IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
HUNTINGTON DIVISION

CHRISTOPHER FAIN, *et al.*, individually and on behalf of all others similarly situated, *Plaintiffs,* v. WILLIAM CROUCH, *et al.*, *Defendants.*	CIVIL ACTION NO. 3:20-cv-00740 HON. ROBERT C. CHAMBERS, JUDGE

EXPERT DISCLOSURE REPORT OF DR. STEPHEN B. LEVINE, M.D.

I. CREDENTIALS & SUMMARY OF OPINIONS

A. Academic and Clinical Activities

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

2. Since July 1973, my specialties have included psychological problems and conditions relating to individuals' and couples' sexuality, therapies for sexual problems, and the relationship between love, intimate relationships, and wider mental health. In 2005, I received the Masters and Johnson Lifetime Achievement Award from the Society of Sex Therapy and Research. I am a Distinguished Life Fellow of the American Psychiatric Association. In 2021 I was placed in the Case Western Reserve University's Department of Psychiatry's Hall of Fame.

3. In 1974, I founded the Case Western Reserve University Gender Identity Clinic, and have served as Co-Director of a gender clinic since that time. Across the years, our Clinic

treated hundreds of patients who were experiencing a transgender identity. An occasional child was seen during this era. I was the primary psychiatric caregiver for several dozen of our patients and supervisor of the work of other therapists. I was an early member of the Harry Benjamin International Gender Dysphoria Association (later known as the World Professional Association for Transgender Health, or WPATH) and served as the Chairman of the committee that developed the 5th version of the *WPATH Standards of Care*. In 1993 the Gender Identity Clinic was renamed, moved to a new location, and became independent of Case Western Reserve University. I continued to serve as Co-Director. It has subsequently been renamed the Gender Diversity Clinic.

4. I have been a visiting professor at Stanford University and St. Elizabeth's Hospital in Washington, D.C., as well a grand rounds presenter at various departments of psychiatry over many years. I have served as a book and manuscript reviewer for numerous professional publications. I have been the Senior Editor of the first (2003), second (2010) and third (2016) editions of the *Handbook of Clinical Sexuality for Mental Health Professionals*. In addition to five other solo authored books, I authored *Psychotherapeutic Approaches to Sexual Problems*, published in 2020; it has a chapter titled "The Gender Revolution." I am a frequent reviewer of submitted papers to the *Archives Sexual Behavior*, *Journal of Sex & Marital Therapy*, and J*ournal of Sexual Medicine*. I am an infrequent or occasional reviewer for 25 other journals in various medical specialties and psychological and sociologic journals on topics related to human sexuality. I have published 180 article and book chapters, nineteen of which focus on gender identity. A November 2021 publication, *Reflections on The Clinician's Role with Individuals Who Self-Identify as Transgender*, was published in the Archives of Sexual Behavior. Another publication, *Reconsidering Informed Consent for Trans-Identified Children, Adolescents, and*

Young Adults, which I am the lead author of, has been tentatively accepted for publication by the Journal of Sex & Marital Therapy awaiting minor changes.

5. I have received the following grants for scientific research and/or program development:

1. Twenty-three separate pharmaceutical company grants to study various pro-sexual medications;
2. U.S. National Institute of Health grant for the study of sexual consequences of Systemic Lupus Erythematosis. Co-principal investigator; and
3. Five separate grants from the private Sihler Mental Health Foundation create the Program for Professionals which evaluated medical and religious leaders accused of sexual offenses; to establish a Center for Marital and Sexual Health; to create a placebo-controlled research study on Clomipramine for premature ejaculation; to create a follow-up study of clergy accused of sexual impropriety; and to establish a new clinical service for women with breast cancer.

6. Over the years I have lectured frequently to professional groups. During the previous two years, these lectures have included:

1. The Mental Health Professionals' Role with the Transgendered: Making the Controversies Clear, given to Grand Rounds at the University Hospitals of Cleveland on March 12, 2021;
2. Psychotherapeutic Approaches to Sexual Problems, an invited lecture to the American Psychiatric Association Annual Meeting on May 1, 2021 (similar lecture in May 2020);

3. Seven years of six-hour Continuing Education Courses at the American Psychiatric Association Meetings on Love and Sexuality;
4. Grand Rounds at Akron General Hospital on Clinical Considerations in Dealing with Transgender Identified Individuals October 28, 2021;
5. Grand Rounds at Cleveland Clinic Foundation on Sexuality Education of Psychiatric Residents on June 25, 2020;
6. Grand Rounds at Cleveland Clinic Foundation June 2019 Transgenderism: Beware! Repeated by invitation at Akron General Hospital and at National meeting of American Association of Behavioral Health in 2019 in Washington, DC;
7. Three-hour workshop at Society of Sex Therapy and Research in April 2020 on Therapy for Sexual Problems;
8. Workshop on "Let's talk about sex!" at the American Association of Directors of Psychiatric Residency Training in March 2020 in Dallas, Texas;
9. Three-hour continuing education seminar with Massachusetts Department of Corrections Gender Identity Staff Fall 2019 in Foxboro, MA;
10. Four-hour workshop at Harvard Student Health Clinic in Boston on January 26, 2022;
11. Three one-hour lectures on Transgender Phenomena in June 2022 at Henry Ford Hospital Department of Psychiatry in Detroit; and
12. Semi-annual 2.5 hour lectures on the Ethical Prohibition against sex with patients at the Case Western Reserve University Department of Ethics seminars.

B. Expert Witness Testimony

7. In 2019, I was qualified as an expert and testified concerning the diagnosis, understanding, developmental paths and outcomes, and therapeutic treatment of transgenderism and gender dysphoria, particularly as it relates to children, in the matter of *In the Interest of J.A.D.Y. and J.U.D.Y.*, Case No. DF-15-09887-S, 255th Judicial District, Dallas County, TX (the "*Younger* litigation"). In addition, I have given testimony in:

1. U.S. District Court for the Eastern District of Massachusetts, Judge Mark L. Wolf's independent, court-appointed witness in *Michelle Kosilek vs. Massachusetts* of a transgender inmate within the Massachusetts prison system. I have been retained by the Massachusetts Department of Corrections as a consultant on the treatment of transgender inmates since 2007.
2. Deposition in the *Battista vs. Massachusetts Dept. of Corrections* case (transsexual issue) in Cleveland, October 2009;
3. Witness for Massachusetts Dept. of Corrections in their defense of a lawsuit brought by prisoner Katheena Soneeya. March 22, 2011 Deposition in October 2018 in Cleveland and 2019 in Boston;
4. Witness for *State of Florida vs. Reyne Keohane*, July 2017;
5. Pennsylvania legislative testimony. Written submission and live testimony before a committee of the Pennsylvania legislature, March 2020 (Engaged by Pennsylvania Family Institute);
6. *In the Interests of the Younger Children*. Expert testimony by deposition and at trial in Dallas, TX. (Engaged by Texas counsel Odeneal & Odeneal) (Dallas Cty. Dist. Ct. 2019);

7. *Doe v. Madison Metropolitan School District*. Expert declaration submitted February 19, 2020, rebuttal declaration submitted August 14, 2020;
8. *Hecox v. Idaho*. Expert declaration submitted June 4, 2020. (D. Idaho);
9. *In the matter of Rhys & Lynn Crawford*. March 30, 2021, *Tingley v. Washington State* (W.D. Wa.);
10. *Bell v. The Tavistock & Portman NHS Foundation Trust* [2020] EWHC (Admin) 3274 [64] in High Court of London, Decision handed down on December 1, 2020. The High Court cited evidence I offered about how young people mature through adolescence.
11. In the High Court of Justice Queen's Bench Division administrative court. *The Queen (on the application of) L. and Hampshire County Council*;
12. *North Carolina, Kadal v. Folwell* (M.D.N.C)
13. *Hennessy-Waller v. Snyder*, Case No. CV-20-00335-TUC-SHR, 2021 WL 1192842, at *5-6 & n.10 (D. Ariz. Mar. 30, 2021). The District of Arizona relied on evidence I submitted regarding the guidelines for treating adolescents with gender dysphoria.

8. In addition to the above, I have been retained by the defense in this case to serve as an expert witness. My compensation is $400 per hour. My compensation for depositions is $500 per hour. My compensation is not dependent upon the outcome of this litigation or the substance of my opinions.

9. A fuller review of my professional experience, publications, and awards is provided in my curriculum vitae, a copy of which is attached hereto as **Exhibit A**.

C. Summary of Opinions

10. Below is a key summary of my opinions in this case.

- The right to bodily autonomy via "gender-affirming" hormonal and surgical interventions should not be confused with medical necessity. An objective test for medical necessity of transgender interventions does not exist. The diagnosis is self-generated by the patient, and merely recorded by the clinician. The choice of interventions is granted based on a patient's wish. In transgender healthcare, this is often wrongly equated with medical necessity.
- Medically necessary care should not be conflated with "gender-affirming" care. The latter has not been shown to result in significant lasting improvements in mental health or reduction in suicidality/suicide long-term. Multiple quality systematic reviews of evidence failed to show credible improvements. Claims that such care is highly effective come from studies that are methodologically weak and biased.
- There are significant risks of complications associated with gender-affirming hormonal and surgical interventions. The established risks include adverse effects on bone health, cardiovascular health, and fertility. There are many other risks that are just now emerging in the literature.
- There is a crisis of inadequate or absent mental health assessments prior to undergoing transition. Because of the unfortunate politicization of transgender healthcare, ethical mental health clinicians report intense pressure to confirm every gender-dysphoric patient as transgender, and to recommend gender-affirming treatments. There is also an entire industry of mental health clinicians, hormone prescribers, surgeons and even hospitals who have built lucrative lines of

business from scaling the costly "transgender healthcare" model. Females as young as 13 are treated with mastectomies based on perfunctory evaluations.

- The risks of providing on-demand "gender-affirming" interventions are going to be borne out disproportionately by youth and by vulnerable populations. While the Plaintiffs are mature adults, patients who most commonly seek gender-affirming interventions are teenagers and young adults, 2-10% of whom currently identify as transgender. The majority suffer from a heavy burden of mental illness. This marked epidemiologic shift occurred around 2014-2015 and remains poorly understood. The evidence of hormonal and surgical treatment regret among patients coming from this population is starting to mount.
- There is a range of treatments to ameliorate gender dysphoria, from non-invasive to highly invasive. Gender dysphoria has many causes, and many ways to ameliorate it. The narrative that "only hormones and surgeries work" dominating the US is both erroneous and motivated by considerations other than the long-term well-being of the patient. In contrast, a growing number of European nations are now prioritizing psychotherapy as the first line of treatment for gender-dysphoric young people.
- To determine whether West Virginia Medicaid and PEIA should be forced to categorically cover medical and surgical interventions for gender dysphoria, one will need to consider the balance of benefits and harms of such a decision. The potential benefits of reduced out-of-pocket burdens for mature adults must be carefully weighed against long-term health risks; risks of harming youth; and the significant cost implications to the already-strained system. It is my opinion that given

the current poor state of transgender healthcare, West Virginia should invest in a process that, at a minimum, assures safeguarding of vulnerable youth, before any change to the status quo is contemplated.

II. EXPERT TESTIMONY

A. My Assessment of the Plaintiff's Expert Witness Statements

11. I have reviewed the expert disclosure reports of the plaintiffs' experts that were submitted during discovery in this litigation. It is my educated opinion that these disclosures misrepresent the body of evidence regarding the safety and efficacy of hormonal and surgical interventions for gender dysphoria. The degree of misrepresentation varies from unduly focusing on weak unreliable studies that purport positive treatment results while ignoring problematic findings that come from more reliable high-quality studies, to outright misrepresenting the results of studies. Unfortunately, this type of biased promotion of the erroneous narrative of purportedly proven benefits of hormones and surgeries has become endemic in the field of transgender medicine.[1]

12. I maintain that while well-meaning and sincere in their beliefs, their apparent clinical certainty simplifies the weighty issues involved. They do not know what happens to most of their patients over time; they do not know the error rates of their clinical decisions; they pay no

[1] Clayton A, Malone WJ, Clarke P, Mason J, D'Angelo R. Commentary: The Signal and the Noise—questioning the benefits of puberty blockers for youth with gender dysphoria—a commentary on Rew et al. (2021). *Child Adoles Ment Health*. Published online December 22, 2021:camh.12533. doi:10.1111/camh.12533

attention to the well-known medical, social, and psychological problems of adult trans communities as consistently reported in cross-sectional studies over the years.[2]

13. Medicine learns about the efficacy of its treatments by careful follow up of its patients. Long-term follow up, and quality studies demonstrating long-term efficacy of interventions in the area of transgender health are conspicuously lacking. Scientific commitment requires professionals to separate beliefs from what science has firmly established.

14. Unfortunately, the testimonies by the two expert witnesses for the Plaintiffs are guided by their individual and passionately-held beliefs regarding the benefits of hormones and surgeries, not by the best available evidence, which raises serious questions about the risk/benefit profile of these interventions.

15. The body of evidence shows a lack of long-term demonstrated efficacy, and points to a growing risk of harm and regret, especially among young patients who are now seeking these interventions in record numbers. It is with these vulnerable patients' long-term health and wellbeing in mind that I share the below.

B. Expert Witness Statement by Dr. Karasic.

16. In my review of the "Expert Disclosure Report of Dan H. Karasic, M.D.," dated January 14, 2022 ("Karasic"), I note that Dr. Karasic makes a variety of inaccurate and misleading statements. They range from inaccurate information about the nature of sex and gender dysphoria, to biased overviews of what is known about various therapies for gender dysphoria, to misrepresentations of outcomes of therapies—all with a strong bias toward pharmacological and

[2] Dhejne C, Lichtenstein P, Boman M, Johansson ALV, Långström N, Landén M. Long-Term Follow-Up of Transsexual Persons Undergoing Sex Reassignment Surgery: Cohort Study in Sweden. Scott J, ed. *PLoS ONE*. 2011;6(2):e16885. doi:10.1371/journal.pone.0016885

surgical interventions. In addition, Dr. Karasic makes a number of sweeping and purportedly scientific assertions without any references at all. Below are examples of Dr. Karasic's misinterpretations and misrepresentations of the state of evidence.

17. Dr. Karasic's testimony conflates sex and gender identity. Dr. Karasic states, "[a]side from external genital characteristics, chromosomes, and endogenous hormones, other factors related to sex include...gender identity, and variations in brain structure and function."[3] This directly contradicts a recent Scientific Statement by the Endocrine Society, which implores researchers to not conflate biological sex, which is binary and straightforward in over 99% of the cases, with the concept of gender identity, which can indeed represent a wide spectrum.[4]

18. Despite the increasing ability of hormones and various surgical procedures to reconfigure some male bodies to visually pass as female, or vice versa, the biology of the person remains as defined by his (XY) or her (XX) chromosomes, including cellular, anatomic, and physiologic characteristics and the particular disease vulnerabilities associated with that chromosomally defined sex. For instance, the XX (genetically female) individual who takes testosterone to stimulate certain male secondary sex characteristics will nevertheless remain unable to produce sperm and father children. Contrary to the assertions of certain members of the medical community, the aspiration of some trans individuals to become "a complete man" or "a complete woman" is not biologically attainable.[5] [6] It is possible for some individuals to "pass" unnoticed as the opposite gender that they aspire to be—but with limitations, costs, and risks.

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[3] Karasic, p.5, para 20

[4] Bhargava A, et al. Considering Sex as a Biological Variable in Basic and Clinical Studies: An Endocrine Society Scientific Statement. *Endocrine Reviews*, Volume 42, Issue 3, June 2021, Pages 219–258, https://doi.org/10.1210/endrev/bnaa034.

[5] Levine SB. Informed Consent for Transgendered Patients. *Journal of Sex & Marital Therapy*. 2019;45(3):218-229. doi:10.1080/0092623X.2018.1518885

[6] Levine SB. Reflections on the Clinician's Role with Individuals Who Self-identify as Transgender. *Arch Sex Behav*. Published online September 15, 2021. doi:10.1007/s10508-021-02142-1

19. The binary nature of sex (with extremely rare exceptions known as Differences of Sexual Development /DSD or "intersex disorders"[7]) in no way invalidates one's subjective sense of a discordant gender identity. The push toward conflation of sex and gender identity is largely a politically-motivated move, which does a disservice to science, and which can cause direct medical harm to the patient.[8] [9]

20. Dr. Karasic misrepresents treatment recommendations from an advocacy organization as scientific facts. In his witness statement, Dr. Karasic regards treatment recommendations issued by the advocacy organization *The World Professional Association of Transgender Health* (WPATH) as "authoritative protocols." WPATH's core mission, since its inception, has been to destigmatize transgender identities and to advocate for easy access and broad insurance coverage for transgender-related procedures.[10] WPATH guidelines, entitled "Standards of Care" (SOC), do favor medicalized approaches to the management of gender dysphoria. While these guidelines have been influential in years past, they are increasingly coming under scrutiny, with a growing list of countries abandoning their use.

21. A recently published systematic review found the current WPATH SOC7 guidelines to be of very low quality and unfit tools for clinical decision-making, noting "incoherence"

[7] Lee PA, Houk CP, Ahmed SF, Hughes IA, in collaboration with the participants in the International Consensus Conference on Intersex organized by the Lawson Wilkins Pediatric Endocrine Society and the European Society for Paediatric Endocrinology. Consensus Statement on Management of Intersex Disorders. *PEDIATRICS*. 2006;118(2):e488-e500. doi:10.1542/peds.2006-0738

[8] Stroumsa D, Roberts EFS, Kinnear H, Harris LH. The Power and Limits of Classification — A 32-Year-Old Man with Abdominal Pain. *N Engl J Med*. 2019;380(20):1885-1888. doi:10.1056/NEJMp1811491

[9] Whitley CT, Greene DN. Transgender Man Being Evaluated for a Kidney Transplant. *Clinical Chemistry*. 2017;63(11):1680-1683. doi:10.1373/clinchem.2016.268839

[10] Fraser L. Psychotherapy in the World Professional Association for Transgender Health's *Standards of Care* : Background and Recommendations. *International Journal of Transgenderism*. 2009;11(2):110-126. doi:10.1080/15532730903008057

within the recommendations.[11] (A similar low-quality assessment was given to the Endocrine Society guidelines, which Dr. Karasic refers to, and which, incidentally, has been co-authored by many of the several of the same authors as SOC7).

