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UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF ARIZONA

D.H., by and through his mother, Janice Hennessy-Waller; and John Doe, by 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.

No. 4:20-cv-335-SHR

REPLY BRIEF IN SUPPORT OF PLAINTIFFS D.H. AND JOHN DOE'S MOTION FOR PRELIMINARY INJUNCTION

ORAL ARGUMENT REQUESTED

I. INTRODUCTION

D.H.'s and John's treating providers are clear and consistent: delaying male chest reconstruction surgery any further will cause irreparable damage to their health and wellbeing, putting them at risk for serious negative mental health consequences. D.H. and John meet the eligibility requirements for male chest reconstruction surgery under the prevailing standards of care, and their providers have determined that it is medically necessary for them. Yet, AHCCCS's categorical exclusion singles out gender-confirmation surgeries for differential treatment. That exclusion violates the Medicaid Act and the Affordable Care Act (ACA), and serves no legitimate, much less important, state interest.

Defendant's opposition relies on the opinions of two doctors who have little, if any, experience treating transgender adolescents and whose views contradict the well-established standards of care for treating gender dysphoria in minors. Even Defendant significantly disagrees with their opinions; AHCCCS covers services, including hormone therapy, that Drs. Laidlaw and Levine believe are not safe and effective. *See, e.g.*, Michael Laidlaw, *The Pediatric Endocrine Society's Statement on Puberty Blockers Isn't Just Deceptive. It's Dangerous*, Public Discourse (2020), *available at*, https://www.thepublicdiscourse.com/2020/01/59422/ (last visited Oct. 25, 2020).

Although Defendant attempts to position Drs. Laidlaw and Levine as one side of a reasoned scientific debate, the opinions they express have no credible foundation or support. The views proffered by Drs. Laidlaw and Levine contradict the well-established standards of care developed by WPATH and endorsed by the major medical associations in the United States, including the American Medical Association, American Academy of Pediatrics, American Psychiatric Association, and Endocrine Society, among many others. For that reason, other federal courts have declined to rely on Dr. Levine's opinions. *Hecox v. Little*, No. 1:20-CV-00184, 2020 WL 4760138, at *29 n.33 (D. Idaho Aug. 17, 2020); *Edmo v. Idaho Dep't of Corr.*, 358 F. Supp. 3d 1103, 1125 (D. Idaho 2018); *Norsworthy v. Beard*, 87 F. Supp. 3d 1164, 1188 (N.D. Cal. 2015) (Giving "very little weight" to Dr. Levine's opinion, in part, because he fabricated an anecdote in his report).

Contrary to Defendant's suggestion, nothing in the declarations submitted by Drs. Laidlaw or Levine undermine the sufficiency of the evidence presented by Plaintiffs in support of this motion. In contrast to the substantial evidence and expert opinions submitted by D.H. and John, proffered by health care providers with extensive expertise treating transgender minors and grounded in the medical literature and standards that govern this field, Defendant has proffered doctors who lack relevant expertise and whose opinions fall well outside the views of any qualified medical experts on transgender minors. In similar cases, federal courts consistently grant preliminary injunctive relief to transgender litigants where defendants rely on the outdated and unscientific opinions of professionals like Drs. Laidlaw and Levine. *See, e.g.*, *Hecox*, 2020 WL 4760138, at *39; *Flack v. Wis. Dep't of Health Servs.*, 328 F. Supp. 3d 931, 934 (W.D. Wis. 2018); *Bd. of Educ. of the Highland Local Sch. Dist. v. U.S. Dep't of Educ.*, 208 F. Supp. 3d 850, 870 (S.D. Ohio 2016); *Norsworthy*, 87 F. Supp. 3d at 1195.

Defendant cannot manufacture a "debate" where none truly exists.[1] The research on "desistance," central to Defendant's argument, is of questionable utility even in children, but is irrelevant for adolescents. Reply Expert Declaration of Aron Janssen ("Janssen Reply Decl."), Doc. 25-1, ¶ 10; Reply Expert Declaration of Loren Schechter ("Schechter Reply Decl."), Doc. 25-2, ¶ 9. There is broad consensus, even among the key authors of the studies on "desistance," that after puberty starts, as it has for D.H. and John, it is not appropriate to withhold medical and surgical treatment for gender dysphoria. Janssen Reply Decl. ¶ 17. Defendant also repeatedly questions D.H.'s and John's ability to consent to male chest reconstruction surgery yet fails to address the reasoned professional opinions of their treating mental health providers to the contrary, disregarding their significant experience treating transgender young people generally, and D.H. and John, specifically. *See id.* ¶ 34;

[1] Although Defendant critiques Plaintiffs for refusing to disclose their health records at this early stage, those records were irrelevant to her experts, who generally dispute the standards of care and opined that D.H.'s and John's co-occurring conditions, which were detailed in the declarations submitted in support of the instant motion, are a sufficient basis for denying them medically necessary care. As Plaintiffs' experts explain, there is no valid medical basis for that opinion, which contradicts well-established standards of practice and care.

Declaration of Dr. Mischa Peck ("Peck Decl."), Doc. 4-2, ¶ 6; Declaration of Tamar Reed ("Reed Decl."), Doc. 5-2, ¶ 4.

For the reasons set forth in their opening brief and herein, Defendant is legally obligated to cover D.H.'s and John's male chest reconstruction surgery.

II. ARGUMENT

A. Preliminary Injunction Standard

Defendant suggests that a heightened "mandatory injunction" standard applies to Plaintiffs' motion. But Defendant is mistaken.[2] Plaintiffs seek a prohibitive injunction that would enjoin Defendant from enforcing a regulation that prohibits coverage for surgeries to treat gender dysphoria, including male chest reconstruction surgery. The injunction would require Defendant to review D.H.'s and John's authorization requests for male chest reconstruction surgery to treat gender dysphoria the same way AHCCCS does for any other treatment or service for beneficiaries under age 21. The fact that this injunction would result in AHCCCS covering medically necessary surgeries for D.H. and John does not make it a "mandatory injunction." *Hernandez v. Sessions*, 872 F.3d 976, 998 (9th Cir. 2017) (injunction to "prevent[] future constitutional violations" is "a classic form of prohibitory injunction") (citing *Ariz. Dream Act Coal. v. Brewer*, 757 F.3d 1053, 1060–61 (9th Cir. 2014)). For example, the Ninth Circuit did not apply a heightened injunction standard when it enjoined a Medicaid regulation thereby requiring the state pay for services that otherwise would have been denied. *M.R. Dreyfus*, 697 F.3d 706, 725 (9th Cir. 2012); *see also*, *Newton-Nations v. Rogers*, 316 F.Supp.2d 883 (D. Ariz. 2004) (applying prohibitory injunction standard to enjoin increase in co-pays, incidentally making administration of AHCCCS more costly).

And, even if a heightened injunction standard applies, Plaintiffs satisfy that standard. Mandatory injunctions "are permissible when 'extreme or very serious damage will result' that is not 'capable of compensation in damages,' and the merits of the case are not

[2] Defendant also incorrectly asserts that granting D.H. and John's motion would provide them with all the relief they seek. Def. Br. at 2. But, D.H. and John seek class certification and much broader injunctive relief. Thus, this motion is targeted to their urgent medical need for male chest reconstruction surgery and will not provide complete legal relief.

'doubtful.'" *Hernandez*, 872 F.3d at 999 (quoting *Marlyn Nutraceuticals v. Mucos Pharm.*, 571 F.3d 873, 878-79 (9th Cir. 2009)); *see* Def. Br. at 8. Here, the merits of Plaintiffs' case are far from "doubtful," and Plaintiffs have established that without access to medically necessary male chest reconstruction surgery they are at risk of "very serious" injury that is "not capable of compensation in damages." Whatever standard is applied, a preliminary injunction is warranted for the reasons set forth below and in Plaintiffs' motion, *see* Doc. 3.

B. Likelihood of Success on the Merits

1. EPSDT requires coverage of male chest reconstruction surgery.

Defendant claims that "AHCCCS does not discriminate against its transgender members or exclude gender dysphoria treatment . . . . [it] merely draws the line at gender reconstruction surgery." But the Early and Periodic Screening, Diagnostic and Treatment (EPSDT) provisions of the Medicaid Act prohibit Defendant from excluding coverage of medically necessary services for individuals under age 21. *Hern v. Beye*, 57 F.3d 906 (10th Cir. 1995), did not hold otherwise. *See* Def. Br. at 14. That case did not even involve an EPSDT claim. *Hern*, 57 F.3d at 910-11. Under EPDST, Defendant must cover any service included in the Medicaid Act when it is "necessary . . . to correct or ameliorate" an illness or condition, regardless of whether and how the service is covered for adults. 42 U.S.C. §§ 1396d(r)(5), 1396a(a)(10)(A), 1396d(a)(4)(B). Defendant does not argue, nor could she, that male chest reconstruction surgery is not included in the Medicaid Act. *See* 42 U.S.C. § 1396d(a)(2)(A) (outpatient hospital services), (5)(A) (services furnished by a physician); *see also Flack v. Wis. Dep't Health Servs.*, 395 F. Supp. 3d 1001 (W.D. Wis. 2019). Given that male chest reconstruction surgery is necessary to correct or ameliorate Plaintiffs' condition, it must be covered pursuant to EPSDT. *See Katie A., ex rel. Ludin v. L.A. County*, 481 F. 3d 1150, 1154 (9th Cir. 2007).

Defendant's contention that there is "legitimate debate" as to the safety and efficacy of the surgery has no scientific support. As explained above and in the reply expert declarations, there is no such debate. Male chest reconstruction surgery is not experimental, "risky," or "unproven." Def. Br. at 13 (citing *Ellis v. Patterson*, 859 F.2d 52, 55 (8th Cir.

1988)); Schechter Reply Decl. ¶ 4. Rather, "the medical profession has reached a formal consensus as to the safety and efficacy of surgical treatments for severe gender dysphoria," including for adolescents like D.H. and John Doe.[3] *Flack*, 395 F. Supp. 3d at 1016*; see* Schechter Reply Decl. ¶ 4; Expert Declaration of Aron Janssen, Doc. 5-5, ¶ 37–47.

