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13	CHLOÉ E. BROCKMAN	
14	SUPERIOR COURT OF THE STATE OF CALIFORNIA	
15	IN AND FOR THE COUNTY OF SAN JOAQUIN – STOCKTON BRANCH	
16	CHLOE E. BROCKMAN a/k/a CHLOE COLE, an individual	Case No.: STK-CV-UMM-2023-0001612
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17 18	Plaintiff,	DECLARATION OF STEPHEN B.
		DECLARATION OF STEPHEN B. LEVINE, M.D.
18	Plaintiff, v. KAISER FOUNDATION HOSPITALS,	
18 19	Plaintiff, v. KAISER FOUNDATION HOSPITALS, INC., a California Corporation, THE PERMANENTE MEDICAL GROUP, INC.,	
18 19 20	Plaintiff, v. KAISER FOUNDATION HOSPITALS, INC., a California Corporation, THE	LEVINE, M.D. Dept.: 11B
18 19 20 21	Plaintiff, v. KAISER FOUNDATION HOSPITALS, INC., a California Corporation, THE PERMANENTE MEDICAL GROUP, INC., a California Corporation, LISA KRISTINE TAYLOR, M.D., an individual, HOP NGUYEN LE, M.D., an individual,	LEVINE, M.D.
18 19 20 21 22	Plaintiff, v. KAISER FOUNDATION HOSPITALS, INC., a California Corporation, THE PERMANENTE MEDICAL GROUP, INC., a California Corporation, LISA KRISTINE TAYLOR, M.D., an individual, HOP NGUYEN LE, M.D., an individual, SUSANNE E. WATSON, PHD., an individual, LILIT ASULYAN PSYD, an	Dept.: 11B Judge: Hon. Robert T. Waters
18 19 20 21 22 23	Plaintiff, v. KAISER FOUNDATION HOSPITALS, INC., a California Corporation, THE PERMANENTE MEDICAL GROUP, INC., a California Corporation, LISA KRISTINE TAYLOR, M.D., an individual, HOP NGUYEN LE, M.D., an individual, SUSANNE E. WATSON, PHD., an individual, LILIT ASULYAN PSYD, an individual, and ESTER BALDWIN, LCSW, PHD, an individual, and DOES 1 through 50,	Dept.: 11B Judge: Hon. Robert T. Waters Assigned for All Purposes
18 19 20 21 22 23 24	Plaintiff, v. KAISER FOUNDATION HOSPITALS, INC., a California Corporation, THE PERMANENTE MEDICAL GROUP, INC., a California Corporation, LISA KRISTINE TAYLOR, M.D., an individual, HOP NGUYEN LE, M.D., an individual, SUSANNE E. WATSON, PHD., an individual, LILIT ASULYAN PSYD, an individual, and ESTER BALDWIN, LCSW, PHD, an individual, and DOES 1 through 50, inclusive,	Dept.: 11B Judge: Hon. Robert T. Waters
18 19 20 21 22 23 24 25	Plaintiff, v. KAISER FOUNDATION HOSPITALS, INC., a California Corporation, THE PERMANENTE MEDICAL GROUP, INC., a California Corporation, LISA KRISTINE TAYLOR, M.D., an individual, HOP NGUYEN LE, M.D., an individual, SUSANNE E. WATSON, PHD., an individual, LILIT ASULYAN PSYD, an individual, and ESTER BALDWIN, LCSW, PHD, an individual, and DOES 1 through 50,	Dept.: 11B Judge: Hon. Robert T. Waters Assigned for All Purposes Action Filed: February 22, 2023

DECLARATIN OF STEPHEN B. LEVINE, M.D.

- I, Stephen B. Levine, M.D., declare as follows:
- 1. I am a physician that has been retained by Plaintiff Chloe E. Brockman ("Chloe") as an expert witness in the above-captioned matter.
- 2. I am a Clinical Professor of Psychiatry at Case Western Reserve University School of Medicine, and a psychiatrist at DeBalzo, Elgudin, Levine, Risen, LLC.
 - 3. Attached hereto as **Exhibit 1** is a true and correct copy of my curriculum vitae.
- 4. Attached hereto as **Exhibit 2** is a true and correct copy of a signed, written declaration that I submitted in the case of John and Jane Doe1, et al., v. Madison Metropolitan School District, Case No. 20-CV-454 located in the State of Wisconsin, Dane County, Circuit Court. The declaration addresses the current state of the medical research pertaining to "Gender Affirming Care" ("GAC"), best evidence practices and standards of care, and related issues.
- 5. I am familiar with Chloe's clinical history; the "Gender Affirming Care" ("GAC") she was provided; and her subsequent detransition.
- 6. Based on my review of the foregoing, I have formed the following opinions, which are based on my training and experience as a clinical psychiatrist. I have also consulted the following medical literature and other sources, which informed my opinions in this matter:
 - a. Prominent medical organizations, including the Society of Evidence-Based Gender Medicine, the Association of American Physicians and Surgeons, the American College of Pediatrics, the Alliance for Therapeutic Choice, Do No Harm Medicine, and the International Federation for Therapeutic and Counseling Choice have all issued statements opposing the adoption of GAC standards for minors.
 - b. The U.S. Centers of Medicare and Medicaid Services' criteria for treatment of gender dysphoria with cross-sex hormone therapy and surgical treatment both include the requirement that the patient be "at least 18 years of age," indicating that minors are not eligible to receive GAC. *See* Centers for Medicare & Medicaid Services, "Billing and Coding: Gender Reassignment Services for Gender Dysphoria," *available at* https://www.cms.gov/ medicare-coverage-

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- c. The American Academy of Pediatricians ("AAP") has recently called for a "systematic review" of the medical literature concerning GAC for minors. Dr. Gordon Guyatt, an epidemiologist at McMaster University credited as the developer of the field of evidence-based medicine, opined that "[b]ased on previous systematic reviews, the A.A.P.'s report will most likely find low-quality evidence for pediatric gender care." According to Dr. Guyatt, "The policies of the Europeans are much more aligned with the evidence than are the Americans." Andrè Van Mol, "AAP calls for 'systemic review of evidence,' yet reaffirms 2018 gender-affirming care policy," CMDA (Aug. 28, 2023) available at https://cmda.org/aap-calls-for- systematic-review-of-evidence-yet-reaffirms-2018-gender-affirming-care-policy/.
- d. Countries like Sweden, Finland, and the United Kingdom have sharply decreased the availability of GAC for minors, only doing so "under tight restrictions and against the findings of their own systematic reviews." Leor Sapir, "Yes, Europe is Restricting 'Gender-Affirming Care," CITY JOURNAL (Feb. 13, 2023), available at https://www.city-journal.org/article/yes-europe-is-restricting-gender-affirmingcare; Levine, S.B., Abbruzzese, E. Current Concerns About Gender-Affirming Therapy Adolescents. Curr Sex Health Rep 15, 113–123 (2023).https://doi.org/10.1007/s11930-023-00358-x
- e. Between 2015 and 2018, there were at least 417 pediatric transgender patients at the Northern California Kaiser Clinic alone. Ted Handler, et al., "Trends in Referrals to Pediatric Transgender Clinic" (Nov. 2019), available at https://pubmed.ncbi.nlm.nih.gov/31619510/.
- f. At Kaiser's Oakland facility, doctors performed seventy "top surgeries" on teenagers between 13 and 18 in 2019, up from just five in 2013. Azeen Ghorayshi, "More Trans Teens Are Choosing 'Top Surgery," THE NEW YORK TIMES (Sept. 26, 2022), available at https://www.nytimes.com/2022/09/26/health/top-surgery-transgender- teenagers.html#:~:text=One%20hospital%2C%20Kaiser%20Permanente%20Oakla

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- g. A Kaiser whistleblower leaked a Diversity Equity & Inclusion training program that promoted the notion that children as young as three years old could identify as transgender. Hannah Grossman, "Horrified hospital employee leaks DEI training pushing 3-year-olds identifying as transgender," Fox News (Sept. 4, 2023), available at https://www.foxnews.com/media/horrified-hospital-employee-leaks-dei-training-promoting-3-year-olds-identifying-as-trans.
- h. Hundreds of Kaiser mental health care professionals have gone on strike because of their inability to provide proper counseling and therapy to Kaiser patients and Kaiser has been repeatedly fined by the State of California for its many violations in this regard, including fraudulent reporting of alleged improvements in its system. https://www.kqed.org/news/11923034/were-drowning-why-kaiser-mental-health-workers-are-striking
- "Brain maturation during adolescence (ages 10-24 years) could be governed by several factors...sex hormones including estrogen, progesterone, and testosterone can influence the development and maturation of the adolescent brain...Furthermore, the adolescent brain evolves its capability to organize, regulate impulses, and weigh risks and rewards; however, these changes can make adolescents highly vulnerable to risk-taking behavior...Plasticity permits adolescents to learn and adapt in order to acquire independence; however, plasticity also increases an individual's vulnerability toward making improper decisions because the brain's region-specific neurocircuitry remains under construction, thus making it difficult to think critically and rationally before making complex decisions." Mariam Arain, et al., "Maturation brain" available ofthe adolescent (Apr. 3, 2013), at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3621648/.
- j. One of the foremost objective medical literature reviews in the U.S. is performed by the Hayes Corporation ("Hayes"). Hayes regularly reviews the research underlying medical treatments and is nationally authoritative, serving companies that cover 83%

- of insured Americans. See, Hayes, Inc., *The Hayes Difference:* https://www.hayesinc.com/about-hayes/.
- k. Hayes reviewed cross-sex hormone administration for adolescent gender dysphoria in 2014 and gave it the lowest "D2" rating: the research findings were "too spare" and "too limited" to even *suggest* conclusions. Hayes Corporation, "Sex Reassignment Surgery for the Treatment of Gender Dysphoria" (May 15, 2014), available at https://spaces.hightail.com/space/CiCkJj4sMA.
- Hayes more recently examined the extant evidence for gender reassignment surgery for minors and again concluded that it merited its lowest "D2" rating: "insufficient published evidence to assess the safety and/or impact on health outcomes or patient management." Hayes Corporation, "Sex Reassignment Surgery for the Treatment of Gender Dysphoria" (Aug. 1, 2018), available at https://spaces.hightail.com/space/CiCkJj4sMA/files/fi-0f902690-02c9-4b49-8d82-913596a3bc0d/fv-d02ab28b-d87d-4282-be6f-

719e516e7dd0/Hayes%20Sex%20Adult-

Minor%20Gender%20Affirming%20Sex%20Reassignment%20surgery%202018.p df#pageThumbnail-1.

- m. The most thorough follow-up of sex-reassigned people—extending over 30 years and conducted in Sweden, where the culture is strongly supportive of the transgendered—documents their lifelong mental unrest. Ten to 15 years after surgical reassignment, the suicide rate of those who had undergone sex-reassignment surgery rose to almost 20 times that of comparable peers. Cecilia Dhejne, et al., "Long-Term Follow-Up of Transsexual Persons Undergoing Sex Reassignment Surgery: Cohort Study in Sweden" (Feb. 222, 2011), available at https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0016885.
- n. "Evidence from the 10 available prospective follow-up studies from childhood to adolescence (reviewed in the study by Ristori and Steensma) indicates that for ~80% of children who meet the criteria for [gender dysphoria], the [gender dysphoria]

- recedes with puberty." Riitttakerttu Kaltiala-Heino, et al., "Gender dysphoria in adolescence: current perspectives" (Mar. 2, 2018), *available at* https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5841333/#:~:text=Childhood%2 https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5841333/#:~:text=Childhood%2 https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5841333/#:~:text=Childhood%2 https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5841333/#:~:text=Childhood%2 https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5841333/#:~:text=Childhood%2 https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5841333/#:~:text=Childhood%2 <a href="https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5841333/#:~:text=Childhood%2 <a href="https://www.ncbi.nlm.nih.gov/pmc/articles/PMC58
- o. The American Psychiatric Association's DSM-5 notes gender dysphoria desistence rates of 62%-97.5%. American Psychiatric Association, *Diagnostic and Statistical Manual of Mental Disorders: Fifth Edition Text Revision DSM-5-TR*TM, AMERICAN PSYCHIATRIC ASSOCIATOIN PUBLISHING, page 517 (https://ebooks.appi.org/epubreader/diagnostic-statistical-manual-mental-disorders-fifth-edition-text-revision-dsm5tr).
- p. The APA Handbook on Sexuality and Psychology states: "Premature labeling of gender identity should be avoided. . .This approach runs the risk of neglecting individual problems the child might be experiencing and may involve an early gender role transition that might be challenging to reverse if cross-gender feelings do not persist." W. Bockting, Ch. 24: Transgender Identity Development, in 1 American Psychological Association Handbook on Sexuality and Psychology 744, 750 (D. Tolman & L. Diamond eds., 2014).
- 7. First, anyone who detransitions so soon after a surgical intervention represents a failure of the mental health care that was provided to that person.
- 8. Second, Chloe's providers did not properly evaluate, recognize, and treat her comorbidities. Some of the supporting analysis for this opinion is as follows:
 - a. Chloe's providers failed to evaluate, diagnose, and treat body dysmorphia. Chloe had various things about her body that she did not like, such as her nose, breasts, and shoulders, which is not uncommon in children. Chloe appears to have erroneously thought that she could not live as a girl. Chloe's providers did not appreciate this differential diagnostic possibility or evaluate this. Children are often unhappy about various things about themselves, and the provider's job is to evaluate why. Her

providers failed to do this and failed to evaluate, diagnose, and treat her body dysmorphia symptoms, assuming they only indicated her gender dysphoria diagnosis, which of course they were primed to do because of their setting—the gender clinic.

- b. Additionally, Chloe's providers failed to evaluate how Chloe felt about living with a healed cleft palate, nasal voice, and how that may have impacted her socialization issues. The ability to speak and the appearance of one's face have significant impacts on a child's confidence, fear of rejection, frustration at not having been readily understood, and her willingness to develop socialization skills.
- c. Chloe has been under-weight her whole life, but she has never been evaluated for an eating disorder, which is another issue that should have been considered.
- d. Chloe reported having mixed feelings about her gender as early as age 9 (she started dressing as a boy when she was at age 6–9), which would appear to be prepubescent, childhood onset gender dysphoria for which there are very high desistence rates. The studies in this area show between 67%–93% of cases in this category desist. Furthermore, the outcome of gender dysphoria that presents in adolescence is not well studied, which is an important factor to consider. This later onset dysphoria also has medically significant rates of desistence and detransition that is accelerating with the social contagion occurring around this issue. This issue cannot and should not have been ignored. Tomboy behaviors, preference for boy activities (not what she strongly indicated) should make a child-focused mental health professional wonder what it is about femaleness that is so unacceptable. This inquiry was not done.
- e. In addition, Chloe's providers failed to evaluate and treat her social anxiety, socialization problems, disruptive behavior disorder, learning disabilities (which impact self-image and socialization), and depression and low moods that correlate in the records to times when Chloe felt that she did not have friends. Even when a diagnosis of gender dysphoria is made, the evaluator needs to recognize the

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predisposing vulnerability factors as well as the precipitating factors. Without such awareness, the psychotherapist does not know what to focus the discussion upon to increase the young patient's self-understanding.

- f. Her parents' concerns and these issues that were present concurrently with or prior to Chloe's perceived gender dysphoria should have been given considerable weight. But, as soon as Chloe stated that she thought she was a boy, her providers immediately put her on the track to gender transition and treated these gender dysphoria symptoms as a top priority. They should not have treated the symptom of gender dysphoria as the top priority, as these symptoms were only one of an extensive list of co-morbidities/symptoms. The relationship between her evolving conviction of gender dysphoria and other indicators that she was not functioning well should have been more thoroughly considered. This would have required an ongoing regular psychotherapeutic inquiry prior to introducing puberty blockers, hormones, and surgery. The diagnosis of gender dysphoria dictated the treatment, rather than dictating an investigation of her development utilizing her parents' and her personal knowledge. Every other mental health issue that teenagers experience is first carefully evaluated and then treated with psychotherapy. The concept that this subset of teenager mental health struggles should be singled out for chemical/surgical intervention rather than psychotherapy is naïve, based on unsubstantiated assumptions of a genetic determination, forever fixed feeling state that can only be treated medically and surgically, and dangerously deprives the patient and her family of the opportunity to understand and better cope with her internal conflicts.
- g. Additionally, Chloe's providers continued to push her through transgender medications and surgery even though her co-morbidities were not improving with this treatment. Instead, her mental health symptoms and socialization problems continued and periodically—recurrently—worsened during this "treatment." Her providers should have recognized this issue and stopped this treatment. They also should have recognized that the improvement she experienced after initial transition

events was only temporary and taken responsibility to investigate the meaning of her worsening state. Nobody considered that the continuing and worsening depression indicated that Chloe was not responding to this ill-conceived course of so-called "medically necessary treatment." This would have indicated they previously made a serious judgment error. This would have helped Chloe and her parents. They did not have the courage or wisdom to raise this possibility with other staff and more importantly with the patient and her family. Her providers should have explored and attempted other treatment methods, particularly before approving her for the double mastectomy. Instead, they just steamrolled ahead with "treatment," keeping their fingers crossed.

- h. There was also a significant lack of follow-up and continuity of care in Chloe's case, which is necessary to properly evaluate, diagnose, and treat her symptoms. It was never clear which professional was in charge, which person was the central responsible therapist, and whether the goals were to ameliorate her mental health challenges or simply to keep her in the trans treatment conveyer belt. This failure of one person, either a mental health professional, pediatrician, or endocrinologist to be the lead and liaison for all ongoing challenges, illustrates an unacceptable policy failure of Kaiser's claim of multi-disciplinary care.
- i. A handful of 30-minute psychotherapy sessions with different mental health providers cannot possibly have been adequate to address the conspicuous mental health symptoms and functional impairments from her ongoing co morbidities. Initial and ongoing assessment would require a minimum of several, one-hour, weekly psychotherapy sessions with a therapist committed to helping Chloe with her mental life. After this period of formal assessment, Chloe would have needed regular, one-hour, psychotherapy sessions most likely on a weekly basis for an extended period of time to address and treat her numerous depression, anxiety, and school avoidance symptoms.
- 9. Third, there was a significant problem of informed consent that breached the standard

- a. Attached hereto as **Exhibit 3** is the article "Reconsidering Informed Consent for Trans Identified Children Adolescents and Young Adults," which contains many opinions that apply to Chloe's case and constitute supporting analysis for this opinion. Without restating everything, a few of the key points are as follows.
- b. Informed consent is a process that takes time and that requires proper evaluation and diagnosis. Here, the entire informed consent process is tainted and undermined by the inadequate assessment of Chloe's mental health condition and her comorbidities. Inadequate assessment will necessarily result in failure to address the risks, benefits, and options for treatment. Chloe's providers should have spent several one-hour weekly sessions with Chloe and her parents for legal and ethical informed consent to occur. They also should have spent a significant number of sessions meeting separately with Chloe's parents so that they, who have legal and ethical responsibility to provide the actual consent, understood the problems of adult trans person, the possibility of desistence, the lack of follow up studies, and the worry about her mental health making her unable to think clearly about her trans state.
- c. The informed consent process was also undermined by grossly overstating the importance of treating the gender dysphoria symptoms with chemical/surgical transition and the failure to disclose in manner that the minor and the parents could grasp the rate of post-surgical problems such as failure of nipple-areolar complex to heal properly.
- d. Chloe's providers failed to discuss with Chloe desistence and detransition, the lack of accurate models for predicting whether Chloe's gender dysphoria would desist, and the possibility that Chole would experience regret following this course of treatment if her gender dysphoria desisted.
- e. Chloe's providers also did not discuss or disclose the low quality of the evidence that underlies the practice of pediatric gender transition and the implications of treating her based on this low-quality evidence. Essentially, when the evidence is low quality,

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Archives of sexual behavior, 51(2), 685–690. https://doi.org/10.1007/s10508-022-02287-7) Numerous other studies have also found similar slightly elevated rates. (Wiepjes CM, et al. Trends in suicide death risk in transgender people: results from the Amsterdam Cohort of gender dysphoria study (1972–2017) Acta Psychiatr

there is a significant risk that the patient will not experience the desired effects of the

proposed interventions. The failure to disclose the risks is a very important issue and

f. Chloe's providers did not discuss or disclose the high-quality evidence

demonstrating that transgender individuals who undergo chemical/surgical treatment

continue to have increased psychiatric morbidity, suicidality, and an increased risk

of suicide in the long term as compared with the general population. The informed

consent discussion regarding suicide was also highly problematic. Chloe's parents

were falsely told by Dr. Susanne E. Watson and Ms. Asulyan that their daughter was

at a high risk for suicide if she did not transition¹. This type of statement, in addition

to being false and manipulative, represents a serious failure of informed

consent. Suicide rates for trans youth are elevated above the general population, but

are not elevated to the point that would warrant such a statement. The largest scale

study of trans-youth suicide found the rate of completed suicides to be 0.03% over a

10-year period, which translates into an annual rate of 13 per 100,000. (Biggs M.