22. A newly released draft of the upcoming SOC8 version of the guidelines appears to continue to suffer from a number of serious methodological problems that will limit its clinical use.[12] It is perhaps not surprising that a growing number of countries are deviating from WPATH and Endocrine Society guidelines and are developing their own treatment guidelines that prioritize psychological treatments for youth. They include such pioneers in gender-affirming care as Sweden, Finland, and the UK. [13] [14] [15]

23. As the Co-Chair of WPATH SOC5 Committee, I have had first-hand experience with the organization and its evolution toward its current state of advocacy at the expense of rigorous science. I will detail my experiences in separate section of this document. My experience appears to be consistent with that of the incoming president of WPATH, a transgender woman and surgeon, Dr. Bowers, who recently admitted that activism within WPATH has taken over science, and that, within WPATH, any deviation from the hormonal and surgical "gender-affirming" treatment model is currently not tolerated: "There are definitely people [in WPATH] who are trying to keep out anyone who doesn't absolutely buy the party line that everything should be

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[11] Dahlen S, Connolly D, Arif I, Junejo MH, Bewley S, Meads C. International clinical practice guidelines for gender minority/trans people: systematic review and quality assessment. *BMJOpen*. 2021;11(4):e048943. doi:10.1136/bmjopen-2021-048943

[12] Society for Evidence-Based Gender Medicine. *WPATH SOC8 Draft Guideline*, Jan. 16, 2022, https://segm.org/draft_SOC8_lacks_methodological_rigor

[13] Society for Evidence-Based Gender Medicine. *One Year Since Finland Broke with WPATH "Standards of Care,"* July 2, 2021, https://segm.org/Finland_deviates_from_WPATH_prioritizing_psychotherapy_no_surgery_for_minors

[14] Society for Evidence-Based Gender Medicine. *Sweden's Karolinska Ends All Use of Puberty Blockers and Cross-Sex Hormones for Minors Outside of Clinical Studies*, May 5, 2021, https://segm.org/Sweden_ends_use_of_Dutch_protocol

[15] Cass Review, Independent Review of Gender Identity Services for Children and Young People, *About the Review*, https://cass.independent-review.uk/about-the-review/

affirming, and that there's no room for dissent." [16] Can an organization with such a stance legitimately represent itself as a scientific organization, or be relied upon to issue unbiased, science-based information to inform the care of gender dysphoric individuals?

24. Of note, in 2016, Health and Human Services (HHS) came under significant pressure from activists to adopt the WPATH "Standards of Care" as the prevailing guideline for determining medical necessity considerations for gender-affirming surgeries. After conducting a thorough evaluation of the evidence, the HHS refused, explaining their opinions in this way: "Based on our review of the evidence and conversations with the experts and patient advocates, 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, and given that WPATH acknowledges the guidelines should be flexible, we are not in the position to endorse exclusive use of WPATH for coverage. The MACs, Medicare Advantage plans, and Medicare providers can use clinical guidelines they determine useful to inform their determination of whether an item or service is reasonable and necessary."[17] More generally, in that same Decision Memo, the HHS refused to mandate coverage for transgender surgeries, leaving it up to the individual states to decide, due to lack of evidence of long-term benefits.

25. Dr. Karasic incorrectly asserts that gender-affirming treatments for gender dysphoria are "highly effective." [18] In his expert witness testimony, Dr. Karasic states that hormonal and surgical treatments for gender dysphoria are "highly effective," suggesting that an expected

[16] Abigail Shrier, *Top Trans Doctors Blow the Whistle on 'Sloppy' Care*, Oct. 4, 2021, https://bariweiss.substack.com/p/top-trans-doctors-blow-the-whistle
[17] Decision Memo for Gender Dysphoria and Gender Reassignment Surgery (CAG-00446N) :109. "WPATH Standards of Care" p. 41. https://www.cms.gov/medicare-coverage-database/view/ncacal-decision-memo.aspx?proposed=N&NCAId=282
[18] Karasic, p.9, para 31

outcome of such treatments is "significant or potentially complete relief." [19] However, the most generous way to describe the state of evidence regarding the efficacy of hormonal and surgical interventions is "mixed," and more accurately, lacking any evidence of lasting long-term improvements in psychological functioning.

26. There are indeed a number of studies that show positive results, but such studies are typically short-term and suffer from significant methodological limitations. For example, several such studies that have made recent headlines in the US rely on the same large online panel of respondents recruited by politically active organizations promoting transgender rights. [20] [21] [22] The problems with those studies have been widely recognized. [23] [24] [25]

27. In contrast, long-term studies from quality samples, as well as independent systematic reviews that synthesize and evaluate the entire body of evidence, rather than being swayed by individual studies, nearly universally conclude that the benefits of hormonal and surgical interventions are of very low certainty. For example, two recent systematic reviews of evidence for hormonal interventions for youth conducted by the UK National Institute for Health

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[19] Karasic, p.1, para 39

[20] Turban JL, King D, Carswell JM, Keuroghlian AS. Pubertal Suppression for Transgender Youth and Risk of Suicidal Ideation. *Pediatrics*. 2020;145(2):e20191725. doi:10.1542/peds.2019-1725

[21] Turban JL, Beckwith N, Reisner SL, Keuroghlian AS. Association Between Recalled Exposure to Gender Identity Conversion Efforts and Psychological Distress and Suicide Attempts Among Transgender Adults. *JAMA Psychiatry*. 2020;77(1):68. doi:10.1001/jamapsychiatry.2019.2285

[22] James, S. E., Herman, J. L., Rankin, S., Keisling, M., Mottet, L., & Anafi, M. (2016). The Report of the 2015 U.S. Transgender Survey. Washington, DC: National Center for Transgender Equality

[23] Biggs M. Puberty Blockers and Suicidality in Adolescents Suffering from Gender Dysphoria. *Arch Sex Behav*. 2020;49(7):2227-2229. doi:10.1007/s10508-020-01743-6

[24] D'Angelo R, Syrulnik E, Ayad S, Marchiano L, Kenny DT, Clarke P. One Size Does Not Fit All: In Support of Psychotherapy for Gender Dysphoria. *Arch Sex Behav*. Published online October 21, 2020. doi:10.1007/s10508-020-01844-2

[25] Biggs, Michael (2022): Comment on Turban et al. 2022: Estrogen is associated with greater suicidality among transgender males, and puberty suppression is not associated with better mental health outcomes for either sex. figshare. Journal contribution. https://doi.org/10.6084/m9.figshare.19018868.v1

and Care Quality (NICE), which is tasked with evaluating the efficacy of all treatments provided by UK's publicly-funded National Health Service (NHS), found both puberty blockers and cross-sex hormonal treatments for youth to be of questionable benefit. They concluded that the reported benefits come from "small, uncontrolled observational studies, which are subject to bias and confounding, and are of very low certainty." [26] [27] In this context, the "very low certainty" designation means that even when a study reports positive results, there is a high likelihood that patients will not experience the benefits of the proposed interventions outside of the study settings, in the real world.[28] Similar conclusions of very low certainty of benefits have been reached by a number of other independent systematic reviews of evidence both in the US and internationally. [29] [30] [31]

28. The results of independent evidence reviews by agencies responsible for ensuring equitable access to high quality healthcare and prudent use of scarce healthcare resources, stand

[26] National Institute for Health and Care Excellence - NICE, Evidence review: Gonadotrophin releasing hormone analogues for children and adolescents with gender dysphoria, 11 March 2021, at https://www.evidence.nhs.uk/document?id=2334888&returnUrl=search%3fq%3dtransgender%26s%3dDate

[27] National Institute for Health and Care Excellence - NICE, Evidence review: Gender-affirming hormones for children and adolescents with gender dysphoria, p. 14. 11 March 2021, at https://www.evidence.nhs.uk/document?id=2334889&returnUrl=search%3ffrom%3d2021-03-10%26q%3dEvidence%2bReview%26to%3d2021-04-01

[28] Balshem H, Helfand M, Schünemann HJ, et al. GRADE guidelines: 3. Rating the quality of evidence. *Journal of Clinical Epidemiology*. 2011;64(4):401-406. doi:10.1016/j.jclinepi.2010.07.015

[29] Hayes, Inc., Sex Reassignment Surgery for the Treatment of Gender Dysphoria, Hayes Directory (Aug. 1, 2018).

[30] Decision Memo for Gender Dysphoria and Gender Reassignment Surgery (CAG-00446N). :109. https://www.cms.gov/medicare-coverage-database/view/ncacal-decision-memo.aspx?proposed=N&NCAId=282

[31] Gender affirmation surgery for gender dysphoria - effects and risks: Health Technology Assessment review 2018. Swedish Health Authority. Published online 2018. https://alfresco-offentlig.vgregion.se/alfresco/service/vgr/storage/node/content/workspace/SpacesStore/441006af-62a7-4f19-be73-6d698bf635f5/2018_102%20Rapport%20K%C3%B6nsdysfori.pdf?a=false&guest=true&fbclid=IwAR2_BBlVfFBKok9XZ7JiTXfwOfTgcCXIzAySkh6wlXUJK8s_L_8XZy-tdIA

in sharp contrast to systematic reviews of evidence commissioned and paid for by WPATH, which Dr. Karasic prefers to rely upon. These advocacy-driven reviews also accept that the quality of the evidence is low, but paradoxically conclude *with confidence* that hormonal and surgical treatments produce desired and lasting results. [32] The problems with activism-driven research and conflicts of interest influencing research outcomes have become endemic in the field of gender medicine. [33]

29. Dr. Karasic misrepresents what is known about the connection between gender-affirming treatments and suicide. Dr. Karasic makes a bold claim that failure to obtain gender-affirming medical and surgical interventions puts patients at heightened risk suicidality.[34] This assertion is directly contradicted by a key longitudinal study that examined this very question. [35, 36] The study, which utilized Sweden's entire health registry, accounted for every patient ever treated, and followed patients over a 10-year time period, found that gender-dysphoric patients who took hormones and underwent surgeries did not fare any better in the long-term than similarly gender-dysphoric patients who did not obtain these interventions. Specifically, there was no difference in the rates of ongoing levels of mental illness and no difference in the rates of serious suicide attempts. In fact, the "surgery" group had nearly twice as many suicide attempts than the group that did not receive surgery, although the difference did not reach statistical significance.[37]

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[32] Baker KE, Wilson LM, Sharma R, Dukhanin V, McArthur K, Robinson KA. Hormone Therapy, Mental Health, and Quality of Life Among Transgender People: A Systematic Review. *Journal of the Endocrine Society*. 2021;5(4):bvab011. doi:10.1210/jendso/bvab011

[33] Society for Evidence-Based Gender Medicine, *The Signal—and the Noise—in the Field of Gender Medicine*, Jan. 31, 2022, https://segm.org/flawed_systematic_review_puberty_blockers

[34] Karasic, p.1; p.8, para 28.

[35] Bränström R, Pachankis JE. Reduction in Mental Health Treatment Utilization Among Transgender Individuals After Gender-Affirming Surgeries: A Total Population Study. *AJP*. 2020;177(8):727-734. doi:10.1176/appi.ajp.2019.19010080

[36] Correction to Bränström and Pachankis. *AJP*. 2020;177(8):734-734. doi:10.1176/appi.ajp.2020.1778correction

[37] Society for Evidence-Based Gender Medicine, *Correction of a Key Study: No Evidence of "Gender-Affirming" Surgeries Improving Mental Health*, Aug. 30, 2020, https://segm.org/ajp_correction_2020

30. Instead of reflecting on the findings (or lack thereof) of this very prominent study, Dr. Karasic instead relies on a much lower quality study which did not include long-term follow-up, accounted for only 33% of the patients treated (compared to the 100% in the above-referenced study), and did not even attempt to evaluate suicidality. [38]

31. It is of note that the suicidality argument has been extensively misused by the proponents of rapid medicalization of gender-dysphoric individuals, and particularly minors, with the dark and emotive narrative of a choice between a "dead son or a live daughter." The rates of suicide attempts and completed suicide are significantly elevated in transgender-identifying patients compared to the general population. However, it is well-established that suicides are complex events and can rarely be attributed to a single cause.

32. The rate of death by suicide in gender dysphoric youth in the UK has recently been estimated to be 0.03% over a 10-year period. [39] The rate of suicides for transgender adults in Sweden is estimated to be 0.6% over a 20-year period.[40] A key longitudinal study from the Netherlands found that suicides occur at similar rates during all stages of transition, from the time the individual is placed on a wait list, and through decades following the final surgery. [41] This latter fact is the key reason why mental health treatments should be applauded by psychiatrists such as Dr. Karasic, rather than dismissed as ineffective or even stigmatized as unethical.

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[38] Owen-Smith AA, Gerth J, Sineath RC, et al. Association Between Gender Confirmation Treatments and Perceived Gender Congruence, Body Image Satisfaction, and Mental Health in a Cohort of Transgender Individuals. *The Journal of Sexual Medicine*. 2018;15(4):591-600. doi:10.1016/j.jsxm.2018.01.017

[39] Biggs M. Suicide by Clinic-Referred Transgender Adolescents in the United Kingdom. *Arch Sex Behav*. Published online January 18, 2022. doi:10.1007/s10508-022-02287-7

[40] Socialstyrelsen [National Board of Health and Welfare]. *Utvecklingen Av Diagnosen Könsdysfori [The Evolution of the Diagnosis of Gender Dysphoria]*. Socialstyrelsen [Swedish Health Authority]; 2020. Accessed October 29, 2020. https://www.socialstyrelsen.se/om-socialstyrelsen/pressrum/press/vanligt-med-flera-psykiatriska-diagnoser-hos-personer-med-konsdysfori/

[41] Wiepjes CM, den Heijer M, Bremmer MA, et al. Trends in suicide death risk in transgender people: results from the Amsterdam Cohort of Gender Dysphoria study (1972–2017). *Acta Psychiatr Scand*. 2020;141(6):486-491. doi:10.1111/acps.13164

33. Dr. Karasic conflates "medically indicated care" with affirmation and misrepresents the role of mental health services in treatment gender-dysphoric individuals as ineffective and unethical. Dr. Karasic asserts that "medically-indicated care" is "aligning an individual patient's body and presentation with their internal sense of self." [42]He asserts that other than gender-affirming hormones and surgeries, "no alternative treatments have been demonstrated to be effective." He further goes on to state, "gender identity change efforts provide no benefit and instead do harm." [43] Presumably, with these two statements, Dr. Karasic attempts to put to bed the vigorous ongoing debate in the scientific community about how to best care for the exponential and poorly understood rise in trans identifications in youth. Even the authors of the seminal study that gave rise to the practice of pediatric medical and surgical gender transition worldwide, known as the "Dutch Study," recently conceded the difficulty in determining "who will benefit from medical gender affirmation and for whom … mental health support might be more appropriate." [44]

34. It is a well-established fact that in both adult and pediatric populations of gender dysphoric individuals, the prevalence of co-occurring mental illness is extremely high.[45] According to a comprehensive data source from a major US-based health system, Kaiser Permanente, over 70% of gender-dysphoric youth suffer from comorbid mental health issues, and in the majority of these cases the mental health issues predated the onset of gender dysphoria. [46]

[42] Karasic, p.8., para 28.
[43] Karasic, para 29, p 9.
[44] de Vries ALC. Challenges in Timing Puberty Suppression for Gender-Nonconforming Adolescents. *Pediatrics*. 2020;146(4):e2020010611. doi:10.1542/peds.2020-010611
[45] Hanna B, Desai R, Parekh T, Guirguis E, Kumar G, Sachdeva R. Psychiatric disorders in the U.S. transgender population. *Ann Epidemiol*. 2019;39:1-7.e1. doi:10.1016/j.annepidem.2019.09.009
[46] Becerra-Culqui TA, Liu Y, Nash R, et al. Mental Health of Transgender and Gender Nonconforming Youth Compared With Their Peers. *Pediatrics*. 2018;141(5):e20173845. doi:10.1542/peds.2017-3845

35. While scientists may never fully agree to what extent the high burden of mental illness is the result versus the cause of one's transgender identification, there is little doubt that vulnerable individuals considering embarking on a life-long pursuit of medical interventions need extensive psychological evaluations and support, and their mental health conditions need to be appropriately treated.