Similarly, Defendant's claim that "neither [Plaintiff] has yet demonstrated medical necessity for the service," is inaccurate. D.H.'s and John's mental health providers referred them for male chest reconstruction and Dr. Schechter assessed D.H. and John and found them to be good candidates for the surgery. They have also lived as male for multiple years and started testosterone more than a year ago. Peck Decl. ¶ 14–17; Reed Decl. ¶ 10; Expert Declaration of Loren Schechter, Doc. 5-6, ¶ 49. That is more than the standards of care require. *See* WPATH SOC at 21. Defendant also disregards the fact that AHCCCS's categorical exclusion prevents transgender beneficiaries from establishing medical necessity for male chest reconstruction surgery. EPSDT requires Defendant to remove the exclusion and evaluate each Plaintiff's request for services based on medical necessity.

2. *AHCCCS's exclusion violates the Comparability Requirement.*

The Medicaid Act also requires AHCCCS to ensure that the "medical assistance made available to any [categorically needy] individual . . . shall not be less in amount, duration, or scope than the medical assistance made available to any other such individual." 42 U.S.C. § 1396a(a)(10)(B); 42 C.F.R. § 440.240. Thus, Defendant's argument that "the exclusion applies to all transgender persons alike" is unavailing. Def. Br. at 14. Her obligation is to ensure that AHCCCS does not "discriminat[e] among individuals with the same medical needs stemming from different medical conditions." *Davis v. Shah*, 821 F.3d 231, 258 (2d Cir. 2016). AHCCCS covers chest reconstruction surgery, including for adolescents, when necessary to treat other conditions; accordingly, it must cover that

[3] Defendant cites *Rush v. Parham*, 625 F.2d 1150, 1156 (5th Cir. 1980), for the proposition that gender affirming surgery is experimental. *See* Def. Br. at 13. That case is four decades old. Even assuming that the court was correct, and it was reasonable for Georgia to characterize the service as experimental in the mid-1970s, that same determination is wholly unreasonable today.

treatment for gender dysphoria. *See Flack.*, 395 F. Supp. 3d at 1019 (holding exclusion for "transsexual surgery" impermissibly "discriminates on the basis of diagnosis").

As Defendant correctly states, "need is the only basis upon which distinctions between recipients can be made without violating the comparability requirement." *V L. v. Wagner*, 669 F. Supp. 2d 1106, 1117 (N.D. Cal. 2009). As described above and in the extensive declarations accompanying Plaintiffs' motion, male chest reconstruction surgery is medically necessary for individuals with gender dysphoria, including some adolescents. Defendant tries to circumvent her obligation to cover the surgery by arguing that individuals with gender dysphoria do not have the same need for chest reconstruction surgery as individuals with other conditions. But where the same service is required to treat multiple medical conditions, the need for the service is rarely identical. *See Davis v. Shah*, 821 F.3d 231, 258 (2d Cir. 2016). Recognizing that fact, the Second Circuit held a rule that covered orthopedic footwear and compression stockings to treat complications for some conditions, but not others, violated the comparability requirement. *Id.* Here, Plaintiffs have established that the only reason that AHCCCS will not cover the surgery they need is because it was prescribed to treat gender dysphoria, instead of another condition such as breast cancer or fibrocystic breast disease. That differential treatment violates the Medicaid Act.

3. Section 1557 prohibits excluding surgical care for gender dysphoria.

Federal courts have consistently held that discrimination against transgender people is sex discrimination, including under Section 1557 of the ACA. *Prescott v. Rady Children's Hosp.-San Diego*, 265 F. Supp. 3d 1090, 1098–99 (S.D. Cal. 2017) (Section 1557); *see also Adams v. Sch. Bd. of St. Johns Cty.*, 968 F.3d 1286, 1304 (11th Cir. 2020) (Title IX); *Schwenk v. Hartford*, 204 F.3d 1187, 1201–02 (9th Cir. 2000) (Gender Motivated Violence Act). The Supreme Court's decision in *Bostock v. Clayton County, Ga.* is the latest in a long line of such cases. 140 S. Ct. 1731, 1737 (2020).[4] Even before *Bostock* confirmed

[4] Justice Alito's recognition of the implications of *Bostock* on health care benefits further demonstrates the majority opinion's definition of sex discrimination is to be applied consistently across federal sex-discrimination statutes.

that discrimination against transgender people constitutes sex discrimination, insurance exclusions that discriminated against transgender people were consistently struck down. *See, e.g., Flack v. Wis. Dept. of Health Srvcs.*, 395 F.Supp.3d 1001 (W.D. Wis. 2019); *Boyden v. Conlin*, 341 F.Supp.3d 979 (W.D. Wis. 2018); *see also Kadel v. Folwell*, 446 F.Supp.3d 1 (M.D.N.C. 2020) (denying motion to dismiss on Title IX, Section 1557, and equal-protection claims).

Defendant's claim that the exclusion is not discriminatory because AHCCCS covers other treatments for gender dysphoria is without merit. Section 1557 protects individuals from discrimination in covered health care settings and health insurance plans. As a covered entity, AHCCCS's categorical exclusion denies D.H. and John medically necessary surgical care because they are transgender. The surgery would have been covered if D.H. and John were males with gynecomastia or females who required chest surgery to treat cancer or traumatic injury. And, as detailed above and in the accompanying expert declarations, there is no other legitimate basis for denying D.H. and John coverage for male chest reconstruction surgery. Thus, AHCCCS is making an impermissible distinction based on transgender status, and therefore sex. That AHCCCS covers other treatments for gender dysphoria or would also discriminate transgender women seeking coverage for similar treatments is no defense. To the contrary, by discriminating against transgender men and transgender women equally, AHCCCS doubles its liability. *Bostock*, 140 S. Ct. at 1741.

The recent change in the federal regulations implementing Section 1557 does not affect D.H. and John's likelihood of success on this claim. As Defendant correctly noted, those regulations have been enjoined because the regulations were found to be arbitrary and capricious, and "contrary to law" for failing to address the effect of *Bostock* on Section 1557. *Walker v. Azar*, 2020 WL 4749859, at *8–10 (E.D.N.Y. Aug. 17, 2020). But even if that were not the case, the ACA prohibits discrimination based on sex, which, as the Supreme Court recently affirmed, encompasses discrimination based on transgender status. For reasons discussed above, any negative inference that might be drawn from the regulations cannot be reconciled with the plain text of Section 1557 or the body of caselaw

interpreting sex-discrimination protections to prohibit discrimination against transgender people, including *Bostock*. Consequently, Defendant has provided no basis to doubt that D.H. and John are likely to succeed on their Section 1557 claim.

4. AHCCCS's exclusion violates the Equal Protection Clause.

Defendant's exclusion of coverage for gender-confirmation surgery is subject to heightened scrutiny, which it cannot survive. As *Bostock* clearly holds, discrimination based on transgender status is a form of sex discrimination. 140 S. Ct. at 1741; *see also Grimm v. Gloucester Cnty. Sch. Bd.*, 972 F.3d 586, 607–08 (4th Cir. 2020); *Adams*, 968 F.3d at 1296 (11th Cir. 2020); *Whitaker v. Kenosha Unified Sch. Dist. No. 1*, 858 F. 3d 1034, 1051 (7th Cir. 2017); *Smith v. City of Salem*, 378 F.3d 566, 572 (6th Cir. 2004). Defendant provides no basis for ignoring this controlling precedent. The two cases she cites pre-date *Bostock* and have been superseded by that case. *Druley v. Patton*, 601 F.App'x 632, 635 (10th Cir. 2015), relied on *Etsitty v. Utah Transit Authority*, 502 F.3d 1215, 1227 (10th Cir. 2007), which erroneously held that Title VII does not protect transgender employees and is no longer good law.[5] In *Jamison v. Davue*, the court, in dicta, instructed a *pro se* plaintiff that transgender status is not a suspect class under the Equal Protection Clause, without any analysis or citation, 2012 WL 996383, *4 (E.D.Cal. 2012); this instruction was then cited in the other district court decisions citied by Defendant. *See, e.g.*, *Braninburg* v. *Coalinga State Hosp.*, 2012 WL 3911910, *8 (E.D. Cal. 2012); *Kaeo-Tomaselli* v. *Butts*, 2013 WL 399184, *5 (D. Haw. 2013); *Murillo* v. *Parkinson*, 2015 WL 3791450, *12 (C.D. Cal. 2015). Plainly, however, that instruction has been superseded by *Bostock*.

AHCCCS's attempt to avoid heightened scrutiny by reframing its categorical exclusion as "a facially neutral policy regarding one specific category of services" is unavailing. The policy excludes all surgical treatments needed by transgender people to

[5] Defendant's reliance on *Stevens v. Williams* and *Johnston* v. *University of Pittsburgh* fails for the same reason. Those courts also relied on cases predating, and superseded by, *Bostock*. *See Johnston*, 97 F. Supp. 3d 657, 677 (W.D. Pa. 2015) (citing *Ulane v. E. Airlines, Inc.*, 742 F.2d 1081, 1086 (7th Cir. 1984)); *Stevens*, 2008 WL 916991, *13 (D. Or. 2008) (citing *Holloway v. Arthur Andersen & Co.*, 566 F.2d 659 (9th Cir. 1977)).

treat gender dysphoria, while covering the same surgical treatments for non-transgender people undergoing treatment for other medical conditions. As the court explained in *Norsworthy v. Beard*, a policy that expressly excludes gender-confirmation surgeries is discriminatory on its face. *See* 87 F. Supp. 3d 1104, 1109, 1119–20 (N.D. Cal. 2015).

AHCCCS cannot show that this sex-based exclusion is supported by an exceedingly persuasive or even legitimate justification. AHCCCS asserts that it has a sufficient interest in excluding male chest reconstructive surgery because of its cost and irreversibility. But AHCCCS covers many expensive and irreversible procedures for a host of conditions, even for minors. And in any case, the mere fact that denying coverage for a procedure would save money cannot satisfy even rational basis review, much less the heightened scrutiny that applies here. *See Diaz v. Brewer*, 656 F.3d 1008, 1014 (9th Cir. 2011). Nor can AHCCCS claim a legitimate interest in excluding coverage for surgical care that is supported by the well-established standards for the treatment of gender dysphoria, especially when AHCCCS otherwise adheres to those standards to cover other treatments for gender dysphoria. There is no legitimate, much less exceedingly persuasive, justification for covering some medically necessary treatments for gender dysphoria, but not others. Thus, the justifications proffered by Defendant cannot even satisfy rational basis.

C. D.H. and John continue to experience irreparable harm.

Defendant's attempts to diminish the ongoing and pervasive harm D.H. and John experience are inconsistent with the direct and substantial evidence before this Court.