(2022). Suicide by Clinic-Referred Transgender Adolescents in the United Kingdom.

represents a failure of informed consent.

to teens who have other disorders such as depression, eating disorders, autism spectrum, and other mental health conditions commonly found in transgender

spectrum, and other mental neutrin conditions commonly round in transgender

Scand. 2020;141(6):486–491.) And other studies have found the rates to be similar

identifying youth, which are all known to independently contribute to the probability

¹ This statement is additionally misleading as Chloe was not suicidal until after the "gender affirming care." The first instance of suicidal ideation does not appear in her records until August 2019—two years after first presenting to Kaiser with gender dysphoria. Chloe felt confused about her gender before this date, but was not suicidal. If suicidality was a serious concern for those with gender dysphoria, suicidality would have manifested much earlier.

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of suicide. So, although elevated compared to the general population of teens, the suicide rates for trans-youth are a far cry from the epidemic of trans suicides that Dr. Watson and Ms. Asulyan claimed. Also, there are no studies demonstrating that hormones or surgery reduce suicidality in the long term. The most recent study tracking two years of hormonal treatment among 16-year-olds found that 2/315 adolescents suicided while on hormones (Chen et al, 2023). In sum, the informed consent discussion regarding suicide grossly overstated the risk of suicide and the capacity of transition to prevent suicide. It also failed to recognize that Chloe's comorbidities were factors in any suicide analysis, failed to discuss the risks, benefits, and options for treating these other co-morbidities first. Thus, the discussion of suicide represented mis-information that seriously undermined the ability of Chloe and her parents to give informed consent, representing a breach of the standard of care. When a therapist raised the specter of suicide without hormonal care, this should be recognized by all as shamefully coercive to the parents.

10. Finally, Chloe, a young troubled adolescent, did not have the ability to give informed consent. Chloe was a child who had no concept of sexual intimacy with a member of the opposite

1	sex and no idea that she may want to have children of her own. At the ages of 13-15, she did not
2	and could not appreciate the meaning of losing her fertility, losing her ability to breast feed, losing
3	her breasts, lowering her voice, and losing vaginal health and sexual functioning.
4	I declare until penalty of perjury under the laws of the State of California that the foregoing
5	is true and correct. Executed on 12, 2024, at <u>Berchward</u> .
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7	Station of Lowe 116
8	Stephen B. Levine, M.D.
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Brief Introduction

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

Personal Information

Date of birth 1/14/42

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

Board Certification 6/76 American Board of Neurology and Psychiatry

Education

1963 BA Washington and Jefferson College

1967 MD Case Western Reserve University School of Medicine

1967-68 internship in Internal Medicine University Hospitals of Cleveland

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

1970-73 Psychiatric Residency, University Hospitals of Cleveland

1974-77 Robert Wood Johnson Foundation Clinical Scholar

Appointments at Case Western Reserve University School of Medicine

1973 - Assistant Professor of Psychiatry

1979 - Associate Professor

1982 - Tenure

1985 - Full Professor

1993 - Clinical Professor

Honors

Summa Cum Laude, Washington & Jefferson

Teaching Excellence Award - 1990 and 2010 (residency program)

Visiting Professorships:

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

Named to America's Top Doctors consecutively since 2001

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

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

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

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

Professional Societies

- 1971 American Psychiatric Association; fellow
- 2005 American Psychiatric Association Distinguished Life Fellow
- 1973 Cleveland Psychiatric Society
- 1973 Cleveland Medical Library Association
 - 1985 Life Fellow
 - 2003 Distinguished Life Fellow
- 1974 Society for Sex Therapy and Research
 - 1987-89 President
- 1983 International Academy of Sex Research
- 1983 Harry Benjamin International Gender Dysphoria Association
 - 1997-98 Chairman, Standards of Care Committee
- 1994-99 Society for Scientific Study of Sex

Community Boards

1999-2002 - Case Western Reserve University Medical Alumni Association

1996-2001 - Bellefaire Jewish Children's Bureau

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

Editorial Boards

1978-80 Book Review Editor Journal Sex and Marital Therapy

Manuscript Reviewer for:

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

Prospectus Reviewer for:

- Guilford
- Oxford University Press

- Brunner/Routledge
- Routledge

Administrative Responsibilities

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

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

Co-leader of case conferences at DELRLLC.com

Recent Expert Witness Appearances

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

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

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

Witness for State of Florida vs. Reyne Keohane July 2017

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

Consultancy

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

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

Virginia Department of Corrections - evaluation of an inmate

New Jersey Department of Corrections - evaluation of an inmate

Idaho Department of Corrections - workshop 2016

Grant Support/Research Studies

TAP - studies of Apomorphine sublingual in treatment of erectile dysfunction

Pfizer - Sertraline for premature ejaculation

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

NIH - Systemic lupus erythematosis and sexuality in women

Sihler Mental Health Foundation

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

Alza - controlled study of a novel SSRI for rapid ejaculation

Pfizer - Viagra and self-esteem

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

Johnson & Johnson - controlled studies of Dapoxetine for rapid ejaculation

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

Lilly-Icos - study of Cialis for erectile dysfunction

VIVUS - study for premenopausal women with FSAD

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

Medtap - interview validation questionnaire studies

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

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

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

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

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

National registry trial for women with HSDD

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

Palatin - study of SQ Bremelanotide for HSDD and FSAD

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

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

HRA - qualitative and cognitive interview study for men experiencing PE

Publications

A) Books

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

B) Research and Invited Papers

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

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

- 5) Some thoughts on the pathogenesis of premature ejaculation. J. Sex & Marital Therapy 1975; 1:326-334
- 6) Marital Sexual Dysfunction: Introductory Concepts. Annals of Internal Medicine 1976;84:448-453
- 7) Marital Sexual Dysfunction: Ejaculation Disturbances 1976; 84:575-579
- 8) Yost MA: Frequency of female sexual dysfunction in a gynecology clinic: An epidemiological approach. Archives of Sexual Behavior 1976;5:229-238
- 9) Engel IM, Resnick PJ, Levine SB: Use of programmed patients and videotape in teaching medical students to take a sexual history. Journal of Medical Education 1976;51:425-427
- 10) Marital Sexual Dysfunction: Erectile dysfunction. Annals of Internal Medicine 1976;85:342-350
- 11) Articles in Medical Aspects of Human Sexuality
 - (a) Treating the single impotent male. 1976; 10:123, 137
 - (b) Do men enjoy being caressed during foreplay as much as women do? 1977; 11:9
 - (c) Do men like women to be sexually assertive? 1977;11:44
 - (d) Absence of sexual desire in women: Do some women never experience sexual desire? Is this possibility genetically determined? 1977; 11:31
 - (e) Barriers to the attainment of ejaculatory control. 1979; 13:32-56.
 - (f) Commentary on sexual revenge.1979;13:19-21
 - (g) Prosthesis for psychogenic impotence? 1979;13:7
 - (h) Habits that infuriate mates. 1980;14:8-19
 - (i) Greenberger-Englander, Levine SB. Is an enema an erotic equivalent?1981; 15:116
 - (j) Ford AB, Levine SB. Sexual Behavior and the Chronically Ill Patients. 1982; 16:138-150
 - (k) Preoccupation with wife's sexual behavior in previous marriage 1982; 16:172
 - (l) Co-existing organic and psychological impotence. 1985;19:187-8
 - (m) Althof SE, Turner LA, Kursh ED, Bodner D, Resnick MI, Risen CB. Benefits and Problems with Intracavernosal injections for the treatment of impotence. 1989;23(4):38-40
- 12) Male Sexual Problems. Resident and Staff Physician 1981:2:90-5
- 13) Female Sexual Problems. Resident and Staff Physician 1981:3:79-92
- 14) How can I determine whether a recent depression in a 40 year old married man is due to organic loss of erectile function or whether the depression is the source of the

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- 15) Corradi RB, Resnick PJ Levine SB, Gold F. For chronic psychologic impotence: sex therapy or psychotherapy? I & II Roche Reports; 1977
- 16) Marital Sexual Dysfunction: Female dysfunctions 1977; 86:588-597
- 17) Current problems in the diagnosis and treatment of psychogenic impotence. Journal of Sex & Marital Therapy 1977; 3:177-186
- 18) Resnick PJ, Engel IM. Sexuality curriculum for gynecology residents. Journal of Medical Education 1978; 53:510-15
- 19) Agle DP. Effectiveness of sex therapy for chronic secondary psychological impotence Journal of Sex & Marital Therapy 1978; 4:235-258
- 20) DePalma RG, Levine SB, Feldman S. Preservation of erectile function after aortoiliac reconstruction. Archives of Surgery 1978; 113-958-962
- 21) Conceptual suggestions for outcome research in sex therapy Journal of Sex & Marital Therapy 1981; 6:102-108
- 22) Lothstein LM. Transsexualism or the gender dysphoria syndrome. Journal of Sex & Marital Therapy 1982; 7:85-113
- 23) Lothstein LM, Levine SB. Expressive psychotherapy with gender dysphoria patients Archives General Psychiatry 1981; 38:924-929
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- 25) Shumaker R. Increasingly Ruth: Towards understanding sex reassignment surgery Archives of Sexual Behavior 1983; 12:247-61
- 26) Psychiatric diagnosis of patients requesting sex reassignment surgery. Journal of Sex & Marital Therapy 1980; 6:164-173
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- 30) Commentary on Beverly Mead's article: When your patient fears impotence. Patient Care 1982; 16:135-9
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- 32) Clinical overview of impotence. Physician and Patient 1983; 8:52-55.
- 33) An analytical approach to problem-solving in sexual medicine: a clinical introduction to the psychological sexual dysfunctions. II. British Journal of Sexual Medicine

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EXPERT AFFIDAVIT OF							
Defendant.							
MADISON METROPOLITAN SCHOOL DISTRICT							
v.							
Plaintiffs,	Case No. 20-CV- 454						
JOHN and JANE DOE 1, et al	.,						
STATE OF WISCONSIN	CIRCUIT COURT	DANE COUNTT					
STATE OF WISCONSIN	CIRCUIT COURT	DANE COUNTY					

DR. STEPHEN B. LEVINE, M.D.

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STATE OF OHIO)
) SS
CUYAHOGA COUNTY)

Stephen B. Levine, being duly sworn, states as follows:

I. CREDENTIALS & SUMMARY OF OPINIONS

- 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 became an Assistant Professor of Psychiatry at Case Western in 1973, and became a Full Professor in 1985.
- 2. Since July 1973 my specialties have included psychological problems and conditions relating to sexuality and sexual relations, therapies for sexual problems, and the relationship between love and intimate relationships and wider mental health. 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.
- 3. I have served as a book and manuscript reviewer for numerous professional publications. I have been the Senior Editor of the first (2003), second (2010) and third (2016) editions of the *Handbook of Clinical Sexuality for Mental Health Professionals*. In addition to five other solo-authored books, I have authored *Psychotherapeutic Approaches to Sexual Problems*, published in 2020; it has a chapter titled "The Gender Revolution".
- 4. I first encountered a patient suffering what we would now call gender dysphoria in July 1973. In 1974, I founded the Case Western Reserve University Gender Identity Clinic, and have served as Co-Director of that clinic since that time. Across the years, our Clinic treated hundreds of patients who were experiencing a transgender identity. An occasional child was seen during this era. I was the primary psychiatric care-giver for several dozen of our patients and

supervisor of the work of other therapists. I was an early member of the Harry Benjamin International Gender Dysphoria Association (later known as WPATH) and served as the Chairman of the Standards of Care Committee that developed the 5th version of its Standards of Care. In 1993 the Gender Identity Clinic was renamed, moved to a new location, and became independent of Case Western Reserve University. I continue to serve as Co-Director.

- 5. In 2006, Judge Mark Wolf of the Eastern District of Massachusetts asked me to serve as an independent, court-appointed expert in a litigation involving the treatment 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.
- 6. 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 2019 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").
- 7. A fuller review of my professional experience, publications, and awards as well as identification of cases in which I have provided expert testimony within the last 13 years, is provided in my curriculum vitae, a copy of which is attached hereto as Exhibit A.
- 8. In this declaration, I offer, explain, and identify my opinions and the bases for my opinions in this matter. Each of the opinions set forth herein is based on my professional expertise and experience as described above and I hold each of the opinions set forth herein to a reasonable degree of certainty within my field. The facts upon which I rely are the type of facts reasonably relied upon by experts within my field. A summary of my opinions is as follows:

- a. Sex as defined by biology and reproductive function cannot be changed. While hormonal and surgical procedures may enable some individuals to "pass" as the opposite gender during some or all of their lives, such procedures carry with them physical, psychological, and social risks, and no procedures can enable an individual to perform the reproductive role of the opposite sex. (Section II.A.)
- b. The diagnosis of "gender dysphoria" encompasses a diverse array of conditions, with widely differing pathways and characteristics depending on age of onset among other things. Data from one population (e.g. adults) cannot be assumed to be applicable to others (e.g. children). (Section II.B.)
- c. Among psychiatrists and psychotherapists who practice in the area, there are currently widely varying views concerning both the causes of and appropriate therapeutic response to gender dysphoria in children. Existing studies do not provide a basis for a scientific conclusion as to which therapeutic response results in the best long-term outcomes for affected individuals. (Sections II.E, II.F.)
- d. A majority of children (in several studies, a large majority) who are diagnosed with 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. (Section IV.)
- e. Some recent studies suggest that active affirmation of transgender identity in young children will substantially reduce the number of children "desisting" from transgender identity. This raises concern that this will increase the number of individuals who suffer the multiple long-term physical, mental, and social limitations that are strongly associated with living life as a transgender person. (Section IV.)

- f. Thus, social transition is itself an important intervention with profound implications for the long term mental and physical health of the child. When a mental health professional evaluates a child or adolescent and then recommends social transition, presumably that professional is available to help with interpersonal, familial, and psychological problems that may arise. However, many adolescents transition without mental health assessment and ongoing care, leaving themselves and their families on their own to deal with subsequent problems. (Section IV.)
- g. In most cases, parental involvement is necessary for an accurate and thorough diagnosis of a child or adolescent presenting with gender dysphoria or a desire for a transgender identity, as well as for effective psychotherapeutic treatment and support of the young person. (Section V.)
- h. The knowledge-base concerning the cause and treatment of gender dysphoria available today has low scientific quality. (Section VI.)
- i. There are no studies that show that affirmation of transgender identity in young children reduces suicide, suicidal ideation, or improves long-term outcomes as compared to other therapeutic approaches. Meanwhile, multiple studies show that adult individuals living transgender lives suffer much higher rates of suicide and negative physical and mental health conditions than does the general population. (Section VI.)
- j. In light of what is known and not known about the impact of affirmation on the incidence of suicide, suicidal ideation, and other indicators of mental and physical health, it is scientifically baseless and it is unethical to assert that a child or adolescent who express an interest in a transgender identity will kill him- or herself unless adults and peers affirm that child in a transgender identity. (Section VI.)

- k. Putting a child or adolescent on a pathway towards life as a transgender person puts that individual at risk of a wide range of long-term or even life-long harms, including: sterilization (whether chemical or surgical) and associated regret and sense of loss; inability to experience orgasm (for trans women); physical health risks associated with exposure to elevated levels of cross-sex hormones; surgical complications and lifelong after-care; alienation of family relationships; inability to form healthy romantic relationships and attract a desirable mate; elevated mental health risks. (Section VII.)
- 1. Informed consent is ethically required for potentially life-altering psychological or medical procedures. However, the informed consent process is not simple. In some cases, it may not be possible to obtain meaningful informed consent to place a child on a psychological pathway that carries with it all the lifetime risks (including sterilization, limited sexual response, and social marginalization) that I detail in this report. The child is not competent to weigh how these risks or issues will impact his or her lifetime happiness. At a minimum, informed consent of parents is essential, although it may not be sufficient. (Section VIII.)
- m. With rare exceptions, educators do not have the professional training and experience necessary to guide children and parents through the difficult and potentially life-altering decisions surrounding social transition to a transgender identity, nor can they effectively fill the place of parents in the complex process of diagnosis and therapeutic support of children who suffer from gender dysphoria. Educators have a limited time of involvement with their students, whereas the children's developmental challenges persist as they change grades or schools. (Section VIII.A.)

II. BACKGROUND ON THE FIELD

A. The biological base-line of sex

- 9. The sex of a human individual at its core structures the individual's biological reproductive capabilities—to produce ova and bear children as a mother, or to produce semen and beget children as a father. Sex determination occurs at the instant of conception, depending on whether a sperm's X or Y chromosome fertilizes the egg. Medical technology can be used to determine a fetus's sex before birth. It is thus not literally correct to assert that doctors "assign" the sex of a child at birth; anyone can identify the sex of an infant by genital inspection. What the general public may not understand, however, is that every nucleated cell of an individual's body is chromosomally identifiably male or female—XY or XX.
- 10. The self-perceived gender of a child, in contrast, arises in part from how others label the infant: "I love you, son (daughter)." This designation occurs thousands of times in the first two years of life when a child begins to show awareness of the two possibilities. As acceptance of the designated gender corresponding to the child's sex is the outcome in >99% of children everywhere, anomalous gender identity formation begs for understanding. Is it biologically shaped? Is it biologically determined? Is it the product of how the child was privately regarded and treated? Does it stem from trauma-based rejection of maleness or femaleness, and if so flowing from what trauma? Is it a symptom of another, as of yet unrevealed emotional disturbance? The answers to these relevant questions are not scientifically known.
- 11. Under the influence of hormones secreted by the testes or ovaries, numerous additional sex-specific differences between male and female bodies continuously develop postnatally, culminating in the dramatic maturation of the primary and secondary sex characteristics with puberty. These include differences in hormone levels, height, weight, bone mass, shape and development, musculature, body fat levels and distribution, and hair patterns, as well as

physiological differences such as menstruation. These are genetically programmed biological consequences of sex which also serve to influence the consolidation of gender identity during and after puberty.

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

B. Definition and diagnosis of gender dysphoria

13. Specialists have used a variety of terms over time, with somewhat shifting definitions, to identify and speak about a distressing incongruence between an individual's sex as determined by their chromosomes and their thousands of genes, and the gender with which they eventually subjectively identify or to which they aspire. Today's American Psychiatric Association *Diagnostic and Statistical Manual of Mental Disorders* ("DSM-5") employs the

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

term Gender Dysphoria and defines it with separate sets of criteria for adolescents and adults on the one hand, and children on the other.

- 14. There are at least five distinct pathways to gender dysphoria: early childhood onset; onset near or after puberty with no prior cross gender patterns; onset after homosexual life style; adult onset after years of heterosexual transvestism; and onset in later adulthood with few or no prior indications of cross-gender tendencies or identity. The early childhood onset pathway and the more recently observed onset around puberty pathway are relevant to this matter.
- 15. Gender dysphoria has very different characteristics depending on age and sex at onset. Young children who are living a transgender identity commonly suffer materially fewer symptoms of concurrent mental distress than do older patients.² The developmental and mental health patterns for each of these groups are sufficiently different that data developed in connection with one of these populations cannot be assumed to be applicable to another. (*Id.* at 9.)
- 16. The criteria used in DSM-5 to identify Gender Dysphoria include a number of signs of discomfort with one's natal sex and vary somewhat depending on the age of the patient, but in all cases require "clinically significant distress or impairment in . . . important areas of functioning" such as social, school, or occupational settings.
- 17. When these criteria in children, (or adolescents, or adults) are not met, two other diagnoses may be given. These are: Other Specified Gender Dysphoria and Unspecified Gender

² K. Zucker (2018), The Myth of Persistence: Response to "A Critical Commentary on Follow-Up Studies & 'Desistance' Theories about Transgender & Gender Non-Conforming Children" by Temple Newhook et al., INT'L J. OF TRANSGENDERISM at 10, DOI: 10.1080/15532739.2018.1468293 ("Myth of Persistence").

Dysphoria. Specialists sometimes refer to children who do not meet criteria as being "subthreshold."

18. Children who conclude that they are transgender are often unaware of a vast array of adaptive possibilities for how to live life as a man or a woman—possibilities that become increasingly apparent over time to both males and females. A boy or a girl who claims or expresses interest in pursuing a transgender identity often does so based on stereotypical notions of femaleness and maleness that are based on constrictive notions of what men and women can be.³ A young child's—or even adolescent's—understanding of this topic is quite limited. Nor do they have the perspective that discomfort with the body and perceived social role is not new to civilization; what is new is the option to become a trans person.

C. Definition of an "expert in the field"

- 19. In my opinion, in order to be considered an expert qualified to diagnose a child or adolescent who may suffer from gender dysphoria or related conditions, or to advise or opine on therapy options, and associated risks and benefits, for children and adolescents presenting with gender-related issues, a healthcare professional should have at least the following qualifications:
 - a. Enough knowledge of child development to be able to elicit relevant information by history about situation of the pregnancy (wanted, natural, reproductively-assisted), maternal health during pregnancy, health of the child from birth on, timing of the attainment of pediatric developmental milestones, immediately apparent and later revealed congenital abnormalities, parental relationship, post-partum depression, influence of other children in the family, and onset and progression of the cross-gender behavior. It is to be expected that the clinician be able to ask about what was happening

³ S. Levine (2017), Ethical Concerns About Emerging Treatment Paradigms for Gender Dysphoria, J. of Sex & Marital Therapy at 7, DOI: 10.1080/0092623X.2017.1309482 ("Ethical Concerns").

between parents and child and between parents shortly before the onset of cross-gender behaviors (Levine (2018), *Informed Consent* at 8);

- b. The ability to discern attitudes towards homosexuality in parents and grandparents;
- c. A familiarity with the controversies concerning ethical considerations surrounding possible interventions in the life of a child and family affected by transgenderism;⁴
- d. An understanding of the literature concerning developmental influences on children's gender dysphoria including sensitivity to autistic spectrum influences;
 - e. Ability to recognize, identify, and treat psychiatric co-morbidities;
- f. Experience with psychiatric adolescent outcomes in terms of psychiatric symptoms, orientation, and social problems;
- g. An awareness of the negative as well as the positive potential short- and longterm impacts of alternative interventions on the patient and his or her family;
- h. Regular reading of journal articles about the treatment of children and adolescents with gender dysphoria;
- i. Knowledge of the literature concerning both persistence and desistance of gender dysphoria in children.
- 20. It is not realistic to expect educators or school counselors to have these qualifications. They are the result of professional training followed by intense concentrated experience with patients with mental illness, developmental difficulties short of serious mental illness, and working with the psychodynamics of individual and family lives.