36. Recently-released guidance from a professional psychiatry association adopted the position that extensive psychotherapeutic support should be the first line of treatment for gender-dysphoric individuals and especially minors, stating: "There are polarised views and mixed evidence regarding treatment options for people presenting with gender identity concerns, especially children and young people. It is important to understand the different factors, complexities, theories, and research relating to Gender Dysphoria." [47]A set of guidelines released by Finland, a key pioneer in pediatric gender transition, recently reversed course and now states that psychotherapy, rather than hormones and surgeries, should be the first line of treatment for gender-dysphoric youth. [48]

[47] The Royal Australian & New Zealand College of Psychiatrists, *Recognising and addressing the mental health needs of people experiencing Gender Dysphoria / Gender Incongruence*, Aug. 2021, https://www.ranzcp.org/news-policy/policy-and-advocacy/position-statements/gender-dysphoria

[48] Society for Evidence-Based Gender Medicine, *One Year Since Finland Broke with WPATH "Standards of Care,"* July 2, 2021, https://segm.org/Finland_deviates_from_WPATH_prioritizing_psychotherapy_no_surgery_for_minors

37. In a growing number of instances, especially among gender-dysphoric youth, proper therapeutic exploration has led to a resolution of gender dysphoria.[49] [50] [51] [52] [53] It is true that quality evidence proving long-term effectiveness of psychotherapy interventions is missing—just as they are lacking for the hormonal and surgical interventions. However, Dr. Karasic's attempts to stigmatize gender-exploratory psychotherapy as "gender identity change efforts,"[54] or to stigmatize as "unethical" appear to be politically motivated to maintain his beliefs with little concern for the patient's long-term outcomes in mind. Such efforts will only serve to limit access to quality healthcare for the already struggling and vulnerable group of gender dysphoric patients. [55]

38. Dr. Karasic inaccurately portrays what is known – and not known—about treatment regret. Dr. Karasic claims with certainty that regret for transgender-related procedures is extremely low. To support his assertion, he points to several sources, not the least of which is a

[49] Schwartz D. Clinical and Ethical Considerations in the Treatment of Gender Dysphoric Children and Adolescents: When Doing Less Is Helping More. *Journal of Infant, Child, and Adolescent Psychotherapy*. Published online November 22, 2021:1-11. doi:10.1080/15289168.2021.1997344
[50] Spiliadis A. Towards a gender exploratory model: Slowing things down, opening things up and exploring identity development. *Metalogos Systemic Therapy Journal*. 2019;35:1-9. https://www.ohchr.org/Documents/Issues/SexualOrientation/IESOGI/Other/Rebekah_Murphy_TowardsaGenderExploratoryModelslowingthingsdownopeningthingsupandexploringidentitydevelopment.pdf
[51] Bonfatto M, Crasnow E. Gender/ed identities: an overview of our current work as child psychotherapists in the Gender Identity Development Service. *Journal of Child Psychotherapy*. 2018;44(1):29-46. doi:10.1080/0075417X.2018.1443150
[52] Churcher Clarke A, Spiliadis A. 'Taking the lid off the box': The value of extended clinical assessment for adolescents presenting with gender identity difficulties. *Clin Child Psychol Psychiatry*. 2019;24(2):338-352. doi:10.1177/1359104518825288
[53] Lemma A. Trans-itory identities: some psychoanalytic reflections on transgender identities. *The International Journal of Psychoanalysis*. 2018;99(5):1089-1106. doi:10.1080/00207578.2018.1489710
[54] Karasic, p.9, para 29
[55] D'Angelo R, Syrulnik E, Ayad S, Marchiano L, Kenny DT, Clarke P. One Size Does Not Fit All: In Support of Psychotherapy for Gender Dysphoria. *Arch Sex Behav*. Published online October 21, 2020. doi:10.1007/s10508-020-01844-2

seminal study in the field of pediatric gender medicine, which is known as the "Dutch Study," and which serves as the key pillar for the practice of pediatric gender transition.[56]

39. In describing the outcomes of the Dutch study, Dr. Karasic states, "none of the youth who received puberty blockers, hormones, and surgery, and followed over an 8-year period expressed regret".[57] What Dr. Karasic's assessment fails to reveal is that this "low regret" statistic excludes 4 patients (6% of the initial sample of 70) who were severely harmed by the treatment; they were merely dropped from the study's conclusions. This includes 1 death of a young person from surgical complications, and 3 cases of adolescents who developed new-onset obesity and diabetes in the course of being treated with hormones. Several more youths refused to engage with the researchers when they were contacted, leading to more questions.

40. Nor does Dr. Karasic accurately report the length of the study follow-up: rather than 8 years, these outcomes were assessed merely 1.5 years after the final phase of the treatment was completed. It is well-known in transgender research that regret takes approximately 10 years after the completion of procedures to materialize.[58]

41. Dr. Karasic also fails to reflect on the extensive vetting that the patients in the study from the Netherlands received, and how different the process of gender transition in the US is conducted. Most of the cases of gender dysphoria presenting with a wish for sex reassignment today are adolescents, many of whom came to identify as transgender first time after puberty,

[56] de Vries ALC, McGuire JK, Steensma TD, Wagenaar ECF, Doreleijers TAH, Cohen-Kettenis PT. Young Adult Psychological Outcome After Puberty Suppression and Gender Reassignment. *Pediatrics*. 2014;134(4):696-704. doi:10.1542/peds.2013-2958

[57] Karasic, para 42, p12.

[58] Wiepjes CM, Nota NM, de Blok CJM, et al. The Amsterdam Cohort of Gender Dysphoria Study (1972–2015): Trends in Prevalence, Treatment, and Regrets. *The Journal of Sexual Medicine*. 2018;15(4):582-590. doi:10.1016/j.jsxm.2018.01.016

with no history of childhood gender incongruence.[59] [60] Such cases were explicitly disqualified by the Dutch protocol as having high potential for being a "false positive" and leading to future regret.[61]

42. To assert low regret rates, Dr. Karasic also leans heavily on a "pooled review." The profound limitations of this poor-quality, error-ridden review, conducted by a group of surgeons, rather than evidence evaluation experts, have been outlined in a recent publication.[62] In addition to been plagued by significant errors, such is misstating sample sizes of the included studies, and inaccurately categorizing the interventions received by the patients, the review suffers from a number of other limitations.

43. For example, the definition of "regret" in the reviewed studies is very narrow. To be considered a "regretter," an individual had to change legal sex markers, reverse surgeries, or start hormonal interventions to revert the body to the original state. [63] [64] However, few individuals know how to successfully navigate complex legal matters, and even fewer can afford to undergo reversal procedures, either due to financial limitations, or the physical impossibility to reverse surgeries. Regret in ordinary lives, let alone trans lives, is far more complicated, nuanced, conflictual, and often increases over time as the results of an experience is appreciated.

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[59] Kaltiala-Heino R, Sumia M, Työläjärvi M, Lindberg N. Two years of gender identity service for minors: overrepresentation of natal girls with severe problems in adolescent development. *Child Adolesc Psychiatry Ment Health*. 2015;9(1):9. doi:10.1186/s13034-015-0042-y

[60] Zucker KJ. Adolescents with Gender Dysphoria: Reflections on Some Contemporary Clinical and Research Issues. *Arch Sex Behav*. 2019;48(7):1983-1992. doi:10.1007/s10508-019-01518-8

[61] Levine et al., (in press). Reconsidering Informed Consent for Trans-Identified Children, Adolescents, and Young Adults. Journal of Sex & Marital Therapy.

[62] Expósito-Campos P, D'Angelo R. Letter to the Editor: Regret after Gender-affirmation Surgery: A Systematic Review and Meta-analysis of Prevalence. *Plastic and Reconstructive Surgery - Global Open*. 2021;9(11):e3951. doi:10.1097/GOX.0000000000003951

[63] Karasic, para 43, p12.

[64] Bustos VP, Bustos SS, Mascaro A, et al. Regret after Gender-affirmation Surgery: A Systematic Review and Meta-analysis of Prevalence. *Plastic and Reconstructive Surgery - Global Open*. 2021;9(3):e3477. doi:10.1097/GOX.0000000000003477

44. Additionally, the studies evaluated the outcomes of highly selected populations of patients who had to be approved for gender-transition following extensive psychiatric evaluations—a process that transgender rights advocates have decried as discriminatory, and which has been largely abandoned in the US. However, even these older studies likely significantly underestimate true rate of regret. They routinely lose to follow-up 30%-40% of individuals; those who drop out of care are more likely to be adversely affected.[65]

45. More pertinent to the current situation at hand, the recent relaxation of criteria for eligibility for these interventions appears to have created a growing number of regretters in the last several years—or at the very least, individuals who wish to stop gender-affirming treatments and reverse their effects. Two recent studies from the UK, a country that still maintains that some psychological evaluations, albeit abbreviated ones, are necessary, estimated that the rate of detransition is approximately 10% after a short period of time, and an even higher rate of dropping out of care for unknown reasons.[66] [67] Two other recent studies of detransitioners—individuals who underwent medical transition and later stopped or reversed transgender interventions—revealed that they felt rushed into transition, that their self-identification as transgender was a mistaken attribution of their generalized distress, same-sex attraction, or a myriad of other factors that were not properly explored. [68] [69]

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[65] D'Angelo R. Psychiatry's ethical involvement in gender-affirming care. *Australas Psychiatry*. 2018;26(5):460-463. doi:10.1177/1039856218775216

[66] Boyd I, Hackett T, Bewley S. Care of Transgender Patients: A General Practice Quality Improvement Approach. *Healthcare*. 2022;10(1):121. doi:10.3390/healthcare10010121

[67] Hall R, Mitchell L, Sachdeva J. Access to care and frequency of detransition among a cohort discharged by a UK national adult gender identity clinic: retrospective case-note review. *BJPsych open*. 2021;7(6):e184. doi:10.1192/bjo.2021.1022

[68] Vandenbussche E. Detransition-Related Needs and Support: A Cross-Sectional Online Survey. *Journal of Homosexuality*. Published online April 30, 2021:20. doi:10.1080/00918369.2021.1919479

[69] Littman L. Individuals Treated for Gender Dysphoria with Medical and/or Surgical Transition Who Subsequently Detransitioned: A Survey of 100 Detransitioners. *Arch Sex Behav*. Published online October 19, 2021. doi:10.1007/s10508-021-02163-w

46. Three-quarters of them did not return to the doctors who recommended or administered gender-affirmative interventions to tell them about detransition.[70] This highlights that individual clinician experiences of low regret, such as the ones reported by Dr. Karasic, need to be balanced with an objective and rigorous outcomes analysis, which is sorely lacking.

47. Dr. Karasic fails to acknowledge the ongoing vigorous scientific debate in the scientific community. It appears that Dr. Karasic believes that a widespread scientific consensus regarding the safety and efficacy of gender-affirming interventions exists. While it is true that many US-based medical societies either do not oppose or even endorse these interventions, this should not be mistaken for scientific consensus—nor should it be forgotten that US medical societies have quite a history of endorsing interventions at one point, only to retract their positions later. While the lobotomy example, with major medical societies endorsing the procedure, is often cited, a much more recent example with the opioid treatment guidelines is readily available. To quote the incoming president of WPATH who reflected on the state transgender care in the US, "This is typical of medicine. We zig and then we zag, and I think maybe we zigged a little too far to the left…"[71]

48. There have been over 50 recent publications in peer-reviewed journals questioning the approach to care for gender dysphoric youth.[72] Key international pioneers of medical transition, from Sweden to Finland to the UK, in the last 48 months have recognized the profound lack of evidence that these interventions lead to long-term improvements and have also

[70] See Littman L. Individuals Treated for Gender Dysphoria with Medical and/or Surgical Transition Who Subsequently Detransitioned: A Survey of 100 Detransitioners. *Arch Sex Behav*. Published online October 19, 2021. doi:10.1007/s10508-021-02163-w

[71] Abigail Shrier, *Top Trans Doctors Blow the Whistle on 'Sloppy' Care*, Oct. 4, 2021, https://bariweiss.substack.com/p/top-trans-doctors-blow-the-whistle

[72] Society for Evidence-Based Gender Medicine, *B. Scientists Debate Medical Affirmation of Minors*, https://segm.org/studies (literature listing)

noted growing evidence that they can result in harm. As a result, these health systems are now deviating from the gender-affirmative model and are prioritizing psychological interventions for young people presenting with gender dysphoria.

49. The Karolinska Hospital, which is the home of the Nobel Prize for Medicine, announced in May that they will cease all medical transitions for those under 18 in general medical practice, only allowing them in strictly controlled clinical trial settings.

50. The situation is starting to shift in the US as well, as concerned clinicians, and even the leaders of WPATH are calling into question the irresponsible promotion of the medicalization model for minors. [73] [74] [75] Remarkably, WPATH issued a public statement reprimanding these professional for speaking out.[76]

51. Improper analysis of financial impact. Finally, Dr. Karasic rushes to assure that the cost of providing transgender interventions is exceedingly low. However, these assertions seem questionable. For example, treatment with puberty blockers can cost $6,000-$40,000 per year per child.[77] The cost of cross-sex hormones is lower, but these costs are greatly amplified by the life-long nature of hormonal supplementation. The cost of surgeries, re-operations, and occa-

[73] Anderson, E., Edwards-Leeper, L. (2021, November 24). The mental health establishment is failing trans kids. *Washington Post.* Accessed December 20, 2021 https://www.washingtonpost.com/outlook/2021/11/24/trans-kids-therapy-psychologist/

[74] Anderson, E. (2022, January 3). Opinion: When it comes to trans youth, we're in danger of losing our way. *The San Francisco Examiner*. Accessed January 5th, 2022 http://www.sfexaminer.com/opinion/are-we-seeing-a-phenomenon-of-trans-youth-social-contagion/

[75] Malone, W. J., Hruz, P. W., Mason, J. W., & Beck, S. (2021). 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." *Journal of Clinical Endocrinology and Metabolism*, 106(8), e3287–e3288. https://doi.org/10.1210/clinem/dgab205

[76] https://www.wpath.org/media/cms/Documents/Public%20Policies/2021/Joint%20WPATH%20USPATH%20Letter%20Dated%20Oct%2012%202021.pdf

[77] https://www.legacyhealth.org/-/media/Files/PDF/Services/Children/Transgender-Services/Resources/PUBERTAL-SUPPRESSION-MEDICATION-COVERAGE.pdf

sional requests to reverse the surgeries for those who regret the interventions, are in tens to hundreds of thousands of dollars, with some cases reaching into the millions.[78] The costs of treating side-effects of the treatments, such as the well-documented increase in cardiovascular complications, or the increasing evidence that bone health may be compromised long-term when such treatments are started in adolescence, also has to be factored in. [79] [80] [81] [82]

52. Last but not least, the costs of fertility preservations must be factored in. Adults undergoing cross-sex hormonal or surgical intervention have either diminished or lost fertility.[83] Children treated with puberty blockers followed by cross-sex-hormones are expected to be sterile.[84] This has given rise to an industry of fertility preservation for this population. Few children can comprehend the loss of future fertility, and as of today very few pursue these offers.[85] However, as these treatments continue to gain momentum, fertility preservation, including novel techniques of extracting immature eggs of young females and maturing them in vitro, are expected to

[78] https://www.newsweek.com/we-need-balance-when-it-comes-gender-dysphoric-kids-i-would-know-opinion-1567277
[79] Alzahrani T, Nguyen T, Ryan A, et al. Cardiovascular Disease Risk Factors and Myocardial Infarction in the Transgender Population. *Circ: Cardiovascular Quality and Outcomes*. 2019;12(4). doi:10.1161/CIRCOUTCOMES.119.005597
[80] Getahun D, Nash R, Flanders WD, et al. Cross-sex Hormones and Acute Cardiovascular Events in Transgender Persons. *Ann Intern Med*. 2018;169(4):205-213. doi:10.7326/M17-2785
[81] Klink D, Caris M, Heijboer A, van Trotsenburg M, Rotteveel J. Bone Mass in Young Adulthood Following Gonadotropin-Releasing Hormone Analog Treatment and Cross-Sex Hormone Treatment in Adolescents With Gender Dysphoria. *The Journal of Clinical Endocrinology & Metabolism*. 2015;100(2):E270-E275. doi:10.1210/jc.2014-2439
[82] Biggs M. Revisiting the effect of GnRH analogue treatment on bone mineral density in young adolescents with gender dysphoria. *J Pediatr Endocrinol Metab*. 2021;34(7):937-939. doi:10.1515/jpem-2021-0180
[83] Cheng PJ, Pastuszak AW, Myers JB, Goodwin IA, Hotaling JM. Fertility concerns of the transgender patient. *Transl Androl Urol*. 2019;8(3):209-218. doi:10.21037/tau.2019.05.09
[84] Laidlaw MK, Van Meter QL, Hruz PW, Van Mol A, Malone WJ. Letter to the Editor: "Endocrine Treatment of Gender-Dysphoric/Gender-Incongruent Persons: An Endocrine Society Clinical Practice Guideline." *J Clin Endocrinol Metab*. 2019;104(3):686-687. doi:10.1210/jc.2018-01925
[85] Nahata L, Tishelman AC, Caltabellotta NM, Quinn GP. Low Fertility Preservation Utilization Among Transgender Youth. *J Adolesc Health*. 2017;61(1):40-44. doi:10.1016/j.jadohealth.2016.12.012

gain momentum. [86] In addition, requests for reversal of such procedures are expected to increase, and therefore must factored into the final financial impact estimate.

53. These costs have to be considered in the context of the rapid rise in the rate of transgender identification, especially among youth. While Dr. Karasic estimates the prevalence of transgender identification to be 0.5%, recent studies of youth suggest it ranges from 2% to 9%.[87] [88] Although not all of trans-identifying individuals will choose to undergo medical interventions, the majority do, and this proportion will only increase when such interventions are provided at no cost to the patient, and when access to non-invasive treatments with psychotherapy is effectively curbed as "unethical."

54. The data already show that the numbers of individuals seeking transgender interventions on West Virginia Medicaid increased from 30 individuals in 2016, to 686 individuals through the end of September in 2021, a 2,300% increase in less than 5 years. Applying the upper bound of the current estimate of 9% trans-identification, as many as 30,000 West Virginia youth could be identifying as transgender, and an unknown number of them could be pursuing hormonal and surgical interventions in the future.

55. A proper economic analysis associated with the cost of providing gender-affirming interventions by West Virginia Medicaid and PEIA needs to be conducted before the asser-

[86] Mattawanon N, Spencer JB, Schirmer DA, Tangpricha V. Fertility preservation options in transgender people: A review. *Rev Endocr Metab Disord*. 2018;19(3):231-242. doi:10.1007/s11154-018-9462-3
[87] Kidd KM, Sequeira GM, Douglas C, et al. Prevalence of Gender-Diverse Youth in an Urban School District. *Pediatrics*. 2021;147(6):e2020049823. doi:10.1542/peds.2020-049823
[88] Johns MM, Lowry R, Andrzejewski J, 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. *MMWR Morb Mortal Wkly Rep*. 2019;68(3):67-71. doi:10.15585/mmwr.mm6803a3

tions of negligible costs, which are boldly made by Dr. Karasic, are accepted. Whatever the impressive skills of individual physicians maybe, economic analysis is not one of them. This includes myself. Others must be relied upon to answer the question.

