APPEAL NO. 21-15668

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

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

Plaintiffs-Appellants,

v.

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

Defendant-Appellee

On Appeal from the United States District Court
for the District of Arizona
Case No. 4:20-cv-335-SHR
Hon. Scott J. Rash

BRIEF OF *AMICUS CURIAE* SOCIETY FOR EVIDENCE BASED MEDICINE SUPPORTING AFFIRMANCE IN FAVOR OF DEFENDANT-APPELLEE

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Pursuant to Fed. R. App. P. 29(a)(2), Plaintiffs-Appellants and Defendant-Appellee have consented to this filing.

IDENTITY AND INTEREST OF AMICUS CURIAE[1]

The Society for Evidence-based Gender Medicine ("SEGM") is a non-profit professional association promoting safe, compassionate, ethical, evidence-based healthcare for children, adolescents, and young adults with gender dysphoria. Over 100 clinicians and researchers from multiple specialties, hailing from 10 countries, supply SEGM's expertise.[2]

There is broad scientific consensus that hormonal and surgical interventions for gender dysphoria, known as "gender-affirming care," are supported by only low-quality evidence. This consensus gives rise to SEGM's concern about providing poorly-evidenced interventions, many of which are risky and irreversible, to gender-dysphoric youth whose identities and pre-frontal cerebral cortices are still evolving, and who often struggle with other significant co-occurring mental health challenges.[3]

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[1] Pursuant to Fed. R. App. P. 29(a)(4)(e), no counsel for any party authored this brief in whole or in part, and no person or entity, other than *amicus* or its counsel, made a monetary contribution intended to fund the preparation or submission of this brief.

[2] Where available, this Brief includes links to the articles cited. If the Court requires access to any article for which a link is not provided, SEGM will provide it.

[3] The United States Supreme Court acknowledges this developmental fact: "It is increasingly clear that adolescent brains are not yet fully mature in regions and systems related to higher-order executive functions such as impulse control, planning ahead, and risk avoidance." *Miller v. Alabama*, 567 U.S. 460, 472, n.5 (2012) (*quoting* Am. Psych. Ass'n amicus brief).

Proponents of medical gender affirmation, such as masculinizing mastectomies,[4] assert that all available medical technologies should be deployed to achieve a physical appearance that matches one's internal sense of gender identity (which can reside anywhere on the male-female continuum or outside it, be binary or non-binary, and fixed or shifting/evolving). They believe that medical treatments should begin early to prevent or stall puberty—an intervention leading to cross-sex hormones in nearly every case, often followed by irreversible surgeries. They do not view the unknown risk/benefit profile of these interventions as a barrier but assert that patients should have the right to exercise body autonomy regardless of their age, mental health status, or other complicating factors.

SEGM recognizes the right of mature adults to undergo gender-affirming interventions despite the low quality of evidence on which the interventions are based but is very concerned about applying experimental procedures to vulnerable youth, whose gender identity is still developing and whose ability to meaningfully consent to interventions with unknown long-term outcomes is highly uncertain. SEGM formed this conclusion after thorough evaluation of the evidence, further informed by direct experience working with this population.

SEGM's concern for gender-dysphoric youth is reinforced by a recent surge of minors with a new, poorly understood variant of gender dysphoria, complicated by

[4] Appellants' use of "male chest reconstruction" is inaccurate. Neither Appellant presents with a male chest that requires reconstructive surgery. Instead, Appellants seek to make their female chest anatomy appear masculine through surgery.

multiple mental health issues. This further amplifies the risks of applying irreversible interventions not based on quality, reliable scientific evidence.

As Amicus, SEGM hopes to serve the Court by highlighting, curating, and contextualizing the relevant evidence in an objective manner.

ARGUMENT

Young people struggling with gender dysphoria deserve respect, compassion, and high-quality, evidence-based care exemplifying "conscientious, explicit, and judicious use of current best evidence in making decisions about the care of individual patients."[5] Unfortunately, the quality of evidence in gender medicine is very low, and the field has become politicized, hindering the pursuit of evidence-based medicine.

Gender medicine has experienced an intensifying scientific debate over the past 24 months. Dozens of scientific publications have challenged the practice of treating minors with invasive interventions with unknown risk/benefit profiles that irreversibly impact future reproductive and sexual health.[6] Besides serious concerns about the risks these interventions pose to fertility, bone, and brain development, and the well-documented increased risk for heart attacks and strokes,[7] new risks of potential lasting psychological harm have also emerged: increasing numbers of young

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[5] D.L. Sackett, et al. *Evidence Based Medicine: What It Is and What It Isn't*, 312 BRIT. MED. J., Issue 7023, 71 (Jan. 1996).

[6] SEGM, *Studies – Scientists Debate Medical Affirmation of Minors*.

[7] Michael Biggs, *Revisiting the Effect of GnRH Analogue Treatment on Bone Mineral Density in Young Adolescents with Gender Dysphoria,* J. PED. ENDOCRINOLOGY AND METABOLISM (Apr. 26, 2021). *See also generally,* SEGM, *Studies – Health Risks of Medical and Surgical Gender Reassignment* (collecting linked sources).

patients who reidentified with their sex upon reaching maturity[8] are voicing deep regret about the loss of their breasts, sex organs, and irreversible changes to their physical appearance and voice.

These debates led to significant changes in clinical practice worldwide. The Karolinska Hospital in Sweden—the research and teaching hospital of the Karolinska Institute that grants the Nobel Prize in Medicine—suspended all pediatric gender transitions outside research settings effective May 1, 2021.[9] Finland, another leader of pediatric medical transition, revised its minors' treatment guidelines in 2020, stating psychotherapy should be first-line treatment, delaying surgery until adulthood, and urging caution about the uncertainties of medical transition for those age 25 and under due to ongoing brain development.[10] England paused pediatric medical transitions in late 2020, and the U.K. National Health Service (NHS) formed an independent multi-disciplinary group to re-evaluate the practice of pediatric transitions (the "Cass Review").[11]

The experience of these European countries as pioneers of medical transition and their early research spurred gender affirmation treatments as the primary and

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[8] *See* Elie Vandenbussche, *Detransition-Related Needs and Support: A Cross-Sectional Online Survey*, J. HOMOSEXUALITY (Apr. 30, 2021). *See also generally,* SEGM, *Studies – Health Risks of Medical and Surgical Gender Reassignment* (collecting linked sources).