Defendant seeks to minimize those harms by claiming that the "principal source" of "medical harm" to D.H. and John is "the binding that each Plaintiff wears." In fact, the principal source of harm is the denial of medically needed care, which will have a permanent negative impact on their mental and physical health. Defendant ignores the serious harms to D.H.'s and John's mental health due to the continued denial of care as detailed in the extensive declarations by Plaintiffs, their health care providers, and experts. *See, e.g.*, Declaration of D.H., Doc. 5, ¶ 9–15; Declaration of John Doe, Doc. 4, ¶ 14–17; Peck Decl. ¶ 21; Reed Decl. ¶¶ 12–13; Janssen Reply Decl. ¶ 33; Schechter Reply Decl. ¶ 15. Without

male chest reconstruction surgery, D.H.'s and John's mental health will deteriorate, which is particularly concerning given their history of self-harm, suicidal ideation, and, for D.H., psychiatric hospitalizations. The delay in obtaining this critical surgical care also impairs D.H.'s and John's ability to treat their co-occurring mental health conditions, making those conditions more difficult to treat. Those too are irreparable injuries.

Moreover, Defendant fails even to acknowledge, much less rebut, the extensive evidence that the binding prevents D.H. and John from engaging in a variety of activities, including sports, dancing, and other recreational and social activities that are critical to both their short- and long-term health and well-being. The binding places significant limitations on Plaintiffs' ability to function, preventing D.H. from fully engaging in school and interfering in John's social interactions with his peers. These lost opportunities are quintessential irreparable injuries; they will negatively affect Plaintiffs for their rest of their lives, in ways that money damages cannot remedy. *McCormick v. Sch. Dist. of Mamaroneck*, 370 F.3d 275 (2d Cir. 2004); *Doe v. Wood Cty. Bd. of Educ.*, 888 F. Supp. 2d 771 (S.D.W. Va. 2012). Defendant also dismisses the serious risk that binding will exacerbate D.H.'s asthma during the pendency of this case. No amount of monetary damages will give him back that lost lung capacity, which is particularly damaging for D.H. because of its likely impact on his ability to return to dancing.

Defendant's efforts to distinguish the cases cited by Plaintiffs lack merit. The fact that Plaintiffs' gender dysphoria is not as predictably lethal as AIDS once was does not change the fact that D.H. and John proffered substantial evidence that they qualify for male chest reconstruction under the prevailing standards of care and that their health and wellbeing will be irreparably damaged, including the possibility of serious depression and suicidality, if they are forced to wait until after trial for relief. *See* Def. Br. at 11 (citing *Chalk v. U.S. Dist. Court Cent. Dist. of Cal.*, 840 F.2d 701 (9th Cir. 1988)). As courts have recognized in other cases, the harms caused to transgender youth by denials of medically needed care or by the enforcement of policies that undermine their medical treatment warrant preliminary relief. *See, e.g., Whitaker v. Kenosha Unified Sch. Dist.*, Case No. 16-

CV-943-PP, 2016 WL 5239829, at *4-6 (E.D. Wis. Sept. 22, 2016) (declarations supported finding of irreparable harm if school continued to treat plaintiff differently because he is transgender), *aff'd*, 858 F.3d 1034 (7th Cir. 2017); *Highland Local Sch. Dist.*, 208 F. Supp. 3d at 870 ("Some issues in this case are difficult, but determining whether Jane has been harmed from the School District's policy is not one of them.").

Further, D.H. and John have established irreparable harm due to their strong likelihood of success on the merits of each of their claims. Violations of federal constitutional rights and statutory antidiscrimination protections are irreparable injuries. *Melendres v. Arpaio*, 695 F.3d 990, 1002 (9th Cir. 2012); *see Silver Sage Partners, Ltd. v. City of Desert Hot Springs*, 251 F.3d 814, 827 (9th Cir. 2001) (recognizing presumption of irreparable injury in Fair Housing Act claim); *Smallwood v. Nat'l Can Co.*, 583 F.2d 419, 420 (9th Cir. 1978) (same, but on Title VII claim). That principle applies in full force here.

D. The balance of harms decisively favors D.H. and John.

When considering whether to issue a preliminary injunction, the Court should consider the parties' respective "competing claims of injury," and "the effect on each party of the granting or withholding of the requested relief." *Arc of Cal. v. Douglas*, 757 F.3d 975, 991 (9th Cir. 2014). Contrary to Defendant's claim, Plaintiffs have established "that chest reconstruction surgery is safe, effective, and urgent for them." Def. Br. at 18; *see* WPATH SOC 21; Janssen Decl. ¶ 46; Schechter Decl. ¶¶ 23–37. Thus, Defendant's suggestion that AHCCCS would be harmed by covering services that are ineffective or unsafe is not relevant here. Also, the cost of male chest reconstruction surgery for D.H. and John would be miniscule, at best, in proportion to AHCCCS's budget, and cannot outweigh the irreparable harm to D.H. and John. *See, e.g.*, *Flack*, 395 F. Supp. 3d at 1008.

Defendant has proffered no harm sufficient to overcome the serious physical and emotional harm D.H. and John experience due to AHCCCS's categorical exclusion for surgical care to treat gender dysphoria. The balance of equities weighs heavily in favor of prohibiting Defendant from denying D.H. and John coverage for male chest reconstruction surgery, a critical and medically necessary treatment for their gender dysphoria.

Respectfully submitted,

DATED: OCTOBER 26, 2020

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/s/ Daniel C. Barr

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UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF ARIZONA

D.H., by and through his mother, Janice Hennessy-Waller; and John Doe, by 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.

No. 4:20-cv-335-SHR

REPLY EXPERT DECLARATION OF ARON JANSSEN, M.D. IN SUPPORT OF PLAINTIFFS' MOTION FOR PRELIMINARY INJUNCTION

I, Aron Janssen, M.D., hereby declare as follows:

1. I submit this expert declaration based on my personal knowledge.

2. If called to testify in this matter, I would testify truthfully and based on my expert opinion.

3. In preparing this declaration, I was provided with and reviewed the following additional case-specific materials: (1) Expert Declaration of Michael Laidlaw, MD, and accompanying exhibits; and (2) Expert Declaration of Stephen Levine, MD, and accompanying exhibits.

4. The opinions contained in this declaration are based solely on the information I have been provided by Plaintiffs' counsel as well as my extensive experience studying and treating patients with gender dysphoria.

Discussion

Drs. Laidlaw and Levine Lack the Necessary Expertise

5. According to his CV, Dr. Laidlaw is an endocrinologist with no specific training or board certification in working with pediatric or transgender patient populations. Expert Declaration of Dr. Michael Laidlaw, Dkt. 18-1, at 17-19 ("Laidlaw Decl."). Yet, his declaration provides extensive—and, as discussed below, unsupported—opinions about the mental health dimensions of gender dysphoria and appropriate protocols for assessing a patient's preparedness for male chest reconstruction surgery, an assessment he would never perform as an endocrinologist and one that he does not have the formal training or qualifications necessary to perform.

6. Although Dr. Laidlaw claims to have experience working with patients with gender dysphoria, he provides no indication of whether that experience includes treatment of adolescents, the subject of this case, or the depth of that experience. Laidlaw Decl. ¶ 9. His claims of expertise are also belied by his lack of familiarity with the subject matter. For example, Dr. Laidlaw critiques a peer-reviewed journal article on chest dysphoria because, in part, the term "chest dysphoria" is not a clinical diagnosis or mentioned in the DSM-5. Laidlaw Decl. ¶ 34. That term, however, was not coined by the author, but is a commonly

used term of art to refer to the unique psychological distress people with gender dysphoria experience associated with their chest. Dr. Laidlaw also suggests that D.H.'s and John's increased chest dysphoria sometime after starting testosterone is because of their co-occurring conditions. Laidlaw Decl. ¶ 21. But, increased chest dysphoria is a common response to starting testosterone among transgender males. A provider who regularly works with transgender young people would not attribute that response to a patient's co-occurring conditions. Transgender young people experience an improvement in their mental health upon starting hormone-replacement therapy because that medication helps bring their body into closer alignment with their gender identity. As those hormones take effect, however, some transgender young people experience increased distress regarding the parts of their body the hormones cannot change. This is particularly true for transgender males whose voice will drop and will start growing facial hair—two visible markers of masculinity—but will still have a female-appearing chest.

7. Likewise, when Dr. Laidlaw discussed dosing of testosterone, one of the rare occasions Dr. Laidlaw opined on matters within the purview of an endocrinologist, he made errors that would not have been made by a medical provider that regularly treats transgender patients. Although a testosterone level of 300-1000 ng/dL would be concerning for a nontransgender female, *see* Laidlaw Decl. ¶ 20, that is a typical range of testosterone in males during puberty. And, likening doses of testosterone for transgender males to abusing steroids, is misleading and inaccurate. *Id.* The highest dose recommended for adolescents under the Endocrine Society Guidelines ranges from 100-125 mg every two weeks, which is, at most, one fifth of the levels studied in the article Dr. Laidlaw cites on steroid abuse.[1] Not surprisingly, induction of male puberty in transgender males has the same effects as those typically seen in nontransgender males (*e.g.* increased libido, potential for changes in mood, and increased body hair growth). It does not cause the complications and side effects that accompany steroid abuse.

[1] Many, if not all, of the studies contained in the meta-analysis cited by Dr Laidlaw involved nontransgender male participants whose starting levels of testosterone are much higher than those of transgender men.

8. Even though Dr. Levine is a psychiatrist, he is also unqualified to make the opinions asserted in his declaration. According to his CV, Dr. Levine is not board certified in child and adolescent psychiatry, which requires specialized training in child development that is essential for working with transgender young people and their families. Expert Declaration of Stephen Levine, Dkt. 18-2, at 49 ("Levine Decl."). His declaration and CV indicate that he does not have significant clinical experience working with adolescents experiencing gender dysphoria, the patient population at the heart of this case, and suggests that any such experience occurred decades ago. Levine Decl. ¶ 5.