56. Dr. Karasic is neither neutral nor logical in his assertions, betraying the mindset of an activist, rather than a dispassionate clinician pursing evidence. Dr. Karasic makes a number of sweeping statements that are self-contradictory. He acknowledges that "gender dysphoria [sic](uncapitalized) is distress related to the incongruence between one's gender identity and attributes related to one's sex…"[89] yet characterizes the role of mental health services to aid in the amelioration of gender dysphoria as conversion efforts that are unethical. [90] In all other areas of medicine treating distress with psychotherapy (alone or in conjunction with other interventions) is the standard treatment approach. He states that having gender dysphoria "is widely accepted as a variation in human development" and not a disorder,[91] yet asserts that the state of West Virginia should provide extensive medical and surgical interventions to treat this condition.

57. Dr. Karasic must pick a side: is gender dysphoria an illness that needs treatments, or is it a normal variation of human diversity with no significant inherent disadvantages, which needs no intervention? If treatments are needed, then why would one set of treatments, namely, hormones and surgeries, which carries a heavy continuing medical burden, be widely offered and privileged by being excused from having to demonstrate long-term safety and efficacy as is required in all other areas of medicine. Why should another set of treatments, namely psychological, which are non-invasive and a commonly-accepted approach to treating all other forms of distress, be labeled as "unethical"? Such contradictions abound the highly politicized field of

[89] Karasic, para 22, p.6
[90] Karasic, para 21, p.6
[91] Karasic, para 27, p.7

transgender medicine, where a mere acknowledgement that the majority of gender-dysphoric people suffer from mental illness is either positioned as transphobic or is dismissed as merely resulting from the stress of being a minority. The reality is much more complex.

58. I am also concerned by Dr. Karasic's apparent attempts to silence scientific debate. For example, in 2017, Dr. Karasic[92] attempted to suppress the presentation of a key research paper at a scientific conference. [93] The research paper in question noted a sharp rise in trans identification among adolescent females with no childhood history of gender dysphoria and urged more research. [94]

59. The dramatic increase in the incidence of youths declaring a transgender identity in the last several years, and a marked demographic shift toward adolescent females seeking gender reassignment, described by the "offending" paper, has since been recognized by every pediatric gender clinic in the world. [95] [96] [97] In fact, this profound epidemiologic shift, and the lack of understanding of its etiology and appropriate interventions, is one of the key reasons why leading pediatric gender clinics throughout the world are currently changing their treatment guidelines toward much more caution—an approach that Dr. Karasic equates to "opposing trans care."

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[92] Alliance Health Project, University of California San Francisco. *Activist Psychiatrist Dan Karasic, MD Retiring*, June 11, 2020, https://alliancehealthproject.ucsf.edu/blog/activist-psychiatrist-dan-karasic-md-retiring

[93] Brie, J. 4thWaveNow, WPATH & The Advocate aim to suppress new research on adolescent gender dysphoria, Feb. 25, 2018, https://4thwavenow.com/2018/02/25/wpath-the-advocate-aim-to-suppress-new-research-on-adolescent-gender-dysphoria/

[94] Littman L. Parent reports of adolescents and young adults perceived to show signs of a rapid onset of gender dysphoria. Romer D, ed. *PLoS ONE*. 2018;13(8):e0202330. doi:10.1371/journal.pone.0202330

[95] de Graaf NM, Giovanardi G, Zitz C, Carmichael P. Sex Ratio in Children and Adolescents Referred to the Gender Identity Development Service in the UK (2009–2016). *Arch Sex Behav*. 2018;47(5):1301-1304. doi:10.1007/s10508-018-1204-9

[96] Kaltiala-Heino R, Bergman H, Työläjärvi M, Frisen L. Gender dysphoria in adolescence: current perspectives. *AHMT*. 2018;Volume 9:31-41. doi:10.2147/AHMT.S135432

[97] Zucker KJ. Adolescents with Gender Dysphoria: Reflections on Some Contemporary Clinical and Research Issues. *Arch Sex Behav*. 2019;48(7):1983-1992. doi:10.1007/s10508-019-01518-8

60. Dr. Karasic was not alone in attempting to suppress this research—pressured by other activists, the journal editors subjected the paper to a rarely conducted second peer review post-publication, following which the research was vindicated and republished with no substantive changes to its findings and conclusions. [98] Unfortunately, such politicization of research in the area of transgender medicine has become common. It is quite possible that such advocacy will hurt the very people these actions intend to protect—gender-dysphoric individuals in general, and vulnerable LGBT youth in particular.

61. Dr. Karasic's former employer characterizes him as an "activist psychiatrist." [99] While his activism for transgender rights is admirable, mixing politics and clinical matters creates a dangerous combination. I maintain that Dr. Karasic's "expert opinion" submission should be viewed as that of an ardent advocate of transgender rights and body autonomy. However, the submitted opinion is demonstrably biased and lacks the scientific rigor and credibility to be used as an expert opinion in determining whether these interventions are safe, effective, and medically necessary.

C. Expert Witness Statement by Dr. Schechter.

62. I have also reviewed the "Expert Disclosure Report of Loren S. Schechter, M.D.," dated January 14, 2022 ("Schechter"). Dr. Schechter appears to be highly qualified to perform various types of plastic surgery procedures (from Botox, to facelifts and "mommy makeover" surgeries, to gender confirmation surgeries).[100] He also claims to be an expert in the surgical and

[98] Littman L. The Use of Methodologies in Littman (2018) Is Consistent with the Use of Methoologies in Other Studies Contributing to the Field of Gender Dysphoria Research: Response to Restar (2019). *Arch Sex Behav*. 2020;49(1):67-77. doi:10.1007/s10508-020-01631-z

[99] Alliance Health Project, University of California San Francisco. *Activist Psychiatrist Dan Karasic, MD Retiring*, June 11, 2020, https://alliancehealthproject.ucsf.edu/blog/activist-psychiatrist-dan-karasic-md-retiring

[100] Loren S. Schechter, MD, "Body," https://drlschechter.com/body/

post-operative care body of literature for gender-affirmative care, as evidenced by his work on WPATH's "Standards of Care" surgery and post-operative sections. However, Dr. Schechter seems to be unaware of the body of literature that shows that gender-affirming interventions fail to improve mental health or to reduce suicidality or suicide long-term.[101, 102]

63. In fact, he appears to be unaware of a key systematic review of surgeries for adults conducted by the HHS in 2016, which found no evidence of benefits of surgeries, and even posited that surgeries themselves may be contributing to the markedly elevated rate of morbidity and mortality found in the post-operative transgender populations.[103, 104] Another systematic review of evidence by the Hayes Corporation, which reviews treatments for insurance payers for 84% of insured Americans,[105] reviewed evidence for gender reassignment surgery, rating the quality of evidence from "A" (strongest) to "D2" (weakest). [106] 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."[107] The rating of the same surgeries for adults was "C," indicating "[p]otential but unproven benefit." Hayes noted,

[101] Correction to Bränström and Pachankis. *AJP*. 2020;177(8):734-734. doi:10.1176/appi.ajp.2020.1778correction

[102] Wiepjes CM, den Heijer M, Bremmer MA, et al. Trends in suicide death risk in transgender people: results from the Amsterdam Cohort of Gender Dysphoria study (1972–2017). *Acta Psychiatr Scand*. 2020;141(6):486-491. doi:10.1111/acps.13164

[103] Decision Memo for Gender Dysphoria and Gender Reassignment Surgery (CAG-00446N). :109. https://www.cms.gov/medicare-coverage-database/view/ncacal-decision-memo.aspx?proposed=N&NCAId=282

[104] Dhejne C, Lichtenstein P, Boman M, Johansson ALV, Långström N, Landén M. Long-Term Follow-Up of Transsexual Persons Undergoing Sex Reassignment Surgery: Cohort Study in Sweden. Scott J, ed. *PLoS ONE*. 2011;6(2):e16885. doi:10.1371/journal.pone.0016885

[105] Hayes, Inc., Sex Reassignment Surgery for the Treatment of Gender Dysphoria, Hayes Directory (Aug. 1, 2018).

[106] Hayes, Inc., The Hayes Difference, https://www.hayesinc.com/about-hayes/.

[107] Hayes Inc., The Hayes Rating, https://www.hayesinc.com/about-hayes/.

"substantial uncertainty remains about safety and/or impact on health outcomes because of poor-quality studies, sparse data, conflicting study results, and/or other concerns."[108]

64. Dr. Schechter's lack of familiarity with quality systematic reviews and seminal studies in this area can be excused by the fact that his focus is on improving surgical care and on pursuing new frontiers, including Dr. Schechter's pioneering work of uterine transplantation for biological males who identify as female.[109]

65. It seems that Dr. Schechter's expertise in providing gender-affirming surgeries and training others to do the same makes him a stellar choice for an expert witness in cases where these types of surgeries may have been inadequately performed (which is, unfortunately, a frequent occurrence [110] [111]). However, he is a lesser-informed and, arguably, a problematically conflicted expert when it comes to elucidating the evidence on whether various types of transgender surgeries he performs should be viewed as medically necessary and qualifying for coverage with the Federal and State funds.

D. Understanding WPATH and its "Standards of Care"

66. Dr. Karasic and Dr. Schechter note that they are members of WPATH, invoke the guidelines that that organization publishes, and assert that those guidelines are "widely recognized" and "authoritative." (Karasic 32, 34; Schechter 22.) Accordingly, I provide some context concerning that private organization and its guidelines.

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[108] Id.
[109] Schechter, p.5
[110] Dreher PC, Edwards D, Hager S, et al. Complications of the neovagina in male-to-female transgender surgery: A systematic review and meta-analysis with discussion of management: Systematic Review of Neovaginal Complications. *Clin Anat*. 2018;31(2):191-199. doi:10.1002/ca.23001
[111] Walt Heyer, *The Federalist. 9 Transgender Patients Complain Of Mutilation, Botched Sex-Change Surgeries In Oregon*, Dec. 6, 2018, https://thefederalist.com/2018/12/06/9-transgender-patients-complain-mutilation-botched-sex-change-surgeries-oregon/

67. I was a member of the Harry Benjamin International Gender Dysphoria Association from 1974 until 2001. From 1997 through 1998, I served as the Chairman of the eight-person International Standards of Care Committee that issued the fifth version of its guidelines in 1999. I resigned my membership in 2002 due to my regretful conclusion that the organization and its recommendations had become dominated by politics and ideology, rather than by scientific process, as it was years earlier. In approximately 2007, the Henry Benjamin International Gender Dysphoria Association changed its name to the World Professional Association for Transgender Health, or WPATH.

68. WPATH is a voluntary membership organization. Since at least 2002, attendance at its biennial meetings has been open to trans individuals who are not licensed professionals. While this ensures taking patients' values, sensibilities, and perceived needs into consideration, it limits the ability for honest, methodologically competent debate. It also means that WPATH can no longer be considered a purely professional organization.

69. WPATH takes a narrow and ideologically driven view on increasingly controversial issues as to which there is a wide range of opinion among professionals. WPATH explicitly views itself as not merely a scientific organization, but also as an advocacy organization. (Levine, *Reflections*, at 240.) These are obviously incompatible goals. WPATH is supportive of those who want sex-reassignment surgery even though the purported benefits of such surgery is not borne out by the evidence. Skepticism as to the benefits of sex-reassignment surgery to patients, and strong alternate views, are not well tolerated in discussions within the organization or their educational outreach programs (as its current president recently pointed out). Such views

have been known to be shouted down and effectively silenced by the large numbers of nonprofessional adults who attend the organization's biennial meetings. Skepticism is not welcomed by those whose careers are based on providing these "treatments."

70. A group of respected endocrinologists recently recognized that "despite the misleading name, WPATH Standards of Care 7 are . . . practice guidelines, not standards of care."[112] "Unlike standards of care, which should be authoritative, unbiased consensus positions designed to produce optimal outcomes, practice guidelines are suggestions or recommendations to improve care that, depending on their sponsor, may be biased." WPATH aspires to be both a scientific organization and an advocacy group for the transgendered. These aspirations sometimes conflict. The limitations of its guidelines, however, are not primarily political. They are caused by the lack of rigorous research in the field, which allows room for passionate convictions on how to care for the transgendered to hold sway.

71. In recent years, WPATH has fully adopted some mix of the medical and rights paradigms discussed above. It has downgraded the role of counseling or psychotherapy as a requirement for these life-changing processes. WPATH no longer considers preoperative psychotherapy to be a requirement. It is important to WPATH that the person has gender dysphoria; the pathway to the development of this state is not. (Levine, *Reflections*, at 240.) Two separate evaluations, one from Canada and one from the U.K. reviewed WPATH's guidelines and found them untrustworthy.[113]

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[112] W. Malone, et al. (2021), 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. of Clin. Endocrinol. & Metab.* at 1, doi: 10.1210/clinem/dgab205.

[113] S. Dahlen, et al. (2021) International Clinical Practice Guidelines for Gender Minority/Trans People: Systematic Review and Quality Assessment. *BMJ Open* 11(4). doi: 10.1136/bmjopen-2021-048943. PMID: see also https://genderreport.ca/bias-not-evidence-dominate-transgender-standard-of-care/

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

73. For example, in 2010 the WPATH Board of Directors issued a statement advocating that incongruence between sex and felt gender identity should cease to be identified in the DSM as a pathology.[114] This position was debated but not adopted by the (much larger) American Psychiatric Association, which maintained the definitions and diagnoses of gender dysphoria as a pathology in the DSM-5 manual issued in 2013.

74. In my experience most current members of WPATH have little ongoing experience with the mentally ill, and many trans care facilities are staffed by mental health professionals who are not deeply experienced with recognizing and treating frequently associated psychiatric comorbidities. Moreover, they have been educated in affirmative care without understanding the points I am making in this report. Because the 7th version of the WPATH guidelines deleted the requirement for therapy, trans care facilities that consider those guidelines sufficient are permitting patients to be counseled to transition by means of social presentation, hormones, and surgery by individuals with Master's degrees rather than medical or PhD psychology degrees.

[114] WPATH De-Psychopathologisation Statement (May 26, 2010), available at wpath.org/policies

75. As a result of the downgrading of the role of the psychiatric assessment of patients, new "gender affirming" clinics have arisen in many urban settings that quickly (sometimes within an hour's time) recommend transition. Indeed, Dr. Karasic recommends surgery for each of the named Plaintiffs following a single Zoom call with each. Patients and their families are not told they are entering an unproven, experimental, and potentially dangerous process.

76. Concerned parents who came wanting to know what is going on in their children are overwhelmed and feel disoriented, fearful for the health and safety of their children, and dependent on the professional. In has been ten years since the WPATH guidelines were last revised. Much has changed in that interval.

77. The increased incidence of post-pubertal gender dysphoria in biological females since the 7th edition of the WPATH guidelines is a cause for alarm among all knowledgeable professionals. As the Dahlen et al. study pointed out, standards of care throughout medicine have the ethical standard that no more than 30% of those formulating the recommendations should earn their income based on the guidelines offered. Experts in methodology are required, in addition, to be clinicians. But the majority of WPATH's writers' group were those whose income is derived from trans care. Their "inconsistent" recommendations did not flow from scientific evidence.

78. It is my understanding that the complex committee process that will generate the final version of SOC8 is at least two years delayed; this is most likely because of controversies with the organization about what is the best policy to govern children and adolescents. Voting on policy is the product of inadequate science, which ideally, speaks for itself in dictating treatment guidelines.

79. I have reviewed the draft SOC8 guidelines released by WPATH at the end of 2021. I, along with many other professionals, found it sorely lacking. While it purports to be evidence-based, none of the recommendations are linked to the evidence, as is done in a high-quality guideline. WPATH fails to acknowledge the well-documented phenomenon known as "rapid-onset gender dysphoria" now commonly occurring among adolescents, despite the fact that multiple clinicians report this is just what they are observing is happening.[115] There is also no chapter on detransition, despite the evidence that a growing number of young people regret transition and wish to reverse it. [116] [117] Yet, WPATH contains a chapter on eunuchs and describes a "male-to-eunuch gender dysphoria," and mentions the longevity benefits of pre-pubertal castration.

80. Thus, it is my opinion that WPATH is a problematically conflicted organization that misrepresents itself as credible scientific group.

E. Key Opinions

81. I would like to elucidate the key dilemmas in the area of transgender care. Some of the statements may be somewhat repetitive with the information presented in the rebuttals of the Plaintiffs' witnesses above, so I will do my best to minimize such repetition.

1. The right to bodily autonomy via "gender-affirming" hormonal and surgical interventions should not be confused with medical necessity

[115] Hutchinson A, Midgen M, Spiliadis A. In Support of Research Into Rapid-Onset Gender Dysphoria. *Arch Sex Behav*. 2020;49(1):79-80. doi:10.1007/s10508-019-01517-9

[116] *See* Vandenbussche E. Detransition-Related Needs and Support: A Cross-Sectional Online Survey. *Journal of Homosexuality*. Published online April 30, 2021:20. doi:10.1080/00918369.2021.1919479

[117] *See* Littman L. Individuals Treated for Gender Dysphoria with Medical and/or Surgical Transition Who Subsequently Detransitioned: A Survey of 100 Detransitioners. *Arch Sex Behav*. Published online October 19, 2021. doi:10.1007/s10508-021-02163-w

82. Individuals suffering from gender dysphoria who wish to re-align the body with their inner sense of self in some specific way have this right. Their desires interact with medical and surgical technologies such that, if patient wants it and we can attain it, why not? However, this should not be equated with medical necessity.