[9] SEGM, *Sweden's Karolinska Ends All Use of Puberty Blockers and Cross-Sex Hormones for Minors Outside of Clinical Studies* (May 5, 2021).

[10] SEGM, *One Year Since Finland Broke with WPATH "Standards of Care"* (July 2, 2021).

[11] The Cass Review, *Independent Review of Gender Identity Services for Children and Young People*.

often sole treatment for gender-dysphoric patients. Now, however, Europe recognizes the emerging problems and retreats from invasive treatments of vulnerable minors.

That several U.S. medical societies persist in endorsing treatments[12] Europe now severely limits does not establish consensus in the medical community supporting gender affirmation surgery for minors. Physicians regularly contact SEGM, deeply concerned that medical societies are endorsing non-evidence-based, irreversible, and risky gender reassignment interventions to distressed and vulnerable minors. They fear history is repeating itself, with medical societies first enthusiastically endorsing the use of risky drugs[13] and invasive surgeries[14] on vulnerable people, only to reverse course later—a process which has, in some instances, taken decades to crest. The delay in recognizing harms is especially concerning in this case, since many adverse outcomes of gender reassignment (besides the immediate side-effects) take nearly a decade to materialize.[15]

After reviewing the available evidence, SEGM concluded that gender-reassignment surgeries, including masculinizing mastectomies, cannot be considered safe, effective, and medically necessary for minors. SEGM asserts that compassion for gender-dysphoric youth is providing evidence-based medicine that meets the same

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[12] James M. Cantor, *Transgender and Gender Diverse Children and Adolescents: Fact-Checking of AAP Policy*, 46 J. SEX & MARITAL THERAPY 307, 313 (2020).

[13] Ronald Hirsch, *The Opioid Epidemic: It's Time to Place Blame Where It Belongs*, 114 MISSOURI MEDICINE, Issue 2, 82–90 (Mar.-Apr. 2017), available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6140023/.

[14] BBC News, *The Strange and Curious History of Lobotomy* (Nov. 8, 2011).

[15] *See* Cecilia Dhejne, et al., *Long-Term Follow-up of Transsexual Persons Undergoing Sex Reassignment Surgery: Cohort Study in Sweden*, 6 PLOS ONE, Issue 2, 5 (Feb. 2011).

high bar required of all significant medical interventions: the benefits must outweigh the risks.

I. GENDER DYSPHORIA IN ADOLESCENT FEMALES WITH MENTAL HEALTH PROBLEMS HAS SURGED FOR REASONS THAT REMAIN POORLY UNDERSTOOD.

In under a decade, there has been a sharp increase in cases of gender-dysphoric youth seeking gender reassignment. The newly presenting cases are markedly different from historical presentations, with a disproportionately large increase in adolescent females with significant mental health and neurocognitive problems.[16] Those cases present much like the Appellants do, and these types of cases were **explicitly disqualified** from medical gender reassignment in the treatment protocol[17] used in the seminal study[18] for the practice for pediatric gender transition.

As recently as 2013, the DSM-5 diagnostic criteria for gender dysphoria estimated this condition occurs in 0.002%-0.014% adults, with females representing

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[16] *See* Kenneth J. Zucker, *Adolescents with Gender Dysphoria: Reflections on Some Contemporary Clinical and Research Issues*, 48 ARCHIVES OF SEXUAL BEHAVIOR, Issue 7, 1983–92 (Oct. 2019); Nastasja M. de Graaf and Polly Carmichael, *Reflections on Emerging Trends in Clinical Work with Gender Diverse Children and Adolescents*, 24 CLINICAL CHILD PSYCH. AND PSYCHIATRY, Issue 2, 353–64 (Apr. 2019). *See also generally*, SEGM, *Studies–Novel Epidemiological Trend: adolescent-onset gender dysphoria with mental health comorbidities* (collecting linked sources).

[17] Peggy Cohen-Kettenis, et al. *The Treatment of Adolescent Transsexuals: Changing Insights*, 5 J. SEXUAL MED., Issue 8, 1894 (Aug. 2008).

[18] Annelou de Vries et al. *Puberty Suppression in Adolescents with Gender Identity Disorder: A Prospective Follow-Up Study*, 8 J. SEXUAL MED., Issue 8, 2276–83 (Aug. 2011).

the lower band (2-3 per 100,000 adult females).[19] The prevalence of gender dysphoria in children and adolescents has never been estimated.[20]

In the mid-2000s, pediatric gender clinicians worldwide began to report increasing numbers of pediatric referrals. They also reported that the types of cases presenting for care began to change. Previously, most were prepubescent boys, but the newly presenting cases are overrepresented by adolescent females, the majority of whom have significant mental health problems and neurocognitive comorbidities, such as autism-spectrum disorder or ADHD.[21] This trend became particularly pronounced in 2014 and continues to grow. [*See* Figure 1.]

In 2017, the Centers for Disease Control and Prevention found that 1.8% of U.S. high schoolers reported a transgender identity;[22] a 2021 study reports that nearly 10% of U.S. youth may be transgender-identified.[23]

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[19] American Psychiatric Ass'n, *Diagnostic and Statistical Manual of Mental Disorders,* p. 454 (5th ed., American Psychiatric Press (2013)).

[20] This Brief refers to "pediatrics" as the practice of medicine for patients under age 18; "children" as pre-pubescent; "adolescents" as pubescent individuals; and "young people" and "youth" as those 25 and under, consistent with the common practice of treating 18–25-year-olds as distinct from mature adults.