9. He too used language throughout his declaration that laid bare his lack of expertise in treating adolescents with gender dysphoria. For example, on a number of occasions, Dr. Levine referred to transgender people as "transgendered." *See, e.g.*, Levine Decl. ¶¶ 47, 78, 104. That word has long been abandoned by practitioners and researchers in the field of transgender health care because it is offensive to transgender people and unnecessarily confusing. Similarly, Dr. Levine's declaration contains numerous claims that are false or misleading. For example, he claims that it is inaccurate to "assert that doctors 'assign' the sex of a child at birth." Levine Decl. ¶ 11. Yet, approximately 1 in 1,000 babies are born with intersex conditions, some of which cannot be diagnosed based on an inspection of a newborn's genitalia and others that result in a "mosaic" of sex chromosomes in their cells. Doctors routinely assign these children to one gender or another at birth. Nor is gender dysphoria "the only psychiatric condition to be treated by surgery." Levine Decl. ¶ 22. For example, deep brain stimulation (DBS) is a procedure that can be used to treat Obsessive Compulsive Disorder and Major Depression. DBS requires a surgical procedure to place a device called a neurostimulator in the brain; the neurostimulator, sometimes called a "brain pacemaker," then sends electrical impulses, through implanted electrodes, to specific targets in the brain.

Diagnosis and Treatment of Gender Dysphoria in Adolescents

10. Despite Drs. Laidlaw and Levine's assertions to the contrary, scientific research and clinical experience has foreclosed any credible debate about the diagnosis and

benefits of treatment for gender dysphoria in childhood. But, because male chest reconstruction surgery is not medically appropriate until adolescence, this declaration will focus primarily on their statements that apply to adolescents with gender dysphoria. As such, any studies or statements not directly addressed in this declaration, such as the significant misrepresentations Drs. Laidlaw and Levine make regarding the research regarding "persistence" and "desistence," should not be construed as agreement. *See* Laidlaw Decl. ¶ 22; Levine Decl. ¶¶ 28, 35, 56, 58-67, 99-103.

11. Contrary to the portrayal in Drs. Laidlaw's and Levine's declarations, the gender affirmative model of treatment requires a careful and thorough assessment of a patient's mental health, including co-occurring conditions, history of trauma, substance use, among many other factors. Laidlaw Decl. ¶¶ 23-26; Levine Decl. ¶¶ 51, 57. That assessment requires an exploration of the patient's psychological distress surrounding their gender identity, including its sources and manifestations. Without that detailed history and assessment, a provider could not accurately diagnose a patient with gender dysphoria. The number of sessions that assessment requires will vary greatly depending on the patient's presentation and the complexity of the issues the patient is navigating. Further, in conducting that assessment, the mental health provider is drawing from their professional training and experience in working with transgender young people, exercising professional judgment, and tailoring the assessment to each individual patient.

12. That comprehensive assessment is also needed to inform possible future care, specifically referrals for surgical treatment. The referral process involves an assessment of the patient's gender dysphoria, co-occurring conditions, and the surgical procedure's likely affect on the patient's overall mental health and functioning. As part of that process, mental health providers also discuss the risks, benefits, and alternatives to surgery with transgender young people and their parents. This gives the mental health provider an opportunity to assess whether the transgender young person's co-occurring conditions are interfering with their ability to fully assent to the procedure and whether those conditions would impede their ability to comply with necessary post-surgical care.

13. Where the gender-affirmative model differs from other approaches is that it does not presume that being transgender is incompatible with a young person's short- and long-term health and wellbeing. That is consistent with DSM-5 diagnostic criteria which is "focus[ed] on dysphoria as the clinical problem, not identity per se." American Psychiatric Association, *Diagnostic and Statistical Manual of Mental Disorders (DSM-5)*, 451 (2013). And, despite Drs. Laidlaw and Levine's characterization to the contrary, the gender-affirmative model is not synonymous with a rubber-stamp recommendation that all patients undergo a gender transition. *See* Laidlaw Decl. ¶¶ 23-25; Levine Decl. ¶¶ 51, 57. Instead, the focus of the gender-affirmative model is supporting overall health and wellbeing, regardless of whether the young person continues to identify as transgender. As a result, I have had patients who presented with some symptoms of gender dysphoria, but who ultimately did not meet the diagnostic criteria for a variety of reasons and therefore I recommended treatments other than transition to alleviate their psychological distress.

14. The other treatment modalities outlined in Dr. Levine's declaration are inconsistent with the prevailing standards of care because those modalities withhold treatments known to ameliorate the patient's gender dysphoria, which is unethical and contrary to a provider's oath to "first, do no harm." Levine Decl. ¶¶ 28-42. Although Dr. Levine refers to his preferred modality as the "psychotherapy model," this approach is more appropriately characterized as "gender identity conversion efforts" because its goal is to bring the patient's gender identity into alignment with their assigned sex and forecloses gender transition as a treatment for gender dysphoria. Levine Decl. ¶¶ 30-35. A recent study found that experiencing those conversion efforts was associated with greater odds of attempting suicide, especially for those had those experiences in childhood. Jack Turban, et al., *Association between recalled exposure to gender identity conversion efforts and psychological distress and suicide attempts among transgender adults*, 77 JAMA Psychiatry 68 (2020). That conclusion is further supported by the extensive evidence that rejection of a young person's gender identity from family and peers are the strongest predictors for adverse mental health outcomes. This is not an appropriate therapeutic

modality and every leading medical and mental health organization has issued clear statements that those practices are discredited, harmful, and ineffective, including the American Medical Association,[2] the American Academy of Pediatrics,[3] and the American Academy of Child & Adolescent Psychiatry.[4]

Treatment for Gender Dysphoria is Evidence Based

15. Many well-established treatment protocols in psychiatry—and likely in every discipline of medicine—do not have the level of evidentiary support that Drs. Laidlaw and Levine seek to impose on treatment for gender dysphoria. Laidlaw Decl. ¶¶ 31-34, 36-37; Levine Decl. ¶ 71-77, 114. The evidentiary basis for those treatment protocols are developed, and regularly updated, using a combination of peer-reviewed research and the extensive clinical experience of providers who regularly treat patients with that condition. Those treatment protocols are considered the standard of care and are safe and effective for the conditions they are intended to treat. For example, in children, Zoloft is FDA approved to treat Obsessive-Compulsive Disorder, but is also regularly used to treat depression and anxiety, such that the use of Zoloft is considered the standard of care for children who require medication to treat those conditions.

16. Although there are still no imaging or laboratory tests that assist clinicians in the diagnosis and treatment of gender dysphoria, there are measurable and objective criteria mental health providers use to diagnose and treat gender dysphoria, including the DSM-5 diagnostic criteria and the ever-growing body of research on gender dysphoria. For example, studies repeatedly point to the strength of a young person's cross-gender identification as an important factor in the diagnostic process. A recent study found cross-

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[2] American Medical Association, *Health care needs of lesbian, gay, bisexual and transgender populations, H-160.991. 2017*, https://policysearch.ama-assn.org/policyfinder/detail/H-160.991%20?uri=%2FAMADoc%2FHOD.xml-0-805.xml (lasted visited Oct. 23, 2020).

[3] Jason Rafferty, et al., Ensuring comprehensive care and support for transgender and gender-diverse children and adolescents, 142 Pediatrics (2018), *available at*, https://pediatrics.aappublications.org/content/pediatrics/142/4/e20182162.full.pdf (last visited Oct. 23, 2020).

[4] The American Academy of Child & Adolescent Psychiatry, *Conversion Therapy* (2018), https://www.aacap.org/AACAP/Policy_Statements/2018/Conversion_Therapy.aspx (last visited Oct. 23, 2020).

gender identification of transgender children who had not yet undergone any transition to be indistinguishable from that of nontransgender study participants and transgender participants who had already undergone a social transition. Rae, J., et al., *Predicting early-childhood gender transitions*, 30 Psychological Science 669 (2019); *see also* Selin Gülgöz, et al., *Similarity in Transgender and Cisgender Children's Gender Development*, 116 *Proceedings of the Nat'l Acad. Of Sci. of the U.S.* 24480 (2019).[5] Research also shows that social transition significantly improves the mental health of transgender young people, bringing their mental health profiles into alignment with their nontransgender peers. Kristina Olson, et al., *Mental health of transgender children who are supported in their identities*, 137 Pediatrics 1 (2016);[6] *see also* Jack Turban, et al., *Pubertal suppression for transgender youth and risk of suicidal ideation*, 145 Pediatrics 1 (2020) (transgender people who accessed puberty suppression treatment were 70% less likely to contemplate suicide). Those guideposts, among others, assist clinicians to differentiate a young person who shows some symptoms consistent with gender dysphoria but for whom a gender transition would not be recommended, and a young person who has the type of persistent gender dysphoria seen in transgender people.

17. Another related measure is whether a young person's gender dysphoria continues into or intensifies at the onset of puberty. That further confirms the accuracy of a young person's gender dysphoria diagnosis. Even researchers who oppose treatment of gender dysphoria in childhood adhere to the gender-affirmative model for transgender adolescents and recognize the importance of medical and surgical treatments for gender dysphoria in adolescence. Jack Turban, Annelou DeVries & Kenneth Zucker, *Gender Incongruence & Gender Dysphoria*, in *Lewis's Child and Adolescent Psychiatry: A Comprehensive Textbook*, (A Martin, et al., eds., 5th ed., 2018). A longitudinal study

[5] These studies also demonstrate there is no support for Dr. Levine's suggestion that social transition in childhood causes transgender young people to continue identifying as transgender into adolescence and beyond.

[6] Anxiety was the only area where transgender young people differed from the nontransgender controls. On that measure, transgender young people showed slightly elevated levels of anxiety, but were still in the pre-clinical range.

following a cohort of transgender young people in the Netherlands from puberty suppression through surgical treatment found that the cohort had global functioning that was equivalent to the Dutch population. Annelou De Vries, et al., *Young adult psychological outcome after puberty suppression and gender reassignment*, 134 *Pediatrics* 696 (2014). And, in fact, the cohort of transgender participants were nearly twice as likely to pursue higher education (58% v. 31%). *Id.*

18. Drs. Laidlaw and Levine criticize the extensive body of research supporting the current standard of care for the treatment of gender dysphoria based on purported concerns that generally lack a sound scientific basis; at the same time, they rely heavily on articles and other sources that lack peer review or other indicia of reliability to support their own views. For example, in response to the brain-imaging studies identifying biological sources of gender identity, Dr. Levine claims "there is no evidence that these patients have any defining abnormality in brain structure that precedes the onset of gender dysphoria." Levine Decl. ¶ 24. This critique fails to account for the fact that medical providers would have no basis for conducting a brain imaging study on transgender people prior to the onset of gender dysphoria. Equally concerning, however, is Dr. Levine's reliance on the Littman study for his claim that gender dysphoria is driven by cultural influences. *Id.* Although purporting to provide a basis for Dr. Levine's speculations, the study was based on an anonymous survey, allegedly of parents, about the etiology of their child's gender dysphoria. Participants were recruited from websites promoting this social-contagion theory, and the children were not surveyed or assessed by a clinician. Those serious methodological flaws render the study meaningless. The only conclusion that can be drawn from that study is that a self-selected sample of anonymous people recruited through websites that predisposed participants to believe that transgender identity can be influenced by social factors believe those social factors influence children to identify as transgender.