83. The list of gender-affirming interventions is ever-growing. It is not limited to puberty blockers, cross sex hormones, breast augmentation, and genital restructuring. Rather, it now commonly includes facial surgeries involving nose, chin, forehead, lips, eyes; vocal cord surgery; hair transplantation; [118] and a growing list of procedures for patients who identify as non-binary, which include phallos-preserving vaginoplasty (the construction of a neovagina while preserving the penis) and nullification procedures (which obliterate all sex organs).[119] As surgical techniques advance, so will the list of physical modification procedures, which will one day include advances such as uterine transplantation to allow trans women to gestate. The opportunities to modify a human body to match one's internally held sense of self are nearly limitless, with a willing surgeon and available financial compensation.

84. Advocates for affirmative care insist these are not cosmetic procedures when a person has gender dysphoria, and indeed growing numbers of states are compelled to cover such procedures under the umbrella of transgender healthcare.[120] [121] The advocates of the affirmative

[118] Arocha Hair Restoration and Transplant Center, "Hair Transplants as a Part of Gender Reassignment Surgery," https://arochahairrestoration.com/gender-reassignment/hair-transplants-gender-reassignment-surgery/

[119] Align Surgical Associates, Inc., "Phallus-Preserving Vaginoplasty," https://www.alignsurgical.com/non-binary/phallus-preserving-vaginoplasty/

[120] COLORADO BENEFITS FOR HEALTH CARE COVERAGE 38, https://www.cms.gov/CCIIO/Resources/DataResources/ehb (listing covered "Gender Affirming Care").

[121] Washington State Senate Bill 5313-S2, amended by House Amendment 456, adopted Mar. 24, 2021, https://lawfilesext.leg.wa.gov/biennium/2021-22/Pdf/Amendments/House/5313-S2%20AMH%20CODY%20H1369.1.pdf

approach agree that not all people who identify as transgender need medical treatments. However, they assert that such treatments *are* medically necessary for those who desire them. In fact, "patient desire" for transgender interventions has supplanted the traditional definition of medical necessity used in all other areas of medicine. [122] The power of their rhetorical device –medically necessary—is considerable; it rests on the trusted reputation of the medical profession. Our noble profession tries hard but is not always correct.

85. West Virginia Medicaid defines medical necessity as "items or services furnished to a patient that are reasonable and necessary for the diagnosis or treatment of illness or injury, to improve the functioning of a malformed body member, to attain, maintain, or regain functional capacity, for the prevention of illness, or to achieve age appropriate growth and development." [123] PEIA defines a service as medically necessary in a similar fashion.[124] Asserting medical necessity for transgender treatments is challenging for several reasons, starting with the fact that the very ***nature of the diagnosis is in flux.***

86. First, the two prevailing diagnostic systems sharply disagree on the very fundamental aspect of the diagnosis—patient distress. [125] According to DMS-5, the patient must experience significant distress to qualify for the diagnosis of "gender dysphoria." To be considered

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[122] Turban JL, King D, Kobe J, Reisner SL, Keuroghlian AS. Access to gender-affirming hormones during adolescence and mental health outcomes among transgender adults. Radix AE, ed. *PLoS ONE*. 2022;17(1):e0261039. doi:10.1371/journal.pone.0261039

[123] National Academy for State Health Policy, "State Definitions of Medical Necessity under the Medicaid EPSDT Benefit," Apr. 23, 2021, https://www.nashp.org/medical-necessity/

[124] "A service is considered to be medically necessary if it is: consistent with the diagnosis and treatment of the injury or illness; in keeping with generally accepted medical practice standards; not solely for the convenience of the patient, family or health care provider; not for custodial, comfort or maintenance purposes; rendered in the most cost-efficient setting and level appropriate for the condition; and not otherwise excluded from coverage under the PEIA PPB Plans. See Summary Plan Description, PPB Plan A, B & D, Plan Year 2020, pg. 54. https://peia.wv.gov/Forms-Downloads/Pages/Summary-Plan-Descriptions.aspx

[125] See Levine et al., (in press). Reconsidering Informed Consent for Trans-Identified Children, Adolescents, and Young Adults. Journal of Sex & Marital Therapy.

for medical necessity, the contemplated treatments, therefore, must show that they can reduce the distress associated with "gender dysphoria." However, according to ICD-11, a diagnostic category which has come into effect in January 2022, and which is expected to supersede DSM-5 in regards to determining eligibility for transgender interventions, having distress is no longer required to be diagnosed, and rather than "gender dysphoria," the diagnosis is called "gender incongruence." If ICD-11 is to be relied on for medical necessity determination, it stands to reason that the contemplated interventions should aim to resolve the said "incongruence" in order to achieve "congruence." However, what "congruence" with one's body means is a highly personal feeling not subject to objective medical criteria. Few individuals (transgender or not) feel entirely happy with their bodies, which is one of the reasons for the booming cosmetic surgery industry in the US. Having the diagnosis for gender dysphoria / gender incongruence does not imply medical necessity for hormone replacement therapy or surgical intervention. There are many patients with gender dysphoria who do not want hormones while they are exploring their evolving identities and social roles.

87. Second, while the DSM-5 diagnosis of "gender dysphoria" (DSM-5) and its ICD-11 counterpart "gender incongruence" are actual diagnoses (albeit contradictory), it is the term "transgender" that is widely used in the context of medical necessity of hormonal and surgical interventions. However, it is not clear how the term "transgender" interacts with the diagnoses in the DSM-5 and ICD-11. For example, it is well-known that gender dysphoria can be a manifestation of underlying mental health conditions and resolves once those conditions are treated. [126] In this case, is the effected individual "transgender" while they experience gender dysphoria, but no longer "transgender" once it resolves?

[126] Urban-Kowalczyk M. Gender Dysphoria as a Clinical Manifestation of Schizophrenia – Case Series. *European Psychiatry*. 2015;30:1773. doi:10.1016/S0924-9338(15)31366-3

88. Third, there is no objective test to confirm that someone is "transgender" beyond an individual's thoughts and feelings, which are subject to change. I and other clinicians have witnessed reinvestment in the patient's biological sex in some individual patients following a period of time. There are now studies confirming that identifying as transgender for some period of time, and then re-identifying with one's sex is not an infrequent phenomenon. Such processes appear to be increasing now that quality mental health assessments are bypassed in favor of vastly eased access hormones and surgeries.

89. In the gender clinic that I founded in 1974 and continue to co-direct, we have seen many instances of individuals who claimed a transgender identity for a time, but ultimately changed their minds and reclaimed the gender identity congruent with their sex. I have published a paper on a patient who sought my therapeutic assistance to reclaim his male gender identity after 30 years living as a woman and is, in fact, living as a man today.[127] I have seen several Massachusetts inmates and trans individuals in the community abandon their trans female identity after several years.[128] A surgical group prominently active in the sex-reassignment surgery field has published a report on a series of seven male-to-female patients requesting surgery to transform their surgically constructed female genitalia back to their original male form.[129]

90. Even more importantly, the majority (61-98%) of children who identify as transgender will reidentify with their sex before reaching maturity absent any interventions. [130]

[127] Levine SB. Transitioning Back to Maleness. *Arch Sex Behav*. 2018;47(4):1295-1300. doi:10.1007/s10508-017-1136-9
[128] *See* Levine SB. Reflections on the Clinician's Role with Individuals Who Self-identify as Transgender. *Arch Sex Behav*. Published online September 15, 2021. doi:10.1007/s10508-021-02142-1
[129] Djordjevic et al. (2016), Reversal Surgery in Regretful Male-to-Female Transsexuals After Sex Reassignment Surgery, *J. Sex Med.* 13(6) 1000, DOI: 10.1016/j.jsxm.2016.02.173.
[130] Ristori J, Steensma TD. Gender dysphoria in childhood. International Review of Psychiatry. 2016;28(1):13-20. doi:10.3109/09540261.2015.1115754

[131] Many professionals are unfamiliar with these eleven research studies indicating a high natural resolution rate of gender dysphoria children by late adolescence.[132] I have personally seen children desist even before puberty in response to thoughtful parental interactions and a few meetings of the child with a therapist. However, treating a child with gender-affirming interventions appears to solidify this identity in nearly 100% of the cases.[133] [134] [135]

91. I noted an increasingly visible online community of young women who have desisted after claiming a male gender identity at some point during their teen years.[136] One such online community has over 20,000 members. [137] While it would be wrong to assert that each of the members have detransitioned, it is reasonable to assume that many are considering it and many have accomplished some degree of it. "Desisters" and "detransitioners" appear to come from a cohort of young adults who began to transition in high numbers as teens 5-7 years ago.

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[131] Singh D, Bradley SJ, Zucker KJ. A Follow-Up Study of Boys With Gender Identity Disorder. *Front Psychiatry*. 2021;12. doi:10.3389/fpsyt.2021.632784

[132] Cantor J. M. (2020). Transgender and Gender Diverse Children and Adolescents: Fact-Checking of AAP Policy. *Journal of Sex & Marital Therapy*, *46*(4), 307–313. https://doi.org/10.1080/0092623X.2019.1698481

[133] Zucker, *Myth of Persistence*, at 8 (citing H. Meyer-Bahlburg (2002), Gender Identity Disorder in Young Boys: A Parent- & Peer-Based Treatment Protocol, *Clinical Child Psychology & Psychiatry* 7, 360 at 362.).

[134] Brik T, Vrouenraets LJJJ, de Vries MC, Hannema SE. Trajectories of Adolescents Treated with Gonadotropin-Releasing Hormone Analogues for Gender Dysphoria. *Arch Sex Behav*. 2020;49(7):2611-2618. doi:10.1007/s10508-020-01660-8

[135] Carmichael P, Butler G, Masic U, 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. Santana GL, ed. *PLoS ONE*. 2021;16(2):e0243894. doi:10.1371/journal.pone.0243894

[136] Entwistle K. Debate: Reality check – Detransitioner's testimonies require us to rethink gender dysphoria. *Child Adolesc Ment Health*. Published online May 14, 2020:camh.12380. doi:10.1111/camh.12380

[137] Reddit, Detransition Subreddit, https://www.reddit.com/r/detrans/

This phenomenon is driven primarily by adolescent females, although adolescent males also present for care in much higher numbers than previously observed.[138] For example, at a London pediatric gender clinic in 2000-2001, 26 requests for services occurred; in 2019-2020, 2728 referrals were recorded—more than a 100-fold increase.[139,140] The explosive growth of urban trans health centers in the US also reflects a similar trend.

92. Researchers are just starting to explore the phenomenon of rapid trans-identification followed by re-identification with their biological sex. Before this, neither advocates nor skeptics of hormonal and surgical interventions had any sense of the rate of these phenomena. One of the first studies to note the phenomenon or rapid trans-identification in teen years following a gender-normative childhood was by Littman.[141] This is the research that Dr. Karasic worked hard to suppress, as discussed above. The phenomenon she described has now been confirmed by every major pediatric gender clinic in the world. [142] [143] [144] Two very recent studies from several UK clinics that suggest the rate of detransition among patients who transitioned in recent years is as high as 10% in the first 18 months of treatment and could be much higher if the

[138] Zucker K. J. (2019), Adolescents with Gender Dysphoria: Reflections on Some Contemporary Clinical and Research Issues, *Archives of Sexual Behavior*, 48(7), 1983-1992. https://doi.org/10.1007/s10508-019-01518-8

[139] de Graaf, N. M., Carmichael, P., Steensma, T. D., & Zucker, K. J. (2018). Evidence for a Change in the Sex Ratio of Children Referred for Gender Dysphoria: Data From the Gender Identity Development Service in London (2000-2017). *The Journal of Sexual Medicine*, 15(10), 1381–1383. https://doi.org/10.1016/j.jsxm.2018.08.002.

[140] Zucker K. J. (2017). Epidemiology of gender dysphoria and transgender identity. *Sexual Health*, 14(5), 404–411. https://doi.org/10.1071/SH17067

[141] *See* L. Littman (2018), Parent Reports of Adolescents & Young Adults Perceived to Show Signs of a Rapid Onset of Gender Dysphoria, *PLoS ONE* 13(8): e0202330 at 13.

[142] *See* de Graaf NM, Giovanardi G, Zitz C, Carmichael P. Sex Ratio in Children and Adolescents Referred to the Gender Identity Development Service in the UK (2009–2016). *Arch Sex Behav*. 2018;47(5):1301-1304. doi:10.1007/s10508-018-1204-9

[143]*See* Kaltiala-Heino R, Bergman H, Työläjärvi M, Frisen L. Gender dysphoria in adolescence: current perspectives. *AHMT*. 2018;Volume 9:31-41. doi:10.2147/AHMT.S135432

[144] Zucker KJ. Adolescents with Gender Dysphoria: Reflections on Some Contemporary Clinical and Research Issues. *Arch Sex Behav*. 2019;48(7):1983-1992. doi:10.1007/s10508-019-01518-8

patients lost to follow-up are accounted for (20%+ dropped out of treatment). Two more studies that pursued in-depth exploration of the motivations that lead one to a trans identification and later desistance have been published, showing that social influence, uncontrolled mental illness, and other factors had led these individuals to an erroneous temporary conclusion that they were transgender. [145] [146] [147] [148]

93. Although numerous studies have been undertaken to attempt to demonstrate a distinctive physical "brain structure" associated with transgender identity, as of yet there is no credible scientific evidence that these patients have any defining abnormality in brain structure that precedes the onset of gender dysphoria.[149,150] More recent studies demonstrating diverse MRI patterns seem to be adding to the hypothesis that the brain may be different in these groups, but whether the differences are caused by the identity or themselves cause the identity is unclear. Most authorities in the field are clear such data are used to build an etiological hypothesis and do not justify statements suggesting gender dysphoria is a biological illness.[151]

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[145] *See* Boyd I, Hackett T, Bewley S. Care of Transgender Patients: A General Practice Quality Improvement Approach. *Healthcare*. 2022;10(1):121. doi:10.3390/healthcare10010121

[146] *See* Hall R, Mitchell L, Sachdeva J. Access to care and frequency of detransition among a cohort discharged by a UK national adult gender identity clinic: retrospective case-note review. *BJPsych open*. 2021;7(6):e184. doi:10.1192/bjo.2021.1022

[147] *See* Vandenbussche E. Detransition-Related Needs and Support: A Cross-Sectional Online Survey. *Journal of Homosexuality*. Published online April 30, 2021:20. doi:10.1080/00918369.2021.1919479

[148] *See* Littman L. Individuals Treated for Gender Dysphoria with Medical and/or Surgical Transition Who Subsequently Detransitioned: A Survey of 100 Detransitioners. *Arch Sex Behav*. Published online October 19, 2021. doi:10.1007/s10508-021-02163-w

[149] Mueller, De Cuypere & T'Sjoen. Transgender research in the 21st century: A selective critical review from a neurocognitive perspective. *American Journal of Psychiatry* 174: 12, 2017.

[150] Frigerio et al (2021) Structural, functional, and metabolic brain differences as a function of gender identity or sexual orientation: A systematic review of the human neuroimaging literature. *Archives of Sexual Behavior*. 503329-3352. https://doi.org/10.1007/s10508-021-02005-9

[151] See Mueller SC, et al The Neuroanatomy of Transgender Identity: Mega-Analytic Findings From the ENIGMA Transgender Persons Working Group. *J Sex Med*. 2021 Jun;18(6):1122-1129. doi: 10.1016/j.jsxm.2021.03.079. Epub 2021 May 22. PMID: 34030966

94. Thus, because the causal mechanisms of gender incongruence are not scientifically established, the available diagnoses are contradictory in terms of what the nature of the problem that is addressed is, it is challenging to even begin to establish the basis for medical necessity.

B. Medically-necessary care should not be conflated with "gender-affirming" care. The latter has not been shown to result in significant lasting improvements in mental health or reduction in suicidality/suicide long-term.

95. Further, to demonstrate medical necessity, one must be able to demonstrate that treatments "improve the functioning of a malformed body member, to attain, maintain, or regain functional capacity, for the prevention of illness, or to achieve age appropriate growth and development." [152] However, despite decades of research, no convincing evidence exists that either hormonal or surgical interventions result *in lasting improvements* to the individuals' functioning, mental health, substance abuse, or suicidality. The research purporting to show these benefits comes from poor-quality, short-term studies, and is contradicted by longer-term, higher-quality studies and quality systematic reviews of evidence. [153] [154] [155] [156] I note that the Plaintiffs' expert

[152] *See* National Academy for State Health Policy, "State Definitions of Medical Necessity under the Medicaid EPSDT Benefit," Apr. 23, 2021, https://www.nashp.org/medical-necessity/
[153] Correction to Bränström and Pachankis. *AJP*. 2020;177(8):734-734. doi:10.1176/appi.ajp.2020.1778correction
[154] Hayes, Inc., Sex Reassignment Surgery for the Treatment of Gender Dysphoria, Hayes Directory (Aug. 1, 2018).
[155] See National Institute for Health and Care Excellence - NICE, Evidence review: Gonadotrophin releasing hormone analogues for children and adolescents with gender dysphoria, 11 March 2021, at https://www.evidence.nhs.uk/document?id=2334888&returnUrl=search%3fq%3dtransgender%26s%3dDate
[155] *See* National Institute for Health and Care Excellence - NICE, Evidence review: Gender-affirming hormones for children and adolescents with gender dysphoria, 11 March 2021, at https://www.evidence.nhs.uk/document?id=2334889&returnUrl=search%3ffrom%3d2021-03-10%26q%3dEvidence%2bReview%26to%3d2021-04-01
[156] *See* Decision Memo for Gender Dysphoria and Gender Reassignment Surgery (CAG-00446N). :109. https://www.cms.gov/medicare-coverage-database/view/ncacal-decision-memo.aspx?proposed=N&NCAId=282

witnesses do not address the quality of evidence in favor of their opinions. But it is an ethical principle throughout medicine that treatment should be based on science.