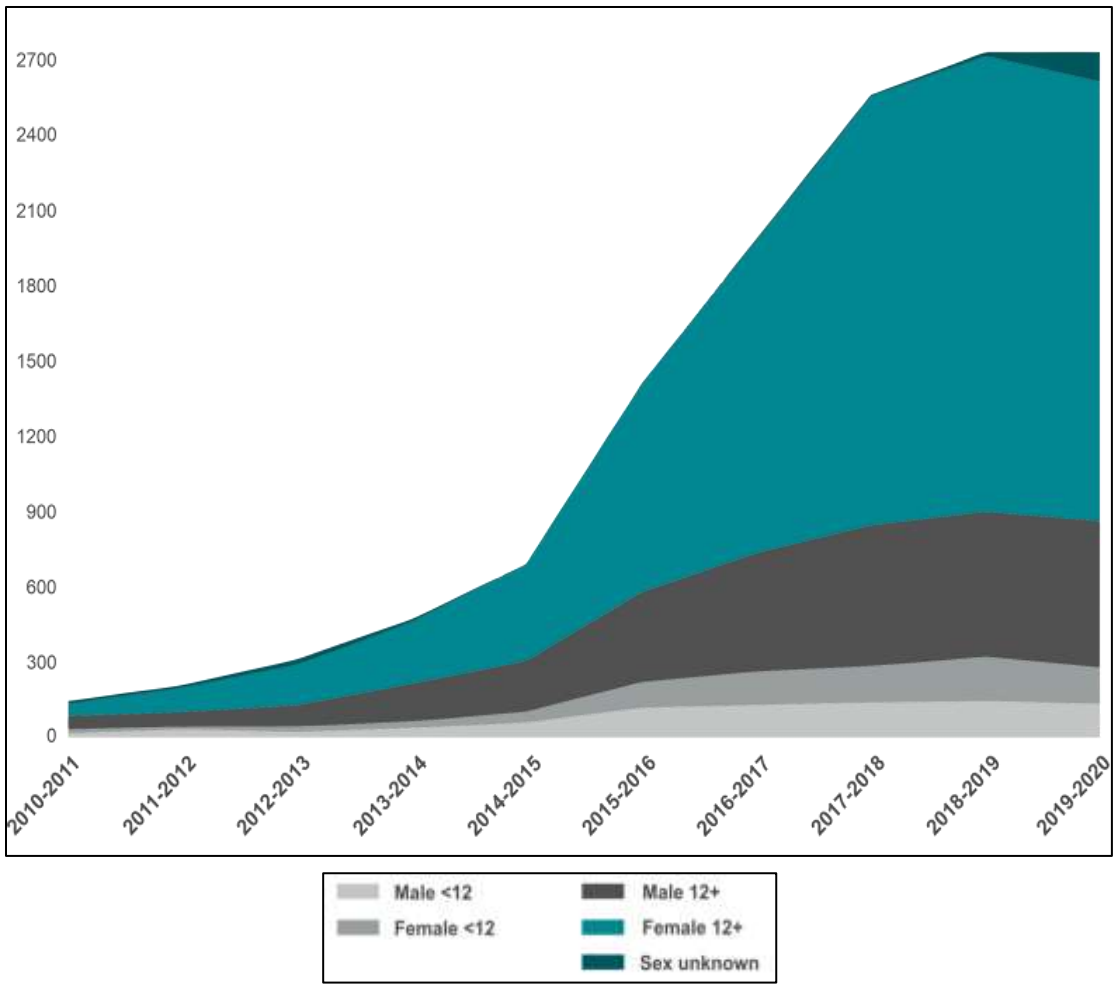
[21] *See* de Graaf & Carmichael, *supra* n.16, p. 7; John F. Strang et al., *Increased Gender Variance in Autism Spectrum Disorders and Attention Deficit Hyperactivity Disorder,* 43 ARCHIVES OF SEXUAL BEHAVIOR 8, 1529 (Nov 2014).

[22] Michelle M. Johns et al., *Transgender Identity and Experiences of Violence Victimization, Substance Use, Suicide Risk, and Sexual Risk Behaviors among High School Students—19 States and Large Urban School Districts, 2017,* 68 MORBIDITY AND MORTALITY WEEKLY REPORT 3, 67 (Jan. 2019).

[23] Kacie M. Kidd et al., *Prevalence of Gender-Diverse Youth in an Urban School District,* 147 PEDIATRICS, Issue 6, 2 (June 2021).

The sharp rise in youth reporting transgender identification also increased the numbers seeking to permanently alter their bodies through hormonal and surgical gender reassignment. The U.K. pediatric Gender Identity Development Service ("GIDS") reported a 1,800% increase in patients seeking gender reassignment in less than 10 years, which rose sharply since 2015:

Figure 1: Referrals to GIDS, Under Age 18 (U.K.)[24]



[24] *See* SEGM website, *https://segm.org/*.

The U.S. has seen explosive growth in the numbers of providers offering pediatric gender reassignment, from 1 clinic in 2006 to well over 60, with many more individual, unaffiliated providers offering these services.

There is a vigorous scientific debate regarding the causes of this marked epidemiological change. Some assert this increase merely reflects society's increased visibility and acceptance of transgender identities; others theorize it is related to maladaptive coping and social influence, known to disproportionately affect adolescent females.[25] It is not known which cases from this novel patient population (or how many) will persist as transgender-identified long-term and which will re-identify with their biological sex. In the past, 67% of children meeting the diagnostic criteria for gender dysphoria no longer had the diagnosis as adults, with an even higher, 93% rate of natural resolution of gender-related distress for the less significantly impacted,[26] many realizing as adults that they are gay, lesbian, or bisexual.[27] The possibility of an identity change upon reaching maturity[28] is particularly concerning for this case, since the masculinizing mastectomies sought are irreversible.

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[25] Lisa Littman, *Parent Reports of Adolescents and Young Adults Perceived to Show Signs of a Rapid Onset of Gender Dysphoria,* 13 PLOS ONE, Issue 8 (Aug. 2018).

[26] Kenneth J. Zucker, *The myth of persistence: Response to "A critical commentary on follow-up studies and 'desistance' theories about transgender and gender non-conforming children" by Temple Newhook et al (2018),* 19 INT'L J. TRANSGENDERISM, Issue 2, 4, table 1 (2018).

[27] *See* Jiska Ristori and Thomas D. Steensma, *Gender Dysphoria in Childhood*, 28 INT'L REVIEW OF PSYCH., Issue 1, 3 (Jan. 12, 2016).

[28] Singh, D., et al., *A Follow-Up Study of Boys With Gender Identity Disorder*, 12 FRONTIERS IN PSYCHIATRY, Issue 12 (Mar. 2021).

Another key concern is that most recently-presenting cases of adolescent gender dysphoria are accompanied by significant mental health comorbidities, and frequently lack a documented history of transgender identity beginning in early childhood—both presentations were explicitly disqualified from gender-affirming interventions in the foundational research on the topic.[29] Therefore, it is not yet known whether treating such cases with irreversible masculinizing mastectomies will help or hurt them long-term, but the medical risks and harms documented to date (*e.g.*, over 40% permanent loss of sensation),[30] and the risk of profoundly negative psychological effects of regret[31] in those who reidentify with their sex upon reaching maturity, and are left with permanently changed bodies and unknown future fertility, cannot be ignored.