19. Further, a significant proportion of the sources cited by Drs. Laidlaw and Levine were published in nonscientific journals, including *Public Discourse*, a general-interest opinion journal edited by Ryan Anderson, an outspoken opponent of treatment for

gender dysphoria who has no medical training. *See* Laidlaw Decl. at 8; Masthead – Public Discourse, https://www.thepublicdiscourse.com/masthead/ (last visited Oct. 23, 2020).

Assessing Co-Occurring Conditions & Referrals for Surgery

20. Both Drs. Laidlaw and Levine include extensive discussions of co-occurring conditions—even suggesting diagnoses for D.H. and John without examining them. Laidlaw Decl. ¶¶ 13-26; Levine Decl. ¶¶ 19, 55. Each suggests that transgender people have an underlying psychopathology by virtue of being transgender. *See* Laidlaw Decl. ¶ 23; Levine Decl. ¶¶ 21-25, 50-51, 83. The American Psychiatric Association unequivocally repudiated that outdated view in the DSM-5, revising the diagnostic criteria (and name) to recognize the clinical distress as the focus of the treatment, not the patient's transgender status. *See* DSM-5 at 451. As in other aspects of their declarations, Drs. Laidlaw and Levine's reliance on scientific research is selective, cannot support their conclusions, and is inconsistent with the prevailing standards of care.

21. Studies on transgender young people have long reported data on co-occurring conditions. Johanna Olson, et al., *Baseline Physiologic and Psychosocial Characteristics of Transgender Youth Seeking Care for Gender Dysphoria*, 57 J. of Adol. Health 374 (2015) (finding 35% of participants with clinical levels depression and prevalence of moderate and severe depression among participants was 9% and 11%, respectively); Sari L. Reisner, et al., *Mental health of transgender youth in care at an adolescent urban community health center: A matched retrospective cohort study*, 56 J. of Adol. Health 274 (2015) (finding approximately 51% of participants had a diagnosis of depression and 27% were diagnosed with anxiety); Norman Spack, et al., *Children and Adolescents With Gender Identity Disorder Referred to a Pediatric Medical Center*, 129 Pediatrics 419 (2012) (finding 40% had mental health diagnoses prior to contact with the clinic, including, among others, depression (58%), general anxiety disorder (7%), bipolar (7%), PDD-NOS (9%), and ADHD/ADD (5%)); Brian S. Mustanski, et al., *Mental Health Disorders, Psychological Distress, and Suicidality in a Diverse Sample of Lesbian, Gay, Bisexual, and Transgender Youths*, 100 Am. J. of Pub. Health 2426 (2010) (One third of participants met criteria for

any mental disorder, 17% for conduct disorder, 15% for major depression, and 9% for posttraumatic stress disorder.). The existence—and prevalence—of co-occurring conditions among transgender young people is unsurprising. Transgender young people must cope with many stressors from the fear of rejection from family and peers to pervasive societal discrimination. Not to mention, their underlying gender dysphoria can cause significant psychological distress, which, if left untreated, can result in the co-occurring conditions identified in studies on transgender young people. And, given that transgender young people typically delay disclosing their transgender status or initially experience family rejection following disclosure, it is not uncommon for transgender young people to engage with psychological or psychiatric care for other reasons prior to being diagnosed with gender dysphoria.

22. Transgender young people, however, are not outliers in this regard. Research and clinical experience show that most psychiatric conditions are highly correlated with other co-occurring psychiatric conditions. For example, young people with depression are very likely to have at least one other diagnosable condition, most often anxiety. *See, e.g.*, E. Jane Costello, et al., *Prevalence and development of psychiatric disorders in childhood and adolescence*, 60 Archives of Gen. Psychiatry 837 (2003) ("There was strong heterotypic continuity from depression to anxiety" and finding approximately 30% of participants diagnosed with a depressive disorder were also diagnosed with an anxiety disorder). Likewise, a study on children diagnosed with Attention-Deficit/Hyperactivity Disorder found between 74-79% participants had additional co-occurring psychiatric conditions. Timothy Wilens, et al., *Psychiatric Comorbidity and Functioning in Clinically Referred Preschool Children and School-Age Youths With ADHD*, 41 J. of Am. Academy of Child & Adol. Psychiatry 262 (2002).

23. Thus, Dr. Laidlaw's reliance on the prevalence data in the study by Kaltiala-Heino is misleading. Laidlaw Decl. ¶ 23. First and foremost, the prevalence rates reported in that study are significantly higher than other data on co-occurring conditions in transgender young people. His reliance on a single outlier study is particularly troubling

because the prevalence data in those other studies are largely consistent with one another, suggesting a high level of reliability. Second, the small size of the study and its design prevented its authors from drawing any causal connections between the co-occurring conditions and the medical necessity or mental health benefits of surgical care to treat the participant's gender dysphoria. Instead, the study was focused on developing categories that describe the various clinical presentations of young people with gender dysphoria in that clinic. Yet, Dr. Laidlaw cites this study as a basis for his belief that transgender young people must demonstrate their co-occurring conditions have been "thoroughly treated" prior to obtaining male chest reconstruction surgery, a conclusion that is contrary to the standards of care and the study's own conclusions. *Id.*

24. In suggesting D.H. and John need further assessment for co-occurring conditions, Dr. Laidlaw also implies that mental health providers who follow the gender-affirmative model of therapy do not conduct a thorough assessment of their patients. Laidlaw Decl. ¶ 23. As noted above, conducting a detailed assessment is a central feature of the gender-affirmative model, and such an assessment would have explored the categories of potential co-occurring conditions identified by Dr. Laidlaw. Based on the declarations of Dr. Peck and Ms. Reed, both have extensive experience working with transgender young people and have an extended therapist-patient relationship with John and D.H., respectively. Declaration of Dr. Mischa Cohen Peck, Dkt. 4-2, ¶¶ 6, 8 ("Peck Decl."); Declaration of Tamar Reed, Dkt. 5-2, ¶¶ 4-5. There is nothing in their declarations that suggest either conducted anything short of a comprehensive assessment of their patient's mental health.

25. Equally concerning is Dr. Laidlaw's assertion that John may have dissociative identity disorder (previously known as multiple personality disorder), a complex psychiatric condition, without having assessed John—an assessment he would not be qualified to conduct. Laidlaw Decl. ¶ 18 n.1. That opinion is based on John's description of his experience of puberty as "being detached" from his body. *Id.*; Peck Decl. ¶ 12. Young people commonly describe distressing or traumatic experiences as an out-of-body

experience; it is a coping mechanism that allows them to separate and protect themselves from that experience. Given the distress the onset of puberty causes for transgender young people, it is not surprising that John recounted his experience in those terms; it is an experience I have heard from many of my patients, including transgender patients, both around the onset of puberty and during times of stress or trauma.

26. Like any patient, transgender young people will develop a variety of ways to cope with the psychological distress they experience, especially when untreated, to regain control of their lives. Some strategies can be healthy and promote psychological and overall health, like exercise and drawing, while other strategies can cause further damage, such as self-harm or restricted eating. Dr. Laidlaw attempts to draw a connection between D.H.'s and John's history of engaging in self-harming behaviors[7] to a litany of psychological conditions. Laidlaw Decl. ¶ 19. The suggestion that the mere presence self-harming behaviors requires further assessment for the co-occurring conditions listed in his declaration is inconsistent with the research on those behaviors and the prevailing standard of care. Self-harming behaviors are considered a non-specific maladaptive coping mechanism, meaning those behaviors are used by patients in response to a wide range of psychological conditions and stressors. Because those behaviors are not associated with a specific condition, the standard of care is to explore the triggers for the self-harming behaviors and to help redirect patients towards positive—or, at least, less harmful—coping mechanisms, while treating the underlying condition so that the triggering events are less frequent.

27. For transgender males, the presence and appearance of their chest repeatedly triggers their gender dysphoria throughout the day, from seeing their body while getting dressed in the morning to being misperceived as female by others. Although therapy can greatly assist transgender males in developing more positive coping mechanisms, it cannot completely resolve the underlying psychological distress, thereby impairing their ability to achieve sustained relief from gender dysphoria. Male chest reconstruction surgery removes

[7] These behaviors are also referred to by the term non-suicidal self-injury or NSSI.

this significant source of dysphoria, reducing the transgender person's overall level of distress and improving their psychological functioning.

28. Both Drs. Laidlaw and Levine, however, suggest that the existence of co-occurring conditions, history of self-harming behaviors, or history of suicidal ideation or attempts should disqualify D.H. and John from consideration for male chest reconstruction surgery. Laidlaw Decl. ¶¶ 23-26; Levine Decl ¶¶ 31–32. The scientific research and clinical experience working with transgender young people demonstrates that the opposite is true. *See, e.g.*, Richard Bränström & John E. Pachankis, *Toward Rigorous Methodologies for Strengthening Causal Inference in the Association Between Gender-Affirming Care and Transgender Individuals' Mental Health: Response to Letters*, 177 Am. J. Psychiatry 769 (2020);[8] Johanna Olson-Kennedy, et al., *Chest Reconstruction and Chest Dysphoria in Transmasculine Minors and Young Adults Comparisons of Nonsurgical and Postsurgical Cohorts*, 172 JAMA Pediatrics 431, 434 (2018); Annelou De Vries, et al., *Young adult psychological outcome after puberty suppression and gender reassignment*, 134 *Pediatrics* 696 (2014). In fact, transgender males who are experiencing severe chest dysphoria manifesting in suicidal ideation, suicide attempts, or psychiatric hospitalizations are among the most in need of male chest reconstruction surgery. For those patients, therapy and medication have proved to be a temporary band aid and continuing that treatment protocol would cause the patient's mental health to deteriorate further with very dangerous consequences.