96. In evaluating claims of scientific or medical knowledge, it is important to recognize the widely accepted hierarchy of reliability when it comes to "knowledge" about medical or psychiatric phenomena and treatments. Unfortunately, in this field opinion is too often confused with knowledge. In order of increasing confidence, such "knowledge" may be based upon data comprising:

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

b. A single case or series of cases (what could be called anecdotal evidence),

c. A series of cases with a control group,

d. A cohort study,

e. A randomized double-blind clinical trial,

f. An overview of the multiple studies (e.g., narrative review, descriptive review, etc.),

g. A systematic review of all available studies on a given topic. It may also include meta-analysis of multiple trials that maximizes the number of patients treated despite their methodological differences to detect trends from larger data sets.

97. Individual studies can suffer from methodological limitations that make them unreliable. As an experienced reviewer of submitted manuscripts to well respected scientific journals, I find myself frequently pointing out to authors that their conclusions are presented with too much confidence, certainty, or authority given the limitations that they have described in their

article. The danger of this is that when they or others quote their findings in a sentence or two, there is no hint of the studies known limitations. This phenomenon is one of the reasons why whenever possible, clinical and policy decision-makers more heavily rely on systematic reviews of evidence. Systematic reviews utilize reproducible methods to systematize and categorize all available knowledge. However, to be credible systematic reviews need to be conducted according to strict metrological standards. To date, every credible quality systematic review of evidence in the area of transgender medicine have found the evidence to be of low to very low quality, and the findings of benefits to be uncertain.

98. Cochrane reviews are generally considered the gold standard of systematic reviews in medicine.[157] Cochrane goes to great lengths to assure that researchers conducting the reviews of evidence are free from problematic conflicts of interest, and that they follow a strict and highly reproducible research methodology. A 2020 Cochrane review of hormonal treatment outcomes for male-to-female transitioners older than 16 years found "insufficient evidence to determine the efficacy or safety of hormonal treatment approaches." It is remarkable that six decades after the first transitioned male-to-female patient, quality evidence for the benefit of transition is still lacking.[158]

99. The National Institute of Health and Care Excellence (NICE) is another organization known for its excellence and expertise in evidence evaluation. They undertook two systematic evidence reviews of the use of GnRH agonists ("puberty blockers") and cross-sex hormones as treatments for gender dysphoric patients <18 years old. These reviews were led by Dr. Hilary

[157] Deshpande S, Misso K, Westwood M, et al. Not All Cochrane Reviews Are Good Quality Systematic Reviews. *Value in Health*. 2016;19(7):A371. doi:10.1016/j.jval.2016.09.142

[158] See Haupt, C., Henke, M. et. al., Cochrane Database of Systematic Reviews, Review – Intervention, Antiandrogen or Estradiol Treatment or Both during Hormone Therapy in Transitioning Transgender Women, 28 November 2020. https://doi.org/10.1002/14651858.CD013138.pub2, at https://www.cochranelibrary.com/cdsr/doi/10.1002/14651858.CD013138.pub2/full

Cass and published in March 2021. The reviews found the evidence of benefit of using puberty blocking drugs and cross sex hormones to treat young people struggling with gender identity as "very low certainty." For puberty blockers, the review's conclusions stated, "The results of the studies that reported impact on the critical outcomes of gender dysphoria and mental health (depression, anger and anxiety), and the important outcomes of body image and psychosocial impact (global and psychosocial functioning), in children and adolescents with gender dysphoria are of very low certainty using modified GRADE. They suggest little change with GnRH [puberty blockers] analogues from baseline to follow-up."[159] To state it plainly, the review found no credible evidence that puberty blockers improve functioning of children. A similar conclusion of very low certainty was drawn regarding the evidence of treatment with cross-sex hormones. The review noted a possibility of benefits, but stated, "[a]ny potential benefits of gender-affirming hormones must be weighed against the largely unknown long-term safety profile of these treatments in children and adolescents with gender dysphoria."[160] NICE reviews did not address surgeries, but other systematic reviews did.

100. Another expert systematic review, conducted by the Hayes Corporation, which reviews treatments for insurance payers for 84% of insured Americans, reviewed evidence for gender reassignment surgery, rating the quality of evidence from "A" (strongest) to "D2" (weakest). The evidence of gender-affirming surgery for minors earned the lowest "D2" rating: "insuf-

[159] *See* National Institute for Health and Care Excellence - NICE, Evidence review: Gonadotrophin releasing hormone analogues for children and adolescents with gender dysphoria, p. 13. 11 March 2021, at https://www.evidence.nhs.uk/document?id=2334888&returnUrl=search%3fq%3dtransgender%26s%3dDate

[160] See National Institute for Health and Care Excellence - NICE, Evidence review: Gender-affirming hormones for children and adolescents with gender dysphoria, p. 14. 11 March 2021, at https://www.evidence.nhs.uk/document?id=2334889&returnUrl=search%3ffrom%3d2021-03-10%26q%3dEvidence%2bReview%26to%3d2021-04-01

ficient published evidence to assess the safety and/or impact on health outcomes or patient management." The rating for surgeries for adults was a higher grade of "C," indicating "[p]otential but unproven benefit." Hayes noted, "substantial uncertainty remains about safety and/or impact on health outcomes because of poor-quality studies, sparse data, conflicting study results, and/or other concerns." [161]

101. The Centers for Medicare & Medicaid Services, within the U.S. Department of Health and Human Services (HHS) conducted a systematic review of evidence of gender-affirming surgeries for adults. The HHS refused to mandate coverage for these services due to insufficient evidence of benefit. Remarkably, the HHS stated: "Further, we cannot exclude [gender-affirming] therapeutic interventions as a cause of the observed excess morbidity and mortality."[162]

102. The public health authorities in Sweden and Finland, countries that are among the pioneers of medical transition, have recently concluded their own systematic reviews of evidence of gender-affirming interventions, with a focus on youth. Both came to similar conclusions as the systematic reviews above: the evidence of benefit was found to be unconvincing. [163] [164] Consequently, both Finland, and Sweden's leading Karolinksa Hospital (which grants the Nobel Prize

[161] *See* Hayes, Inc., Sex Reassignment Surgery for the Treatment of Gender Dysphoria, Hayes Directory (Aug. 1, 2018).
[162] Decision Memo for Gender Dysphoria and Gender Reassignment Surgery (CAG-00446N). p. 46. :109. https://www.cms.gov/medicare-coverage-database/view/ncacal-decision-memo.aspx?proposed=N&NCAId=282
[163] *See* Gender affirmation surgery for gender dysphoria - effects and risks: Health Technology Assessment review 2018. Swedish Health Authority. Published online 2018. https://alfresco-offentlig.vgregion.se/alfresco/service/vgr/storage/node/content/workspace/SpacesStore/441006af-62a7-4f19-be73-6d698bf635f5/2018_102%20Rapport%20K%C3%B6nsdysfori.pdf?a=false&guest=true&fbclid=IwAR2_BBlVfFBKok9XZ7JiTXfwOfTgcCXIzAySkh6wlXUJK8s_L_8XZy-tdIA
[164]Pasternack I, Söderström I, Saijonkari M, Mäkelä M. Lääketieteelliset menetelmät sukupuolivariaatioihin liittyvän dysforian hoidossa. Systemaattinen katsaus. [Appendix 1 Systematic Review]. Published online 2019:106. Accessed March 1, 2021. https://app.box.com/s/y9u791np8v9gsunwgpr2kqn8swd9vdtx

in Medicine) have either stopped or sharply curtailed the practice of pediatric gender transitions, and now prioritize psychotherapy instead.

103. A review by Professor Carl Heneghan, the editor of the British Medical Journal, and the Director of the Centre for Evidence-Based Medicine in Oxford University, also conducted a review of evidence with a focus on young people (although it was not a "systematic review"). His conclusion was that the evidence for the use of gender-affirming puberty blockers and hormones in youth was of very low quality, and there are substantial risks and unknowns involved. He stated, "The development of these interventions should, therefore, occur in the context of research, and treatments for under 18 gender dysphoric children and adolescents remain largely experimental. There are a large number of unanswered questions that include the age at start, reversibility; adverse events, long term effects on mental health, quality of life, bone mineral density, osteoporosis in later life and cognition. We wonder whether off label use is appropriate and justified for drugs such as spironolactone which can cause substantial harms and even death. We are also ignorant of the long-term safety profiles of the different GAH regimens. The current evidence base does not support informed decision making and safe practice in children." [165]

104. In 2017, the Endocrine Society published clinical guidelines for the treatment of patients with persistent gender dysphoria. [166] These guidelines were based on two systematic reviews, which also found the evidence for hormonal use to be of "very low" and "low" quality

[165] Heneghan C, Jefferson T. Gender-affirming hormone in children and adolescents. BMJ EBM Spotlight. Published February 25, 2019. Accessed October 9, 2020. https://blogs.bmj.com/bmjebmspotlight/2019/02/25/gender-affirming-hormone-in-children-and-adolescents-evidence-review/

[166] See Hembree, W. C. et al. Endocrine Treatment of Gender-Dysphoric/Gender-Incongruent Persons: An Endocrine Society Clinical Practice Guideline. *J Clin Endocrinol Metab*, doi: 10.1210/jc.2017-01658 (2017) p.3-4.

(i.e., which translates into low confidence in the balance of risk and benefits)." Despite this sober assessment, the Endocrine Society instructed clinicians to proceed with treating gender-dysphoric youth with hormonal interventions in its guidelines. However, while the guidelines "recommended" hormonal interventions for gender dysphoric individuals, these recommendations were graded as "weak." The guidelines' authors had this to say about what differentiates a "weak" recommendation from a "strong" one: "the task force has confidence that persons who receive care according to the strong recommendations will derive, on average, more benefit than harm. Weak recommendations require more careful consideration of the person's circumstances, values, and preferences to determine the best course of action." In other words, the Endocrine Society is saying: we cannot be sure that on average, the benefits of administering hormonal interventions will outweigh the harm—for either adults or children." This indeed is a sobering notion.

105. There are, of course, "overviews" and "systematic reviews" that will claim just the opposite—that hormones and surgeries are a proven, safe, and effective treatment. Such reviews are often problematically conflicted. Rather than being conducted by independent experts in evidence evaluation with no conflicts of interest, they are often commissioned by activist clinicians and/or funded by organizations such as WPATH (the organization with a stated goal of creating broad access for hormones and surgeries for all those who wish to receive them) or one of its pharmaceutical company sponsors.

106. I am familiar with least two such recent reviews, which are problematically flawed, although I am certain there are others.[167] [168] One of them was recently harshly critiqued by a group of researchers and exposed as deeply flawed.[169] The authors note that the review of the evidence for puberty blockers, "illustrates a concerning trend, that we have observed in the GD [gender dysphoria] literature, to overstate the evidence underpinning clinical practice recommendations for youth with GD. New publications reference prior ones with increasing and unwarranted confidence, and with the risk of misleading clinicians regarding the state of evidence. There is also a marked asymmetry in outcomes reporting: findings of positive outcomes of medical interventions are trumpeted in abstracts, while their profound limitations cannot be seen by busy clinicians unless they have a subscription to the journal. (Journals typically charge ~$40 per article.) To the best of my knowledge, another group of researchers contacted the publishing journal of the other review, commissioned by WPATH, and which will serve as the basis for WPATH's upcoming SOC8 recommendation, but the editor refused to publish the critique.

107. A discerning consumer of systematic reviews will note that reviews published by independent authorities with no conflict of interest universally find no compelling evidence that gender-affirming treatments lead to demonstrable lasting improvements in mental health, while reviews commissioned and / or led by transgender rights activists tend to find just the opposite.

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[167] Rew L, Young CC, Monge M, Bogucka R. Review: Puberty blockers for transgender and gender diverse youth—a critical review of the literature. *Child Adolesc Ment Health*. 2021;26(1):3-14. doi:10.1111/camh.12437

[168] Baker KE, Wilson LM, Sharma R, Dukhanin V, McArthur K, Robinson KA. Hormone Therapy, Mental Health, and Quality of Life Among Transgender People: A Systematic Review. *Journal of the Endocrine Society*. 2021;5(4):bvab011. doi:10.1210/jendso/bvab011

[169] *See* Clayton A, Malone WJ, Clarke P, Mason J, D'Angelo R. Commentary: The Signal and the Noise—questioning the benefits of puberty blockers for youth with gender dysphoria—a commentary on Rew et al. (2021). *Child Adoles Ment Health*. Published online December 22, 2021:camh.12533. doi:10.1111/camh.12533

108. The question of suicide and whether gender-affirming treatments reduce suicide deserves special consideration. Like many proponents of unfettered access to hormones and surgery, Dr. Karasic raises the specter of suicide and claims that "[t]he denial of medically indicated care to transgender people … causes additional distress and poses other health risks, such as … suicidality."[170] Contrary to such assertions, no studies show that "affirmation" with hormones and surgeries reduces suicides in the long term.

109. Individuals with gender dysphoria are well known to have a higher risk of committing suicide or otherwise suffering increased mortality before and after gender-confirmation. [171] For example, in the United States, the death rates of trans veterans are comparable to those with schizophrenia and bipolar diagnoses—20 years earlier than expected. These crude death rates include significantly elevated suicide rates.[172] Similarly, researchers in Sweden have reported on almost all individuals who underwent sex-reassignment surgery over a 30-year period.[173] The Swedish follow-up study found a suicide rate in the post-surgery population 19.1 times greater than that of the controls after affirmation treatment. Decades later, the suicide rate was still 3.5 times greater among the trans identified Swedish population than other citizens.

[170] Karasic, p.8 para 28
[171] *See* Levine SB. Reflections on the Clinician's Role with Individuals Who Self-identify as Transgender. *Arch Sex Behav*. Published online September 15, 2021. doi:10.1007/s10508-021-02142-1
[172] Levine SB. Ethical Concerns About Emerging Treatment Paradigms for Gender Dysphoria. *Journal of Sex & Marital Therapy*. 2018;44(1):29-44. doi:10.1080/0092623X.2017.1309482
[173] C. Dhejne et al. (2011), Long-Term Follow-Up of Transsexual Persons Undergoing Sex Reassignment Surgery: Cohort Study in Sweden, *PLOS ONE* 6(2) e16885 ("Long Term"); R. K. Simonsen et al. (2016), Long-Term Follow-Up of Individuals Undergoing Sex Reassignment Surgery: Psychiatric Morbidity & Mortality, *Nordic J. of Psychiatry* 70(4).

110. However, there is no evidence that transition reduces suicide rates. For example, a key study from the Netherlands found that suicide rates are similar across all stages of transition from pre-treatment assessment, to several post-surgery.[174]

111. The most conclusive results, however, come from a key paper by Bränström and Panchankis published in 2019. [175] The original paper did not find that hormones improved long-term mental health or suicide attempted, but did find such an effect for surgeries, claiming "the longitudinal association between gender-affirming surgery and reduced likelihood of mental health treatment lends support to the decision to provide gender-affirming surgeries to transgender individuals who seek them." They claimed their research provided the first empirical evidence that gender transition surgeries had long-term mental-health benefits.

112. Seven letters were submitted to the editor from MDs, PhDs, and other methodologists that clarified methodological blunders and/or misrepresentations of the data. These were published in August 2020 along with the original article. Following these letters, the journal editors commissioned independent statistical reviews, and following a re-analysis, the researchers had to admit that there was no evidence that surgeries improved mental health or suicidality either (in fact, suicide attempts were roughly double in the "surgery" compared to the "no surgery" group although the result was not statistically significant).

[174] C.M. Wiepjes, et al. (2020), Trends in Suicide Death Risk in Transgender People: Results from the Amsterdam Cohort of Gender Dysphoria Study (1972–2017), *Acta Psychiatr Scand* 141(6). https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7317390/.

[175] See Bränström R, Pachankis JE: Reduction in Mental Health Treatment Utilization among Transgender Individuals after Gender-affirming Surgeries: A Total Population Study. *Am J Psychiatry* 2020; 177: 727–734.

113. The journal published a correction, along with the authors' statement that "more research" is needed.[176] [177] Remarkably, the journal allowed the original publication with its flawed title, which states that surgeries reduce risk of suicide, to stand uncorrected. The correction is instead residing along with the original article, unconscious, despite the fact that the correction entirely invalidated the study's main conclusion. This illustrates the bias that currently plagues transgender research literature, where studies with "positive" findings are quickly published and lauded, while correction of flawed data are either not undertaken, or if pursued, tend to be "buried." As pervasive and powerful a problem this is within trans medicine, I would like to again emphasize that the Bränström and Panchankis study was undertaken in order to investigate the long term psychological benefits of these increasingly common interventions.

114. Another example of the gross bias in the state of transgender treatment literature toward escalating poor quality "positive" findings while suppressing well-reasoned critique is the 2020 article by Turban, et al.[178] This publication, purporting that puberty blockers prevent suicidality, has been heavily promoted by the journal that published it, and has been widely covered by lay press. The study suffers from very serious limitations and cannot be used to justify such a sweeping claim. It has been rigorously criticized for a range of issues, not least among which was not emphasizing that both those treated and not treated with puberty blockers had high suicidal ideation rates and more patients on these drugs were hospitalized for suicidal plans than the untreated. However, the researchers who escalated these concerns to the journal editor were not permitted to publish their critique. Instead, they had to find other journals to make their critique

[176] See Correction to Bränström and Pachankis. *AJP*. 2020;177(8):734-734.
[177] See Bränström, R. and Pachankis, J. , Toward Rigorous Methodologies for Strengthening Causal Inference in the Association Between Gender-Affirming Care and Transgender Individuals' Mental Health: Response to Letters, *Am J Psychiatry* 2020; 177:769–772; doi: 10.1176/appi.ajp.2020.20050599.
[178] *See* J. Turban et al., Puberty Suppression for Transgender Youth and Risk of Suicidal Ideation, *Pediatrics* 145(2), DOI: 10.1542/peds.2019-1725

public.[179] [180] [181] This is highly unusual for other areas of research, where debate is welcomed. Notably, a recent re-analysis of the same data used by Dr. Turban and his colleagues showed no effect of puberty blockers on mental health, invalidating the study's headline findings. [182]

115. It is important to note that in considering "suicide," mental health professionals distinguish between suicidal thoughts (ideation), suicide gestures, suicide attempts with a lethal potential, and completed suicide. Numerous studies have found suicidal ideation to have been present at some time in life in at least ~40-50% of adolescents and adults before and after various forms of transition. This figure is approximately twice that in gay and lesbian communities. In the heteronormative communities it is approximately 4%.