II. THE BRIEF AND QUESTIONABLE HISTORY OF PEDIATRIC GENDER TRANSITION DOES NOT SUPPORT APPELLANTS' ARGUMENTS.

A. The rationale for gender transition in minors was to improve suboptimal transition outcomes of mature adults.

Medical transitioning of minors is a relatively novel phenomenon. Before the mid-1990s, medical and surgical transition was largely reserved for mature adults, with

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[29] Cohen-Kettenis, et al., *supra* n.17, p.1884.

[30] 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, Issue 5, 431 (May 2018).

[31] Vandenbussche, *supra* n.8.

transitions rarely occurring before age 25. A key long-term study reported the average age of transition as 33 for females, and 36 for males.[32]

The data on long-term outcomes of adult transitioners are mixed. One study found that "[gender reassignment] may reduce psychological morbidity for some individuals while increasing it for others."[33] Another quality study that monitored transitioned individuals for 30 years found high rates of post-transition suicide (19 times the expected norm overall[34], and 40 times the norm for biological females[35]), and significantly elevated all-cause mortality, including increased death rates from cardiovascular disease and cancer, although causality could not be established. Concerningly, these negative outcomes did not become apparent until 10 years after transition.[36]

In 1996, Dutch researchers posited that medical transition would result in more successful outcomes if it were initiated during adolescence. The Dutch reasoned "early intervention" would enhance psychosocial development of gender-dysphoric youth and cosmetic outcomes would be enhanced: "the physical treatment outcomes following interventions in adulthood is far less satisfactory than when treatment is

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32 Dhejne et al., *supra* n.15*,* p.4, table 4.

33 R. Simonsen, et al., *Long-Term Follow-up of Individuals Undergoing Sex Reassignment Surgery: Psychiatric Morbidity and Mortality*, 70 NORDIC J. PSYCH., Issue 4, 1 (2016).

34 Dhejne et al., *supra* n.15, p.5, table 2.

35 *Id.,* supplementary table s1.

36 *Id.,* p.5.

started at an age at which secondary sex characteristics have not yet been (fully) developed."[37]

The Dutch began testing their theories and published papers about their ongoing progress.[38] Their research culminated in their final 2014 paper, which described the outcomes of 55 youths treated with hormonal and surgical gender-reassignment interventions.[39] This paper (known as "the Dutch study"), and the treatment protocol on which it was based ("the Dutch protocol") became the *sole basis* for the "gender-affirmative" treatment of gender-dysphoric youth with hormones and surgeries. Despite the Dutch study's significant limitations outlined below, this experimental protocol entered mainstream medical practice, and, critically, began to be applied to increasingly complex cases for which it was never intended.

B. The Dutch study—the sole basis for medical "gender-affirmation" of minors—explicitly disqualified adolescents with mental health problems.

The Dutch believed that only adolescents with an early-childhood onset of gender dysphoria that persisted into puberty and was not complicated by significant mental health problems would benefit from gender reassignment.[40] To reduce the risk of inappropriately medically transitioning "false positives," the Dutch researchers

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[37] Henriette A. Delemarre-van de Waal and Peggy T. Cohen-Kettenis, *Clinical Management of Gender Identity Disorder in Adolescents: A Protocol on Psychological and Paediatric Endocrinology Aspects*, 155 EURO. J. ENDOCRINOLOGY, suppl 1, S131 (Nov. 2006).

[38] de Vries et al. *supra* n.18.

[39] Annelou de Vries et al., *Young Adult Psychological Outcome After Puberty Suppression and Gender Reassignment*, 130 PEDIATRICS, Issue 4, 696–704 (Oct. 2014).

[40] Cohen-Kettenis, *supra* n.17.

designed a rigorous screening protocol, which **disqualified** cases where gender distress only emerged around adolescence or was accompanied by mental health problems.[41]

This carefully vetted, highly selected group of well-adjusted adolescents became eligible for puberty suppression at age 12; cross-sex hormones at age 16; and surgeries at age 18. Importantly, all adolescents received extensive expert psychological support throughout the treatment course.[42]

C. The Dutch study reported only modest improvements in function while underreporting adverse outcomes.

One year following surgery, the Dutch evaluated the psychological function of 55 youths who successfully completed the final step of the protocol, surgery.[43] The study reported resolution of gender dysphoria and high levels of psychological function, "comparable to same-age peers" in the Dutch population.[44] These positive outcomes quickly propelled the study and the protocol to international attention. However, the Dutch study suffers from several serious limitations:

- Outcomes of youths more likely to have been harmed by the treatment protocol were not accounted for. The study excluded one case of post-surgical death and 3 cases of obesity/diabetes that developed during hormonal treatments. In addition, 5 youths did not engage with the

41 *Id.*
42 de Vries et al., *supra* n.39.
43 *Id.*
44 *Id.,* p.702.

researchers or dropped out.[45] This represents a loss of 13% of the original sample 70[46]—cases with psychological outcomes that were likely worse than those included in the study.

- There was only 1.5-year average postsurgical follow-up of psychological function,[47] and no evaluation of physical health outcomes, despite known health risks.[48]
- Actual improvements in psychological function were small. Depression, anxiety, and anger scores did not improve. Global function improved—but remained in the same clinical range of 71-80 *(no more than a slight impairment in functioning)* both before and after treatment.[49] While the Dutch reported that *post-treatment* psychological function was comparable to peers, they did not report on the *pre-treatment* psychological function relative to peers. The review of the subjects' baseline scores strongly suggest that on average, they were in the healthy psychological range even before the treatment began, likely owing to the stringent selection protocol described above.
- There was no control group, making it impossible to determine whether medical interventions, psychological treatments, or the passage of time

45 *Id.*, p.697.
46 de Vries et al., *supra* n.18.
47 de Vries et al., *supra* n.39, p.698, table 1.
48 SEGM, *Studies – Health Risks of Medical and Surgical Gender Reassignment*.
49 de Vries et al., *supra* n.18, p.700, table 3.

contributed to reported improvements (children's psychological problems tend to decrease as they get older).[50] At least three related studies indicate that gender-dysphoric adolescents receiving *no* medical interventions also experienced improvements.[51] One study reported on 14 adolescents who sought gender reassignment, but were disqualified from treatment due to "psychological or environmental factors."[52] The study found that at follow up, 11 of the 14 no longer wished to transition, and 2 others only slightly regretted not transitioning.[53]

- As few as 32 of the 55 subjects provided answers to key psychological outcome questions.[54] This further shrinks the already small sample size on which the claims of psychological benefits are based and may also introduce bias.