⁴ K. Zucker (2019), *Debate: Different Strokes for Different Folks*, CHILD & ADOLESCENT MENTAL HEALTH, at 1-2, DOI: 10.1111/camh.12330 ("*Debate*").

D. Impact of gender dysphoria on minority and vulnerable groups

21. In considering the appropriate response to gender dysphoria, it is important to know that certain groups of children have an increased prevalence and incidence of trans identities. These include: children of color,⁵ children with mental developmental disabilities,⁶ including children on the autistic spectrum (at a rate more than 7x the general population),⁷ children residing in foster care homes, adopted children (at a rate more than 3x the general population),⁸ children with a prior history of psychiatric illness,⁹ and more recently adolescent girls (in a large recent study, at a rate more than 2x that of boys). (G. Rider at 4.)

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

22. Discussions about appropriate responses by mental health professionals ("MHPs") to actual or sub-threshold gender dysphoria are complicated by the fact that various speakers and

⁵ 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.)

⁶ 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.

⁷ D. Shumer et al. (2016), *Evaluation of Asperger Syndrome in Youth Presenting to a Gender Dysphoria Clinic*, LGBT HEALTH, 3(5) 387 at 387.

⁸ D. Shumer et al. (2017), Overrepresentation of Adopted Adolescents at a Hospital-Based Gender Dysphoria Clinic, TRANSGENDER HEALTH Vol. 2(1) 76 at 77.

⁹ 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."

advocates (or a single speaker at different times) view transgenderism through at least three very different paradigms, often without being aware of, or at least without acknowledging, the distinctions.

- 23. Gender dysphoria is **conceptualized and described by some professionals and laypersons as though it were a serious, physical medical illness that causes suffering**, comparable, for example, to prostate cancer, a disease that is curable before it spreads. Within this paradigm, whatever is causing distress associated with gender dysphoria—whether secondary sex characteristics such as facial hair, nose and jaw shape, presence or absence of breasts, or the primary anatomical sex organs of testes, ovaries, penis, or vagina—should be removed to alleviate the illness. The promise of these interventions is the cure of the gender dysphoria.
- 24. It should be noted, however, that gender dysphoria is a psychiatric rather than a medical diagnosis. Since its inception in DSM-III, it has always and only been specified in the psychiatric DSM manuals. Notably, gender dysphoria is the only psychiatric condition to be treated by surgery, even though no endocrine or surgical intervention package corrects any identified biological abnormality. (Levine, *Reflections*, at 240.)
- 25. Gender dysphoria is alternatively **conceptualized in developmental terms**, as an adaptation to a psychological problem that was first manifested as a failure to establish a comfortable conventional sense of self in early childhood. This paradigm starts from the premise that all human lives are influenced by past processes and events. Trans lives are not exceptions to this axiom. (Levine, *Reflections*, at 238.) MHPs who think of gender dysphoria through this paradigm may work both to identify and address causes of the basic problem of the deeply uncomfortable self, and also to ameliorate suffering when the underlying problem cannot be

solved. They work with the patient and (ideally) family to inquire what forces may have led to the trans person repudiating the gender associated with his sex. The developmental paradigm is mindful of temperamental, parental bonding, psychological, sexual, and physical trauma influences, and the fact that young children work out their psychological issues through fantasy and play.

26. In addition, the developmental paradigm recognizes that, with the important exception of genetic sex, essentially all aspects of an individual's identity evolve—often markedly—across the individual's lifetime. This includes gender. While some advocates assert that a transgender identity is biologically caused, fixed from early life, and eternally present in an unchanging manner, this is not supported by science. Although numerous studies have been undertaken to attempt to demonstrate a distinctive physical brain structure associated with transgender identity, as of yet there is no evidence that these patients have any defining abnormality in brain structure that precedes the onset of gender dysphoria. The belief that gender dysphoria is the consequence of brain structure is challenged by the sudden increase in incidence of child and adolescent gender dysphoria over the last twenty years in North America and Europe. Meanwhile, multiple studies have documented rapid shifts in gender ratios of patients presenting for care with gender-related issues, pointing to cultural influences, ¹⁰ while a recent study documented "clustering" of new presentations in specific schools and among specific friend groups, pointing to social influences (Littman). Both of these findings strongly suggest cultural factors. From the beginning of epidemiological research into this arena, there have always been some countries, Poland and Australia, for example, where the sex ratios were

¹⁰ Levine, *Ethical Concerns*, at 8 (*citing* M. Aitken, T. D. Steensma, et al. (2015), *Evidence for an Altered Sex Ratio in Clinic-Referred Adolescents with Gender Dysphoria*, J. OF SEXUAL MEDICINE 12(3) 756 at 756-63).

reversed as compared to North America and Europe, again demonstrating a powerful effect of cultural influences.

- 27. In recent years, for adolescent patients, intense involvement with online transgender communities or "friends" is the rule rather than the exception, and the MHP will also be alert to this as a potentially significant influence on the identity development of the patient.
- 28. The third paradigm through which gender dysphoria is alternatively conceptualized is from a sexual minority rights perspective. Under this paradigm, any response other than medical and societal affirmation and implementation of a patient's claim to "be" the opposite gender is a violation of the individual's civil right to self-expression. Any effort to ask "why" questions about the patient's condition, or to address underlying causes, is viewed as a violation of autonomy and civil rights. In the last few years, this paradigm has been successful in influencing public policy and the education of pediatricians, endocrinologists, and many mental health professionals.

F. Four competing models of therapy

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

(1) The "watchful waiting" therapy model

- 30. I review below the uniform finding of follow-up studies that the large majority of children who present with gender dysphoria will desist from desiring a transgender identity by adulthood if left untreated. (See infra ¶ 60.)
- 31. When a pre-adolescent child presents with gender dysphoria, a "watchful waiting" approach seeks to allow for the fluid nature of gender identity in children to naturally evolve—that is, take its course from forces within and surrounding the child. Watchful waiting has two versions:
 - a. Treating any other psychological co-morbidities—that is, other mental illnesses as defined by the DSM—that the child may exhibit (separation anxiety, bedwetting, attention deficit disorder, obsessive-compulsive disorder) without a focus on gender (model #1), and
 - b. No treatment at all for anything, but a regular follow-up appointment. This might be labeled a "hands off" approach (model #2).
 - (2) The psychotherapy model: Alleviate distress by identifying and addressing causes (model #3)
- 32. One of the foundational principles of psychotherapy has long been to work with a patient to identify the causes of observed psychological distress and then to address those causes as a means of alleviating the distress. The National Institute of Mental Health has promulgated the idea that 75% of adult psychopathology has its origins in childhood experience.
- 33. Many experienced practitioners in the field of gender dysphoria, including myself, have believed that it makes sense to employ these long-standing tools of psychotherapy for patients suffering gender dysphoria, asking the question as to what factors in the patient's life are the determinants of the patient's repudiation of his or her natal sex. (Levine, *Ethical Concerns*, at 8.) I and others have reported success in alleviating distress in this way for at least some patients,

whether or not the patient's sense of discomfort or incongruence with his or her natal sex entirely disappeared. Relieving accompanying psychological co-morbidities leaves the patient freer to consider the pros and cons of transition as he or she matures.

- 34. Among other things, the psychotherapist who is applying traditional methods of psychotherapy may help—for example—the male patient appreciate the wide range of masculine emotional and behavioral patterns as he grows older. He may discuss with his patient, for example, that one does not have to become a "woman" in order to be kind, compassionate, caring, noncompetitive, and devoted to others' feelings and needs. Many biologically male trans individuals, from childhood to older ages, speak of their perceptions of femaleness as enabling them to discuss their feelings openly, whereas they perceive boys and men to be constrained from emotional expression within the family and larger culture. Men, of course, can be emotionally expressive, just as they can wear pink. Converse examples can be given for girls and women. These types of ideas regularly arise during psychotherapies.
- 35. As I note above, many gender-nonconforming children and adolescents in recent years derive from minority and vulnerable groups who have reasons to feel isolated and have an uncomfortable sense of self. A trans identity may be a hopeful attempt to redefine the self in a manner that increases their comfort and decreases their anxiety. The clinician who uses traditional methods of psychotherapy may not focus on their gender identity, but instead work to help them to address the actual sources of their discomfort. Success in this effort may remove or reduce the desire for a redefined identity. This often involves a focus on disruptions in their attachment to parents in vulnerable children, for instance, those in the foster care system.

¹¹ S. Levine (2017), *Transitioning Back to Maleness*, ARCH. OF SEXUAL BEHAVIOR at 7, DOI: 10.1007/s10508-017-1136-9) ("*Transitioning*").

- 36. Because "watchful waiting" can include treatment of accompanying psychological co-morbidities, and the psychotherapist who hopes to relieve gender dysphoria may focus on potentially causal sources of psychological distress rather than on the gender dysphoria itself, there is no sharp line between "watchful waiting" and the psychotherapy model in the case of prepubescent children.
- 37. To my knowledge, there is no evidence beyond anecdotal reports that psychotherapy can enable a return to male identification for genetically male boys, adolescents, and men, or return to female identification for genetically female girls, adolescents and women. On the other hand, anecdotal evidence of such outcomes does exist; I and other clinicians have witnessed reinvestment in the patient's biological sex in some individual patients who are undergoing psychotherapy. The Internet contains many such reports, and I have published a paper recently on a patient who sought my therapeutic assistance to reclaim his male gender identity after 30 years living as a woman and is in fact living as a man today. (Levine, *Transitioning*, at 1.) I have seen children desist even before puberty in response to thoughtful parental interactions and a few meetings of the child with a therapist.

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

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

need not be addressed by the MHP who is providing supportive guidance concerning the child's gender identity.

- 39. Some advocates, indeed, assert that unquestioning affirmation of any claim of transgender identity in children is essential, and that the child will otherwise face a high risk of suicide or severe psychological damage. I address claims about suicide and health outcomes in Section VI below.
- 40. Some advocates also assert that this "affirmation therapy" model is accepted and agreed with by the overwhelming majority of mental health professionals. However, one respected academic in the field has recently written that, on the contrary, "almost all clinics and professional associations in the world" do not use "gender affirmation" for prepubescent children and instead "delay any transitions after the onset of puberty."¹²
- 41. Even the Standards of Care published by WPATH, an organization which in general leans strongly towards affirmation in the case of adults, does not specify affirmation of transgender identity as the indicated therapeutic response for young children, but rather calls for a careful process of discernment and decision specific to each child, by the family in consultation with the mental health professional.
- 42. Further, the DSM-5 added—for both children and adolescents—a requirement that a sense of incongruence between biological and felt gender must last at least six months as a

¹² J. Cantor (2019), *Transgender and Gender Diverse Children and Adolescents: Fact-Checking of AAP Policy*, J. of Sex & Marital Therapy at 1, DOI: 10.1080.0092623X.2019.1698481.

precondition for a diagnosis of gender dysphoria, precisely because of the risk of "transitory" symptoms and "hasty" diagnosis that might lead to "inappropriate" treatments.¹³

- 43. I do not know what proportion of practitioners are using which model. However, in my opinion, in the case of young children, prompt and thorough affirmation of a transgender identity disregards the principles of child development and family dynamics, and is not supported by science. Rather, the MHP must focus attention on the child's underlying internal and familial issues. Ongoing relationships between the MHP and the parents and the MHP and the child are vital to help the parents, child, other family members, and the MHP to understand over time the issues that need to be dealt with over time by each of them.
- 44. Likewise, since the child's sense of gender develops in interaction with his parents and their own gender roles and relationships, the responsible MHP will almost certainly need to delve into family and marital dynamics.

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

- 45. In almost any discussion of the diagnosis and care of patients suffering gender dysphoria or exhibiting transgender characteristics, the World Professional Association for Transgender Health (WPATH) and the Standards of Care that that organization publishes will be mentioned. Accordingly, I provide some context concerning that private organization.
- 46. I was a member of the Harry Benjamin International Gender Dysphoria Association from 1974 until 2001. From 1997 through 1998, I served as the Chairman of the eight-person International Standards of Care Committee that issued the fifth version of the Standards of Care. I resigned my membership in 2002 due to my regretful conclusion that the organization and its recommendations had become dominated by politics and ideology, rather

¹³ K. Zucker (2015), *The DSM-5 Diagnostic Criteria for Gender Dysphoria*, in C. Trombetta et al. (eds.), MANAGEMENT OF GENDER DYSPHORIA: A MULTIDISCIPLINARY APPROACH, DOI 10.1007/978-88-470-5696-1_4 (Springer-Verlag Italia 2015).

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.

- 47. WPATH is a voluntary membership organization. Since at least 2002, attendance at its biennial meetings has been open to trans individuals who are not licensed professionals. While this ensures taking patients' needs into consideration, it limits the ability for honest and scientific debate, and means that WPATH can no longer be considered a purely professional organization.
- 48. WPATH takes a decided view on issues as to which there is a wide range of opinion among professionals. WPATH explicitly views itself as not merely a scientific organization, but also as an advocacy organization. (Levine, *Reflections*, at 240.) WPATH is supportive to those who want sex reassignment surgery ("SRS"). Skepticism as to the benefits of SRS to patients, and strong alternate views, are not well tolerated in discussions within the organization. Such views have been known to be shouted down and effectively silenced by the large numbers of nonprofessional adults who attend the organization's biennial meetings.
- 49. The Standards of Care ("SOC") is the product of an enormous effort to be balanced, but it is not a politically neutral document. WPATH aspires to be both a scientific organization and an advocacy group for the transgendered. These aspirations sometimes conflict. The limitations of the Standards of Care, however, are not primarily political. They are caused by the lack of rigorous research in the field which allows room for passionate convictions on how to care for the transgendered.
- 50. In recent years, WPATH has fully adopted some mix of the medical and civil rights paradigms. It has downgraded the role of counseling or psychotherapy as a requirement for

these life-changing processes. WPATH no longer considers preoperative psychotherapy to be a requirement. It is important to WPATH that the person has gender dysphoria; the pathway to the development of this state is not. (Levine, *Reflections*, at 240.) The trans person is assumed to have thoughtfully considered his or her options before seeking hormones, for instance.

- 51. Most psychiatrists and psychologists who treat patients suffering sufficiently severe distress from gender dysphoria to seek inpatient psychiatric care are not members of WPATH. Many psychiatrists and psychologists who treat some patients suffering gender dysphoria on an outpatient basis are not members of WPATH. WPATH represents a self-selected subset of the profession along with its many non-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.
- 52. 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. ¹⁴ 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.
- 53. In my experience most current members of WPATH have little ongoing experience with the mentally ill, and many trans care facilities are staffed by MHPs who are not deeply experienced with recognizing and treating frequently associated psychiatric comorbidities. Because the 7th version of the WPATH SOC deleted the requirement for therapy, trans care facilities that consider these Standards sufficient are permitting patients to be

¹⁴ WPATH *De-Psychopathologisation Statement* (May 26, 2010), available at wpath.org/policies (last accessed January 21, 2020).

counseled to transition by means of social presentation, hormones, and surgery by individuals with masters rather than medical degrees. As a result of the downgrading of the role of the psychiatric assessment of patients, new "gender affirming" clinics have arisen in many urban settings that quickly (sometimes within an hour's time) recommend transition. Concerned parents who came wanting to know what is going on in their children are overwhelmed, and feel disoriented, fearful for the health and safety of their children, and dependent on the professional.

III. PATIENTS DIFFER WIDELY AND MUST BE CONSIDERED INDIVIDUALLY.

- 54. In my opinion, it is not possible to make a single, categorical statement about the proper treatment of children presenting with gender dysphoria or other gender-related issues. Indeed, an MHP cannot responsibly opine on the proper treatment of a particular child presenting with gender dysphoria unless and until he or she has had more than one working session with that child, and has taken a thorough developmental history of the child's gender-related issues (or has reviewed such a history prepared by another MHP). This is so for multiple reasons.
- 55. There is no single pathway of development and outcomes governing transgender identity, nor one that predominates over the large majority of cases. Instead, as individuals grow up and age, depending on their differing psychological, social, familial, and life experiences, their outcomes differ widely.
- 56. As to causes in children, details about the onset of gender dysphoria may be found in an understanding of family relationship dynamics. In particular, the relationship between the parents and each of the parents and the child, and each of the siblings and the child should be well known by the MHP.
- 57. Further, a disturbingly large proportion of children who seek professional care in connection with gender issues have a wider history of psychiatric co-morbidities. (*See supra* n. 9.) A 2017 study from the Boston Children's Hospital Gender Management Service program

reported that: "Consistent with the data reported from other sites, this investigation documented that 43.3% of patients presenting for services had significant psychiatric history, with 37.1% having been prescribed psychotropic medications, 20.6% with a history of self-injurious behavior, 9.3% with a prior psychiatric hospitalization, and 9.3% with a history of suicide attempts." (L. Edwards-Leeper, *Psychological Profile*, at 375.) It seems likely that an even higher proportion will have had prior undiagnosed psychiatric conditions.

- 58. As to outcomes, as I explain below, for pre-pubertal children, desistance from transgender identification in favor of a gender corresponding to the child's sex, during or within a few years of puberty, is a likely outcome absent intervention. (*Infra* Section IV.)
- 59. Because the causes, characteristics, social and relational context, and likely future course of gender dysphoria vary widely from individual to individual, it is essential that the MHP spend significant time with an individual patient over multiple sessions to take a careful developmental history, before attempting to decide on a course of therapy for that individual.

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

60. A distinctive and critical characteristic of juvenile gender dysphoria is that multiple studies from separate groups and at different times have reported that in the large majority of patients, absent a substantial intervention such as social transition and/or hormone therapy, it does *not* persist through puberty. A recent article reviewed all existing follow-up studies that the author could identify of children diagnosed with gender dysphoria (11 studies), and reported that "every follow-up study of GD children, without exception, found the same thing: By puberty, the majority of GD children ceased to want to transition." (Cantor at 1.)

Another author reviewed the existing studies and reported that in "prepubertal boys with gender discordance . . . the cross gender wishes usually fade over time and do not persist into adulthood,

with only 2.2% to 11.9% continuing to experience gender discordance."¹⁵ A third summarized the existing data as showing that "Symptoms of GID at prepubertal ages decrease or disappear in a considerable percentage of children (estimates range from 80-95%)."¹⁶

- 61. It is not yet known how to distinguish those children who will desist from that small minority whose trans identity will persist. (Levine, *Ethical Concerns*, at 9.)¹⁷
- 62. Desistance within a relatively short period may also be a common outcome for post-pubertal youths who exhibit recently described "rapid onset gender disorder." I observe an increasingly vocal online community of young women who have reclaimed a female identity after claiming a male gender identity at some point during their teen years. However, data on outcomes for this age group with and without therapeutic interventions is not yet available to my knowledge.
- 63. In contrast, there is now data that suggests that a therapy that encourages social transition dramatically changes outcomes. A prominent group of authors has written that "The gender identity affirmed during puberty appears to predict the gender identity that will persist into adulthood." Similarly, a comparison of recent and older studies suggests that when an "affirming" methodology is used with children, a substantial proportion of children who would

¹⁵ S. Adelson & American Academy of Child & Adolescent Psychiatry (2012), *Practice Parameter on Gay, Lesbian, or Bisexual Sexual Orientation, Gender Nonconformity, and Gender Discordance in Children and Adolescents*, J. Am. ACAD. CHILD ADOLESCENT PSYCHIATRY 51(9) 957 at, 963 ("*Practice Parameter*").

¹⁶ P. T. Cohen-Kettenis, H. A. Delemarre-van de Waal et al. (2008), *The Treatment of Adolescent Transsexuals: Changing Insights*, J. SEXUAL MEDICINE 5(8) 1892 at 1895.

¹⁷ It is also apparent in the adolescent phenomenon of rapid onset of gender dysphoria following a gender normative childhood that childhood gender identity is not inherently stable in either direction.