[8] In his declaration, Dr. Laidlaw misrepresented the differences between the original Bränström study and its subsequent correction. Although the correction concurred that "the [study] design is incapable of establishing a causal effect of gender-affirming [surgical] care on mental health treatment utilization," *id.* at 772, a re-analysis of the data supported an expectation of "a reduction in mental health treatment as a function of time since completing such treatment," *id.* Dr. Laidlaw's discussion of the study's conclusion, however, makes the same analytical misstep he claimed the authors made; just as the data could not prove a causal connection between surgery and the subsequent improvement to the participant's mental health, it also cannot support a finding that the surgery had no effect. *See* Laidlaw, et al., *Letter to the Editor: Gender-Affirmation Surgery Conclusion Lacks Evidence*, 177 *Am. J. Psychiatry* 765-766 (2020). In doing so, Dr. Laidlaw glosses over the study's conclusion that there is a positive correlation between access to surgical treatment for gender dysphoria and improved mental health over time.

29. The prevailing standards of care account for the reality that transgender individuals may be diagnosed with co-occurring conditions. Among the criteria for assessing a transgender patient for male chest reconstruction surgery is determining whether the patient's "significant medical or mental health concerns are . . . reasonably well controlled." WPATH, *Standards of Care for the Health of Transsexual, Transgender, and Gender-Nonconforming People*, 59 (hereafter, "WPATH SOC").

30. That criteria is focused on serious conditions that would interfere with one, or more, of the following: (1) the ability of the provider to accurately diagnose the patient with gender dysphoria; (2) the ability of the patient to provide informed assent (for people under eighteen) or consent (for parents and adults) to the surgery; or (3) the ability of the patient to recover from the surgery, including compliance with post-operative care.

31. The conditions that typically trigger closer assessment under that criteria include schizophrenia, schizoaffective disorder, dissociative identity disorder, and Down Syndrome. Having those conditions—or similar ones—does not automatically preclude a transgender person from undergoing treatment for gender dysphoria. Instead, assessing that person requires providers who are highly specialized in working with transgender people to determine whether the person's co-occurring condition does, in fact, raise any of the concerns noted above. This also means that the assessment process may take longer.

32. Requiring that a transgender patient resolve all co-occurring conditions prior to undergoing surgical care—as suggested by Defendant's experts—is not possible, nor is it ethical. Laidlaw Decl. ¶¶ 23-26; Levine Decl. ¶¶ 29, 31, 34, 55. Nor is resolving all co-occurring conditions before surgical treatment a requirement for other procedures, such as surgeries for Grave's disease or Hyperthyroidism. Gender dysphoria, by definition, is accompanied by clinically significant psychological distress. That distress can take on many different forms (*e.g.*, anxiety, mood disorders, and depression) and vary greatly in severity, resulting in co-occurring conditions. Because psychological distress is not easily compartmentalized, the distress associated with gender dysphoria can also amplify co-occurring conditions that developed independently of the gender dysphoria. In either

situation, gender dysphoria limits the effectiveness of treatment of any co-occurring mental health conditions. Thus, treating the underlying gender dysphoria is essential to alleviating the psychological distress associated with co-occurring conditions.

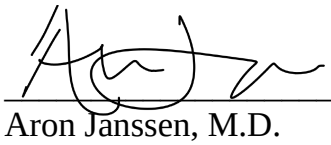
33. Even assuming that it was possible to cure a patient's co-occurring conditions, Drs. Laidlaw and Levine fail to consider the very real harms caused by delaying treatment. Therapy and medications alone are often inadequate to treat gender dysphoria in transgender males. Without male chest reconstruction surgery, their gender dysphoria would continue to worsen. At a minimum, that increased distress would interfere with the treatment for the person's co-occurring conditions, subjecting them unnecessarily to a longer course of treatment. It is far more likely that the gender dysphoria would eclipse the person's co-occurring conditions, not only entirely impeding treatment of those co-occurring conditions, but also resulting in an overall deterioration of their mental health. The increased distress from their gender dysphoria would translate to resorting to negative coping mechanisms (*i.e.* self-harm), suicidal ideation, and suicide attempts—just as it could if that increased distress was attributable to a co-occurring condition.

34. Based on my review of the declarations submitted by D.H.'s and John's healthcare providers, there is no basis to suggest that either of them has co-occurring conditions that are not "reasonably well controlled" as required under WPATH Standards of Care to be eligible for male chest reconstruction. WPATH SOC at 21, 59. To the contrary, the professional opinions of those providers are that not only are their co-occurring conditions well controlled, but that having male chest reconstruction surgery will help alleviate the symptoms of those co-occurring conditions.

35. Thus, undergoing male chest reconstruction surgery may allow D.H. and John, a transgender patient to "thoroughly treat[]" their co-occurring conditions as Dr. Laidlaw envisions. Laidlaw Decl. ¶ 23. As a result, withholding or denying treatment in the manner suggested by Drs. Laidlaw and Levine is irresponsible and unethical.

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

Executed this 26th th day of October, 2020 at Chicago, Illinois.



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UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF ARIZONA

D.H., by and through his mother, Janice Hennessy-Waller; and John Doe, by 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.

No. 4:20-cv-335-SHR

REPLY EXPERT DECLARATION OF LOREN S. SCHECHTER, M.D. IN SUPPORT OF PLAINTIFFS' MOTION FOR PRELIMINARY INJUNCTION

I, Loren S. Schechter, M.D., declare as follows:

1. I have been retained by counsel for the Plaintiffs as an expert in the above-captioned lawsuit. I submitted an expert witness declaration ("Schechter Decl."), Dkt. 5-6, in connection with Plaintiffs' motion for a preliminary injunction in this case. I submit this declaration to respond to points raised in the declarations of Michael K. Laidlaw, M.D. ("Laidlaw Decl."), Dkt. 18-1] and Stephen B. Levine, M.D. ("Levine Decl."), Dkt. 18-2, which Defendants submitted in connection with their response to Plaintiffs' motion for a preliminary injunction.

2. My background, qualifications, and compensation for my services in this case, and the bases for my opinions in this case are described in my original declaration. In preparing this declaration, I was provided with and reviewed the following additional case-specific materials: (1) Expert Declaration of Michael Laidlaw, MD, and accompanying exhibits; and (2) Expert Declaration of Stephen Levine, MD, and accompanying exhibits.

3. I have personal knowledge of the matters stated in this supplemental declaration.

4. Both Dr. Laidlaw and Dr. Levine claim that male chest reconstruction surgery is not a safe and effective treatment for gender dysphoria.[1] That claim is flatly inconsistent with mainstream medical standards. It is my professional opinion – supported by the prevailing consensus of the medical community – that male chest reconstruction is a safe, effective, and medically accepted treatment for individuals with gender dysphoria, including adolescents.

[1] Based on my review of Dr. Laidlaw's declaration and CV, it appears that he has no clinical experience treating individuals with gender dysphoria. The language Dr. Laidlaw used in his declaration reflects his lack of familiarity with this area of medicine. For example, he claims that treatments for individuals with gender dysphoria "must be optimal, efficacious, and safe." *Id.* ¶ 11. His use of the term "optimal" implies that there is one way to treat or care for a particular condition, and that is simply not true. There are only "optimal" treatments for a particular patient. As is the case with many medical conditions, there are various treatments available for gender dysphoria, including surgery. As part of a surgical consultation, surgeons discuss the risks, benefits, and options of available procedures with their patients. This discussion includes a consideration of the patients' medical history as well as other factors. What is "optimal" for one person with gender dysphoria might not be "optimal" for another person with the same medical condition.

WPATH is a Professional Medical Association

5. Both Dr. Laidlaw and Dr. Levine attempt to discount the broad medical consensus that gender confirming surgeries are medically necessary by claiming that WPATH is an "advocacy organization" and not a "purely" professional one. *See* Laidlaw Decl. ¶ 33; Levine Decl. ¶ 46. First, most medical associations and societies engage in advocacy on behalf of health care professionals, their patients, and their medical specialty generally. For example, the Endocrine Society – of which Dr. Laidlaw is a member – describes itself as devoted to "advocating on behalf of the global endocrinology community," including patients with endocrine conditions. Endocrine Soc'y, Who We Are, https://www.endocrine.org/about-us; *see also* Endocrine Soc'y, Advocacy, https://www.endocrine.org/advocacy, Endocrine Soc'y, Shaping Healthcare and Research Policy, https://www.endocrine.org/our-community/shaping-healthcare-and-research-policy. Similarly, the American Society of Plastic Surgeons uses advocacy "to support its members in the provision of excellent patient care." Am. Soc'y of Plastic Surgeons, About ASPS, https://www.plasticsurgery.org/about-asps. Far from being unique, engaging in advocacy is the norm among professional medical associations. *See, e.g.*, Am. Medical Ass'n, Health Care Advocacy, https://www.ama-assn.org/health-care-advocacy; Am. Psychiatric Ass'n, Make a Difference Through APA Advocacy, https://www.psychiatry.org/psychiatrists/advocacy; Am, Acad. of Pediatrics, Advocacy, https://services.aap.org/en/advocacy/.

6. Second, WPATH has transgender members who are licensed professionals in the wide range of specialties associated with transgender health as well as transgender members who bring the voice of the community into the organization. The presence and participation of transgender people in WPATH in no way restricts "honest and scientific debate" among professionals. *Cf.* Levine Decl. ¶ 45. To the contrary, it enriches the discussion of important topics, just as the participation of patients and patient support groups does during discussions at conferences for other professional societies to which I belong. Having transgender members is vital to WPATH and the development of the

Standards of Care, but notably, voting privileges are limited to members who are professionals. Thus, the implication that the participation of transgender members degrades WPATH's scientific integrity or impartiality has no merit.[2] Moreover, in conjunction with WPATH's biennial conference, it hosts a meeting that is limited to surgeons and healthcare professionals directly involved in surgical care (a meeting that I started at the 2007 WPATH Biennial meeting in Chicago, and continue to organize and participate in at each of the subsequent meetings). During the meeting, surgeons openly discuss a wide range of issues, including surgical techniques and ethical questions.

7. Finally, Dr. Laidlaw and Dr. Levine ignore that many other professional medical associations agree that gender-confirming surgery is a medically necessary treatment for individuals with gender dysphoria. *See, e.g.*, Schechter Decl. ¶ 32 (noting that the American Medical Association, American College of Obstetricians and Gynecologists, and American Academy of Pediatrics have all issued policy statements and guidelines that are in accordance with the WPATH Standards of Care); *see also* Am. Psychological Ass'n, Guidelines for Psychological Practice With Transgender and Gender Nonconforming People (2015), https://www.apa.org/practice/guidelines/transgender.pdf; Am. Psychiatric Ass'n, *A Guide for Working With Transgender and Gender Nonconforming Patients* (2017), https://www.psychiatry.org/psychiatrists/cultural-competency/education/transgender-and-gender-nonconforming-patients.