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50 Thomas Achenbach, Leslie Rescorla, *Manual for the ASEBA School-Age Forms & Profiles,* University of Vermont, Research Center for Children, Youth, & Families, p.183 (2001).

51 Rosalia Costa et al., *Psychological Support, Puberty Suppression, and Psychosocial Functioning in Adolescents with Gender Dysphoria*, 12 J. SEXUAL MED., Issue 11, 2206–14 (2015); Yolanda L. S. Smith et al., *Adolescents with Gender Identity Disorder Who Were Accepted or Rejected for Sex Reassignment Surgery: A Prospective Follow-up Study*, 40 J. AM. ACAD. OF CHILD & ADOLESCENT PSYCH., Issue 4, 472–81 (Apr. 2001); Tim C. van de Grift, et al., *Effects of Medical Interventions on Gender Dysphoria and Body Image: A Follow-Up Study*, 79 PSYCHOSOMATIC MED., Issue 7, 815–23 (Sept. 2017).

52 Smith et al., *supra* n.50, p.473.

53 *Id.*, p.477.

54 de Vries et al. *supra* n.39, p.700, table 3.

Notably, there was an attempt to replicate the protocol at one of the world's preeminent gender clinics, GIDS in the U.K., but the experiment failed at the puberty blocker phase, without showing any positive psychological improvements.[55]

Despite these profound limitations, the 2014 Dutch study became the sole basis for the practice of medical transitioning of minors worldwide—a practice that has rapidly expanded in the last several years. The Dutch study, along with its 2011 predecessor[56] are the *only* studies cited by the Endocrine Society treatment guidelines as evidence of the benefit of medically transitioning gender-dysphoric adolescents.[57]

In summary, the Dutch study is a weak basis for the practice of gender-affirmation of youth, including provision of masculinizing mastectomies. Further, since the Dutch protocol excluded adolescents with serious mental health problems, and did not provide surgeries on those under 18, neither the study itself nor the Endocrine Society's own treatment recommendations can be used to support Appellants' desire to have masculinizing mastectomies: their situations clearly place them outside the parameters of the population for whom the Dutch protocol was designed.

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[55] Polly Carmichael et al., *Short-Term Outcomes of Pubertal Suppression in a Selected Cohort of 12- to 15-Year-Old Young People with Persistent Gender Dysphoria in the UK*, 16 PLOS ONE, Issue 2, 1 (Feb. 2021).

[56] de Vries et al., *supra* n.39.

[57] Wylie C. Hembree et al., *Endocrine Treatment of Gender-Dysphoric/Gender-Incongruent Persons: An Endocrine Society Clinical Practice Guideline*, 102 J. OF CLINICAL ENDOCRINOLOGY & METABOLISM, Issue 11, 3882, 3884 (Dec. 2017).

III. MASCULINIZING MASTECTOMIES FOR MINORS ARE AN EXPERIMENTAL INTERVENTION BASED ON LOW QUALITY EVIDENCE.

The WPATH and the Pediatric Endocrine Society (collectively hereafter "Appellants' Amici") claim proven benefits of masculinizing mastectomies for minors. However, the evidence of this is weak and inconclusive for adults, and virtually nonexistent for minors.

Below we provide a brief overview of what is known about all gender-affirmative surgeries (including masculinizing mastectomies), and an overview of a much more limited body of evidence regarding masculinizing mastectomies.

A. Long-term evidence regarding gender-affirming surgeries (which includes masculinizing mastectomies) is of low quality and inconclusive.

Evidence-based care relies on systematic reviews of evidence to minimize biases and mistakes inherent in individual studies.[58] Two recent, high quality, independent systematic reviews of evidence for gender-affirming surgery deemed the quality of the evidence to be low, and the benefits, uncertain.

1. Health and Human Services (HHS) systematic review found the evidence for adult gender affirmation surgery inconclusive.

In 2016, the HHS conducted a systematic review of evidence for gender-affirming surgeries in adults. The review found "the clinical evidence is inconclusive,"

[58] Julian P. T. Higgins et al., *Cochrane Handbook for Systematic Reviews of Interventions,* eds. (Wiley-Blackwell 2008).

for the benefits of surgery and cautioned, "we cannot exclude therapeutic interventions [hormones and surgeries] as a *cause* of the observed excess morbidity and mortality."[59] HHS refused to mandate coverage for adult surgeries.[60]

2. The highly respected Hayes Review found the evidence for surgeries for minors and adults inconclusive.

In 2018, the Hayes Corporation ("Hayes"), which reviews treatments for insurance payers for 84% of insured Americans,[61] conducted a systematic review of evidence for gender reassignment surgery.[62] Hayes evaluated all seven aspects that AHCCCS must consider when weighing scientific evidence, per Arizona Administrative Code R9-22-203B, rating the quality of evidence from "A" (strongest) to "D2" (weakest).

The evidence for gender reassignment surgery for minors earned the lowest "D2" rating: "insufficient published evidence to assess the safety and/or impact on health outcomes or patient management."[63] The rating of the same surgeries for adults was "C," indicating "[p]otential but unproven benefit." Hayes noted, "substantial uncertainty remains about safety and/or impact on health outcomes

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59 U.S. Department of Health and Human Services, *Decision Memo for Gender Dysphoria and Gender Reassignment Surgery (CAG-00446N)*, Centers for Medicare & Medicaid Services, 46 (Aug. 30, 2016) ("HHS Decision Memo").