¹⁸ C. Guss et al. (2015), Transgender and Gender Nonconforming Adolescent Care: Psychosocial and Medical Considerations, CURR. OPIN. PEDIATR. 26(4) 421 at 421 ("TGN Adolescent Care").

otherwise have desisted by adolescence—that is, achieved comfort identifying with their natal sex—instead persist in a transgender identity. (Zucker, *Myth of Persistence*, at 7.)¹⁹

64. Indeed, a review of multiple studies of children treated for gender dysphoria across the last three decades found that early social transition to living as the opposite sex severely reduces the likelihood that the child will revert to identifying with the child's natal sex, at least in the case of boys. That is, while, as I review above, studies conducted before the widespread use of social transition for young children reported desistance rates in the range of 80-98%, a more recent study reported that fewer than 20% of boys who engaged in a partial or complete social transition before puberty had desisted when surveyed at age 15 or older. (Zucker, *Myth of Persistence*, at 7; Steensma (2013).)²⁰ Some vocal practitioners of prompt affirmation and social transition even claim that essentially *no* children who come to their clinics exhibiting gender dysphoria or cross-gender identification desist in that identification and return to a gender identity consistent with their biological sex.²¹ This is a very large change as compared to the desistance rates documented apart from social transition. Some researchers who generally

¹⁹ One study found that social transition by the child was found to be strongly correlated with persistence for natal boys, but not for girls. (Zucker, *Myth of Persistence*, at 5 (citing T.D. Steensma, J.K. McGuire et al. (2013), *Factors Associated with Desistance & Persistence of Childhood Gender Dysphoria: A Qualitative Follow-up Study*, J. OF THE AM. ACAD. OF CHILD & ADOLESCENT PSYCHIATRY 52, 582.).)

²⁰ Only 2 (3.6%) of 56 of the male desisters observed by Steensma et al. had made a complete or partial transition prior to puberty, and of the twelve males who made a complete or partial transition prior to puberty, only two had desisted when surveyed at age 15 or older. Steensma (2013) at 584.

²¹ See, e.g., B. Ehrensaft (2015), Listening and Learning from Gender-Nonconforming Children, THE PSYCHOANALYTIC STUDY OF THE CHILD 68(1) 28 at 34: "In my own clinical practice . . . of those children who are carefully assessed as transgender and who are allowed to transition to their affirmed gender, we have no documentation of a child who has 'desisted' and asked to return to his or her assigned gender."

advocate prompt affirmation and social transition also acknowledge a causal connection between social transition and this change in outcomes.²²

- 65. Accordingly, I agree with a noted researcher in the field who has written that social transition in children must be considered "a form of psychosocial treatment." (Zucker, *Debate*, at 1.)
- 66. So far as I am aware, no study yet reveals whether the life-course mental and physical health outcomes for this relatively new class of "persisters" are more similar to those of the general non-transgender population, or to the notably worse outcomes exhibited by the transgender population generally.
- 67. However, I agree with Zucker who has written, "...we cannot rule out the possibility that early successful treatment of childhood GID [Gender Identity Disorder] will diminish the role of a continuation of GID into adulthood. If so, successful treatment would also reduce the need for the long and difficult process of sex reassignment which includes hormonal and surgical procedures with substantial medical risks and complications." By the same token, a therapeutic methodology for children that *increases* the likelihood that the child will continue to identify as the opposite gender into adulthood will *increase* the need for the long and potentially problematic processes of hormonal and genital and cosmetic surgical procedures.
- 68. Not surprisingly, given these facts, encouraging social transition in children remains controversial. Supporters of such transition acknowledge that "Controversies among

²² See Guss, TGN Adolescent Care, at 2. "The gender identity affirmed during puberty appears to predict the gender identity that will persist into adulthood." "Youth with persistent TNG [transgender, nonbinary, or gender-nonconforming] identity into adulthood... are more likely to have experienced social transition, such as using a different name... which is stereotypically associated with another gender at some point during childhood."

²³ 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.).

providers in the mental health and medical fields are abundant . . . These include differing assumptions regarding . . . the age at which children . . . should be encouraged or permitted to socially transition These are complex and providers in the field continue to be at odds in their efforts to work in the best interests of the youth they serve."²⁴

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

V. PARENTAL INVOLVEMENT IS ESSENTIAL IN MOST CASES FOR ETHICAL TREATMENT OF A CHILD WHO SUFFERS FROM GENDER DYSPHORIA OR SEEKS SOCIAL TRANSITION.

- 70. For many reasons, in the large majority of cases the involvement of one or both parents will be essential to a responsible, effective, and indeed ethical diagnosis and treatment of a child who is or may be suffering from gender dysphoria or one of the related conditions I have described above.
 - A. Parental involvement is necessary for accurate and thorough diagnosis of the child and to discern familial and intrapsychic forces that may contribute to moving the child towards a trans identity.
- 71. A claim or expression of interest in a transgender identity by a child must be the beginning, not the end, of a careful diagnostic and therapeutic process. Transgender identification in a child is not a simple, uniform phenomenon; as I have explained, there is no

²⁴ A. Tishelman et al. (2015), Serving Transgender Youth: Challenges, Dilemmas and Clinical Examples, PROF. PSYCHOL. RES. PR. at 11, DOI: 10.1037/a0037490 ("Serving TG Youth").

single pathway of development and outcomes governing transgender identity, nor one that predominates over the large majority of cases. Instead, as individuals grow up and age, depending on their differing psychological, social, familial, and life experiences, their outcomes differ widely.

- 72. What can be observed by—for example—a teacher or counselor at school, although important, is only one window into the life and psyche of a child. A teacher's perspective emphasizes learning capacities, social interactions, and gender style relative to other similarly aged children, often during just one school year.
- 73. As a starting point, any child suffering serious tension between his or her reproductive biology and sense of gender identity (or desired gender identity) should have the assistance and support of a skilled mental health professional, and a meaningful diagnosis of the child's condition will require a sustained relationship between an MHP and the child over time. The involvement of parents will often be essential to establishing and maintaining this type of relationship between an MHP and the child.
- 74. What the child *means* by a claim of transgender identity may vary widely depending on age. Younger grade school children, for example, have some concept of gender, but what they "know" about the sexes, about the future meaning of male or female, or about gender identity—beyond what they are told by adults or what they pick up unconsciously from mother, father, siblings, and extended family—is limited. Thus, one sees children draw distinctions in colors, clothing, and toys—classic early stereotypes of what it means to be a girl or a boy.

- 75. The child may or may not actually suffer from gender dysphoria, and this should be determined. ²⁵ Input from parents is likely to be important to evaluating whether a child is suffering from "clinically significant distress or impairment in social, school, or other important areas of functioning." (DSM-5)
- 76. Parents, similarly, in many cases will have observed the child over his or her entire lifetime, and so will have unique insight into whether the child's attraction to a transgender identity is longstanding and stable, or whether on the contrary it has been abrupt and associated with intensive online interaction with transgender "communities."
- 77. Likewise, when parental or family dynamics play a role in the child's discomfort with his or her natal sex (*see supra* ¶ 56), it will not be possible to evaluate these influences without parental involvement in the diagnostic and therapeutic process. A thorough evaluation cannot be done as effectively in a short period. Ideally a long-term relationship with parents enables a clear picture of what happened in the family and to the child because a different level of trust often occurs over time between the parents and the MHP.
- 78. In addition, as I detail elsewhere, a large proportion of children (and adults) who present with claims of or attraction to a transgender identity suffer from identifiable psychiatric co-morbidities. (*See supra* ¶ 57.) Regardless of whether these are in any way related to the child's gender identity, it is important that these co-morbidities—if they exist—be identified and that appropriate psychotherapeutic help is obtained for the child. And, regardless of whether co-

²⁵ See D. Shumer, N. Nokoff & N. Spack (2016), Advances in the Care of Transgender Children & Adults, ADV. PEDIATR. (2016) at 7, DOI: 10.1016/j.yapd.2016.04.018: "The Endocrine Society guidelines recommend that children and adolescents with gender concerns be seen by a mental health professional with training in child and adolescent developmental psychology. The mental health professional should: 1) determine whether the individual fulfills DSM criteria for gender dysphoria; 2) inform the individual with respect to possibilities and limitations of sex reassignment and other treatments; and 3) assess for potential psychological comorbidities."

morbidities might be apparent to an MHP given an opportunity to diagnose the child or adolescent before and apart from an expression of a desire for a transgender identity, most parents are not MHPs, and from their perspective the child or adolescent's transgender interest may come "out of the blue," (Littman at 13), and be the first sign that they appreciate that their child should receive professional evaluation.

- 79. At the very least, then, a child who exhibits or expresses an interest in a transgender identity should be evaluated for psychiatric co-morbidities. Again, parental involvement will generally be essential for this to be done, and to be done well.
 - B. Parental involvement is important for effective psychotherapeutic treatment and support of the child.
- 80. Theories as to the causes of particular psychological problems, and how they can best be addressed once identified, continue to vary widely, but a broad consensus has agreed on the importance of identifying and addressing the causes of felt distress. This is accomplished first and foremost by a stable relationship with a professional who has substantial experience in psychotherapy and who is able to form caring and empathetic relationships with the child and parents. It is not possible to be more specific about treatment because child therapists themselves are so diverse in how they think about and perform parent guidance and child interventions. (Zucker, *Debate*.)
- 81. Since the child's sense of gender develops in interaction with his parents and their own gender roles and relationships, the responsible MHP will almost certainly need to delve into family and marital dynamics. (*See supra* ¶ 25.) An ongoing relationship between the MHP and the parents and the child is vital to help the parents, child, other family members, and the MHP to understand the issues that need to be dealt with over time by each of them.

82. For a child to live radically different identities at home and at school, and to conceal what he or she perceives to be his or her true identity from parents, is psychologically unhealthy in itself, and could readily lead to additional psychological problems. Meaningful and healthy "support" of a child struggling with gender issues must include parents. Often, parents are more accepting and supportive of non-standard orientation or identity in their child than the child fears they will be. Even where parents in fact have a difficult time accepting some aspect of their child's identity, the path to psychological health for the child will often require addressing and resolving or reducing that gulf between parent and child, perhaps with the aid of the MHP experienced in family dynamics. Extended secrecy and a "double life" concealed from the parents is rarely the path to psychological health. For this reason at least, schools should not support deceit of parents.

C. Parental involvement is necessary to obtain informed consent.

83. Social transition is itself an important psychotherapeutic intervention in the life of a child, and preliminary evidence indicates that it is an intervention that is likely to have a dramatic impact on the child's life over the long term. The ethical MHP (and the informed and ethical educator) will not undertake such an intervention without obtaining informed consent. The complex and long-term social, medical, and mental health implications of adopting a transgender identity—along with the complicating psychological co-morbidities that accompany transgender feelings in many individuals—make the process of obtaining informed consent lengthy and complex under the best of circumstances. (*See* Section VIII.) Most children are both legally and developmentally *incapable* of giving informed consent to such a life-altering intervention. And parents, of course, cannot give informed consent if the fact of their child's wish to assume a transgender identity is concealed from them.

- 84. All mental health professionals are aware that situations occur in which parents act in a manner that seriously imperils the well-being of their child. This is not the general expectation, and is not lightly assumed. When this is thought to be the situation, medical or mental health professionals or educators may seek judicial intervention to remove children from the custody of their parents. But these processes are surrounded by procedures and safeguards to protect against casual disruption of parental authority and the bond between parents and child. The school alone should not make these decisions.
- VI. THE AVAILABLE DATA DOES NOT SUPPORT THE CONTENTION THAT "AFFIRMATION" OF TRANSGENDER IDENTITY REDUCES SUICIDE OR RESULTS IN BETTER PHYSICAL OR MENTAL HEALTH OUTCOMES GENERALLY.
- 85. I am aware that organizations including The Academy of Pediatrics and Parents, Families and Friends of Lesbians and Gays (PFLAG)) have published statements that suggest that all children who express a desire for a transgender identity should be promptly supported in that claimed identity. This position appears to rest on the belief—which is widely promulgated by certain advocacy organizations—that science has already established that prompt "affirmance" is best for all patients, including all children, who present indicia of transgender identity. As I discuss later below, this belief is scientifically incorrect, and ignores both what is known and what is unknown.
- 86. The knowledge-base concerning the causes and treatment of gender dysphoria has low scientific quality.
- 87. In evaluating claims of scientific or medical knowledge, it is important to understand that it is axiomatic in science that no knowledge is absolute, and to recognize the widely-accepted hierarchy of reliability when it comes to "knowledge" about medical or psychiatric phenomena and treatments. Unfortunately, in this field opinion is too often confused

with knowledge, rather than clearly locating what exactly is scientifically known. In order of increasing confidence, such "knowledge" may be based upon data comprising:

- a. Expert opinion—it is perhaps surprising to educated laypersons that expert opinion standing alone is the lowest form of knowledge, the least likely to be proven correct in the future, and therefore does not garner as much respect from professionals as what follows.
- b. A single case or series of cases (what could be called anecdotal evidence); (Levine, *Reflections*, at 239.)
 - c. A series of cases with a control group;
 - d. A cohort study;
 - e. A randomized double-blind clinical trial;
 - f. A review of multiple trials;
- g. A meta-analysis of multiple trials that maximizes the number of patients treated despite their methodological differences to detect trends from larger data sets.
- 88. Prominent voices in the field have emphasized the severe lack of scientific knowledge in this field. The American Academy of Child and Adolescent Psychiatry has recognized that "Different clinical approaches have been advocated for childhood gender discordance. . . . There have been no randomized controlled trials of any treatment. . . . [T]he proposed benefits of treatment to eliminate gender discordance. . . . must be carefully weighed against. . . possible deleterious effects." (Adelson et al., *Practice Parameter*, at 968–69.)

 Similarly, the American Psychological Association has stated, ". . . because no approach to

working with [transgender and gender nonconforming] children has been adequately, empirically validated, consensus does not exist regarding best practice with pre-pubertal children."²⁶

- 89. Critically, "there are no randomized control trials with regard to treatment of children with gender dysphoria." (Zucker, *Myth of Persistence*, at 8.) On numerous critical questions relating to cause, developmental path if untreated, and the effect of alternative treatments, the knowledge base remains primarily at the level of the practitioner's exposure to individual cases, or multiple individual cases. As a result, claims to certainty are not justifiable. (Levine, *Reflections*, at 239.)
- 90. Large gaps exist in the medical community's knowledge regarding the long-term effects of SRS and other gender identity disorder treatments in relation to their positive or negative correlation to suicidal ideation, attempts, and completion. What is known, however, is not encouraging.
- 91. With respect to suicide, individuals with gender dysphoria are well known to commit suicide or otherwise suffer increased mortality before and after not only social transition, but also before and after SRS. (Levine, *Reflections*, at 242.) For example, in the United States, the death rates of trans veterans are comparable to those with schizophrenia and bipolar diagnoses—20 years earlier than expected. These crude death rates include significantly elevated suicide rates. (Levine, *Ethical Concerns*, at 10.) Similarly, researchers in Sweden and Denmark have reported on almost all individuals who underwent sex-reassignment surgery over a 30-year period.²⁷ The Swedish follow-up study found a suicide rate in the post-SRS population 19.1

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

times greater than that of the controls; both studies demonstrated elevated mortality rates from medical and psychiatric conditions. (Levine, *Ethical Concerns*, at 10.)

- 92. Advocates of immediate and unquestioning affirmation of social transition in children who indicate a desire for a transgender identity sometimes assert that any other course will result in a high risk of suicide in the affected children and young people. Contrary to these assertions, no studies show that affirmation of children (or anyone else) reduces suicide, prevents suicidal ideation, or improves long-term outcomes, as compared to either a "watchful waiting" or a psychotherapeutic model of response, as I have described above.²⁸
- 93. I will also note that any discussion of suicide when considering younger children involves very long-range and very uncertain prediction. Suicide in pre-pubescent children is rare and the existing studies of gender identity issues in pre-pubescent children do not report significant incidents of suicide. The estimated suicide rate of trans adolescents is the same as teenagers who are in treatment for serious mental illness. What trans teenagers do demonstrate is more suicidal ideation and attempts (however serious) than other teenagers.²⁹
- 94. In sum, claims that affirmation will reduce the risk of suicide for children are not based on science. Such claims overlook the lack of even short-term supporting data as well as the lack of studies of long-term outcomes resulting from the affirmation or lack of affirmation of transgender identity in children. It also overlooks the other tools that the profession does have for

K. Simonsen et al. (2016), Long-Term Follow-Up of Individuals Undergoing Sex Reassignment Surgery: Psychiatric Morbidity & Mortality, NORDIC J. OF PSYCHIATRY 70(4).

²⁸ A recent article, J. Turban et al. (2020), *Puberty Suppression for Transgender Youth and Risk of Suicidal Ideation*, PEDIATRICS 145(2), DOI: 10.1542/peds.2019-1725, has been described in press reports as demonstrating that administration of puberty suppressing hormones to transgender adolescents reduces suicide or suicidal ideation. The paper itself does not make that claim, nor permit that conclusion.

²⁹ 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.

addressing depression and suicidal thoughts in a patient once that risk is identified. (Levine, *Reflections*, at 242.)

- 95. A number of data sets have also indicated significant concerns about wider indicators of physical and mental health, including ongoing functional limitations;³⁰ substance abuse, depression, and psychiatric hospitalizations;³¹ and increased cardiovascular disease, cancer, asthma, and COPD.³² Worldwide estimates of HIV infection among transgendered individuals are up to 17-fold higher than the cisgender population. (Levine, *Informed Consent*, at 6.)
- 96. Meanwhile, no studies show that affirmation of pre-pubescent children leads to more positive outcomes (mental, physical, social, or romantic) by, e.g., age 25 or older than does "watchful waiting" or ordinary therapy. Because children's affirmation, social transition, and the use of puberty blockers for transgender children are a recent phenomenon, it could hardly be otherwise.
- 97. Thus, transition of any sort must be justified, if at all, as a life-enhancing measure, not a lifesaving measure. (Levine, *Reflections*, at 242.) In my opinion, this is an important fact that patients, parents, and even many MHPs fail to understand.

³⁰ G. Zeluf, C. Dhejne et al. (2016), *Health, Disability and Quality of Life Among Trans People in Sweden—A Web-Based Survey*, BMC PUBLIC HEALTH 16(903), DOI: 10.1186/s12889-016-3560-5.

³¹ C. Dhejne, R. Van Vlerken et al. (2016), *Mental Health & Gender Dysphoria: A Review of the Literature*, INT'L REV. OF PSYCHIATRY 28(1) 44.

³² C. Dragon, P. Guerino, et al. (2017), *Transgender Medicare Beneficiaries & Chronic Conditions: Exploring Fee-for-Service Claims Data*, LGBT HEALTH 4(6) 404, DOI: 10.1089/lgbt.2016.0208.

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

- 98. As I have detailed above, enabling and affirming social transition in a prepubescent child appears to be highly likely to increase the odds that the child will in time pursue pubertal suppression and persist in a transgender identity into adulthood. I consider the ethical implications of this intervention in the next section. Here, I simply note that fact to observe that the MHP (and parent) must therefore consider long term as well as short term implications of life as a transgender individual when deciding whether to permit or encourage a child to socially transition.
- 99. The multiple studies from different nations that have documented the increased vulnerability of the adult transgender population to substance abuse, mood and anxiety disorders, suicidal ideation, and other health problems warn that assisting the child down the road to becoming a transgender adult is a very serious decision, and stand as a reminder that a casual assumption that transition will improve the child's life is not justified based on numerous scientific snapshots of cohorts of trans adults and teenagers.
- 100. The possibility that steps along this pathway, while lessening the pain of gender dysphoria, could lead to additional sources of crippling emotional and psychological pain, are too often not considered by advocates of social transition and not considered at all by the trans child. (Levine, *Reflections*, at 243.) Many and likely most educators do not have the information and professional experience to give these possibilities appropriate consideration, or to help a child do so.
- 101. I detail below several classes of predictable, likely, or possible harms to the patient associated with transitioning to live as a transgender individual.

A. Physical risks associated with transition

- 102. <u>Sterilization</u>. Obviously, SRS that removes testes, ovaries, or the uterus is inevitably sterilizing. While by no means all transgender adults elect SRS, many patients do ultimately feel compelled to take this serious step in their effort to live fully as the opposite sex. More immediately, practitioners recognize that the administration of cross-sex hormones, which is often viewed as a less "radical" measure, and is now increasingly done to minors, creates at least a risk of irreversible sterility. As a result, even when treating a child, the MHP, patient, and parents must consider loss of reproductive capacity—sterilization—to be one of the major risks of starting down the road. The risk that supporting social transition may put the child on a pathway that leads to intentional or unintentional permanent sterilization is particularly concerning given the disproportionate representation of minority and other vulnerable groups among children reporting a transgender or gender-nonconforming identity. (*See supra* ¶ 21.)
- 103. Loss of sexual response. Puberty-blockers prevent maturation of the sexual organs and response. Some and perhaps many transgender individuals who transitioned as children and thus did not go through puberty consistent with their sex face significantly diminished sexual response as they enter adulthood, and are unable ever to experience orgasm. To my knowledge, data quantifying this impact has not been published. In the case of males, the cross-sex administration of estrogen limits penile genital function. Much has been written about the negative psychological and relational consequences of anorgasmia among non-transgender individuals that is ultimately applicable to the transgendered. (Levine, *Informed Consent*, at 6.)

³³ 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").

104. Other effects of hormone administration. While it is commonly said that the effects of puberty blockers are reversible after cessation, in fact controlled studies have not been done of how completely this is true. However, it is well known that many effects of cross-sex hormones cannot be reversed should the patient later regret his transition. After puberty, the individual who wishes to live as the opposite sex will in most cases have to take cross-sex hormones for life.

been quantified in terms of exact risk.³⁴ However, a recent study found greatly elevated levels of strokes and other acute cardiovascular events among male-to-female transgender individuals taking estrogen. Those authors concluded, "it is critical to keep in mind that the risk for these cardiovascular events in this population must be weighed against the benefits of hormone treatment."³⁵ Another group of authors similarly noted that administration of cross-sex hormones creates "an additional risk of thromboembolic events"—which is to say blood clots (Guss et al., *TGN Adolescent Care* at 5), which are associated with strokes, heart attack, and lung and liver failure. Clinicians must distinguish the apparent short-term safety of hormones from likely or possible long-term consequences, and help the patient or parents understand these implications as well. The young patient may feel, "I don't care if I die young, just as long I get to live as a woman." The mature adult may take a different view.

