseling context, not merely “disclosure” of
11 facts. In my experience, a too-rapid or too-eager attachment to some outcome is a red
12 warning flag that the patient is not able to tolerate knowledge of the risks and
13 alternative approaches.
14
15

16 110. In my experience, in the area of transgender therapy, rather than the
17 type of information and engagement that I have described, even mental health
18 professionals too often encourage or permit decisions based on a great deal of patient
19 and professional blind optimism about the future. (Levine, *Ethical Concerns*, at 3-4.)
20

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

23 111. The psychiatrist or psychologist treating a child must have in view not
24 merely (or not even primarily) making the child “happy” now, but making him or her
25 as healthy and happy as possible across the entire trajectory of life, to the extent that is
26 predictable. Certainly, avoiding suicide is one important aspect of a “life course”
27 analysis, and recognizes that “today” is not the only goal. But as I have reviewed
28

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

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

11 **C. Special concerns and ethical rules**

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

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

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

3
4 Executed this 28th day of September, 2020 at Beachwood, Ohio.

5
6 *Stephen B. Levine MD*

7 Stephen B. Levine, M.D.
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Declaration of Stephen B. Levine Sept 26

Final Audit Report

2020-09-28

Created:	2020-09-28
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EXHIBIT A

Stephen B. Levine, M.D.

Curriculum Vita

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. (excelling 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 erythematosus 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 ofbremelanotide 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 FSDD-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. *Scandinavian Journal of Haemology* 1984; 33:(supplement 40).75-
- 39) Agle DP, Heine P. Hemophilia 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.
- 47) Kursh E, Bodner D, Resnick MI, Althof SE, Turner L, Risen CB, Levine SB. Injection Therapy for Impotence. *Urologic Clinics of North America* 1988; 15(4):625-630
- 48) Bradley SJ, Blanchard R, Coates S, Green R, Levine S, Meyer-Bahlburg H, Pauly I, Zucker KJ. Interim report of the DSM-IV Subcommittee for Gender Identity Disorders. *Archives of Sexual Behavior* 1991;;20(4):333-43.
- 49) Sexual passion in mid-life. *Journal of Clinical Practice in Sexuality* 1991 6(8):13-19
- 50) Althof SE, Turner LA, Levine SB, Risen CB, Bodner DR, Resnick MI. Intracavernosal injections in the treatment of impotence: A prospective study of sexual, psychological, and marital functioning. *Journal of Sex & Marital Therapy* 1987; 13:155-167

- 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;
- 54) Althof SE, Turner LA, Levine SB, Risen CB, Bodner D, Kursh ED, Resnick MI. Sexual, psychological, and marital impact of self injection of papaverine and phentolamine: a long-term prospective study. *Journal of Sex & Marital Therapy*
- 55) Althof SE, Turner LA, Levine SB, Risen CB, Bodner D, Kursh ED, Resnick MI. Why do so many men drop out of intracavernosal treatment? *Journal of Sex & Marital Therapy*. 1989; 15:121-9
- 56) Turner LA, Althof SE, Levine SB, Risen CB, Bodner D, Kursh ED, Resnick MI. Self injection of papaverine and phentolamine in the treatment of psychogenic impotence. *Journal of Sex & Marital Therapy*. 1989; 15(3):163-78
- 57) Turner LA, Althof SE, Levine SB, Risen CB, Bodner D, Kursh ED, Resnick MI. Treating erectile dysfunction with external vacuum devices: impact upon sexual, psychological, and marital functioning. *Journal of Urology* 1990; 141(1):79-82
- 58) Risen CB, Althof SE. An essay on the diagnosis and nature of paraphilia *Journal of Sex & Marital Therapy* 1990; 16(2):89-102.
- 59) Althof SE, Turner LA, Levine SB, Risen CB, Bodner DB, Kursh ED, Resnick MI. Through the eyes of women: the sexual and psychological responses of women to their partners' treatment with self-injection or vacuum constriction therapy. *International Journal of Impotence Research (supplement 2)*1990; 346-7.
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- 61) Kursh E, Turner L, Bodner D, Althof S, Levine S. A prospective study on the use of the vacuum pump for the treatment of impotence. *International Journal of Impotence Research (supplement 2)*1990; 340-1.
- 62) Althof SE, Turner LA, Levine SB, Risen CB, Bodner DB, Kursh ED, Resnick MI. Long term use of intracavernous therapy in the treatment of erectile dysfunction in *Journal of Sex & Marital Therapy* 1991; 17(2):101-112
- 63) Althof SE, Turner LA, Levine SB, Risen CB, Bodner DB, Kursh ED, Resnick MI. Long term use of vacuum pump devices in the treatment of erectile dysfunction in *Journal of Sex & Marital Therapy* 1991;17(2):81-93
- 64) Turner LA, Althof SE, Levine SB, Bodner DB, Kursh ED, Resnick MI. A 12-month