60 *Id.*

61 Hayes, Inc., *Sex Reassignment Surgery for the Treatment of Gender Dysphoria*, HAYES DIRECTORY (Aug. 1, 2018).

62 Hayes, Inc., *The Hayes Difference*, https://www.hayesinc.com/about-hayes/.

63 Hayes Inc., *The Hayes Rating*, https://www.hayesinc.com/about-hayes/.

because of poor-quality studies, sparse data, conflicting study results, and/or other concerns."[64]

Since the HHS and the Hayes reviews came out, one long-term study on surgical outcomes was published, initially reporting a long-term improvement in mental health attributed to gender affirmation surgery. However, after over a dozen scientists identified serious methodological oversights in the analysis,[65] and results were re-analyzed using more rigorous methods, this finding was invalidated. The journal issued an official correction to the study, stating the results demonstrated "no advantage of surgery in relation to subsequent mood or anxiety disorder-related health care visits or prescriptions or hospitalizations following suicide attempts in that comparison."[66]

There was also a non-statistically significant, but clinically concerning near-doubling of serious suicide attempts requiring hospitalization in the group of individuals who had undergone surgery, compared to those who had not. [67]

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64 *Id.*

65 SEGM, *Correction of a Key Study: No Evidence of "Gender-Affirming" Surgeries Improving Mental Health* (Aug. 30, 2020) (discussing criticism and correction of the Bränström study). Appellee's expert, Dr. Michael Laidlaw, was among those critiquing the study. *See* Andre Van Mol et al., *Gender-Affirmation Surgery Conclusion Lacks Evidence*, 177 AM. J. PSYCH., Issue 8, 765-766 (2020).

66 *Correction to Bränström and Pachankis*, 177 AM. J. PSYCH., Issue 8, 734–734 (2020).

67 Bränström, Richard, and 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. PSYCH., Issue 8, 772 (Aug. 2020), table 1.

B. The body of evidence specific to masculinizing mastectomies, especially for minors, is short-term and inconclusive, with uncertain long-term impact on quality of life and mental health.

Appellants' Amici rely on two recent studies not considered by the HHS and Hayes reviews to support masculinizing mastectomies for minors: Olson-Kennedy et al. (2018),[68] and Agarwal et al. (2018).[69] [Doc. 9, p. 11; Doc. 8, p. 18.] Both studies suffer from significant limitations as described below. Appellants' Amici also overstate the weight of a publication[70] that assessed studies on masculinizing mastectomies available to date, stating that the publication "convincingly concluded" the benefits.[71] However, the referenced publication's authors state that the conclusion was based on a "small amount of available data."[72]

1. The study by Olson-Kennedy et al. did not use validated tools to demonstrate improved health or quality of life resulting from masculinizing mastectomies for youth.

Olson-Kennedy et al. (2018) is the only U.S. study evaluating the outcomes of masculinizing mastectomies for gender dysphoric youth.[73] The study examined outcomes of 68 patients who underwent masculinizing mastectomies, some as young

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68 Olson-Kennedy et al., *supra* n.30.

69 Cori A. Agarwal 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,* 71 J. PLASTIC, RECONSTRUCTIVE & AESTHETIC SURGERY, Issue 5, 651-77 (May 2018).

70 Simone Mahfouda, et al. *Gender-Affirming Hormones and Surgery in Transgender Children and Adolescents*, 7 THE LANCET DIABETES & ENDOCRINOLOGY, Issue 6, 484–98 (June 2019).

71 Doc. 8, pp.19-20.

72 Mahfouda, et al., *supra* n.69, p.1.

73 Olson-Kennedy, et al, *supra* n.30.

as 13, comparing them to a group of gender dysphoric youth who had not yet had surgery. Those who had surgery were found to have significantly less "chest dysphoria."[74]

WPATH refers to "chest dysphoria" as a "condition that describes significant distress related to breasts." [Doc. 8, p. 18.] However, there is no recognized medical condition known as "chest dysphoria" in any standard diagnostic classifications. Further, the "chest dysphoria scale" is a non-standard measure constructed by the study authors; it has unclear validity and uncertain clinical implications. The study suffers from additional limitations including:

- Significant loss of subjects to follow-up, with nearly 30% of the original sample of 93 missing, potentially masking adverse outcomes;
- Lack of long-term follow-up: less than 2-year average post-surgery follow-up may overstate positive results: studies of regret in dysphoric adults show that on average, regret emerges around the 8-year mark;[75]
- A significant rate of complications, including over 40% of respondents reporting permanent loss of sensation, which may erode satisfaction as minors become sexually active.

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74 *Id.*

75 Cecilia Dhejne et al., *An Analysis of All Applications for Sex Reassignment Surgery in Sweden, 1960–2010: Prevalence, Incidence, and Regrets*, 43 ARCHIVES OF SEXUAL BEHAVIOR, Issue 8, 1535–45 (May. 2014).

Appellants' Amici's reliance on the Olson-Kennedy study is misplaced given these limitations.

2. The Agarwal study was short-term and lost over 50% of respondents.

The study by Agarwal, et al. (2018) is another that Appellants' Amici highlight as proof of benefits of masculinizing mastectomies. This study analyzed short-term post-mastectomy outcomes of 42 gender dysphoric subjects (ages 18-50).[76] The respondents reported significant satisfaction with surgical results. The study's significant limitations include:

- Just 6-months of follow-up, leaving long-term outcomes an untested and open question;[77]
- Loss of over 50% of respondents from the eligible sample of 87, raising questions about whether those who chose not to participate had better, worse, or similar outcomes to the participants;[78]
- Reliance on specialized plastic surgery and eating disorders outcomes measurement instruments which focus on body image, rather than standard measures of psychological function. This raises questions about clinical implications of the results.[79]

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76 Agarwal, et al., *supra* n.68, p.654, table 1.
77 *Id.* p.656.
78 *Id.* p.653.
79 *Id.*

Given the >18 age of the participants and other limitations outlined above, this study does not support use of masculinizing mastectomies in minors.

C. There is no evidence that delaying masculinizing mastectomies until the age of maturity leads to worsened mental health outcomes.

In their argument for the provision of masculinizing mastectomies for minors, Appellants' Amici contend "research has confirmed the negative impact of delaying treatment until adulthood for adolescents experiencing gender dysphoria." [Doc. 8, p. 14.] To support this statement, they cite a law review footnote, which in turn references a study that discusses only the Dutch protocol's minimum age for *cross-sex hormones* eligibility (not surgical intervention):

> Age 16 was chosen because some cognitive and emotional maturation is desirable when starting partially irreversible interventions and Dutch adolescents are legally competent to make a medical decision without parents' consent. However, as secondary sex characteristics develop before the age of 16, waiting for medical interventions is highly upsetting for most younger adolescents.[80]

The quote says nothing about negative health impacts due to inability to obtain a masculinizing mastectomy. Indeed, the quote opposes Appellants' Amici assertion, indicating that eligibility for irreversible procedures should be based on established age criteria for cognitive maturity, rather than on the minors' wishes. In fact, the Dutch protocol did not allow gender reassignment surgeries for persons under 18.[81]

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80 de Vries et al., *supra* n.18, p.2277.