³⁴ 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").

³⁵ 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.

- 106. <u>Health risks inherent in complex surgery</u>. Complications of surgery exist for each procedure,³⁶ 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.
- 107. <u>Disease and mortality generally</u>. The MHP, the patient, and in the case of a child the parent, must also be aware of the wide sweep of strongly negative health outcomes among transgender individuals, as I have detailed above.

B. Social risks associated with transition

- 108. <u>Family and friendship relationships</u>. 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 as siblings who marry and have children of their own do not wish the transgender individual to be in contact with those children. By adulthood, the friendships of transgender individuals tend to be confined to other transgender individuals (often "virtual" friends known only online) and the generally limited set of others who are comfortable interacting with transgender individuals. (Levine, *Ethical Concerns*, at 5.)
- 109. Long term psychological and social impact of sterility. The life-long negative emotional impact of infertility on both men and women has been well studied. While this impact has not been studied specifically within the transgender population, the opportunity to be a parent is likely a human, emotional need, and so should be considered an important risk factor when considering gender transition for any patient. However, it is particularly difficult for parents of a young child to seriously contemplate that child's potential as a future parent and

³⁶ 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.).

grandparent. This makes it all the more critical that the MHP spend substantial and repeated time with parents to help them see the implications of what they are considering.

- 110. Sexual-romantic risks associated with transition. 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 cisgender 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. (Levine, *Ethical Concerns*, at 5, 13.) Nor is the problem all on the other side; transgender individuals commonly become strongly narcissistic, unable to give the level of attention to the needs of another that is necessary to sustain a loving relationship.³⁷
- 111. Social risks associated with delayed puberty. The social and psychological impact of remaining puerile for, e.g., three years while one's peers are undergoing puberty, and of undergoing puberty at a substantially older age, have not been systematically studied, although clinical mental health professionals often hear of distress and social awkwardness in those who naturally have a delayed onset of puberty. In my opinion, individuals in whom puberty is delayed multiple years are likely to suffer at least subtle negative psychosocial and self-confidence effects as they stand on the sidelines while their peers are developing the social relationships (and attendant painful social learning experiences) that come with adolescence. (Levine, Informed Consent, at 9.)

³⁷ S. Levine, *Barriers to Loving: A Clinician's Perspective*, at 40 (Routledge, New York 2013).

C. Mental health costs or risks

- 112. 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 (or, in a manner that is consistent with the stereotypes of the other 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. (Levine, *Informed Consent*, at 9.)
- 113. In addition, individuals often pin excessive hope in transition, believing that transition will solve what are in fact ordinary social stresses associated with maturation, or mental health co-morbidities. Thus, transition can result in deflection from mastering personal challenges at the appropriate time, or addressing conditions that require treatment.
- 114. Whatever the reason, transgender individuals including transgender youth certainly experience greatly increased rates of mental health problems. I have detailed this above with respect to adults living under a transgender identity. Indeed, Swedish researchers in a long-term study (up to 30 years since SRS, with a median time since SRS of > 10 years) concluded that individuals who have SRS should have postoperative lifelong psychiatric care. (Dhejne, *Long Term*, at 6-7.) With respect to youths a cohort study found that transgender youth had an elevated risk of depression (50.6% vs. 20.6%) and anxiety (26.7% vs. 10.0%); a higher risk of suicidal ideation (31.1% vs. 11.1%), suicide attempts (17.2% vs. 6.1%), and self-harm without lethal intent (16.7% vs. 4.4%) relative to the matched controls; and a significantly greater

proportion of transgender youth accessed inpatient mental health care (22.8% vs. 11.1%) and outpatient mental health care (45.6% vs. 16.1%) services.³⁸

D. Regret following transition is not an infrequent phenomenon.

- 115. The large numbers of children and young adults who have desisted as documented in both group and case studies each represent "regret" over the initial choice in some sense.
- 116. The phenomenon of desistance or regret experienced *later* than adolescence or young adulthood, or among older transgender individuals, has to my knowledge not been quantified or well studied. However, it is a real phenomenon. I myself have worked with multiple individuals who have abandoned trans female identity after living in that identity for years, and who would describe their experiences as "regret."
- 117. I have seen several Massachusetts inmates and trans individuals in the community abandon their [trans] female identity after several years. (Levine, *Reflections*, at 239.) In the gender clinic which I founded in 1974 and to this day, in a different location, continue to codirect, 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.
- 118. More dramatically, a surgical group prominently active in the SRS field has published a report on a series of seven male-to-female patients requesting surgery to transform their surgically constructed female genitalia back to their original male form.³⁹
- 119. I noted above an increasingly visible online community of young women who have desisted after claiming a male gender identity at some point during their teen years. (*See supra* \P 62.) Given the rapid increase in the number of girls presenting to gender clinics within

³⁸ S. Reisner et al. (2015), Mental Health of Transgender Youth in Care at an Adolescent Urban Community Health Center: A Matched Retrospective Cohort Study, J. OF ADOLESCENT HEALTH 56(3) at 6, DOI:10.1016/j.jadohealth.2014.10.264; see also supra ¶ 21.

³⁹ 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.

the last few years, the phenomena of regret and desistance by young women deserves careful attention and study by MHPs.

120. Thus, one cannot assert with any degree of certainty that once a transgendered person, always a transgendered person, whether referring to a child, adolescent, or adult, male or female.

VIII. MEDICAL ETHICS & INFORMED CONSENT

- A. The obligation of the mental health professional to enable and obtain informed consent
- 121. I have reviewed above the knowledge and experience that, in my view, a mental health professional should have before undertaking the responsibility to counsel or treat a child who is experiencing gender dysphoria or transgender identification. The MHP who undertakes this type of responsibility must also be guided by the ethical principles that apply to all health care professionals. One of the oldest and most fundamental principles guiding medical and psychological care—part of the Hippocratic Oath—is that the physician must "first, do no harm." This states an ethical responsibility that cannot be delegated to the patient. Physicians themselves must weigh the risks of treatment against the harm of not treating. If the risks of treatment outweigh the benefits, ethics prohibit the treatment.
- 122. A distinct ethical responsibility of physicians, when a significant risk exists of adverse consequences to any procedure or therapy, is to ensure that the patient understands and is legally able to consent to the treatment, and does consent. To achieve informed consent, the MHP must do at least the following:
 - a. The MHP must reasonably inform himself regarding the particular situation of his patient;

- b. The MHP must reasonably inform himself concerning the state of knowledge concerning relevant methodologies and outcomes;
- c. The MHP must honestly inform the patient concerning not only the benefits of treatment, but also the risks and downsides of treatment, and alternative treatments.
- d. The MHP must conclude that the patient (or the decision maker, such as parent or healthcare power of attorney) has comprehended what he or she has been told and possesses a cognitive capacity to make a decision based on an adequate understanding of his or her unique life circumstances.
- 123. Perfunctory "consent" is inadequate to fulfill the professional's ethical obligation to obtain informed consent. At the very least, a patient (or parent) considering the life-altering choice of transition should be helped or indeed required by their clinicians to grapple with four relevant questions:
 - a. "What benefits do you expect that the consolidation of this identity, gender transition, hormones, or surgery will provide?
 - b. "What do you understand of the social, educational, vocational, and psychological risks of this identity consolidation and gender role transition?
 - c. "What do you understand about the common and rare, short- and long-term medical and health risks of hormone and surgical interventions?
 - d. "What have you considered the nature of your life will be in 10 to 20 years?" (Levine, *Informed Consent*, at 3.)
- 124. The answers of the patient will enable the professional to make a judgment about how realistic he or she is being. For example, the biological boy who envisions himself as a happy, attractive, socially accepted 21-year-old girl in future college years has probably not been

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

- 125. Most commonly, meaningful engagement with difficult and painful questions such as those above requires a process that will consist of multiple discussions in a psychotherapeutic or counseling context, not merely "disclosure" of facts. In my experience, a too-rapid or too-eager attachment to some outcome is a red warning flag that the patient is not able to tolerate knowledge of the risks and alternative approaches.
- 126. In my experience, in the area of transgender therapy, rather than the type of information and engagement that I have described, even mental health professionals too often encourage or permit decisions based on a great deal of patient and professional blind optimism about the future. (Levine, *Ethical Concerns*, at 3-4.)
- 127. In my judgment, few if any educators who are not also trained mental health professionals will have the knowledge and the training needed to engage in the probing process of informed consent that I have described above, and few will even be aware of the full implications of this ethical principle. They may also be unaware of—or even reject—the well-recognized developmental, ethical, and legal limits on the ability of children to *grant* consent to serious medical or psychotherapeutic interventions. When the clinical experience and areas of competence of even PhD school psychologists are considered, it is usually apparent that their training and professional experiences to date do not equip them to guide parents and children through the uncertainties and ethical dilemmas inherent in children and adolescents who are struggling with gender identity issues or experiencing a sense of transgender identity.

- B. The interests of the patient, as well as necessary disclosures and consent, must be considered from a life course perspective.
- 128. The psychiatrist or psychologist treating a child must have in view not merely (or not even primarily) making the child "happy" now, but making him or her as healthy and happy as possible across the entire trajectory of life, to the extent that is predictable. Certainly, avoiding suicide is one important aspect of a "life course" analysis, and recognizes that "today" is not the only goal. But as I have reviewed above, there is much more across the future decades of the patient's life that also needs to be taken into account.
- 129. Further, I do not believe that a patient can meaningfully be said to know what will make him "happy" over the long term, prior to receiving, understanding, and usually discussing the type of information that I have described above in connection with informed consent. With respect to children who are not equipped to understand, evaluate, and feel the life implications of such information, it is doubtful that there is any meaningful way in which they can be said to "know" what will make them happy over the long term. It is for similar reasons that parents ordinarily make a great many decisions, both large and small, for their young children.
- and women undergo elective sterilization, there is a distinct likelihood of eventual regret. It has been documented that the younger the age of sterilization, the greater incidence of regret and increased numbers of requests to reverse the sterilized state. Thus, the medical profession and the courts are quite clear about sterilization: the adult patient must be cognitively able to prudently consider the future consequences in terms of his or her life circumstances. In minors sterilization should be done only to save a life.⁴⁰ This observation has implications for facilitating or even

⁴⁰ See S. D. Hillis et al. (1999), Poststerilization Regret: Findings from the United States Collaborative Review of Sterilization, Obstetrics. & Gyn. 93(6) 889; A. Burgart et al. (2017), Ethical Controversy About Hysterectomy for a Minor, Pediatrics 139(6),

permitting children or adolescents to embark on a path of social transition that within a few years may psychologically steer that individual towards sterilizing chemical or surgical procedures.

C. Special concerns and ethical rules governing experimentation on patients

- 131. When psychiatric or medical research is done on subjects the informed consent process is far more rigorous than in ordinary medical and psychiatric procedures. For example, in a recent study of an agent to assist women who are distressed by their lack of sexual desire that I was a part of, the Informed Consent document was 19 pages long.
- the more recently documented phenomenon of "rapid onset gender dysphoria" among adolescents means that therapeutic responses to these conditions are still at a primitive stage of development, and must be considered to be experimental, rendering adequately informed consent all the more essential, and all the more difficult to obtain. Claims that a civil right is at stake do not change the fact that what is proposed is a social and medical experiment. (Levine, *Reflections*, at 241.)

D. Ethical principles do not permit using patients as "change agents."

133. Some advocates assert that various mental health pathologies commonly observed in patients who have transitioned result from societal prejudice, and would not occur if society were different. This is, of course, a hypothesis rather than demonstrated fact, and it is in any case ethically irrelevant to the treatment of an individual patient. If a therapy or life course under consideration for a child will predictably lead to social and family isolation and unemployment

DOI:10.1542/peds.2016-3992; K. Curtis et al. (2006), Regret Following Female Sterilization at a Young Age: A Systematic Review, CONTRACEPTION 73, 205,

DOI:10.1016/j.contraception.2005.08.006; A. Tamar-Mattis (2009), *Exploring Gray Areas in the Law About DSD and Sterilization*, ENDOCRINE TODAY, October ed.,

https://www.healio.com/endocrinology/reproduction-androgen-disorders/news/print/endocrine-today/%7Bc6029f85-28ac-43f4-9e7e-0fc897f6313f%7D/exploring-gray-areas-in-the-law-about-dsd-and-sterilization.

later in life given society as it exists, for a MHP or other advisor to recommend or encourage that path nonetheless seems to lose sight of the welfare of the patient. To do so appears to be intentionally using the child as not merely an experiment, but as a change-agent—potentially at great personal cost—rather than seeking the lifetime best interests of that child. (Levine, *Ethical Concerns*, at 9.)

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

- 134. Obviously, most children cannot give legally valid consent to a medical procedure.⁴¹ This is not a mere legal technicality. Instead, it is a legal reflection of a reality of human development that is highly relevant to the ethical requirement of informed consent quite apart from law. The argument that the child is consenting to the transition by his happiness ignores the fact just described.
- 135. Each age group poses different questions about risk comprehension. (Levine, *Informed Consent*, at 3.) While the older patient is perhaps more likely to be formally mental ill and delusional, the young child is chronically unable to comprehend large and complex issues such as the meaning of biological sex, the meaning of gender, and the risks and life implications attendant on social, hormonal, and ultimately surgical transition.
- 136. In my experience, when clinicians actually attempt to understand patients' motives for the repudiation of their natal gender, the developmental lack of sophistication underlying their reasons can become apparent. What must a 12-year-old, for example, understand about masculinity and femininity that enables the conviction that "I can never be happy in my body?" (Levine, *Ethical Concerns*, at 8.) Obviously, this unavoidable gap in comprehension and ability to foresee must be still larger for younger children.

⁴¹ I recognize that in some States or under some circumstances "mature minors" may be legally empowered to grant consent to certain medical procedures.

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

138. For this reason, it is my opinion that asking a child whether he or she wishes to transition to living as the opposite sex, or giving large weight to the child's expressed wishes, by no means satisfies the MHP's ethical obligation to obtain informed consent before assisting that child to transition to living as the opposite sex.

or probable lifetime costs to the child if he or she persists in a transgender identity into adulthood, in my opinion it is not consistent with principles of medical ethics for physicians or other MHPs to suggest that parents should not or have no right to explore possible therapeutic options to assist their child to achieve comfort with the gender corresponding to his or her sex. The use of the label "reparative therapy" by some advocates to lump all such possible therapies together and disparage them does not change this equation. (Levine, *Informed Consent*, at 7.)

Dated: February / , 2020.

Stephen B. Levine

Subscribed and sworn to before me

this 16 day of February, 2020.

Notary Public, State of _ My Commission expires

VICTOR V. ANSELMO, Attorney NOTARY PUBLIC - STATE OF ORIGINA My commission has no or pustion data. Section 147.03 R.C.

Brief Introduction

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

Personal Information

Date of birth 1/14/42

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

Board Certification 6/76 American Board of Neurology and Psychiatry

Education

1963 BA Washington and Jefferson College

1967 MD Case Western Reserve University School of Medicine

1967-68 internship in Internal Medicine University Hospitals of Cleveland

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

1970-73 Psychiatric Residency, University Hospitals of Cleveland

1974-77 Robert Wood Johnson Foundation Clinical Scholar

Appointments at Case Western Reserve University School of Medicine

1973 - Assistant Professor of Psychiatry

1979 - Associate Professor

1982 - Tenure

1985 - Full Professor

1993 - Clinical Professor

Honors

Summa Cum Laude, Washington & Jefferson

Teaching Excellence Award - 1990 and 2010 (residency program)

Visiting Professorships:

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

Named to America's Top Doctors consecutively since 2001

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

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

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

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

Professional Societies

- 1971 American Psychiatric Association; fellow
- 2005 American Psychiatric Association Distinguished Life Fellow
- 1973 Cleveland Psychiatric Society
- 1973 Cleveland Medical Library Association
 - 1985 Life Fellow
 - 2003 Distinguished Life Fellow
- 1974 Society for Sex Therapy and Research
 - 1987-89 President
- 1983 International Academy of Sex Research
- 1983 Harry Benjamin International Gender Dysphoria Association
 - 1997-98 Chairman, Standards of Care Committee
- 1994-99 Society for Scientific Study of Sex

Community Boards

1999-2002 - Case Western Reserve University Medical Alumni Association

1996-2001 - Bellefaire Jewish Children's Bureau

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

Editorial Boards

1978-80 Book Review Editor Journal Sex and Marital Therapy

Manuscript Reviewer for:

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

Prospectus Reviewer for:

- Guilford
- Oxford University Press

- Brunner/Routledge
- Routledge

Administrative Responsibilities

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

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

Co-leader of case conferences at DELRLLC.com

Recent Expert Witness Appearances

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

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

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

Witness for State of Florida vs. Reyne Keohane July 2017

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

Consultancy

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

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

Virginia Department of Corrections - evaluation of an inmate

New Jersey Department of Corrections - evaluation of an inmate

Idaho Department of Corrections - workshop 2016

Grant Support/Research Studies

TAP - studies of Apomorphine sublingual in treatment of erectile dysfunction

Pfizer - Sertraline for premature ejaculation

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

NIH - Systemic lupus erythematosis and sexuality in women

Sihler Mental Health Foundation

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

Alza - controlled study of a novel SSRI for rapid ejaculation

Pfizer - Viagra and self-esteem

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

Johnson & Johnson - controlled studies of Dapoxetine for rapid ejaculation

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

Lilly-Icos - study of Cialis for erectile dysfunction

VIVUS - study for premenopausal women with FSAD

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

Medtap - interview validation questionnaire studies

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

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

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

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

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

National registry trial for women with HSDD

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

Palatin - study of SQ Bremelanotide for HSDD and FSAD

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

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

HRA - qualitative and cognitive interview study for men experiencing PE

Publications

A) Books

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

B) Research and Invited Papers

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

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

- 5) Some thoughts on the pathogenesis of premature ejaculation. J. Sex & Marital Therapy 1975; 1:326-334
- 6) Marital Sexual Dysfunction: Introductory Concepts. Annals of Internal Medicine 1976;84:448-453
- 7) Marital Sexual Dysfunction: Ejaculation Disturbances 1976; 84:575-579
- 8) Yost MA: Frequency of female sexual dysfunction in a gynecology clinic: An epidemiological approach. Archives of Sexual Behavior 1976;5:229-238
- 9) Engel IM, Resnick PJ, Levine SB: Use of programmed patients and videotape in teaching medical students to take a sexual history. Journal of Medical Education 1976;51:425-427
- 10) Marital Sexual Dysfunction: Erectile dysfunction. Annals of Internal Medicine 1976;85:342-350
- 11) Articles in Medical Aspects of Human Sexuality
 - (a) Treating the single impotent male. 1976; 10:123, 137
 - (b) Do men enjoy being caressed during foreplay as much as women do? 1977; 11:9
 - (c) Do men like women to be sexually assertive? 1977;11:44
 - (d) Absence of sexual desire in women: Do some women never experience sexual desire? Is this possibility genetically determined? 1977; 11:31
 - (e) Barriers to the attainment of ejaculatory control. 1979; 13:32-56.
 - (f) Commentary on sexual revenge.1979;13:19-21
 - (g) Prosthesis for psychogenic impotence? 1979;13:7
 - (h) Habits that infuriate mates. 1980;14:8-19
 - (i) Greenberger-Englander, Levine SB. Is an enema an erotic equivalent?1981; 15:116
 - (j) Ford AB, Levine SB. Sexual Behavior and the Chronically Ill Patients. 1982; 16:138-150
 - (k) Preoccupation with wife's sexual behavior in previous marriage 1982; 16:172
 - (l) Co-existing organic and psychological impotence. 1985;19:187-8
 - (m) Althof SE, Turner LA, Kursh ED, Bodner D, Resnick MI, Risen CB. Benefits and Problems with Intracavernosal injections for the treatment of impotence. 1989;23(4):38-40
- 12) Male Sexual Problems. Resident and Staff Physician 1981:2:90-5
- 13) Female Sexual Problems. Resident and Staff Physician 1981:3:79-92
- 14) How can I determine whether a recent depression in a 40 year old married man is due to organic loss of erectile function or whether the depression is the source of the