Male Chest Reconstruction Surgery is Safe and Effective for Individuals who Meet the Prevailing Standards of Care

8. The WPATH Standards of Care set forth the following general criteria for individuals seeking male chest reconstruction to treat their gender dysphoria: (1) The patient has a referral from at least one mental health professional documenting the patient's necessity and preparedness for the surgery; (2) If the patient has other significant medical

[2] Dr. Laidlaw's complaint that WPATH's Standards of Care are developed through a consensus process among its members is curious, at best. WPATH members have dedicated a significant portion of, if not their entire professional careers, to advancing the health and wellbeing of transgender people. That level of expertise is essential in creating a standard-setting document.

or mental health concerns, they are reasonably well-controlled prior to surgery; and (3) The patient has the capacity to make fully informed decisions and to consent for treatment. WPATH, *Standards of Care for the Health of Transsexual, Transgender, and Gender-Nonconforming People*, 59 (hereafter, "WPATH SOC"). With respect to individuals under age 18, the Standards of Care indicate that it is preferable to perform male chest reconstruction after the patient has had "ample time of living in the desired gender role and after one year of testosterone treatment," but that a different approach could be more suitable depending on the individual needs of the patient. WPATH SOC at 21.

9. Dr. Laidlaw and Dr. Levine appear to misunderstand these guidelines. Both declarations include an extensive discussion of treatment for gender dysphoria in children (*i.e.* prior to puberty), but the SOC does not recommend surgical interventions for pre-pubescent children, and in any event, the issue of what interventions are appropriate for children before puberty is irrelevant to the question of whether male chest reconstruction surgeries are clinically appropriate for D.H. and John Doe, both of whom have already commenced puberty.

10. Dr. Laidlaw asserts that "any treatment which alters biological development in children should be used with extreme caution." Laidlaw Decl. ¶ 11. While any surgical intervention should be approached with care, the SOC outline the clinical factors medical and mental health professionals should assess when determining whether surgery is medically necessary to treat a transgender young person's gender dysphoria. Nor do the SOC go beyond clinical practice in other areas for youth. Many nontransgender women have breast reduction surgery before the age of 18 in order to alleviate back pain, neck pain, shoulder grooving from bras straps, and/or skin irritation. Likewise, it is common for nontransgender men as young as 14 to have surgery to treat gynecomastia. Accordingly, the SOC recognize that male chest reconstruction is medically necessary for many adolescents with gender dysphoria who are under age 18. WPATH SOC at 21; *see also* Wylie C. Hembree et al., *Endocrine Treatment of Gender-Dysphoric/Gender-Incongruent Persons: An Endocrine Society Clinical Practice Guideline*, 102 J. Clin. Endocrinology &

Metabolism 3869, 3872 (2017) ("We suggest that clinicians determine the timing of breast surgery for transgender men based upon the physical and mental health status of the individual. There is insufficient evidence to recommend a specific age requirement.").

11. Dr. Laidlaw claims that any co-occurring mental health conditions, "should be thoroughly treated first before considering hormone therapy or gender reassignment surgery." Laidlaw Decl. ¶¶ 23, 26. That position is not supported by any evidence. Co-occurring mental health conditions are not uncommon in patients who need surgery, including patients with gender dysphoria. The WPATH SOC recognize that. They specifically indicate the importance of mental health assessments prior to surgery, as well as the importance of a multi-disciplinary and collaborative approach between surgeons, mental health professionals, and primary care providers. *See* WPATH SOC at 56-57. Working in this interdisciplinary way, surgeons determine if a patient has any medical or mental health conditions that could affect their suitability for surgery or complicate their recovery after surgery. *See* WPATH SOC at 59.

12. In addition, it is wrong to assume that gender-affirming surgeries, like male chest reconstruction surgery, cannot have a positive effect on co-occurring mental health conditions. The overwhelming majority of my patients improve across multiple domains after surgery. For example, before surgery, some patients are unable to exercise because doing so causes intense gender dysphoria, and the size of their chest/breasts makes exercise physically uncomfortable, not unlike nontransgender women seeking breast reduction surgery. After surgery, they are able to exercise more comfortably and, as such, they are able to improve their physical health. Research confirms that male chest reconstruction does improve psychosocial and physical well-being.[3]

13. Dr. Laidlaw goes on to say that the presence of certain co-occurring mental health conditions could make individuals unable to consent to gender affirming surgery.

[3] Agarwal, C, et al, Quality of life improvement after chest wall masculinization in female-to-male transgender patients: A prospective study using the BREAST-Q and Body Uneasiness Test, J Plast Reconstr Aesthet Surg. 2018 May; 71(5), 651-657. *See also* Tim C. van de Grift et al., Body image in transmen: multidimensional measurement and the effects of mastectomy, journal of sexual medicine 2016; 13, 1778-1786.

Laidlaw Decl. ¶¶ 25, 29. Dr. Laidlaw fails to recognize that when individuals under age 18 seek surgery, it is their parent or guardian that must provide informed consent. Of course, adolescents must also assent to gender confirming surgery. Patients with co-occurring mental health conditions, such as depression, anxiety, substance use disorder, and post-traumatic stress disorder, regularly and appropriately assent to surgical care. Generally, these conditions do not prevent patients from understanding the procedure, the risks and complications of the procedure, and the benefits that they can reasonably expect to achieve from surgery. *See* Schechter Decl. ¶ 38.

14. Dr. Laidlaw and Dr. Levine also suggest that the possible complications of male chest reconstruction mean that it is not safe. *See* Laidlaw Decl. ¶ 28; Levine Decl. ¶ 90. Gender confirming surgeries do not have a particularly high complication rate when compared with analogous procedures for other conditions. For example, a study of 7,905 transgender individuals, of whom 1,047 underwent gender affirming surgery between 2009-2015, revealed an overall complication rate for all surgical procedures of only 5.8%.[4] Looking specifically at male chest reconstruction surgery, two recent studies reveal a complication rate of between 11%-12%.[5] In comparison, a 2005 study of cisgender women undergoing breast reduction found a complication rate of 43%.[6] Likewise, a systematic review of cisgender women undergoing nipple-sparing mastectomy and immediate breast reconstruction using breast implants and acellular dermal matrix, found the following complication rates: 11% skin necrosis, 5% nipple necrosis, 12% infection, 1% hematoma, 5% seroma, 4% explantation, and 9% unplanned return to the operating room.[7] In short, the

[4] Lane, M., et al. Trends in gender-affirming surgery in insured patients in the United States. Plastic and Reconstructive Surgery – Global Open. 2018; 6(4), e1738. doi:10.1097/GOX.0000000000001738.

[5] Berry, M., et al. Female-to-male transgender chest reconstruction: A large consecutive, single surgeon experience. J Plast Reconstr Aesthet Surg. 2012 Jun; 65(6):711-9. doi: 10.1016; Agarwal, C. et al. Quality of life improvement after chest wall masculinization in female-to-male transgender patients: A prospective study using the BREAST-Q and Body Uneasiness Test. J Plast Reconstr Aesthet Surg. 2018 May; 71(5):651-657. doi: 10.1016.

[6] Cunningham, B., et al., Analysis of breast reduction complications derived from the BRAVO study. Plast Reconstr Surg. 2005 May; 115(6):1597-604.

[7] Heidemann, L., et al. Complications following nipple-sparing mastectomy and immediate acellular dermal matrix implant-based breast reconstruction-A systematic review and meta-analysis. Plast Reconstr Surg Glob Open. 2018 Jan 12; 6(1):e1625. doi: 10.1097.

complication rates for gender affirming surgeries are lower than or in the same range as the rates for the same surgeries performed to treat other conditions.

15. Moreover, Dr. Laidlaw and Dr. Levine ignore the health risks and complications that can arise from withholding surgical care, including worsening gender dysphoria; anxiety; depression; and self-harm, suicide attempts, and suicide.

16. Dr. Levine also opines that male chest reconstruction is not effective because the surgery does not fully align a patient's body and gender identity, and thus, cannot possibly cure their gender dysphoria. *See* Levine Decl. ¶ 82. First, Dr. Levine misconstrues the purpose of male chest reconstruction. The goal of the procedure is to reduce gender dysphoria. That a surgery might only alleviate – and not cure – the condition being treated, does not mean that it is not medically necessary. For example, a mastectomy performed on a patient who has a genetic predisposition to cancer (BRCA mutation carriers), does not completely eliminate the risk that the patient will develop cancer. And, chest/breast reconstruction following mastectomy does not result in anatomical structures that perfectly restore those that were removed. For example, breast reconstruction surgery for cancer does not restore the ability to breastfeed. Yet, there is no question that when performed in accordance with the standards of care, a risk-reduction mastectomy and chest/breast reconstruction is highly effective and medically necessary in a patient with one of the BRCA genes. Second, many of my patients who have undergone male chest reconstruction have in fact described total relief from their gender dysphoria.

17. Finally, both Dr. Laidlaw and Dr. Levine suggest that gender confirming surgery is not safe and effective because some patients could later regret their transition and the procedure. Dr. Laidlaw offers no support for his opinion. *See* Laidlaw Decl. ¶ 40. Dr. Levine points to his own experience working with "multiple individuals who have abandoned trans female identity after living in that identity for years," Levine Decl. ¶ 100, and vague references to stories on the internet. That Dr. Levine has seen this happen several times in almost 40 years does not mean that it is a common occurrence among transgender individuals generally or among those who have received gender confirming surgery. All

available research—as well as my own clinical experience—indicates that very few patients experience regret when gender confirming surgery is provided in accordance with the WPATH SOC and by a qualified surgeon. Regret of any kind is rare (0.6% in transgender women and 0.3% in transgender men),[8] but "true regrets," as opposed to regrets due to lack of social or familial acceptance, comprise an even smaller percentage (approximately half this group, roughly 0.3% in transgender women and 0.15% in transgender men).[9] Having performed gender confirming surgeries for over 20 years, I have never had a patient request a reversal of male chest reconstruction.