81 de Vires et al. *supra* n.39, p.697.

In summary, the available evidence for gender-affirming surgeries shows inconclusive benefit, with a possibility of harm that cannot be ruled out. The evidence of benefit from masculinizing mastectomies for minors is even weaker. A handful of short-term studies deal primarily with satisfaction and body image, and do not use validated psychological scales. They are limited by weak study designs and suffer from a high loss of subjects to follow-up. To date, no high-quality study has demonstrated that masculinizing mastectomies result in long-term improvements in mental health or quality of life using standard psychological measures, or that the benefits of these surgeries outweigh harms. Furthermore, no study has demonstrated that delaying this procedure until minors reach maturity results in harm.

IV. THERE IS NO MEDICAL CONSENSUS SUPPORTING BENEFICIAL EFFECTS OF MASCULINIZING MASTECTOMIES FOR ADOLESCENT FEMALES.

A. Neither the WPATH nor the Endocrine Society guidelines establish a valid standard of care for masculinizing mastectomies.

Contrary to WPATH and Endocrine Society claims, none of the available treatment guidelines qualify as a standard of care. The Endocrine Society guidelines explicitly state that their "guidelines should not be considered inclusive of all proper approaches or methods, or exclusive of others. The guidelines cannot guarantee any specific outcome, nor do they establish a standard of care."[82] Similarly, WPATH

[82] Hembree, et al., *supra* n.56, p.3895.

concedes that their "Standards of Care" are merely treatment guidelines, rather than standards of care.[83]

Further, the WPATH and Endocrine Society guidelines recently were assessed for quality by a systematic review, which deemed them very low quality and unfit tools for clinical decision-making. Specific to WPATH, the reviewers noted the difficulty of even extracting clear recommendations, describing it as "incoherence within WPATH SOCc7."[84]

In 2016, following its systematic review of evidence of gender-affirmation surgeries, the HHS refused to endorse the exclusive use of WPATH's guidelines, stating, "We are aware some providers consult the WPATH Standards of Care, while others have created their own criteria and requirements for surgery, which they think best suit the needs of their patients. As such… we are not in the position to endorse exclusive use of WPATH for coverage."[85]

Standards of care should provide practitioners with evidence-based standards by which they may reliably inform patients about projected outcomes and do so with a known error rate. Such data are the starting point for obtaining informed consent,

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[83] William J. Malone et al., *Letter to the Editor from William J. Malone et al: "Proper Care of Transgender and Gender-Diverse Persons in the Setting of Proposed Discrimination: A Policy Perspective*, J. CLINICAL ENDOCRINOLOGY & METABOLISM, no. dgab205 (Mar. 2021).

[84] Sara Dahlen et al., *International Clinical Practice Guidelines for Gender Minority/Trans People: Systematic Review and Quality Assessment*, 11 BMJ OPEN, no. e048943, 4, 8 (Apr. 2021).

[85] HHS Decision Memo, *supra* n.58, p.41.

but neither the WPATH nor Endocrine Society guidelines meets that baseline requirement.

B. Using the Dutch protocol outside its unique and tightly controlled experimental framework can lead to medical harm.

Recently, the pioneers of pediatric gender transitions have voiced concern about applying the Dutch protocol to the growing numbers of gender dysphoric youth.

In 2020, Dr. Annelou de Vries, the principal author of the Dutch study on which the gender-affirmative pathway for minors is based, warned clinicians that a "new developmental pathway" of gender dysphoria was emerging, including patients with "more mental health challenges," adding, "these youth did not yet participate in the early evaluation studies. This raises the question whether the positive outcomes of early medical interventions also apply to adolescents who more recently present in overwhelming large numbers for transgender care," and suggested that the newly-presenting cases may benefit from enhanced psychological support rather than hormones and surgeries.[86]

Another prominent Dutch protocol investigator, Dr. Thomas Steensma, likewise cautioned, "[w]e don't know whether studies we have done in the past can still be applied to this time," specifically because of the unexplained surge in adolescents reporting gender dysphoria. "Many more children are registering, and also

[86] Annelou de Vries et al., *Challenges in Timing Puberty Suppression for Gender-Nonconforming Adolescents*, 146 PEDIATRICS, Issue 4, 1 (Oct. 2020).

a different type… Suddenly there are many more girls applying who feel like a boy... now there are three times as many females as males." He warns, "[w]e conduct structural research in the Netherlands. But the rest of the world is blindly adopting our research."[87]

Similarly, Scandinavian countries are backtracking from their pioneering use of pediatric gender transitions. Finland reversed its course in the last 12 months, after its research showed that adolescents with no psychiatric symptoms before transition largely continued to do well after, while "[t]hose who had psychiatric treatment needs or problems in school, peer relationships and managing everyday matters outside of home continued to have problems."[88] New treatment guidelines from the Finnish Health Authority state psychotherapy should be the first-line treatment for gender dysphoric minors, while limiting surgeries to those 18 or older.[89] Effective May 2021, Sweden's world-renowned Karolinska Hospital suspended all pediatric gender transitions outside of clinical trials; other Swedish hospitals followed suit while the Swedish Health Authority updates its treatment guidelines.[90]

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[87] Voorzij, *More research is urgently needed into transgender care for young people: "Where does the large increase of children come from?"* (Feb. 27, 2021) (last visited July 7, 2021).

[88] Riittakerttu Kaltiala et al., *Adolescent Development and Psychosocial Functioning after Starting Cross-Sex Hormones for Gender Dysphoria*, 74 NORDIC J. PSYCH., Issue 3, 1 (Apr. 2020).

[89] SEGM, *One Year Since Finland Broke with WPATH "Standards of Care* (July 2, 2021).

[90] SEGM, *Sweden's Karolinska Ends All Use of Puberty Blockers and Cross-Sex Hormones for Minors Outside of Clinical Studies* (May 8, 2021).

The U.K.'s NHS is also re-evaluating its treatment approach to gender-dysphoric minors in light of two recent systematic reviews it commissioned, which found the evidence supporting medical gender-affirmative treatment of minors to be of very low quality and concluded that the low-certainty of benefits must be carefully weighed against the risks.[91]

V. ETHICAL EXPLORATORY PSYCHOLOGICAL INTERVENTIONS ARE A COMMONLY ACCEPTED PRACTICE FOR TREATING MINORS' DISTRESS AND SHOW EARLY PROMISE IN ALLEVIATING DISTRESS OF GENDER-DYSPHORIC YOUTH.