116. While elevated, suicide in trans-identified individuals remains, thankfully, a relatively rare event. The estimated suicide rate of trans adolescents is similar to that of teenagers who are in treatment for serious mental illness.[183] What trans teenagers do demonstrate is more suicidal ideation and attempts (however serious) than other teenagers.[184] Recently, the UK data was used to estimate the suicide rate in trans-identified teens and found it to be 0.03% over a 10-

[179] See Biggs M. Puberty Blockers and Suicidality in Adolescents Suffering from Gender Dysphoria. *Arch Sex Behav*. 2020;49(7):2227-2229. doi:10.1007/s10508-020-01743-6
[180] *See* D'Angelo R, Syrulnik E, Ayad S, Marchiano L, Kenny DT, Clarke P. One Size Does Not Fit All: In Support of Psychotherapy for Gender Dysphoria. *Arch Sex Behav*. Published online October 21, 2020. doi:10.1007/s10508-020-01844-2
[181] *See* Clayton A, Malone WJ, Clarke P, Mason J, D'Angelo R. Commentary: The Signal and the Noise—questioning the benefits of puberty blockers for youth with gender dysphoria—a commentary on Rew et al. (2021). *Child Adoles Ment Health*. Published online December 22, 2021:camh.12533. doi:10.1111/camh.12533
[182] *See* Biggs, Michael (2022): Comment on Turban et al. 2022: Estrogen is associated with greater suicidality among transgender males, and puberty suppression is not associated with better mental health outcomes for either sex. figshare. Journal contribution. https://doi.org/10.6084/m9.figshare.19018868.v1
[183] de Graaf NM, Steensma TD, Carmichael P, et al. Suicidality in clinic-referred transgender adolescents. *Adolescent Psychiatry*. Published online June 2020:17. doi:https://doi.org/10.1007/s00787-020-01663-9
[184] A. Perez-Brumer, J. K. Day et al. (2017), Prevalence & Correlates of Suicidal Ideation Among Transgender Youth in Cal.: Findings from a Representative, Population-Based Sample of High Sch. Students, *J. Am. Acad. Child Adolescent Psychiatry* 56(9), 739 at 739.

year period, while the adult rate was estimated to be 0.6% over a 20-year period in Sweden .[185] [186]

117. In sum, claims that affirmation will reduce the risk of suicide are not based on science. Such claims overlook the complexity of suicide as a phenomenon which is rarely driven by a single cause and the lack of long-term evidence that gender-affirmation reduces suicides. They also overlook the other tools that the profession does have for addressing depression and suicidal thoughts in a patient once that risk is identified, including cognitive behavioral therapy, medication, a new psychotherapy process. and other proven interventions. Psychiatry, of course, has a long history of striving to prevent suicide in those who seek our care.[187]

C. There are significant risks of complications associated with gender-affirming hormonal and surgical interventions.

118. The risks associated with medical transition are significant. They tend to be underplayed in the literature promoting transgender medical and surgical interventions. The risks affect a range of domains.

[185] Biggs M. Suicide by Clinic-Referred Transgender Adolescents in the United Kingdom. *Arch Sex Behav*. Published online January 18, 2022. doi:10.1007/s10508-022-02287-7
[186] Socialstyrelsen [National Board of Health and Welfare]. *Utvecklingen Av Diagnosen Könsdysfori [The Evolution of the Diagnosis of Gender Dysphoria]*. Socialstyrelsen [Swedish Health Authority]; 2020. Accessed October 29, 2020. https://www.socialstyrelsen.se/om-socialstyrelsen/pressrum/press/vanligt-med-flera-psykiatriska-diagnoser-hos-personer-med-konsdysfori/
[187] *See* Levine S. B. (2021). Reflections on the Clinician's Role with Individuals Who Self-identify as Transgender. *Archives of Sexual Behavior*, 50(8), 3527–3536. https://doi.org/10.1007/s10508-021-02142-1

Disease and mortality generally

119. Hormonal interventions are associated with 3-5 fold increase in rates of heart attacks and strokes, with effects on bone health, and with generally elevated morbidity and mortality of adults. [188] [189] [190] [191] [192]

120. Shortened life expectancy has been repeatedly documented in Sweden, the US, and Denmark..

121. Many of the long-term risks for young people are not yet known, as the practice of medically transitioning minors and young people is relatively new and no long-term data are available.

122. After puberty, the individual who wishes to live as the opposite sex will in most cases have to take cross-sex hormones for most of life. The long-term health risks of this major alteration of hormonal levels have not yet been quantified in terms of exact risk.[193] However, a recent study found greatly elevated levels of strokes and other acute cardiovascular events among male-to-female transgender individuals taking estrogen. Those authors concluded, "it is

[188] *See* Alzahrani T, Nguyen T, Ryan A, et al. Cardiovascular Disease Risk Factors and Myocardial Infarction in the Transgender Population. *Circ: Cardiovascular Quality and Outcomes*. 2019;12(4). doi:10.1161/CIRCOUTCOMES.119.005597

[189] *See* Getahun D, Nash R, Flanders WD, et al. Cross-sex Hormones and Acute Cardiovascular Events in Transgender Persons. *Ann Intern Med*. 2018;169(4):205-213. doi:10.7326/M17-2785

[190] *See* Klink D, Caris M, Heijboer A, van Trotsenburg M, Rotteveel J. Bone Mass in Young Adulthood Following Gonadotropin-Releasing Hormone Analog Treatment and Cross-Sex Hormone Treatment in Adolescents With Gender Dysphoria. *The Journal of Clinical Endocrinology & Metabolism*. 2015;100(2):E270-E275. doi:10.1210/jc.2014-2439

[191] *See* Biggs M. Revisiting the effect of GnRH analogue treatment on bone mineral density in young adolescents with gender dysphoria. *J Pediatr Endocrinol Metab*. 2021;34(7):937-939. doi:10.1515/jpem-2021-0180

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

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

critical to keep in mind that the risk for these cardiovascular events in this population must be weighed against the benefits of hormone treatment."[194]

123. Another group of authors similarly noted that administration of cross-sex hormones creates "an additional risk of thromboembolic events"—blood clots which are associated with strokes, heart attacks, and lung and liver failure.[195] The reason medical follow up of lipid parameters, weight gain, smoking history, and red blood cell counts is recommended for patients on hormones is that these are known predisposing factors to cardiovascular disease in the future.

124. Clinicians must distinguish the apparent short-term safety of hormones from likely or possible long-term consequences, and help the patient or parents understand these implications as well. Although the young patient may feel, "I don't care if I die young, just as long I get to live as a woman," the mature adult may take a different view of such risks, including that of reduced life expectancy.[196]

Health risks inherent in complex surgery

125. Complications of surgery exist for each procedure,[197] and complications in surgery affecting the reproductive organs and urinary tract can have significant anatomical and functional complications for the patient's quality of life. In the famous "Dutch study," one of 70 treated adolescents died as a result of surgery. [198]

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[194] D. Getahun et al. (2018), Cross-Sex Hormones and Acute Cardiovascular Events in Transgender Persons: A Cohort Study, *Annals of Internal Medicine* at 8, DOI:10.7326/M17-2785.
[195] *See* C. Guss et al., *TGN Adolescent Care* at 5.
[196] See Blosnich, J. R., Brown, G. R., Wojcio, S., Jones, K. T., & Bossarte, R. M. (2014). Mortality among Veterans with Transgender-related Diagnoses in the Veterans Health Administration, FY2000–2009. *LGBT Health*, 1, 269–276. doi:10.1089/lgbt.2014.0050
[197] Levine, *Informed Consent*, at 5 (citing T. van de Grift, G. Pigot et al. (2017), A Longitudinal Study of Motivations Before & Psychosexual Outcomes After Genital Gender-Confirming Surgery in Transmen, *J. Sexual Medicine* 14(12) 1621.).
[198] *See* de Vries ALC, McGuire JK, Steensma TD, Wagenaar ECF, Doreleijers TAH, Cohen-Kettenis PT. Young Adult Psychological Outcome After Puberty Suppression and Gender Reassignment. *Pediatrics*. 2014;134(4):696-704. doi:10.1542/peds.2013-2958

126. Non-fatal but serious surgical complications are common for all surgeries, from mastectomies, where a significant proportion of individuals permanently lose sensation, to genital surgeries, which can result in lasting problems with pain, urination, and a myriad of other issues. [199] [200] [201] Re-operations are frequently performed.

Infertility and Sterility

127. Sex-reassignment surgery that removes testes, ovaries, or the uterus is inevitably sterilizing. While by no means all transgender adults elect sex-reassignment surgery, many patients do ultimately feel compelled to take this serious step in their effort to live fully as the opposite sex.

128. Treating children with puberty blockers followed by cross-sex hormones is expected to result in sterility.[202] Fertility preservation is often not possible with children whose gonads have not yet matured. Most children do not opt for fertility preservation when such options are offered.[203] Children cannot adequately anticipate their future desires to be a biological parent. The future psychological burden of sterility for such youth is yet unknown, as no long-term follow-up exists on children who were treated in this manner.

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[199] *See* Olson-Kennedy J, Warus J, Okonta V, Belzer M, Clark LF. Chest Reconstruction and Chest Dysphoria in Transmasculine Minors and Young Adults: Comparisons of Nonsurgical and Postsurgical Cohorts. *JAMA Pediatr*. 2018;172(5):431. doi:10.1001/jamapediatrics.2017.5440

[200] Dreher PC, Edwards D, Hager S, et al. Complications of the neovagina in male-to-female transgender surgery: A systematic review and meta-analysis with discussion of management: Systematic Review of Neovaginal Complications. *Clin Anat*. 2018;31(2):191-199. doi:10.1002/ca.23001

[201] Rashid M, Tamimy MS. Phalloplasty: The dream and the reality. *Indian J Plast Surg*. 2013;46(2):283-293. doi:10.4103/0970-0358.118606

[202] *See* Laidlaw MK, Van Meter QL, Hruz PW, Van Mol A, Malone WJ. Letter to the Editor: "Endocrine Treatment of Gender-Dysphoric/Gender-Incongruent Persons: An Endocrine Society Clinical Practice Guideline." *J Clin Endocrinol Metab*. 2019;104(3):686-687. doi:10.1210/jc.2018-01925

[203] *See* Nahata L, Tishelman AC, Caltabellotta NM, Quinn GP. Low Fertility Preservation Utilization Among Transgender Youth. *J Adolesc Health*. 2017;61(1):40-44. doi:10.1016/j.jadohealth.2016.12.012

[203] Mattawanon N, Spencer JB, Schirmer DA, Tangpricha V. Fertility preservation optio

129. Practitioners must also recognize that the administration of cross-sex hormones creates a risk of infertility or irreversible sterility. These risks have never been properly studied nor quantified in a systematic manner. [204] [205]

130. The life-long negative emotional impact of infertility on both men and women has been well studied. While this impact has not been studied specifically within the transgender population, the opportunity to be a parent is likely a human, emotional need, and so should be considered an important risk factor when considering gender transition for any patient. However, it is particularly difficult for parents of a young child to seriously contemplate that child's potential as a future parent and grandparent. This makes it even more critical that the mental health professional spend substantial and repeated time with parents to help them see the implications of what they are considering. The percentage of transitioned patients who will become increasingly suicidal as they fully realize the meaning of permanent sterility and the loss of the possibility of being a biological parent has never been studied and is thus unknown.

Loss of sexual function

131. Puberty blockers prevent maturation of the sexual organs and response. Some, and perhaps many, transgender individuals who transitioned as children and thus did not go through puberty consistent with their sex face significantly diminished sexual response as they enter adulthood and are unable ever to experience orgasm. Dr. Karasic and Dr. Schechter do not acknowledge these physical effects of puberty blockers.

[204] *See* Cheng PJ, Pastuszak AW, Myers JB, Goodwin IA, Hotaling JM. Fertility concerns of the transgender patient. *Transl Androl Urol*. 2019;8(3):209-218. doi:10.21037/tau.2019.05.09
[205] *See* C. Guss et al., *TGN Adolescent Care* at 4 ("a side effect [of cross-sex hormones] may be infertility") and 5 ("cross-sex hormones . . . may have irreversible effects"); Tishelman et al., *Serving TG Youth* at 8 (Cross-sex hormones are "irreversible interventions" with "significant ramifications for fertility").

132. Additionally, youth will also experience the social, psychological, and interpersonal impact of not being in puberty for 2-5 years while their peers are challenged by the normative processes of maturing bodies and minds. To my knowledge, data quantifying these impacts have not been published. In the case of males, the cross-sex administration of estrogen limits penile genital function.

133. More generally, sexual dysfunction is not an uncommon complication of genital surgery. [206] Much has been written about the negative psychological and relational consequences of anorgasmia among non-transgender individuals that is ultimately applicable to the transgender population.[207]

Psychosocial and other effects

134. Besides puberty blockers' physical side effects like affecting height and bone density, the drugs also have irreversible psychosocial effects. That is because puberty blockers also halt the normal social and psychological process of maturation at that developmentally crucial stage, with lifelong effects.

135. The social and psychological impacts of remaining puerile for, e.g., two-to-five years while one's peers are undergoing pubertal transformations, and of undergoing puberty at a substantially older age, have not been systematically studied. However, clinical mental health professionals often hear of distress and social awkwardness in those who otherwise suffer delayed onset of puberty. In my opinion, individuals in whom puberty is delayed for multiple years are likely to suffer at least subtle negative psychosocial and self-confidence effects as they stand

[206] Dunford C, Bell K, Rashid T. Genital Reconstructive Surgery in Male to Female Transgender Patients: A Systematic Review of Primary Surgical Techniques, Complication Profiles, and Functional Outcomes from 1950 to Present Day. *European Urology Focus*. 2021;7(2):464-471. doi:10.1016/j.euf.2020.01.004
[207] Levine, *Informed Consent*, at 6; see Perelman and Watters, 2016, Delayed Ejaculation in *Handbook of Clinical Sexuality for Mental Health Professionals* 3rd edition, New York, Routledge.

on the sidelines while their peers are developing the social relationships (and attendant painful social learning experiences) that come with adolescence.

136. We should recall that puberty introduces sexual desire, changes socialization patterns, and enables teens to enter into early romantic relationships, all of which can lead to maturation, self-confidence, and an understanding of the complexity of partner relationship. Delaying puberty can reasonably be assumed to increase the adolescent's sense of isolation, otherness, and being an outsider. [208] Please note that social anxiety is a very common symptom among candidates for puberty blocking hormones.

137. The Endocrine Society guidelines rightly recognize both "the sense of social isolation from having the timing of puberty to be so out of sync with peers" and the "potential harm to mental health (emotion and social isolation) if initiation of secondary sex characteristics must wait until the person has reached 16 years of age."[209]

138. Just as medicine does not know what the long-term health effects on bone, brain, and other organs are from delaying puberty between ages 11-16, psychology likewise does not know the long-term effects on coping skills, interpersonal comfort, and sexual function comfort (intimate relationships) of blocking puberty in a young person while one's peers are undergoing their maturational gains in these vital arenas of future mental health. It is well known that many effects of cross-sex hormones cannot be reversed should the patient later regret his transition.

139. Claims that using puberty blockers for gender-transition procedures is "reversible" or that they merely "pause" puberty are also false, misleading, and naive. Based on concerns that virtually all adolescents who begin puberty blockers proceed to cross-sex hormones,

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[208] *See* Levine SB. Informed Consent for Transgendered Patients. *Journal of Sex & Marital Therapy*. 2019;45(3):218-229. doi:10.1080/0092623X.2018.1518885

[209] Wylie C. Hembree, et al., Endocrine Treatment of Gender-Dysphoric/Gender-Incongruent Persons, p. 3885.

the UK National Health Service has officially recommended against such language, stating that "[r]esearchers and clinical staff working in gender identity development should consider carefully the terms that they use in describing treatments e.g. avoid referring to puberty suppression as providing a 'breathing space,' to avoid risk of misunderstanding."[210] This is a wise recommendation, and it should be followed.

Family, friendship, and romantic relationships

140. Gender transition routinely leads to isolation from at least a significant portion of one's family in adulthood. In the case of a juvenile transition, this will be less dramatic while the child is young, but commonly increases over time.