18. The Djordjevic study cited by Dr. Levine does nothing to undermine the necessity or effectiveness of surgical care for gender dysphoria. That article discusses the experiences of seven patients whose treatment leading up to surgery did not follow the WPATH SOC.[10] Contrary to Dr. Levine's implication, that study reaffirms that the prevailing standards of care are effective at assessing medical necessity for surgical care, ensuring that surgery is not performed on patients that would not benefit from those procedures. Having reviewed the declarations of Dr. Peck and Ms. Reed, and having evaluated D.H. and John via tele-health (which is how I conducted all of my consultations at that time and, given the ongoing concerns regarding COVID-19, tele-health consultations remain routine), both D.H. and John meet each of the criteria for male chest reconstruction surgery under the WPATH SOC and that procedure is medically necessary to treat their gender dysphoria. If I were performing male chest reconstruction surgery on D.H. and John, this is the point at which I would seek prior authorization for the procedure. Although, like

[8] Wiepjes, et. al. The Amsterdam Cohort of Gender Dysphoria Study 1972-2015: Trends in Prevalence, Treatment, And Regrets. J Sex Med. 2018 Apr; 15(4):582-590. doi: 10.1016.

[9] *Id*. at 585, 587 (researchers classified "social regrets" as those experienced by individuals who still identified as transwomen, but reported feeling "ignored by surroundings" or regretted loss of relatives," and classified "true regrets" as those experienced by individuals who "thought gender affirming treatment would be a 'solution' for, for example, homosexuality or [lack of] personal acceptance, but, in retrospect, regretted the diagnosis and treatment").

[10] *See* Djordjevic, M., et al. Reversal Surgery in Regretful Male-to-Female Transsexuals After Sex Reassignment Surgery. J Sex Med. 2016 Jun; 13(6):1000-7. doi: 10.1016. Moreover, the study did not even involve individuals who had undergone male chest reconstruction, but only considered the experience of seven transgender women who underwent genital reconstruction surgeries. *See id.*

any surgeon, I would need to examine D.H. and John in person prior to proceeding with surgery, it is highly unlikely, given their age and medical history, that the examination would uncover an issue requiring a delay or cancellation of the surgery.

19. Dr. Laidlaw also makes much of the fact that if a patient does regret undergoing male chest reconstruction, they will be unable to breastfeed. Laidlaw Decl. ¶ 28. But, individuals are unable to breastfeed for a variety of reasons, such as insufficient glandular tissue or certain medical conditions. Moreover, breast reduction surgery, which as I noted above, is often performed on adolescents, can also leave patients unable to breastfeed.

The Peer-Reviewed Research Indicates that Male Chest Reconstruction is Safe and Effective for Individuals Who Meet the Prevailing Standards of Care

20. Dr. Laidlaw and Dr. Levine suggest that there is no "good quality" literature showing that male chest reconstruction surgery is a safe and effective treatment for individuals with gender dysphoria. Laidlaw Decl. ¶¶ 34, 40; Levine Decl. ¶¶ 69-73. Notably, critical review of the scientific literature is one component as to how surgeons evaluate whether a particular procedure is generally safe and effective and whether it is appropriate or recommended for an individual patient. Not only de we consider the literature *en masse*, but we must also account for our own clinical experience and that of our colleagues, as well as our patients' experiences and input. Here, the existing literature indicates that male chest reconstruction is a safe and effective treatment for individuals with gender dysphoria, including adolescents. My own experience, and the documented experience of clinicians across the globe, is consistent with that literature.

21. Moreover, the quality of the evidence supporting gender affirming surgeries is comparable to that supporting many surgeries and clinical procedures. While prospective, randomized, double-blind, placebo-controlled studies are the gold standard, they cannot be used to evaluate many clinical procedures. There are simply inherent limitations to our ability to conduct such studies in clinical medicine. First, it is unethical to withhold medically necessary care. As such, in many situations, clinicians cannot conduct a study

that uses a control group who is deprived of the treatment being studied. For this reason, and the fact that we do not perform gender-affirming surgery on children, it is particularly unsurprising that "[n]o studies show that affirmation of children (or anyone else) reduces suicide, prevents suicidal ideation, or improves long-term outcomes, as compared to either a 'watchful waiting' or a psychotherapeutic model of response." Levine Decl. ¶ 75. No institutional review board would approve such a study for adults or adolescents since "watchful waiting" amounts to withholding beneficial treatment (and is not an approach taken with adults), and the "psychotherapeutic model" amounts to gender identity conversion efforts, an approach that has been debunked as unsound and harmful. Second, it is not possible to perform a double-blind study of surgeries that modify body parts, nor is there a placebo that can mimic such a surgery – unlike studies that use placebo drug regimens, for example, people will know if they have had an operation or not. Third, for relatively uncommon conditions like gender dysphoria, sample sizes of individuals with the condition who are available to participate in a clinical study tend to be small. This is especially true where treatment for a condition has not been covered by insurance programs and plans, and where additional barriers (such as ongoing stigmatization) prevent patients from accessing care. That very lack of access to the procedure results in there being fewer people who have received treatment and who can participate in a prospective study of that treatment's effect.

22. Dr. Laidlaw and Dr. Levine cite a study by Dhejne *et al.* to imply that because individuals who received gender confirming surgeries had higher morbidity and mortality rates compared to the general population, the surgeries are not effective. Laidlaw Decl. ¶ 35; Levine Decl. ¶ 74. They appear to misunderstand that study. First, the study itself clearly states that it is not intended to evaluate whether gender affirming surgeries are effective treatments. Dhejne *et al*. at e16885.[11] Second, the study includes patients who had surgery

[11] *See Science AMA Series: I'm Cecilia Dhejne a fellow of the European Committee of Sexual Medicine, from the Karolinska University Hospital in Sweden. I'm here to talk about transgender health, suicide rates, and my often misinterpreted study. Ask me anything!*, Reddit.com, July 27, 2017 05:14 ("Despite the paper clearly stating that the study was not designed to evaluate whether or not gender-affirming is beneficial, it has been interpreted

prior to the development of the current standards of care. Third, the fact that gender confirming surgeries do not entirely resolve all possible causes of morbidity and mortality among transgender individuals is completely unsurprising. While surgery can treat gender dysphoria by aligning transgender people's bodies with their gender identity, surgery alone cannot fully eliminate the stigma and discrimination that transgender people face.

23. Moreover, it is rare for any surgery to eliminate morbidity and mortality. For example, people who have surgery to remove a cancerous tumor may still experience higher rates of morbidity and mortality than the general population, but that does not mean that they should not undergo the surgery. And, those who receive such surgery generally have reduced morbidity and mortality compared to those with the same condition who do not, even if morbidity and mortality for both groups is higher than average. For instance, one study cited by Dr. Levine concluded that gender-affirming surgeries "may reduce psychological morbidity for some individuals while increasing it for others."[12] The fact that surgery does not always reduce morbidity for everyone who receives it does not mean that the surgery is not safe or effective, particularly given the number of potential confounding factors that can impact morbidity. Similarly, the continued existence of elevated morbidity and mortality rates, compared to the population at large, say nothing about whether a treatment is a safe and effective way to treat a particular condition.

24. Dr. Laidlaw also points to a 2016 decision of the Department of Health & Human Services' Centers for Medicare and Medicaid Services to support his claim that gender confirming surgeries are not effective. Laidlaw Decl. ¶ 36. But, Laidlaw takes that decision out of context and misrepresents it conclusions. In 2014, an impartial adjudicative board in the Department of Health & Human Services concluded, based on decades of studies, that surgical care to treat gender dysphoria is safe, effective, and medically

as such."), https://www.reddit.com/r/science/comments/6q3e8v/science_ama_series_im_cecilia_dhejne_a_fellow_of/.

[12] 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).

necessary.[13] Dep't of Health & Human Servs., Departmental Appeals Bd., Appellate Div., Decision No. 2676 (May 30, 2014), hhs.gov/sites/default/files/static/dab/decisions/board-decisions/2014/dab2576.pdf. As a result, CMS started covering surgical care for gender dysphoria and continues to provide that coverage, including for patients in my practice. The decision Laidlaw cites was focused on whether to issue national standards for determining the medical necessity of surgical treatment for gender dysphoria in Medicare recipients. CMS declined to create those standards based on concerns that are specific to the Medicare population, typically people over 65 years old, because "older adults may respond to health care treatments differently than younger adults." Ctrs. for Medicare & Medicaid Servs., Decision Memo for Gender Dysphoria and Gender Reassignment Surgery, 57 (Aug. 30, 2016). "These differences can be due to, for example, multiple health conditions or co-morbidities, longer duration needed for healing, metabolic variances, and impact of reduced mobility." *Id*. Thus, the CMS memorandum concluded that the appropriateness of surgical care for this population should be determined on an individualized basis.

25. Notably, I have performed gender confirming surgeries on a number of Medicare beneficiaries in recent years. Indeed, most medical and surgical care provided to patients should be individualized, taking into account each patient's unique clinical circumstances. In contrast, the exclusion challenged in this case does not evaluate the medical necessity of surgical care for gender dysphoria on an individualized basis. It categorically excludes all coverage regardless of an individualized showing of medical necessity.

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[13] That decision also discussed the quality of data demonstrating the efficacy of surgical care to treat gender dysphoria, noting regardless of whether the studies were randomized double-blind trials, there was sufficient evidence to prove "a consensus among researchers and mainstream medical organizations that transsexual surgery is an effective, safe and medically necessary treatment for [gender dysphoria]." Dep't of Health & Human Servs., Departmental Appeals Bd., Appellate Div., Decision No. 2676, at 20 (May 30, 2014), hhs.gov/sites/default/files/static/dab/decisions/board-decisions/2014/dab2576.pdf.

D.H. and John Doe Meet the Requirements for Male Chest Reconstruction

26. Based on review of the declarations and materials provided by their treating providers and my clinical assessment of D.H. and John Doe, it is my professional opinion that male chest reconstruction surgery is a safe, effective, and medically necessary treatment for each of them. While I would need to perform an in-person exam prior to surgery, it would be highly unusual for that exam to reveal any contraindication in an adolescent patient.

27. Dr. Laidlaw baldly concludes that D.H. and John were not sufficiently evaluated and treated prior to being recommended for surgery. There is nothing in the declarations of Dr. Cronyn, Tamar Reed, and Dr. Peck, nor in the medical records from the office of Dr. Veenod Chulani, to support that assertion. Those documents indicate that D.H. and John have been evaluated and treated by medical doctors and mental health professionals who have significant experience working with transgender adolescents.

28. In addition, as I indicated in my previous declaration, I see no evidence that D.H. or John has a co-occurring mental health condition that would contraindicate surgery. *See* Schechter Decl. ¶¶ 43-44. Nor do I have any reason to suspect that these conditions render them unable to assent to male chest reconstruction surgery. *See id.*

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

Executed this 23rd th day of October, 2020 at Chicago, Illinois.

Loren S. Schechter, M.D.