Gender-dysphoric adolescents frequently suffer from significant distress. Until the body of evidence is of sufficient quality to support irreversible and risky surgeries, safer alternatives such as psychotherapy should remain the primary treatment modality for gender-dysphoric youth. Psychotherapy is a commonly accepted treatment for alleviating psychological distress and shows promising benefits for treatment of gender-dysphoric youth.

There are many interrelated issues impacting the psychological state of youth with gender dysphoria.[92] Therapy can help young people identify and manage these issues while helping them discover ways to express their internal sense of gender

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[91] NICE *Evidence Review:* *Gonadotrophin Releasing Hormone Analogues for Children and Adolescents with Gender Dysphoria* (Mar. 11, 2021); NICE *Evidence Review:* *Gender-Affirming Hormones for Children and Adolescents with Gender Dysphoria* (Mar. 11, 2021).

[92] Kasia Kozlowska et al, *Attachment Patterns in Children and Adolescents With Gender Dysphoria*, 11 FRONTIERS IN PSYCHOLOGY 1 (2021).

without medical or surgical interventions, thereby providing them the critical opportunity to mature so they can meaningfully consent to irreversible interventions.

The WPATH Standards of Care 7 (SOC7) are often cited to support the notion that psychotherapy in incapable of alleviating gender-related distress. In particular, the following quote from SOC7 is frequently, but wrongly, invoked, "Treatment aimed at trying to change a person's gender identity and expression to become more congruent with sex assigned at birth has been attempted in the past without success, particularly in the long term."[93]

First, this claim suggests an outdated understanding of psychotherapy, as contemporary psychotherapy does not coerce or force identity change. Additionally, SOC7 grounds that claim in four significantly outdated papers (from the 1960s to early 1980s) that deal with mature adults, rather than gender-dysphoric youth. Critically, none support the claim of futility or harms of psychotherapy for gender dysphoric youth:

- Two papers from 1964 and 1969 say nothing about the efficacy of psychotherapy: one describes the use of electric shock therapy for cross-dressing males, and the other explores conflicts around same-sex attraction and the development of gender dysphoria;

[93] World Prof'l Ass'n for Transgender Health, *Standards of Care for the Health of Transsexual, Transgender, and Gender-Conforming People*, 16 (7th vers. 2012).

- The 1965 paper collates disparate case reports and notes that gender-dysphoric adults tend to resist psychotherapy. Reflective of when it was written, it argues that surgical gender reassignment is as legitimate as lobotomy for psychiatric problems.
- The 1984 paper shows that psychotherapy can be effective at ameliorating gender dysphoria without resorting to medical or surgical interventions, particularly for cases where cross-gender identification arose in a complex context of other mental health problems.[94]

Moreover, several recent case reports and case series utilizing contemporary psychotherapeutic approaches have reported successful outcomes: individuals were able to resolve or manage their distress without medical or surgical intervention.[95]

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[94] P. Cohen-Kettenis and B. Kuiper, *Transsexuality and Psychotherapy*, 10 TIJDSCHRIFT VOOR PSYCHOTHERAPIE 153-166 (1984) (abstract at https://www.semanticscholar.org/paper/Transexuality-and-psychotherapy-Cohen-Kettenis-Kuiper/25337c85366442c712c4c11528f7ca2925890b7e).

[95] Anna Churcher Clarke and Anastassis Spiliadis, *'Taking the Lid off the Box': The Value of Extended Clinical Assessment for Adolescents Presenting with Gender Identity Difficulties*, 24 CLINICAL CHILD PSYCHOLOGY & PSYCHIATRY, Issue 2, 338–52 (Apr. 2019); Alessandra Lemma, *Trans-Itory Identities: Some Psychoanalytic Reflections on Transgender Identities*, 99 INT'L J. PSYCHOANALYSIS, Issue 5, 1089–106 (Sept. 2018); Marina Bonfatto and Eva Crasnow, *Gender/Ed Identities: An Overview of Our Current Work as Child Psychotherapists in the Gender Identity Development Service*, 44 J. CHILD PSYCHOTHERAPY, Issue 1, 29–46 (Jan. 2018); Roberto D'Angelo, *The Man I Am Trying to Be Is Not Me*, 101 INT'L J. PSYCHOANALYSIS, Issue 5, 951–70 (Sept. 2020); Roberto D'Angelo, et al., *One Size Does Not Fit All: In Support of Psychotherapy for Gender Dysphoria*, 50 ARCHIVES OF SEXUAL BEHAVIOR, Issue 1, 7–16 (Jan. 2021).

Mental health support as first-line treatment for gender dysphoric youth is consistent with the consensus emerging from the pioneers of gender dysphoria studies in Europe.

CONCLUSION

When the lower court declined to order AHCCCS to fund masculinizing mastectomies for two adolescent females suffering from various mental health challenges in addition to gender dysphoria, it followed sound scientific rationale based on the best available evidence.

The current state of scientific knowledge does not support the assertion that gender-affirming surgical interventions for minors are safe, effective, and medically necessary. The prudent approach is to provide gender-dysphoric youth with enhanced psychological support, addressing co-occurring mental health problems, and creating space for an agenda-free exploration of identity until the age of majority. This appears to be very similar to the approach AHCCCS is already taking by providing standard psychological and psychiatric support to the affected minors.

RESPECTFULLY SUBMITTED: July 7, 2021

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CERTIFICATE OF COMPLIANCE

Pursuant to Fed. R. App. P. 29(a)(5), this amicus curiae brief may not exceed 7,000 words, or one-half the length of a party's brief. Per Fed. R. App. P. 32(g), the undersigned certifies that this brief complies with the type-volume limitations of Fed. R. App. P. 32(a)(7)(B). Exclusive of the sections exempted by Fed. R. App. P. 32(f), the brief contains 6,990 words, according to the word count feature of Microsoft Word 2010 that was used to prepare the brief. The brief uses proportionately spaced Garamond 14-point typeface.

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CERTIFICATE OF SERVICE

I hereby certify that I electronically filed the foregoing Opening Brief with the Clerk of the Court for the United States Court of Appeals for the Ninth Circuit using the Appellate CM/ECF system on July 7, 2021. I certify that all participants in the case are registered CM/ECF users and that service will be accomplished by the Appellate CM/ECF system.

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