- dysfunction? Sexual Medicine Today 1977;1:13
- 15) Corradi RB, Resnick PJ Levine SB, Gold F. For chronic psychologic impotence: sex therapy or psychotherapy? I & II Roche Reports; 1977
- 16) Marital Sexual Dysfunction: Female dysfunctions 1977; 86:588-597
- 17) Current problems in the diagnosis and treatment of psychogenic impotence. Journal of Sex & Marital Therapy 1977; 3:177-186
- 18) Resnick PJ, Engel IM. Sexuality curriculum for gynecology residents. Journal of Medical Education 1978; 53:510-15
- 19) Agle DP. Effectiveness of sex therapy for chronic secondary psychological impotence Journal of Sex & Marital Therapy 1978; 4:235-258
- 20) DePalma RG, Levine SB, Feldman S. Preservation of erectile function after aortoiliac reconstruction. Archives of Surgery 1978; 113-958-962
- 21) Conceptual suggestions for outcome research in sex therapy Journal of Sex & Marital Therapy 1981; 6:102-108
- 22) Lothstein LM. Transsexualism or the gender dysphoria syndrome. Journal of Sex & Marital Therapy 1982; 7:85-113
- 23) Lothstein LM, Levine SB. Expressive psychotherapy with gender dysphoria patients Archives General Psychiatry 1981; 38:924-929
- 24) Stern RG Sexual function in cystic fibrosis. Chest 1982; 81:422-8
- 25) Shumaker R. Increasingly Ruth: Towards understanding sex reassignment surgery Archives of Sexual Behavior 1983; 12:247-61
- 26) Psychiatric diagnosis of patients requesting sex reassignment surgery. Journal of Sex & Marital Therapy 1980; 6:164-173
- 27) Problem solving in sexual medicine I. British Journal of Sexual Medicine 1982; 9:21-28
- 28) A modern perspective on nymphomania. Journal of Sex & Marital Therapy 1982; 8:316-324
- 29) Nymphomania. Female Patient 1982;7:47-54
- 30) Commentary on Beverly Mead's article: When your patient fears impotence. Patient Care 1982; 16:135-9
- 31) Relation of sexual problems to sexual enlightenment. Physician and Patient 1983 2:62
- 32) Clinical overview of impotence. Physician and Patient 1983; 8:52-55.
- 33) An analytical approach to problem-solving in sexual medicine: a clinical introduction to the psychological sexual dysfunctions. II. British Journal of Sexual Medicine

- 34) Coffman CB, Levine SB, Althof SE, Stern RG Sexual Adaptation among single young adults with cystic fibrosis. Chest 1984; 86:412-418
- 35) Althof SE, Coffman CB, Levine SB. The effects of coronary bypass in female sexual, psychological, and vocational adaptation. Journal of Sex & Marital Therapy 1984: 10:176-184
- 36) Letter to the editor: Follow-up on Increasingly Ruth. Archives of Sexual Behavior 1984: 13:287-9
- 37) Essay on the nature of sexual desire Journal of Sex & Marital Therapy 1984; 10:83-96
- 38) Introduction to the sexual consequences of hemophilia. Scandanavian Journal of Haemology 1984; 33:(supplement 40).75-
- 39) Agle DP, Heine P. Hemophila and Acquired Immune Deficiency Syndrome: Intimacy and Sexual Behavior. National Hemophilia Foundation; July, 1985
- 40) Turner LA, Althof SE, Levine SB, Bodner DR, Kursh ED, Resnick MI. External vacuum devices in the treatment of erectile dysfunction: a one-year study of sexual and psychosocial impact. Journal of Sex & Marital Therapy
- 41) Schein M, Zyzanski SJ, Levine SB, Medalie JH, Dickman RL, Alemagno SA. The frequency of sexual problems among family practice patients. Family Practice Research Journal 1988; 7:122-134
- 42) More on the nature of sexual desire. Journal of Sex & Marital Therapy 1987; 13:35-44
- 43) Waltz G, Risen CB, Levine SB. Antiandrogen treatment of male sex offenders. Health Matrix 1987; V.51-55.
- 44) Lets talk about sex. National Hemophilia Foundation January, 1988
- 45) Sexuality, Intimacy, and Hemophilia: questions and answers . National Hemophilia Foundation January, 1988
- 46) Prevalence of sexual problems. Journal Clinical Practice in Sexuality 1988;4:14-16.
- 47) Kursh E, Bodner D, Resnick MI, Althof SE, Turner L, Risen CB, Levine SB. Injection Therapy for Impotence. Urologic Clinics of North America 1988; 15(4):625-630
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- 49) Sexual passion in mid-life. Journal of Clinical Practice in Sexuality 1991 6(8):13-19
- 50) Althof SE, Turner LA, Levine SB, Risen CB, Bodner DR, Resnick MI. Intracavernosal injections in the treatment of impotence: A prospective study of sexual, psychological, and marital functioning. Journal of Sex & Marital Therapy 1987; 13:155-167

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- 52) Turner LA, Froman SL, Althof SE, Levine SB, Tobias TR, Kursh ED, Bodner DR. Intracavernous injection in the management of diabetic impotence. Journal of Sexual Education and Therapy 16(2):126-36, 1989
- 53) Is it time for sexual mental health centers? Journal of Sex & Marital Therapy 1989;
- 54) Althof SE, Turner LA, Levine SB, Risen CB, Bodner D, Kursh ED, Resnick MI. Sexual, psychological, and marital impact of self injection of papaverine and phentolamine: a long-term prospective study. Journal of Sex & Marital Therapy
- 55) Althof SE, Turner LA, Levine SB, Risen CB, Bodner D, Kursh ED, Resnick MI. Why do so many men drop out of intracavernosal treatment? Journal of Sex & Marital Therapy. 1989; 15:121-9
- 56) Turner LA, Althof SE, Levine SB, Risen CB, Bodner D, Kursh ED, Resnick MI. Self injection of papaverine and phentolamine in the treatment of psychogenic impotence. Journal of Sex & Marital Therapy. 1989; 15(3):163-78
- 57) Turner LA, Althof SE, Levine SB, Risen CB, Bodner D, Kursh ED, Resnick MI. Treating erectile dysfunction with external vacuum devices: impact upon sexual, psychological, and marital functioning. Journal of Urology 1990; 141(1):79-82
- 58) Risen CB, Althof SE. An essay on the diagnosis and nature of paraphilia Journal of Sex & Marital Therapy 1990; 16(2):89-102.
- 59) Althof SE, Turner LA, Levine SB, Risen CB, Bodner DB, Kursh ED, Resnick MI. Through the eyes of women: the sexual and psychological responses of women to their partners' treatment with self-injection or vacuum constriction therapy. International Journal of Impotence Research (supplement 2)1990; 346-7.
- 60) Althof SE, Turner LA, Levine SB, Risen CB, Bodner DB, Kursh ED, Resnick MI. A comparison of the effectiveness of two treatments for erectile dysfunction: self injection vs. external vacuum devices. International Journal of Impotence Research (supplement 2)1990; 289-90
- 61) Kursh E, Turner L, Bodner D, Althof S, Levine S. A prospective study on the use of the vacuum pump for the treatment of impotence. International Journal of Impotence Research (supplement 2)1990; 340-1.
- 62) Althof SE, Turner LA, Levine SB, Risen CB, Bodner DB, Kursh ED, Resnick MI. Long term use of intracavernous therapy in the treatment of erectile dysfunction in Journal of Sex & Marital Therapy 1991; 17(2):101-112
- 63) Althof SE, Turner LA, Levine SB, Risen CB, Bodner DB, Kursh ED, Resnick MI. Long term use of vacuum pump devices in the treatment of erectile dsyfunction in Journal of Sex & Marital Therapy 1991;17(2):81-93
- 64) Turner LA, Althof SE, Levine SB, Bodner DB, Kursh ED, Resnick MI. A 12-month

- comparison of the effectiveness of two treatments for erectile dysfunction: self injection vs. external vacuum devices. Urology 1992;39(2):139-44
- 65) Althof SE, The pathogenesis of psychogenic impotence. J. Sex Education and Therapy. 1991; 17(4):251-66
- 66) Mehta P, Bedell WH, Cumming W, Bussing R, Warner R, Levine SB. Letter to the editor. Reflections on hemophilia camp. Clinical Pediatrics 1991; 30(4):259-260
- 67) Successful Sexuality. Belonging/Hemophilia. (Caremark Therapeutic Services), Autumn, 1991
- 68) Psychological intimacy. Journal of Sex & Marital Therapy 1991; 17(4):259-68
- 69) Male sexual problems and the general physician, Georgia State Medical Journal 1992; 81(5): 211-6
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ISSN: (Print) (Online) Journal homepage: https://www.tandfonline.com/loi/usmt20

Reconsidering Informed Consent for Trans-Identified Children, Adolescents, and Young Adults

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To cite this article: Stephen B. Levine, E. Abbruzzese & Julia W. Mason (2022) Reconsidering Informed Consent for Trans-Identified Children, Adolescents, and Young Adults, Journal of Sex & Marital Therapy, 48:7, 706-727, DOI: 10.1080/0092623X.2022.2046221

To link to this article: https://doi.org/10.1080/0092623X.2022.2046221

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Reconsidering Informed Consent for Trans-Identified Children, Adolescents, and Young Adults

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ABSTRACT

In less than a decade, the western world has witnessed an unprecedented rise in the numbers of children and adolescents seeking gender transition. Despite the precedent of years of gender-affirmative care, the social, medical and surgical interventions are still based on very low-quality evidence. The many risks of these interventions, including medicalizing a temporary adolescent identity, have come into a clearer focus through an awareness of detransitioners. The risks of gender-affirmative care are ethically managed through a properly conducted informed consent process. Its elements deliberate sharing of the hoped-for benefits, known risks and long-term outcomes, and alternative treatments—must be delivered in a manner that promotes comprehension. The process is limited by: erroneous professional assumptions; poor quality of the initial evaluations; and inaccurate and incomplete information shared with patients and their parents. We discuss data on suicide and present the limitations of the Dutch studies that have been the basis for interventions. Beliefs about gender-affirmative care need to be separated from the established facts. A proper informed consent process can both prepare parents and patients for the difficult choices that they must make and can ease professionals' ethical tensions. Even when properly accomplished, however, some clinical circumstances exist that remain quite uncertain.

KEYWORDS

Informed consent; ethics; gender dysphoria; gender identity; detransition

Introduction

Reconsideration of the meanings, purposes, indications, and processes of informed consent for transgender-identified youth is urgently needed. Parents of gender atypical children are considering social transition as early as preschool or grade school. Parents of preteens and teens are considering supporting their children's wishes to present in a new gender, take puberty blockers and cross-sex hormones, and plan for surgical alterations. College-aged youth are declaring new identities for the first time and obtaining hormones and surgery without their parents' knowledge.

When uncertain parents of children and teens consult their primary care providers, they are usually referred to specialty gender services. Parents and referring clinicians assume that specialists with "gender expertise" will undertake a thorough evaluation. However, the evaluations preceding the recommendation for gender transition are often surprisingly brief (Anderson & Edwards-Leeper, 2021) and typically lead to a recommendation for hormones and surgery, known as *gender-affirmative* treatment.

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Despite the widely recognized deficiencies in the evidence supporting gender-affirmative interventions (National Institute for Health & Care Excellence, 2020a; 2020b), the process of obtaining informed consent from patients and their families has no established standard. There is no consensus about the requisite elements of evaluations, nor is there unanimity about how informed consent processes should be conducted (Byne et al., 2012). These two matters are inconsistent from practitioner to practitioner, clinic to clinic, and country to country.

Social transition, hormonal interventions, and surgery have profound implications for the course of the lives of young patients and their families. It is incumbent upon professionals that these consequences be thoroughly, patiently clarified over time prior to undertaking any element of transition. The informed consent process does not preclude transition; it merely educates the family about the state of the science underpinning the decision to transition. Social transition, hormones, and surgeries are unproven in a strict scientific sense, and as such, to be ethical, require a thorough and fully informed consent process.

Ethical Concerns About Inadequate Informed Consent

The concept of informed consent in medicine has roots in both ethical theory and law. The ethical foundation is centered in the principles of beneficence, justice, and respect for autonomy, while the legal issues have to do with questions of malpractice (Katz et al., 2016).

Patients consenting to treatment must meet age-based and decisional capacity requirements (Katz et al., 2016). Minors less than the age of consent participate in decision-making by providing assent—an agreement with the intervention. The limited maturational cognitive capacities of minors are the key reason why parents serve as the ethical and legal surrogates for medical decision-making, tasked with signing an informed consent document (Grootens-Wiegers, Hein, van den Broek, & de Vries, 2017).

The informed consent process consists of three main elements: a disclosure of information about the nature of the condition and the proposed treatment and its alternatives; an assessment of patient and caregiver understanding of the information and capacity for medical decision-making; and obtaining the signatures that signify informed consent has been obtained (Katz et al., 2016). The current expectation that clinicians and institutions are required to thoroughly inform their patients about the benefits, risks, and uncertainties of a particular treatment, as well as about alternatives, has a long legal history in the United States (Lynch, Joffe, & Feldman, 2018).

Ethical concerns about inadequate informed consent for trans-identified youth have several potentially problematic sources, including erroneous assumptions held by professionals; poor quality of the evaluation process; and incomplete and inaccurate information that the patients and family members are given.

These concerns are amplified by the dramatic growth in demand for youth gender transition witnessed in the last several years that has led to a perfunctory informed consent process. A rushed process does not allow for a proper discussion of not only the benefits, but the profound risks and uncertainties associated with gender transition, especially when gender transition is undertaken before mature adulthood.

Dramatic growth in demand for services threatens true informed consent

Gender identity variations were thought to be extremely rare a generation ago. While the incidence in youth had not been officially estimated, in adults it was 2-14 per 100,000 (American Psychiatric Association, 2013, p. 454). However, around 2006, the incidence among youth began to rise, with a dramatic increase observed in 2015 (Aitken et al., 2015, de Graaf, Giovanardi, Zitz, & Carmichael, 2018). Currently, 2-9% of U.S. high school students identify as transgender, while in colleges, 3% of males and 5% of females identify as gender-diverse (American College Health Association, 2021; Johns et al., 2019; Kidd et al., 2021).

Whereas previously most of the affected individuals identified as the opposite sex, there is now a growing trend toward identifying as *nonbinary*: neither male nor female or both male and female (Chew et al., 2020). A recent study reported that the majority of transgender-identifying youth (63%) now have a non-binary identity (Green, DeChants, Price, & Davis, 2021). Although the incidence of natal males asserting a trans identity in adolescence has significantly increased, the dramatic increase is driven primarily by the natal females requesting services (Zucker, 2017). Many suffer from significant comorbid mental health disorders, have neurocognitive difficulties such as ADHD or autism or have a history of trauma (Becerra-Culqui et al., 2018; Kozlowska, McClure, et al., 2021).

The increase in rates of transgender identification is reflected in the numbers of youth seeking help from medical professionals. For example, according to data reported by the Tavistock gender clinic in the UK, in 2009, there were 51 requests for services (de Graaf et al., 2018); in 2019-2020, 2728 referrals were recorded—a 53-fold increase in just over a decade (Tavistock & Portman NHS Foundation Trust, 2020). The growing number of urban transgender health centers that have arisen in recent years (HRC, n.d.) reflects the increased demand for gender-related medical care among young people in North America Australia, and Europe.

This unprecedented increase has created pressure on institutions and practitioners to rapidly evaluate these youth and make recommendations about treatment. To respond to growing demand, an innovative *informed consent model of care* has been developed. Under this model, mental health evaluations are not required, and hormones can be provided after just one visit following the collection of a patient's or guardian's consent signature (Schulz, 2018). The provision of transition services under this model of care is available not just to those over 18, but for younger patients as well (Planned Parenthood League of Massachusetts, n.d.).

Although following the informed consent model of care for hormones and surgeries for youth may diminish clinicians' ethical or moral unease (Vrouenraets et al., 2020), we believe this model is the antithesis of true informed consent, as it jeopardizes the ethical foundation of patient autonomy. Autonomy is not respected when patients consenting to the treatment do not have an accurate understanding of the risks, benefits, and alternatives.

b. Assumptions held by professionals influence the integrity of the informed consent process

Gender-dysphoric children and teens can intensely occupy the belief that their lives will be immensely improved by transition. Clinicians who have embraced the gender-affirmative model of care operate on the assumption that children and teens know best what they need to be happy and productive (Ehrensaft, 2017). These professionals, responding to the youths' passionate pleas, see their role as validating the young person's fervent wishes for hormones and surgery and clearing the path for gender transition. In doing so, they privilege the ethical principle of respect for patient autonomy (Clark & Virani, 2021) over their obligations for beneficence and non-maleficence.

Many of the gender-affirmative clinicians subscribe to the theory of *minority stress* – the supposition that the frequently co-occurring psychiatric symptoms of gender-dysphoric individuals are a result of prejudice and discrimination brought about by gender non-conformity (Rood et al., 2016; Zucker, 2019), and that gender transition will ameliorate these symptoms. Some even claim that gender-affirmative care will successfully treat not only depression and anxiety but will also resolve neurocognitive deficits frequently present in gender-dysphoric individuals (Turban, 2018; Turban, King, Carswell, & Keuroghlian, 2020; Turban & van Schalkwyk, 2018). These latter assertions have proven controversial even among the proponents of gender-affirmative interventions (Strang et al., 2018; van der Miesen, Cohen-Kettenis, & de Vries, 2018). The minority stress theory as the sole explanatory mechanism for co-occurring mental health illness has also been questioned in light of the evidence that psychiatric symptoms frequently predate the onset of gender dysphoria (Bechard, VanderLaan, Wood, Wasserman, & Zucker, 2017; Kaltiala-Heino, Sumia, Työläjärvi, & Lindberg, 2015; Kozlowska, Chudleigh, McClure, Maguire,



& Ambler, 2021). Other clinicians recognize the limits of gender-affirmative care and are aware that youth with underlying psychiatric issues are likely to continue to struggle post-transition (Kaltiala, Heino, Työläjärvi, & Suomalainen, 2020), but, unaware of alternative approaches such as gender-exploratory psychotherapy or watchful waiting (Bonfatto & Crasnow, 2018; Churcher Clarke & Spiliadis, 2019; Spiliadis, 2019), these well-meaning professionals continue to treat youth with gender-affirmative interventions despite lingering doubts.

It is common for gender-affirmative specialists to erroneously believe that gender-affirmative interventions are a standard of care (Malone, D'Angelo, Beck, Mason, & Evans, 2021; Malone, Hruz, Mason, Beck, et al:, 2021). Despite the increasingly widespread professional beliefs in the safety and efficacy of pediatric gender transition, and the endorsement of this treatment pathway by a number of professional medical societies, the best available evidence suggests that the benefits of gender-affirmative interventions are of very low certainty (Clayton et al., 2021; National Institute for Health & Care Excellence, 2020a; 2020b) and must be carefully weighed against the health risks to fertility, bone, and cardiovascular health (Alzahrani et al., 2019; Biggs, 2021; Getahun et al., 2018; Hembree et al., 2017; Nota et al., 2019). Recently, emphasis has also been placed on psychosocial risks and as yet unknown medical risks (Malone, D'Angelo, et al., 2021).

Five scientific observations question and refute the assumption that an individual's experience of incongruence of sex and gender identity is best addressed by supporting the newly assumed gender identity with psychosocial and medical interventions.

- 1. The most foundational aspect of the diagnoses of "gender dysphoria" (DSM-5) and "gender incongruence" (ICD-11), requisite for the provision of medical treatment, is in flux, as professionals disagree on whether the presence of distress is a key diagnostic criterion, as stated in the DSM-5, or is irrelevant, as is the case according to the latest ICD-11 criteria (American Psychiatric Association, 2013; World Health Organization, 2019). Further, these diagnoses have never been properly field-tested (de Vries et al., 2021).
- 2. There are no randomized controlled studies demonstrating the superiority of various affirmative interventions compared to alternatives. There isn't even agreement about which outcome measures would be ideal in such studies.
- There are few long-term follow-up studies of various interventions using predetermined outcome measures at designated intervals. Studies that have been conducted are, at best, inconsistent. Higher quality studies with longer-follow-up fail to demonstrate durable positive impacts on mental health (Bränström & Pachankis, 2020a; 2020b).
- Rates of post-transition desistance, increased mental suffering, increased incidence of physical illness, educational failure, vocational inconstancy, and social isolation have not been established.
- 5. Numerous cross-sectional and prospective studies of transgender adults consistently demonstrate a high prevalence of serious mental health and social problems as well as suicide (Asscheman et al., 2011; Dhejne et al., 2011). Controversies about how to deal with trans-identified youth must consider the well described vulnerabilities of transgender adults.

It is equally important to realize that to date, research about alternative approaches, such as psychotherapy or watchful waiting, shares the scientific limitations of the research of more invasive interventions: there are no control groups, nor is there systematic follow-up at predetermined intervals with predetermined means of measurement (Bonfatto & Crasnow, 2018; Churcher Clarke & Spiliadis, 2019; Spiliadis, 2019). Parents and patients need to be informed of this as well.

Perhaps the single most problematic assumption held by some gender clinicians is that the young patients have simply been "born in the wrong body." This assumption seemingly frees clinicians from having to contend with the ethical dilemmas of recommending body-altering



interventions that are based on very low-quality evidence. Despite the principle of development that biology, psychosocial factors, and culture generate behavior, these clinicians may believe that atypical genders are created by biology. This reductionistic approach has been criticized repeatedly (Kendler, 2019).

While the origins of childhood or adolescent onset of gender incongruence have not yet been fully elucidated, brain studies of increasing technical sophistication have yet to demonstrate a distinct structure or pattern that accounts for an atypical gender identity, after statistically controlling for sexual orientation and exposure to exogenous hormones (Frigerio, Ballerini, & Valdés Hernández, 2021). Twin studies also demonstrate that while biology plays a role in one's experience of "gender incongruence," it is far from deterministic (Diamond, 2013).