- comparison of the effectiveness of two treatments for erectile dysfunction: self injection vs. external vacuum devices. *Urology* 1992;39(2):139-44
- 65) Althof SE, The pathogenesis of psychogenic impotence. *J. Sex Education and Therapy*. 1991; 17(4):251-66
 - 66) Mehta P, Bedell WH, Cumming W, Bussing R, Warner R, Levine SB. Letter to the editor. Reflections on hemophilia camp. *Clinical Pediatrics* 1991; 30(4):259-260
 - 67) Successful Sexuality. Belonging/Hemophilia. (Caremark Therapeutic Services), Autumn, 1991
 - 68) Psychological intimacy. *Journal of Sex & Marital Therapy* 1991; 17(4):259-68
 - 69) Male sexual problems and the general physician, *Georgia State Medical Journal* 1992; 81(5): 211-6
 - 70) Althof SE, Turner LA, Levine SB, Bodner DB, Kursh E, Resnick MI. Through the eyes of women: The sexual and psychological responses of women to their partner's treatment with self-injection or vacuum constriction devices. *Journal of Urology* 1992; 147(4):1024-7
 - 71) Curry SL, Levine SB, Jones PK, Kurit DM. Medical and Psychosocial predictors of sexual outcome among women with systemic lupus erythematosus. *Arthritis Care and Research* 1993; 6:23-30
 - 72) Althof SE, Levine SB. Clinical approach to sexuality of patients with spinal cord injury. *Urological Clinics of North America* 1993; 20(3):527-34
 - 73) Gender-disturbed males. *Journal of Sex & Marital Therapy* 19(2):131-141, 1993
 - 74) Curry SL, Levine SB, Jones PK, Kurit DM. The impact of systemic lupus erythematosus on women's sexual functioning. *Journal of Rheumatology* 1994; 21(12):2254-60
 - 75) Althof SE, Levine SB, Corty E, Risen CB, Stern EB, Kurit D. Clomipramine as a treatment for rapid ejaculation: a double-blind crossover trial of 15 couples. *Journal of Clinical Psychiatry* 1995;56(9):402-7
 - 76) Risen CB, Althof SE. Professionals who sexually offend: evaluation procedures and preliminary findings. *Journal of Sex & Marital Therapy* 1994; 20(4):288-302
 - 77) On Love, *Journal of Sex & Marital Therapy* 1995; 21(3):183-191
 - 78) What is clinical sexuality? *Psychiatric Clinics of North America* 1995; 18(1):1-6
 - 79) "Love" and the mental health professions: Towards an understanding of adult love. *Journal of Sex & Marital Therapy* 1996; 22(3)191-20
 - (a) Reprinted in *Issues in Human Sexuality: Current & Controversial Readings with Links to Relevant Web Sites*, 1998-9, Richard Blonna, Editor, Engelwood, Co. Morton Publishing Company, 1998
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- treatments. Medscape Mental Health 2(8):1997 on the Internet. September, 1997.
- 81) Discussion of Dr. Derek Polonsky's SSTAR presentation on Countertransference. Journal of Sex Education and Therapy 1998; 22(3):13-17
 - 82) Understanding the sexual consequences of the menopause. Women's Health in Primary Care, 1998
(a) Reprinted in the International Menopause Newsletter
 - 83) Fones CSL, Levine SB. Psychological aspects at the interface of diabetes and erectile dysfunction. Diabetes Reviews 1998; 6(1):1-8
 - 84) Guay AT, Levine SB, Montague DK. New treatments for erectile dysfunction. Patient Care March 15, 1998
 - 85) Extramarital Affairs. Journal of Sex & Marital Therapy 1998; 24(3):207-216
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(a) Reprinted by the Harry Benjamin International Gender Dysphoria Association, Minneapolis, Minnesota
 - 87) Althof SE, Corty E, Levine SB, Levine F, Burnett A, McVary K, Stecher V, Seftel. The EDITS: the development of questionnaires for evaluating satisfaction with treatments for erectile dysfunction. Urology 1999;53:793-799
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 - 93) Levine SB, Stagno S. Informed Consent for Case Reports: the ethical dilemma between right to privacy and pedagogical freedom. Journal of Psychotherapy: Practice and Research, 2001, 10 (3): 193-201.
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- 96) Understanding Male Heterosexuality and Its Disorders in *Psychiatric Times* XIX(2):13-14, February, 2002
- 97) Erectile Dysfunction: Why drug therapy isn't always enough. (2003) *Cleveland Clinic Journal of Medicine*, 70(3): 241-246.
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- 103) What is love anyway? *J Sex & Marital Therapy* 31(2):143-152,2005.
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- 116) Commentary on David Rowland's editorial, "Will Medical Solutions to Sexual Problems Make Sexological Care and Science Obsolete?" *Journal of Sex and Marital Therapy*, 33(5), 2007 in press
- 117) Real-Life Test Experience: Recommendations for Revisions to the Standards of Care of the World Professional Association for Transgender Health International Journal of Transgenderism, Volume 11 Issue 3, 186-193, 2009
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- 126) Hypoactive Sexual Desire Disorder in Men: Basic types, causes, and treatment. *Psychiatric Times* 27(6)4-34. 2010
- 127) Male Sexual Dysfunctions, an audio lecture, American Physician Institute 2013
- 128) Fashions in Genital Fashion: Where is the line for physicians? Commentary on David Veale and Joe Daniels' Cosmetic Clitoridectomy in a 33-year-old woman. *Archives of Sexual Behavior*, epub ahead of print Sept 24, 2011. *Arch Sex Behav* (2012) 41:735–736 DOI 10.1007/s10508-011-9849-7
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