141. Friendship in general is highly desirable, many trans teens and older individuals desire to interact more fully and extensively with those in the larger population. But, by adulthood, the friendships of transgender individuals tend to be confined to other transgender individuals and the generally limited set of others who are most comfortable interacting with them. [211] Among young adolescent trans-identified teens, friends are often virtual. For some these are their only friends, while for others conversations over the Internet dominate their connections with others.[212]

[210] Investigation into the Study "Early Pubertal Suppression in a Carefully Selected Group of Adolescents with Gender Identity Disorders," National Health Service Health Research Authority (October 14, 2019), https://www.hra.nhs.uk/about-us/governance/feedback-raising-concerns/investigation-study-early-pubertal-suppression-carefully-selected-group-adolescents-gender-identity-disorders/

[211] *See* Levine SB. Ethical Concerns About Emerging Treatment Paradigms for Gender Dysphoria. *Journal of Sex & Marital Therapy*. 2018;44(1):29-44. doi:10.1080/0092623X.2017.1309482

[212] Shrier A. (2019) The Transgender Craze Seducing Our Daughters, Regnery Publishing, Washington, DC

142. There is also a sexual-romantic risk that needs to be considered. After adolescence, transgender individuals find the pool of individuals willing to develop a romantic and intimate relationship with them to be greatly diminished. When a trans person who passes well reveals his or her natal sex, many potential mates lose interest. When a trans person does not pass well, he discovers that the pool of those interested consists largely of individuals looking for exotic sexual experiences rather than genuinely loving relationships. [213],[214]

Potential for worsened mental health

143. One would expect the negative physical and social impacts reviewed above to adversely affect the mental health of individuals who have transitioned. In addition, adult-transitioned individuals find that living as the other sex (or, in a manner that is consistent with the stereotypes of the other sex as the individual perceives them) is a continual challenge and stressor, and many find that they continue to struggle with a sense of inauthenticity in their transgender identity and bear chronic uneasiness. [215]

144. In addition, individuals often pin excessive hope in transition, believing that transition will solve mental health co-morbidities or what are in fact ordinary social stresses associated with maturation. Thus, transition can result in deflection from mastering personal challenges at the appropriate time or addressing conditions that require treatment. Whatever the reason, transgender individuals including transgender youth certainly experience greatly increased rates of mental health problems. I have detailed this above with respect to adults living under a

[213] *See* Levine SB. Ethical Concerns About Emerging Treatment Paradigms for Gender Dysphoria. *Journal of Sex & Marital Therapy*. 2018;44(1):29-44. doi:10.1080/0092623X.2017.1309482
[214] Anzani, A., Lindley, L., Tognasso, G., Galupo, M. P., & Prunas, A. (2021). "Being Talked to Like I Was a Sex Toy, Like Being Transgender Was Simply for the Enjoyment of Someone Else": Fetishization and Sexualization of Transgender and Nonbinary Individuals. *Archives of Sexual Behavior*, 50(3), 897–911. https://doi.org/10.1007/s10508-021-01935-8
[215] *See* Levine SB. Informed Consent for Transgendered Patients. *Journal of Sex & Marital Therapy*. 2019;45(3):218-229. doi:10.1080/0092623X.2018.1518885

transgender identity. Indeed, Swedish researchers in a long-term study (up to 30 years since sex-reassignment surgery, with a median time since sex-reassignment surgery of > 10 years) concluded that individuals who have sex-reassignment surgery should have postoperative lifelong psychiatric care. [216] With respect to youths a cohort study found that transgender youth had an elevated risk of depression (50.6% vs. 20.6%) and anxiety (26.7% vs. 10.0%); a higher risk of suicidal ideation (31.1% vs. 11.1%), suicide attempts (17.2% vs. 6.1%), and self-harm without lethal intent (16.7% vs. 4.4%) relative to the matched controls; and a significantly greater proportion of transgender youth accessed inpatient mental health care (22.8% vs. 11.1%) and outpatient mental health care (45.6% vs. 16.1%) services.[217]

D. There is a crisis of inadequate or absent mental health assessments prior to undergoing transition.

145. Prominent mental health experts in the area of transgender health have recently gone public with their concerns about the state of mental health assessments of youth.

146. Dr. Edwards-Leeper, who claims to have brought the practice of pediatric gender transition from the Netherlands to the US, and Dr. Anderson, a transwoman and a former leader of the US Chapter of WPATH who recently stepped down amid the controversy of her whistle-blowing, said this in a recent interview about the state of mental health care:

"Providers may also be afraid of being cast as transphobic bigots by their local colleagues and referral sources if they engage in gender exploring therapy with patients, as some have equated

[216] *See* Dhejne C, Lichtenstein P, Boman M, Johansson ALV, Långström N, Landén M. Long-Term Follow-Up of Transsexual Persons Undergoing Sex Reassignment Surgery: Cohort Study in Sweden. Scott J, ed. *PLoS ONE*. 2011;6(2):e16885. doi:10.1371/journal.pone.0016885

[217] Reisner et al. (2015), Mental Health of Transgender Youth in Care at an Adolescent Urban Community Health Center: A Matched Retrospective Cohort Study, *J. of Adolescent Health* 56(3) at 6, DOI:10.1016/j.jadohealth.2014.10.264.

this with conversion therapy," and continued, "the field has moved from a more nuanced, individualized and developmentally appropriate assessment process to one where every problem looks like a medical one that can be solved quickly with medication or, ultimately, surgery. As a result, we may be harming some of the young people we strive to support — people who may not be prepared for the gender transitions they are being rushed into."[218] [219]

147. To properly assess medical necessity of various treatments, clinicians must carefully and thoroughly consider each individual patient's clinical history, including mental health comorbidities, previous physical and psychological treatments, characteristic patterns, quality of relationships with each family member, and behavioral and verbal manifestations concerning gender nonconformity to determine the influences upon the patient's gender incongruity. [220] The history will undoubtedly be unique to each patient. So should be treatment recommendations.

148. Unfortunately, currently in the US, if therapists are involved at all, they are typically the "gender-affirming" therapists, who are expected to accept a patient's self-diagnosis of gender dysphoria or gender incongruence based upon the patient's report of a transgender identity. The result of such wide-spread, preconceived, unsupported motives not based in medical science is that the vast majority of patients who present for medical care reporting gender-related distress or with a self-diagnosis of gender dysphoria or gender incongruence based upon a transgender identity, will get rapid approval for hormonal and surgical interventions.

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[218] Edwards-Leeper, Laura and Erica Anderson, "The mental health establishment is failing trans kids," *The Washington Post*, https://www.washingtonpost.com/outlook/2021/11/24/trans-kids-therapy-psychologist/

[219] Anderson, E. (2022, January 3). Opinion: When it comes to trans youth, we're in danger of losing our way. *The San Francisco Examiner*. Accessed January 5th, 2022

[220] *See* Levine SB. Reflections on the Clinician's Role with Individuals Who Self-identify as Transgender. *Arch Sex Behav*. Published online September 15, 2021. doi:10.1007/s10508-021-02142-1

149. Yet according to WPATH, perfunctory mental health assessments, which the draft SOC8 describe as "brief assessment process," are sufficient to approve 14-year-olds for treatment with irreversible cross-sex hormones, 15-year-olds with double mastectomies, and 17-year-olds with removal of their testes. Remarkably, the draft version of SOC8 claims that even if a patient is unable to provide informed consent, this should not be a barrier to surgery: "limits to capacity to consent to treatment should not be an impediment to individuals receiving appropriate GAMST [gender affirmative medical and surgical treatments]." [221]

E. The risks of providing on-demand "gender-affirming" interventions are going to be borne out disproportionately by youth and by vulnerable populations.

150. There has been a recent sharp rise in trans-identification among youth, affecting 2% - 10% of the population, which remains poorly understood. Most are adolescent females with no history of childhood gender dysphoria, although the prevalence of males has also significantly increased. The majority suffer from significant mental health comorbidities. [222] [223]

151. The understanding of this phenomenon remains controversial. One group considers the Internet and rising status of trans persons to influence naïve youngsters to come out as trans while the other group thinks that the knowledge of treatment possibilities has allowed teens

[221] Society for Evidence-Based Gender Medicine, "WPATH SOC8 Draft Guideline," Jan. 16, 2022, https://segm.org/draft_SOC8_lacks_methodological_rigor
[222] Kaltiala-Heino, Riittakerttu, Hannah Bergman, Marja Työläjärvi, and Louise Frisen. "Gender Dysphoria in Adolescence: Current Perspectives." *Adolescent Health, Medicine and Therapeutics* Volume 9 (March 2018): 31–41, https://doi.org/10.2147/AHMT.S135432
[223] Zucker, Kenneth J. "Adolescents with Gender Dysphoria: Reflections on Some Contemporary Clinical and Research Issues." *Archives of Sexual Behavior* 48, no. 7 (October 2019): 1983–92. https://doi.org/10.1007/s10508-019-01518-8

who always felt like the opposite gender to courageously reveal their status. The latter explanation rests on the assumption that trans identities are biologically dictated, which has not been demonstrated to be true.

152. Although research suggests there may be a biological influence, no studies have been able to identify a "transgender brain" once they have controlled for sexual orientation and cross-sex hormonal exposure. [224] [225] Such vital methodological confounds are rarely mentioned by those who present their hypothesis of a biogenic etiology as proven fact.

153. It is unknown how to best care for the rapidly growing group of trans-identified youth. A fundamental issue that is not being addressed is the adult fate of teens undergoing hormonal and surgical interventions. This glaring unanswered question is central for three reasons: first, multiple scientific reviews have pointed out a lack of convincing evidence of improved mental health during adolescence; second, every study of adult trans populations has indicated a high prevalence of various mental health problems; third, the age at which irreversible interventions are offered are getting progressively lower. For example, a key study reports that gender-dysphoric adolescents have had "top surgery" as young as 13.[226]

154. As pointed out earlier, in the absence of such early and aggressive interventions, the majority of children in eleven studies (typically, a large majority) who are diagnosed with

[224] Skorska MN, Chavez S, Devenyi GA, et al. A Multi-Modal MRI Analysis of Cortical Structure in Relation to Gender Dysphoria, Sexual Orientation, and Age in Adolescents. Published online 2021:24.
[225] Hoekzema E, Schagen SEE, Kreukels BPC, et al. Regional volumes and spatial volumetric distribution of gray matter in the gender dysphoric brain. *Psychoneuroendocrinology*. 2015;55:59-71. doi:10.1016/j.psyneuen.2015.01.016

[226] *See* Olson-Kennedy J, Warus J, Okonta V, Belzer M, Clark LF. Chest Reconstruction and Chest Dysphoria in Transmasculine Minors and Young Adults: Comparisons of Nonsurgical and Postsurgical Cohorts. *JAMA Pediatr*. 2018;172(5):431. doi:10.1001/jamapediatrics.2017.5440

gender dysphoria "desist"—that is, their gender dysphoria does not persist—by puberty or adulthood. It is not currently known how to distinguish children who will persist from those who will not. [227] [228] Nor is it known how many of the adolescents from the newly-presenting cohorts, who had no childhood history of gender incongruence, will persist versus desist, and how to best help them overcome their distress.

155. Detransitioners from the novel cohort of youth have begun to vocally voice regret, saying they were let down by the medical establishment.[229] [230]

156. In considering the appropriate response to gender dysphoria, it is important to know that certain groups of children and adolescents have an increased prevalence and incidence

[227] *See* Ristori J, Steensma TD. Gender dysphoria in childhood. International Review of Psychiatry. 2016;28(1):13-20. doi:10.3109/09540261.2015.1115754
[228] *See* Singh D, Bradley SJ, Zucker KJ. A Follow-Up Study of Boys With Gender Identity Disorder. *Front Psychiatry*. 2021;12. doi:10.3389/fpsyt.2021.632784
[229] *See* Vandenbussche E. Detransition-Related Needs and Support: A Cross-Sectional Online Survey. *Journal of Homosexuality*. Published online April 30, 2021:20. doi:10.1080/00918369.2021.1919479
[230] *See* Littman L. Individuals Treated for Gender Dysphoria with Medical and/or Surgical Transition Who Subsequently Detransitioned: A Survey of 100 Detransitioners. *Arch Sex Behav*. Published online October 19, 2021. doi:10.1007/s10508-021-02163-w

of trans identities. These include: children of color,[231] children with mental developmental disabilities,[232] including children on the autistic spectrum (at a rate more than 7x the general population),[233] children residing in foster care homes, adopted children (at a rate more than 3x the general population),[234] children with a prior history of psychiatric illness,[235] and more recently adolescent girls (in a large recent study, at a rate more than 2x that of boys).[236] These data are consistent with Littman's research.[237] Properly protecting vulnerable, marginalized patients from unproven, potentially dangerous treatments should be an essential concern. (G. Rider at 4.)

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

[232] D. Shumer & A. Tishelman (2015), The Role of Assent in the Treatment of Transgender Adolescents, *Int'l J. of Transgenderism* at 1, DOI: 10.1080/15532739.2015.1075929.

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

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

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

[236] G. Rider at 4; See G. Rider et al. (2018), Health and Care Utilization of Transgender/Gender Non-Conforming Youth: A Population Based Study, *Pediatrics* at 4, DOI: 10.1542/peds.2017-1683. (In a large sample, non-white youth made up 41% of the set who claimed a transgender or gender-nonconforming identity, but only 29% of the set who had a gender identity consistent with their sex.); see D. Shumer & A. Tishelman (2015), The Role of Assent in the Treatment of Transgender Adolescents, *Int. J. Transgenderism* at 1, DOI: 10.1080/15532739.2015.1075929; D. Shumer et al. (2016), Evaluation of Asperger Syndrome in Youth Presenting to a Gender Dysphoria Clinic, *LGBT Health*, 3(5) 387 at 387; Shumer et al. (2017), Overrepresentation of Adopted Adolescents at a Hospital-Based Gender Dysphoria Clinic, *Transgender Health*, Vol. 2(1) 76 at 77; L. Edwards-Leeper et al. (2017), Psychological Profile of the First Sample of Transgender Youth Presenting for Medical Intervention in a U.S. Pediatric Gender Center, Psychology of Sexual Orientation and Gender Diversity, 4(3) 374 at 375 ("Psychological Profile"); R. Kaltiala-Heino et al. (2015), Two Years of Gender Identity Service for Minors: Overrepresentation of

157. The lack of knowledge of etiology of the current presentations and future outcomes, combined with the lack of proper assessments, creates a very problematic situation for youth and vulnerable people, who are disproportionately affected by the lack of safeguards and wide accessibly of on-demand hormonal and surgical interventions.

F. There is a range of treatments to ameliorate gender dysphoria, from non-invasive to highly invasive.

158. Gender dysphoria has multiple causal influences and multiple resolutions.

159. As demonstrated above, hormones and surgeries have not been demonstrated to improve long-term outcomes of gender dysphoria sufferers.

Natal Girls with Severe Problems in Adolescent Development, *Child and Adolescent Psychiatry & Mental Health*, 9(9) 1 at 5 (in the 2015 Finland gender identity service statistics, 75% of adolescents assessed "had been or were currently undergoing child and adolescent psychiatric treatment for reasons other than gender dysphoria.").

[237] See L. Littman (2018), Parent Reports of Adolescents & Young Adults Perceived to Show Signs of a Rapid Onset of Gender Dysphoria, *PLoS ONE* 13(8): e0202330 at 13 (Parental survey concerning adolescents exhibiting Rapid Onset Gender Dysphoria reported that *62.5%* of gender dysphoric adolescents had "a psychiatric disorder or neurodevelopmental disability preceding the onset of gender dysphoria.").

160. The results of alternative approaches, such as watchful waiting for children, or gender-psychotherapy, are likewise lacking in long-term evidence. However, emerging evidence suggests that psychotherapy is a promising intervention for young people. [238] [239] [240] [241] [242] It should be noted that a key Finnish gender program recently announced that psychotherapy should be the first line of treatment for all gender dysphoric youth. A growing list of European countries appear to be moving in the same direction.

G. To determine whether West Virginia Medicaid and PEIA should be forced to categorically cover medical and surgical interventions for gender dysphoria, one will need to consider the balance of benefits and harms of such a decision.

161. Plaintiffs advocate for a lessened financial burden to achieve their desires for hormonal and various surgical procedures. These desires assume long lasting psychological benefits. Their personal economic benefits must be weighed against the harms to youth and other vulnerable individuals who include many transgender adults.

[238] Schwartz D. Clinical and Ethical Considerations in the Treatment of Gender Dysphoric Children and Adolescents: When Doing Less Is Helping More. *Journal of Infant, Child, and Adolescent Psychotherapy*. Published online November 22, 2021:1-11. doi:10.1080/15289168.2021.1997344

[239] Spiliadis A. Towards a gender exploratory model: Slowing things down, opening things up and exploring identity development. *Metalogos Systemic Therapy Journal*. 2019;35:1-9. https://www.ohchr.org/Documents/Issues/SexualOrientation/IESOGI/Other/Rebekah_Murphy_TowardsaGenderExploratoryModelslowingthingsdownopeningthingsupandexploringidentitydevelopment.pdf

[240] Bonfatto M, Crasnow E. Gender/ed identities: an overview of our current work as child psychotherapists in the Gender Identity Development Service. *Journal of Child Psychotherapy*. 2018;44(1):29-46. doi:10.1080/0075417X.2018.1443150

[241] Churcher Clarke A, Spiliadis A. 'Taking the lid off the box': The value of extended clinical assessment for adolescents presenting with gender identity difficulties. *Clin Child Psychol Psychiatry*. 2019;24(2):338-352. doi:10.1177/1359104518825288

[242] Lemma A. Trans-itory identities: some psychoanalytic reflections on transgender identities. *The International Journal of Psychoanalysis*. 2018;99(5):1089-1106. doi:10.1080/00207578.2018.1489710

162. Financial considerations must also be taken into account. The life-long costs of transgender interventions which are ever-growing in numbers and complexity, the cost of managing complications, fertility preservation, the costs of covering detransition procedures that will grow in numbers, and even the cost of potential future litigation over lack of safeguarding of youth and vulnerable populations must be accounted before any changes to the current laws are implemented.

163. It is my opinion that if West Virginia Medicaid and PEIA are forced to categorically cover medical and surgical treatments for patients with gender dysphoria without regard for traditional views of medical necessity and in contradiction to the unbiased, peer-reviewed, and high-quality literature cited herein, substantial harmful effects will occur. Vulnerable and impressionable youth will be disproportionately affected.

164. At this late half-century stage of surgical trans care, trans medicine is actually at an early scientific stage of hormonal and surgical trans care. What is glaringly necessary to advance the field is a social commitment to designing and implementing multiple site studies for each of the areas of uncertainty among children, young teens, older adolescents, and adults. It is most prudent and protective to support psychological services for trans-identified individuals, particularly for youth and their families. The least prudent approach would be to open the insurance gates so that all who think they want a medical or surgical intervention for themselves or their child should have it. I hope that I have made the reasons for this final statement abundantly clear.

*****SIGNATURE PAGE TO FOLLOW*****

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

Executed on February 18, 2022.

Stephen B Levine MD

Stephen B. Levine, M.D.