A growing number of clinicians and researchers are noting that the dramatic rise of teens declaring a trans identity appears to be, at least in part, a result of peer influence (Anderson, 2022; Hutchinson, Midgen, & Spiliadis, 2020; Littman 2018; Littman, 2020; Zucker, 2019). Some have noted yet another influx of trans-identified youth emerging during the COVID lockdowns, and have hypothesized that increased isolation coupled with heavy internet exposure may be responsible (Anderson, 2022). While the research into the phenomenon of social influence as a contributor to trans identification of youth is still in its infancy, the possibility that clinicians are providing treatments with permanent consequences to address what may be transient identities in youth poses a serious ethical dilemma.

Poor evaluations

There is a growing recognition that rapid evaluations which disregard factors contributing to the development of gender dysphoria in youth are problematic. In November 2021, two-leaders of the World Professional Organization for Transgender Health (WPATH) warned the medical community that the "The mental health establishment is failing trans kids" (Anderson & Edwards-Leeper, 2021). Frequently, evaluations provided by gender clinicians may only ascertain the diagnosis of gender dysphoria (DSM-5) or its ICD-11 counterpart gender incongruence, and screen for conspicuous mental illness prior to recommending hormones and surgeries. These limited, abbreviated evaluations overlook, and as a result fail to address, the relevant issue of the forces that may have influenced the young person's current gender identity.

Confirming the young person's self-diagnosis of gender dysphoria or gender incongruence is easy. Clarifying the developmental forces that have influenced it and determining an appropriate intervention are not. Contextualizing these forces involves an understanding of child and adolescent developmental processes, childhood adversity, co-existing physical and cognitive disadvantages, unfortunate parental or family circumstances (Levine, 2021), as well as the role of social influence (Anderson, 2022; Anderson & Edwards-Leeper, 2021; Littman, 2018; 2021).

The poor quality of mental health evaluations has been a point of significant discontent for a growing number of parents of gender-dysphoric youth. Increasingly, parents have formed dozens of support groups in North America, Europe, Australia and New Zealand, united in their objections to the idea that the best or the only treatment for their gender-dysphoric children is affirmation (Genspect, 2021). These distressed parents, recognizing that their son or daughter may eventually decide to present to others as a trans person, want a psychotherapeutic investigation to understand what contributed to the development of this identity and an exploration of noninvasive treatment options. Frequently, they cannot find anyone in their community who does not recommend immediate affirmation.

The American Academy of Pediatrics' Committee of Bioethics recognizes that "parents...are better situated than others to understand the unique needs of their children and to make appropriate, caring decisions regarding their children's health care" (Katz et al., 2016). The plight of the families unable to find specialists capable of conducting thorough evaluations draws attention to the widespread acceptance of medical interventions for gender-dysphoric youth as the first line of treatment. The problem is that such care has been established through precedent rather



than through scientific demonstrations of its efficacy. We contend that parents and patients have a right to know this, and that it is the professionals' responsibility and obligation to inform them of the state of knowledge in this arena of care.

Incorrect information shared

In sharing the information with patients and families, two key areas of uncertainty must be emphasized. The first one is the uncertain permanence of a child's or an adolescent's gender identity (Littman, 2021; Ristori & Steensma, 2016; Singh, Bradley, & Zucker, 2021; Vandenbussche, 2021; Zucker, 2017). The second is the uncertain long-term physical and psychological health outcomes of gender transition (National Institute for Health & Care Excellence, 2020a; 2020b). Unfortunately, gender specialists are frequently unfamiliar with, or discount the significance of, the research in support of these two concepts. As a result, the informed consent process rarely adequately discloses this information to patients and their families.

Problematically, it is common for gender clinicians to emphasize the risk of suicide if a young person's wish to transition gender is not immediately fulfilled. There is a significant amount of misinformation surrounding the question of suicidality of trans-identified youth (Biggs, 2022). Providers of gender-affirmative care should be careful not to unwittingly propagate misinformation regarding suicide to parents and youths. They should also be reminded that any conversations about suicide should be handled with great care, due to its socially contagious nature (Bridge et al., 2020; HHS, 2021).

High rate of desistance/natural resolution of gender dysphoria in children is not disclosed

There have been eleven research studies to date indicating a high rate of resolution of gender incongruence in children by late adolescence or young adulthood without medical interventions (Cantor, 2020; Ristori & Steensma, 2016; Singh et al., 2021). An attempt has been made to discount the applicability of this research, suggesting that the studies were based on merely gender non-conforming, rather than truly gender-dysphoric, children (Temple Newhook et al., 2018). However, a reanalysis of the data prompted by this critique confirmed the initial finding: Among children meeting the diagnostic criteria for "Gender Identity Disorder" in DSM-IV (currently "Gender Dysphoria in DSM-5), 67% were no longer gender-dysphoric as adults; the rate of natural resolution for gender dysphoria was 93% for children whose gender dysphoria was significant but subthreshold for the DSM diagnosis (Zucker, et al., 2018). It should be noted that high resolution of childhood-onset gender dysphoria had been recorded before the practice of social transition of young children was endorsed by the American Academy of Pediatrics (Rafferty et al., 2018). It is possible that social transition will predispose a young person to persistence of transgender identity long-term (Zucker, 2020).

The information regarding the resolution of gender dysphoria among those with adolescent-onset gender dysphoria, which is currently the predominant presentation, is less clear. A growing body of evidence suggests that for many teens and young adults, a post-pubertal onset of transgender identification can be a transient phase of identity exploration, rather than a permanent identity, as evidenced by a growing number of young detransitioners (Entwistle, 2020; Littman, 2021; Vandenbussche, 2021). Previously, the rate of detransition and regret was reported to be very low, although these estimates suffered from significant limitations and were likely undercounting true regret (D'Angelo, 2018). However, in the last several years since gender-affirmative care has become popularized, the rate of detransition appears to be accelerating.

According to a recent study from a UK adult gender clinic, 6.9% of those treated with gender-affirmative interventions detransitioned within only 16 months of starting treatment, and another 3.4% had a pattern of care suggestive of detransition, yielding a rate of probable detransition in excess of 10%. Another 21.7% of patients disengaged from the clinic without completing their treatment plan (Hall, Mitchell, & Sachdeva, 2021). While some of these individuals later reengaged with the gender service, the authors concluded, "detransitioning might be more frequent than previously reported." Another study from a UK primary care practice found that 12.2% of those who had started hormonal treatments either detransitioned or documented regret, while the total of 20% stopped the treatments for a wider range of reasons. The mean age of their presentation with gender dysphoria was 20, and the patients had been taking gender-affirming hormones for the average 5 years (17 months-10 years) prior to discontinuing.

Comparing these much higher rates of treatment discontinuation and detransition to the significantly lower rates reported by the older studies, the researchers noted: "Thus, the detransition rate found in this population is novel and questions may be raised about the phenomenon of overdiagnosis, overtreatment, or iatrogenic harm as found in other medical fields" (Boyd, Hackett, & Bewley, 2022 p.15). Indeed, given that regret may take up to 8-11 years to materialize (Dhejne, Öberg, Arver, & Landén, 2014; Wiepjes et al., 2018), many more detransitioners are likely to emerge in the coming years. Detransitioner research is still in its infancy, but two recently published studies examining detransitioner experiences report that detransitioners from the recently-transitioning cohorts feel they had been rushed to medical gender-affirmative interventions with irreversible effects, often without the benefit of appropriate, or in some instances any, psychologic exploration (Littman, 2021; Vandenbussche, 2021).

Clinicians should also disclose to patients and parents that there is no test which can accurately predict who will persist in their transgender identification upon reaching mature adulthood (Ristori & Steensma, 2016). Families should be made aware that a period of strong cross-sex identification in childhood is commonly associated with future homosexuality (Korte et al., 2008). Research in desistance confirms that the majority of youth whose gender dysphoria resolves naturally do indeed grow up to be gay, lesbian, or bisexual adults (Cantor, 2020, Appendix; Singh et al., 2021).

ii. Implications of very low-quality evidence that underlies the practice of pediatric gender transition are not explained

The evidence underlying the practice of pediatric gender transition is widely recognized to be of very low quality (Hembree et al., 2017). In 2020, the most comprehensive systematic review of evidence to date, commissioned by the UK National Health System (NHS) and conducted by the National Institute for Health and Care Excellence (NICE), concluded that the evidence for both puberty blocking and cross-sex hormones is of very low certainty (National Institute for Health & Care Excellence, 2020a; 2020b).

According to the NICE review of evidence for puberty blockers, the studies "are all small, uncontrolled observational studies, which are subject to bias and confounding, and are of very low certainty as assessed using modified GRADE [Grading of Recommendations, Assessment, Development and Evaluations]. All the included studies reported physical and mental health comorbidities and concomitant treatments very poorly" (National Institute for Health & Care Excellence, 2020a, p.13). NICE reached similar conclusions regarding the quality of the evidence for cross-sex hormones (National Institute for Health & Care Excellence, 2020b).

Problematically, the implications of administering a treatment with irreversible, life-changing consequences based on evidence that has an official designation of "very low certainty" according to modified GRADE is rarely discussed with the patients and the families. GRADE is the most widely adopted tool for grading the quality of evidence and for making treatment recommendations worldwide. GRADE has four levels of evidence, also known as certainty in evidence or quality of evidence: very low, low, moderate, and high (BMJ Best Practice, 2021). When evidence is assessed to be "very low certainty," there is a high likelihood that the patients will not experience the effects of the proposed interventions (Balshem et al., 2011).

In the context of providing puberty blockers and cross-sex hormones, the designation of "very low certainty" signals that the body of evidence asserting the benefits of these interventions is



highly unreliable. In contrast, several negative effects are quite certain. For example, puberty blockade followed by cross-sex hormones leads to infertility and sterility (Laidlaw, Van Meter, Hruz, Van Mol, & Malone, 2019). Surgeries to remove breasts or sex organs are irreversible. Other health risks, including risks to bone and cardiovascular health, are not fully understood and are uncertain, but the emerging evidence is alarming (Alzahrani et al., 2019; Biggs, 2021).

iii. The question of suicide is inappropriately handled

Suicide among trans-identified youth is significantly elevated compared to the general population of youth (Biggs, 2022; de Graaf et al., 2020). However, the "transition or die" narrative, whereby parents are told that their only choice is between a "live trans daughter or a dead son" (or vice-versa), is both factually inaccurate and ethically fraught. Disseminating such alarmist messages hurts the majority of trans-identified youth who are not at risk for suicide. It also hurts the minority who are at risk, and who, as a result of such misinformation, may forgo evidence-based suicide prevention interventions in the false hopes that transition will prevent suicide.

The notion that trans-identified youth are at alarmingly high risk of suicide usually stems from biased online samples that rely on self-report (D'Angelo et al., 2020; James et al., 2016; The Trevor Project, 2021), and frequently conflates suicidal thoughts and non-suicidal self-harm with serious suicide attempts and completed suicides. Until recently, little was known about the actual rate of suicide of trans-identified youth. However, a recent analysis of data from the biggest pediatric gender clinic in the world, the UK's Tavistock, found the rate of completed youth suicides to be 0.03% over a 10-year period, which translates into the annual rate of 13 per 100,000 (Biggs, 2022). While this rate is significantly elevated compared to the general population of teens, it is far from the epidemic of trans suicides portrayed by the media.

The "transition or die" narrative regards suicidal risk in trans-identified youth as a different phenomenon than suicidal risk among other youth. Making them an exception falsely promises the parents that immediate transition will remove the risk of suicidal self-harm. Trans patients themselves complain about the so-called "trans broken arm syndrome" - a frustrating pattern whereby physicians "blame" all the problems the patients are experiencing on their trans status, and a result, fail to perceive and respond to other sources of distress (Paine, 2021). Clinicians caring for trans-identified youth should be reminded that suicide risk in all patients is a multi-factorial phenomenon (Mars et al., 2019). To treat trans youths' suicidality as an exception is to deny them evidence-based care.

A recent study of three major youth clinics concluded that suicidality of trans-identifying teens is only somewhat elevated compared to that of youth referred for mental health issues unrelated to gender identity struggles (de Graaf et al., 2020). Another study found that transgender-identifying teens have relatively similar rates of suicidality compared to teens who are gay, lesbian and bisexual (Toomey, Syvertsen, & Shramko, 2018). Depression, eating disorders, autism spectrum conditions, and other mental health conditions commonly found in transgender-identifying youth (Kaltiala-Heino, Bergman, Työläjärvi, & Frisen, 2018; Kozlowska, McClure, et al., 2021; Morandini, Kelly, de Graaf, Carmichael, & Dar-Nimrod, 2021) are all known to independently contribute to the probability of suicide (Biggs, 2022; Simon & VonKorff, 1998; Smith, Zuromski, & Dodd, 2018).

The "transition or suicide" narrative falsely implies that transition will prevent suicides. Clinicians working with trans-identified youth should be aware that although in the short-term, gender-affirmative interventions can lead to improvements in some measures of suicidality (Kaltiala et al., 2020), neither hormones nor surgeries have been shown to reduce suicidality in the long-term (Bränström & Pachankis, 2020a; 2020b). Alarmingly, a longitudinal study from Sweden that covered more than a 30-year span found that adults who underwent surgical transition were 19 times more likely than their age-matched peers to die by suicide overall, with female-to-male participants' risk 40 times the expected rate (Dhejne et al., 2011, Table S1).

Another key longitudinal study from the Netherlands concluded that suicides occur at a similar rate at all stages of transition, from pretreatment assessment to post-transition follow-up (Wiepjes et al., 2020). The data from the Tavistock clinic also did not show a statistically significant difference between completed suicides in the "waitlist" vs. the "treated" groups (Biggs, 2022). Luckily, in both groups, completed suicides were rare events (which may have been responsible for the lack of statistical significance). Thus, we consider the "transition or die" narrative to be misinformed and ethically wrong.

In our experience working with trans-identified youth, an adolescent's suicidality can sometimes arise as a response to parental distress, resistance, skepticism, or wish to investigate the forces shaping the new gender identity before social transition and hormone therapy. When mental health professionals or other healthcare providers fail to recognize the legitimacy of parental concerns, or label the parents as transphobic, this only tends to intensify intrafamilial tension. Clinicians would be well-advised that gender transition is not an appropriate response to suicidal intent or threat, as it ignores the larger mental health and social context of the young patient's life-the entire family is often in crisis. Trans-identified adolescents should be screened for self-harm and suicidality, and if suicidal behaviors are present, an appropriate evidence-based suicide prevention plan should be put in place (de Graaf et al., 2020).

The Dutch Study: the questionable basis for the gender affirmative model of care for youth

Few practitioners of gender-affirmative interventions, and even fewer patients and families, realize that the foundation of the practice of medically transitioning minors stems from a single Dutch proof of concept study, the outcomes of which were documented in two publications (de Vries, Steensma, Doreleijers, Cohen, & Kettenis, 2011; de Vries et al., 2014). The former (de Vries et al., 2011) reported on cases who underwent puberty blockade, while the latter (de Vries et al., 2014) reported on a subset of the cases who completed surgeries.

The Dutch study subjects' high level of psychological functioning at 1.5 years after surgery, which was the study end point, was an impressive feat. However, both of the studies suffer from a high risk of bias due to their study design, which is effectively a non-randomized case series one of the lowest levels of evidence (Mathes & Pieper, 2017; National Institute for Health & Care Excellence, 2020a). In addition, the studies suffer from limited applicability to the populations of adolescents presenting today (de Vries, 2020). The interventions described in the study are currently being applied to adolescents who were not cross-gender identified prior to puberty, who have significant mental health problems, as well as those who have non-binary identities—all of these presentations were explicitly disqualified from the Dutch protocol. Despite these limitations, the Dutch clinical experiment has become the basis for the practice of medical transition of minors worldwide and serves as the basis for the recommendations outlined in the 2017 Endocrine Society guidelines (Hembree et al., 2017).

We contend that the Dutch studies have been misunderstood and misrepresented as providing evidence of the safety and efficacy of these interventions for all youth. It is important that both the strengths and the weaknesses of these two studies are understood, as to date, the Dutch experience presents the best available evidence behind the practice of pediatric gender transition.

Rationale for pediatric transition

Prior to the 1990s, gender transitions were typically initiated in mature adults (Dhejne et al., 2011). However, it was noted that particularly for natal male patients, hormonal and surgical interventions failed to achieve satisfactory results, and patients had a "never disappearing masculine appearance" (Delemarre-van de Waal & Cohen-Kettenis, 2006). The lack of adequate cosmetic outcomes was thought to contribute to the frequently disappointing outcomes of medical



gender transition, with persistently high rates of mental illness and suicidality post-transition (Delemarre-van de Waal & Cohen-Kettenis, 2006; Dhejne et al., 2011; Ross & Need, 1989).

In the mid 1990s, a team of Dutch researchers hypothesized that by carefully selecting a subset of gender-dysphoric children who would likely be transgender-identified for the rest of their lives, and by medically intervening before puberty left an irreversible mark on their bodies, the cosmetic outcomes would be improved—and as a result, mental health outcomes might be improved (Gooren & Delemarre-van de Waal, 1996).

Mixed study findings

In 2014, the Dutch research team published a key longitudinal study of mental health outcomes of 55 youths who completed medical and surgical transition (de Vries et al., 2014). The 2014 paper (sometimes referred to as the "Dutch study") reported that for youth with severe gender dysphoria that started in early childhood and persisted into mid-adolescence, a sequence of puberty blockers, cross-sex hormones, and breast and genital surgeries (including a mandatory removal of the ovaries, uterus and testes), with ongoing extensive psychological support, was associated with positive mental health and overall function 1.5 years post-surgery.

While the Dutch reported resolution of gender dysphoria post-surgery in study subjects, the reported psychological improvements were quite modest (de Vries et al., 2014). Of the 30 psychological measurements reported, nearly half showed no statistically significant improvements, while the changes in the other half were marginally clinically significant at best (Malone, D'Angelo, et al., 2021). The scores in anxiety, depression, and anger did not improve. The change in the Children's Global Assessment Scale, which measures overall function, was one of the most impressive changes—however it too remained in the same range before and after treatment (de Vries et al., 2014).

Problematic discordance between reduced gender dysphoria and lack of meaningful improvements in psychological measures

The discordance between the marked reduction in gender dysphoria, as measured by the UGDS (Utrecht Gender Dysphoria Scale), and the lack of meaningful changes in psychological function using standard measures, warrants further examination. There are three plausible explanations for this lack of agreement. Any one of these three explanations calls into question the widely assumed notion that the medical interventions significantly improve mental health or lessen or eradicate gender dysphoria.

One possible explanation is that gender dysphoria as measured by UGDS, and psychological function as measured by most standard instruments, are not correlated. This contradicts the primary rationale for providing gender-affirmative treatments for youth (which is to improve psychological health and functioning), and if true, ethically threatens these medical interventions. The other plausible explanation stems from the high psychological function of all the subjects at baseline; the subjects were selected because they were free from significant mental health problems (de Vries et al., 2014). As a result, there was little opportunity to meaningfully improve. This explanation highlights a key limitation in applying the study's results to the majority of today's gender-dysphoric youth, who often present with a high burden of mental illness (Becerra-Culqui et al., 2018; Kozlowska, McClure, et al., 2021). The study cannot be used as evidence that these procedures have been proven to improve depression, anxiety, and suicidality.

A third possible explanation for the discordance between only minor changes in psychological outcomes but a significant drop in gender dysphoria comes from a close examination of the UGDS scale itself and how it was used by the Dutch researchers. This 12-item scale, designed by the Dutch to assess the severity of gender dysphoria and to identify candidates for hormones and surgeries, consists of "male" (UGDS-aM) and "female" (UGDS-aF) versions (Iliadis et al., 2020). At baseline and after puberty suppression, biological females were given the "female" scale, while males were given the "male" scale. However, post-surgery, the scales were flipped: biological females were assessed using the "male" scale, while biological males were assessed on the "female" scale (de Vries et al., 2014). We maintain that this handling of the scales may have at best obscured, and at worst, severely compromised the ability to meaningfully track how gender dysphoria was affected throughout the treatment.

Consider this example. At baseline, a gender-dysphoric biological female would rate items from the "female" scale such as: "I prefer to behave like a boy" (item 1); "I feel unhappy because I have to behave like a girl" (item 6) and "I wish I had been born a boy" (item 12). Positive answers to these questions would have contributed to a high baseline gender dysphoria score. After the final surgery, however, this same patient would be asked to rate items from the "male" scale, including the following: "My life would be meaningless if I had to live as a boy" (item 1); "I hate myself because I am a boy" (item 6) and "It would be better not to live than to live as a boy" (item 12). A gender-dysphoric female would not endorse these statements (at any stage of the intervention), which would lead to a lower gender dysphoria score.

Thus, the detected drop in the gender dysphoria scores for biological males and females may have had less to do with the success of the interventions, and more to do with switching the scale from the "female" to the "male" version (and vice-versa) between the baseline and post-surgical period. This, too, may explain why no changes in gender dysphoria were noted between baseline and the puberty blockade phase, and were only recorded after the final surgery, when the scale was switched.

It must be considered that had the researchers administered the "flipped" scale earlier, at the completion of the puberty blocker stage, UGDS scale could have registered a reduction in gender dysphoria. Likewise, however, one must consider the possibility that had both sets of scales been administered to the same individual at baseline, a "reduction" in gender dysphoria could have been registered upon switching of the scale, well before any interventions began. The question here is whether the diminishment of quantitative measures of gender dysphoria is largely an artifact of what scale was used.

It must be noted that the UGDS measure has been demonstrated only to effectively differentiate between clinically referred gender-dysphoric individuals, non-clinically referred controls, and participants with disorders of sexual development, and was not designed to detect changes in gender dysphoria during treatment (Steensma, McGuire, Kreukels, et al. 2013). The presence of items such as "I dislike having erections" (item 11, UGDS-aM), which would have to be rated by birth-females, and "I hate menstruating because it makes me feel like a girl (item 10, UGDS-aF), which would be presented to birth-males, neither of which could be meaningfully rated by either at any stage of the interventions, further illustrates that UGDS has questionable validity for the purpose of detecting meaningful changes in gender dysphoria as a result of medical and surgical treatment.

The updated UGDS scale (UGDS-GS), developed by the Dutch after the publication of their seminal study, has eliminated the two-sex version of the scale in favor of a single battery of questions applicable to both sexes (McGuire et al., 2020). This change may lead to a more reliable measurement of treatment-associated changes in future research. Other gender dysphoria scales also exist (Hakeem, Črnčec, Asghari-Fard, Harte, & Eapen, 2016; Iliadis et al., 2020) and may or may not be better suited for the purposes of measuring the impact of medical interventions on underlying gender distress. Gender dysphoria, of course, may also prove to be a more complex concept than can be measured by any scale.

Other limitations

The two Dutch studies were conducted without a control group (de Vries et al., 2011; de Vires et al., 2014). Nor could the researchers control for mental health interventions, which all the subjects received in addition to hormones and surgery. The Dutch only evaluated mental health outcomes and did not assess physical health effects of hormones and surgery. The sample size was small: the final study reported the outcomes of only 55 children, and as few as 32 were evaluated on key measures of psychological outcomes.

It is important to realize that the Dutch sample was carefully selected, which introduced a source of bias, and also challenges the study's applicability. From the 196 adolescents initially referred, 111 were considered eligible to start puberty blockers, and of this group, only the 70 most mature and mentally stable who proceeded to cross-sex hormones were included in the study (de Vries et al., 2011). Of note, 97% of the selected cases were attracted to members of their natal sex at baseline. All were cross-sex identified, with no cases of nonbinary identities. The final study only followed 55, rather than the original 70 cases, further excluding from reporting the outcomes of subjects who had experienced adverse events, including: one death from surgery-related complications and three cases of obesity and diabetes that rendered subjects ineligible for surgery. Three more subjects refused to be contacted or dropped out of care, which may mask adverse outcomes (de Vries et al., 2014).

There is no knowledge of the fate of 126 patients who did not participate in the Dutch study. Longer term outcomes of the subjects who did participate are lacking. We are aware of only one case of long-term follow-up for a female-to-male patient treated by the Dutch team in the 1990s. The case study describing the subject's functioning at the age of 33 found that the patient did not regret gender transition. However, he reported struggling with significant shame related to the appearance of his genitals and to his inability to sexually function; had problems maintaining long-term relationships; and experienced depressive symptoms (Cohen-Kettenis, Schagen, Steensma, de Vries, & Delemarre-van de Waal, 2011). Notably, these problems had not yet emerged when the same patient was assessed at the age of 20, when he reported high levels of satisfaction in general, and was "very satisfied with the results [of the metoidioplasty]" in particular (Cohen-Kettenis & van Goozen, 1998, p.248). Since the last round of psychological outcomes of the individuals in the Dutch study was obtained when the subjects were around 21 years of age (de Vries et al., 2014), it raises questions how they will fare during the decade when new developmental tasks, such as career development, forming long-term intimate relationships and friendships, or starting families come into focus.

As to the unknown outcomes of the patients rejected by the Dutch protocol, one study did report on 14 adolescents who sought gender reassignment in the same clinic, but were disqualified from treatment due to "psychological or environmental problems" (Smith, Van Goozen, & Cohen-Kettenis, 2001, p. 473). The study found that at follow-up 1-7 years after the original application, 11 of the 14 no longer wished to transition, and 2 others only slightly regretted not transitioning (Malone, D'Angelo, et al., 2021; Smith et al., 2001). This further underscores the importance of conducting research utilizing control groups and following the subjects for an extended period.

A recent attempt to replicate the results of the first Dutch study (de Vries et al., 2011) found no demonstrable psychological benefit from puberty blockade, but did find that the treatment adversely affected bone development (Carmichael et al., 2021). The final Dutch study (de Vries et al., 2014) has never been attempted to be replicated with or without a control group.

The scaling of the Dutch Protocol beyond original indications

The medical and surgical sequence of Dutch protocol has been aggressively scaled worldwide without the careful evaluations and vetting practiced by the Dutch. The protocol's original investigators have recently expressed concern that the interventions they described have been widely adopted on four continents without several of the protocol's essential discriminatory features (de Vries, 2020).

The extensive multi-year multidisciplinary evaluations of the children have been abbreviated or simply bypassed. The medical sequence is routinely used for children with post-pubertal onset of transgender identities complicated by mental health comorbidities (Kaltiala-Heino et al., 2018), and not just for those high-functioning adolescents with persistent early life cross-identifications, as was required by the Dutch protocol (de Vries & Cohen-Kettenis, 2012). Further, it has become increasingly common to socially transition children before puberty (Olson, Durwood, DeMeules, & McLaughlin, 2016), even though this was explicitly discouraged by the Dutch protocol at the time (de Vries & Cohen-Kettenis, 2012).

In addition, medical transition is frequently initiated much earlier than recommended by the original protocol (de Vries & Cohen-Kettenis, 2012). The authors of the protocol were aware that most children would have a spontaneous realignment of their gender identity with sex by going through early- to mid-stages of puberty (Cohen-Kettenis, Delemarre-van de Waal, & Gooren, 2008). The average age of initiating puberty blockade in the Dutch study was around 15. In contrast, currently the age limit has been lowered to the age of Tanner stage II, which can occur as early as 8-9 years (Hembree et al., 2017). Irreversible cross-sex hormones, initiated in the Dutch study at the average age of nearly 17, are currently commonly prescribed to 14-year-olds, and this lower age threshold has been recommended by WPATH Standard of Care 8 draft, the final version of which is due to be released in early 2022. The fact that children are transitioned before their identity is tested against the biological reality and before natural resolution of gender dysphoria has had a chance to occur is a major deviation from the original Dutch protocol. Systematic follow-up, reassessments, and tracking and publishing of outcomes are not performed.

As the lead Dutch researchers have begun to call for more research into the novel presentation of gender dysphoria in youth (de Vries, 2020; Voorzij, 2021) and question the wisdom of applying the hormonal and surgical treatment protocols to the newly presenting cases, many recently educated gender specialists mistakenly believe that the Dutch protocol proved the concept that its sequence helps all gender-dysphoric youth. Although aware of the Dutch study's importance, they seem to be unaware of its agreed upon limitations, and the Dutch clinicians' own discomfort that most new trans-identified adolescents presenting for care today significantly differ from the population the Dutch had originally studied. These facts, of course, underscore the need for a robust informed consent process.

The recommendations for informed consent process for children, adolescents, and young adults

Consent for all stages of gender transition should be explicit, not implied

Noninvasive medical care or care that carries little risk of harm does not require a signed informed consent document; rather, consent is implied through the act of a patient presenting for care. For example, when a parent brings in a child for a skin laceration or abscess, consent for sutures or simple incision and drainage is implied. Similarly, when a child presents with pneumonia and is hospitalized, consent for chest x-ray, IV fluids, and antibiotics is also implied. It is assumed that patients or their guardians agree to the interventions and understand the benefits and risks. When risks are greater, such as prior to surgery, chemotherapy, or another invasive procedure, an informed consent document is signed. Such situations require an explicit, or express informed consent.

In the context of interventions for gender dysphoria or gender incongruence, the uncertainties associated with puberty blocking, cross-sex hormones, and gender-affirmative surgeries are well-recognized (Manrique et al., 2018; National Institute for Health & Care Excellence, 2020a; 2020b; Wilson et al., 2018). In these cases, consent should be explicit rather than implied because of the complexity, uncertainty, and risks involved.

Informed consent for social transition represents a gray area. Evidence suggests that social transition is associated with the persistence of gender dysphoria (Hembree et al.,



2017; Steensma, McGuire, Kreukels, Beekman, & Cohen-Kettenis, 2013). This suggests that social gender transition is a form of a psychological intervention with potential lasting effects (Zucker, 2020). While the causality has not been proven, the possibility of iatrogenesis and the resulting exposure to the risks of future medical and surgical gender dysphoria treatments, qualifies social gender transition for explicit, rather than implied, consent.

Full unbiased disclosure of benefits, risks and alternatives is requisite

When mental health professionals are involved in evaluations and recommendations, the informed consent process begins either as part of an extended evaluation or is integrated in a psychotherapeutic process, separately or together, with the parents and patient. When pediatricians, nurse practitioners, or primary care physicians perform the initial evaluation, the informed consent process is more likely to be labeled as such in a briefer series of

In all settings, the informed consent discussions for gender-affirmative care should include three central ideas:

- The decision to initiate gender transition may predispose the child to persist in their transgender identity long-term.
- Many of the physical changes contemplated and undertaken are irreversible.
- 3. Careful long-term studies have not been done to verify that these interventions enable better physical and mental health or improved social functioning, or that they do not cause harm.

The informed consent process, culminating with a signed document, signifies that parents and patient have been educated about the short- and long-term risks, benefits and uncertainties associated with all relevant stages of the gender-affirmative interventions. The process must also inform the patients and families about the full range of alternative treatments, including the choice of not socially or medically treating the child's or adolescent's current state of gender/ body incongruence.

Decisional capacity to consent needs to be assessed and family should be involved

Trans-identified youth typically present themselves as strongly desiring hormones and ultimately, surgery. It should not be assumed that their eagerness is matched with the capacity to carefully consider the consequences of their realized desires. Trans-identified youth younger than the age of consent should be part of the informed consent process, but they may not be mature enough to recognize or admit their concerns about the proposed intervention. For this reason, it is the parents who, after careful consideration, are responsible for signing an informed consent document.

The issue of the exact age at which adolescents are mature enough to consent to gender transition has proven contentious: courts have been asked to decide about competence to consent to gender-affirmative hormones for youth in the United Kingdom and Australia (Ouliaris, 2021). In the United States, the legal age for medical consent for gender-affirmative interventions varies by state.

When patients are age 18 and older, and in some jurisdictions as young as age 15 (Right to medical or dental treatment without parental consent, 2010), they do not legally require parental approval for medical procedures. But because an individual's change of gender has profound implications for parents, siblings, and other family members, it is usually prudent for clinicians to seek their input directly or indirectly during the informed consent process. This is done by requesting a meeting with the parents.

A recent study by a Dutch research team attempted to evaluate the decisional capacity of adolescents embarking on gender transition (Vrouenraets, de Vries, de Vries, van der Miesen, & Hein, 2021). The researchers administered the MacCAT-T tool, comprised of the understanding, appreciating, reasoning, and expressing a choice domains, to 74 adolescents who were 14.7 years old on average (with the minimum age of 10). They concluded that the adolescents were competent to consent to starting pubertal suppression, calling for similar research for the <12 group, particularly because "birth-assigned girls ... may benefit from puberty suppression as early as 9 years of age" (Vrouenraets et al., 2021 p.7).

This study suffers from two significant limitations involving the MacCAT-T tool. It was never designed for children. Rather, it was designed to assess medical consent capacities of adults suffering from conditions such as dementia, schizophrenia, and other psychiatric disorders. There is a fundamental lack of equivalency between consenting to treatment by adults with cognitive impairments and obtaining consent from healthy children whose age-appropriate cognitive capacities are intact, but who lack the requisite life experiences to consent to profound life-changing medical interventions. We doubt, for example, whether even highly intelligent children who have not had sexual experiences can meaningfully comprehend the loss of future sexual function and reproductive abilities.

In addition, even for adults, the MacCAT-T tool has been criticized for its exclusive focus on cognitive aspects of capacity, failing to account for the non-cognitive aspects such as values, emotions and other biographic and context specific aspects inherent in the complexity of the decision process in real life (Breden & Vollmann, 2004). Children's values and emotions undergo tremendous change during the process of maturation.

The authors' conclusion about their young patients' competence to consent should be compared with what a panel of judges wrote in the challenge to the Tavistock treatment protocol (Bell v Tavistock, 2020):

...the clinical intervention we are concerned with here is different in kind to other treatments or clinical interventions. In other cases, medical treatment is used to remedy, or alleviate the symptoms of, a diagnosed physical or mental condition, and the effects of that treatment are direct and usually apparent. The position in relation to puberty blockers would not seem to reflect that description. [para 135]

...we consider the treatment in this case to be in entirely different territory from the type of medical treatment which is normally being considered. [para 140]

... the combination here of lifelong and life changing treatment being given to children, with very limited knowledge of the degree to which it will or will not benefit them, is one that gives significant grounds for concern. [para 143]

It seems clear that perceptions of children as young as 10 years of age as medically competent vary by country, state, and the institution where the doctor works, and, by clinicians' beliefs about the long-term benefits of these interventions. We maintain that the claim that children can consent to extremely life-altering intervention is fundamentally a philosophical claim (Clark & Virani, 2021). Our view in this matter is that consent is primarily a parental function.

Informed consent should be viewed as a process rather than an event

Most institutions that care for transgender-identified individuals have devised obligatory consent forms that outline the risks and uncertainties of hormonal and surgical gender-affirmative interventions. However, the requisite signatures are frequently collected in a perfunctory manner (Schulz, 2018), akin to signatures collected ahead of a common surgical procedure. The purpose of such informed consent documents appears to be to protect practitioners from lawsuits, rather than attend to the primary ethical foundation of the process.

Although obtaining the signatures is important, the signed document should signify that the process of informed consent has been undertaken over an extended time period and is not simply quickly completed (Vrouenraets et al., 2021). We believe the latter approach poses an ethical concern (Levine, 2019).

The internal dynamics of the trans-identified young person and their families vary considerably. Parental capacities, their private marital and intrafamilial relationships, their cultural awareness, religious and political sensibilities all influence the amount of time necessary to undertake a thorough informed consent process. It is not prudent to suggest a specific duration for the process of informed consent, other than to emphasize that it requires a slow, patient, thoughtful question and answer period as the parents and patient contemplate the meaning of what is known and unknown and whether to embark on alternative approaches to the management of gender dysphoria before the age of full neurological maturity has been reached, mental health comorbidities have been addressed, and a true informed consent by the patient is more likely.

Final thoughts

Sixty years of experience providing medical and surgical assistance to transgender-identified persons have seen many changes in who is treated, when they are treated, and how they are treated. Today, the emphasis has shifted to the treatment of the unprecedented numbers of youth declaring a trans identity. As adolescents pursue social, medical, and surgical interventions, health care providers may experience unease about patients' cognitive and emotional capacities to make decisions with life-changing and enduring consequences. An unrushed informed consent process helps the provider, the parents, and the patient.

Three issues tend to obscure the salience of informed consent: conspicuous mental health problems, uncertainty about the minor's personal capacity to understand the irreversible nature of the interventions, and parental disagreement. Physical and psychiatric comorbidities can contribute to the formation of a new identity, develop as its consequence, or bear no connection to it. Assessing mental health and the minor's functionality is one of the reasons why rapid affirmative care may be dangerous for patients and their families. For example, when situations involve autism, learning disorders, sexual abuse, attachment problems, trauma, separation anxiety, previous depressed or anxious states, neglect, low IQ, past psychotic illness, eating disorders or parental mental illness, clinicians must choose between ignoring these potentially causative conditions and comorbidities and providing appropriate treatment before affirmative care (D'Angelo et al., 2020).

For youth less than the age of majority, informed consent via parents provides a legal route for treatment but it does not make the decision to socially transition, provide hormones, or surgically remove breasts or testes less fraught with uncertainty. The best that health professionals can do is to ensure that the consent process informs the patient and parents of the current state of science, which is sorely lacking in quality research. It is the professionals' responsibility to ensure that the benefits patients and parents seek, and the risks they are assuming, are clearly appreciated as they prepare to make this often-excruciating decision.

Young people who have reached the age of majority, but who have not reached full maturation of the brain represent a unique challenge. It is well-recognized that brain remodeling proceeds through the third decade of life, with the prefrontal cortex responsible for executive function and impulse control the last to mature (Katz et al., 2016). The growing number of detransitioners who had been old enough to legally consent to transition, but who no longer felt they were transgender upon reaching their mid-20's, raises additional concerns about this vulnerable age group (Littman, 2021; Vandenbussche, 2021).

When the clinician is uncertain whether a young person is competent to comprehend the implications of the desired treatment—that is, when informed consent cannot inform the patient—the clinician may need more time with the patient. When parents or guardians do



not agree about whether to use puberty blockers or cross-sex hormones, clinicians are in an uneasy spot (Levine, 2021). This occurs in both intact and divorced families. Australia has given legal instructions to clinicians facing these uncertainties: the court is to be asked to decide (Ouliaris, 2021). The court system in the UK has been grappling with similar issues in recent years. While it is a rare case that ends up in a courtroom, clinicians devoted to a deliberate informed consent process are still likely to encounter ethical dilemmas that they cannot resolve.

Acknowledgments

The authors wish to thank SEGM staff for their grant and bibliographic support.

Funding

This work was supported by the Society for Evidence-based Gender Medicine.

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COURT OF THE STATE OF CALIFOR SAN JOAQUIN SUPERIOR COURT – STOCKTO	FOR COURT USE ONLY	
TITLE OF CASE (Abbreviated) Chloe E. Brockman v. Kaiser Foundation Hos		
ATTORNEY(S) NAME AND ADDRESS Charles S. LiMandri, Esq; Paul M. Jonna, Esq. Robert E. Weisenburger, Esq. LiMANDRI & JONNA LLP P.O. Box 9120 Rancho Santa Fe, California 92067 Tele: (858) 759-9930; Fax: (858) 759-9938		
ATTORNEY(S) FOR: Plaintiff Chloe E. Brockman	Dept. 11B	CASE NO.: STK-CV-UMM-2023- 0001612

PROOF OF SERVICE

I, Rebecca M. Oakley, declare that: I am over the age of 18 years and not a party to the action; I am employed in, or am a resident of the County of San Diego, California, and my business address is P.O. Box 9120, Rancho Santa Fe, CA 92067, Telephone number (858) 759-9930; Facsimile number (858) 759-9938. I further declare that I served the following document(s) on the parties in this action:

Motion for Leave to Amend

- 1. PLAINTIFF CHLOE E. BROCKMAN'S NOTICE OF MOTION AND MOTION FOR LEAVE TO AMEND COMPLAINT TO STATE CLAIM FOR PUNITIVE DAMAGES;
- 2. PLAINTIFF CHLOE E. BROCKMAN'S MEMORANDUM OF POINTS AND AUTHORITIES IN SUPPORT OF MOTION FOR LEAVE TO AMEND COMPLAINT TO STATE CLAIM FOR PUNITIVE DAMAGES:
- 3. PLAINTIFF CHLOE E. BROCKMAN'S NOTICE OF LODGMENT OF CONFIDENTIALLY MARKED DOCUMENTS IN SUPPORT OF MOTION FOR LEAVE TO AMEND COMPLAINT TO STATE CLAIM FOR PUNITIVE DAMAGES;
- 4. DECLARATION OF CHLOE E. BROCKMAN:
- 5. DECLARATION OF CHARLES S. LIMANDRI IN SUPPORT OF PLAINTIFF CHLOE E. BROCKMAN'S MOTION FOR LEAVE TO AMEND COMPLAINT TO STATE CLAIM FOR PUNITIVE DAMAGES;
- 6. DECLARATION OF JOCELYN T. BROCKMAN;
- 7. DECLARATION OF ROBIN A. DEA, M.D.;
- 8. DECLARATION OF NATHAN SZAJNBERG, M.D.;
- 9. DECLARATION OF MICHAEL LAIDLAW, M.D.;
- 10. DECLARATION OF JOHN PERROTTI, M.D.;
- 11. DECLARATION OF STEPHEN B. LEVINE, M.D.;
- 12. DECLARATION OF TIM CROSBY, LMFT;
- 13. DECLARATION OF KAYLA LOVDAHL;
- 14. DECLARATION OF ELISABETH "BETH" BOURNE;
- 15. DECLARATION OF LAUREN WOHL-SANCHEZ; and
- 16. [Proposed] ORDER In SUPPORT OF PLAINTIFF CHLOE E. BROCKMAN'S MOTION FOR LEAVE TO AMEND COMPLAINT TO STATE CLAIM FOR PUNITIVE DAMAGES.

Motion to Seal

1. PLAINTIFF CHLOE E. BROCKMAN'S NOTICE OF MOTION AND MOTION TO SEAL DOCUMENTS LODGED IN SUPPORT OF MOTION FOR LEAVE TO AMEND

COMPLAINT TO STATE CLAIM FOR PUNITIVE DAMAGES;

- 2. PLAINTIFF CHLOE E. BROCKMAN'S MEMORANDUM OF POINTS AND AUTHORITIES IN SUPPORT OF MOTION TO SEAL DOCUMENTS LODGED IN SUPPORT OF MOTION FOR LEAVE TO AMEND COMPLAINT TO STATE CLAIM FOR PUNITIVE DAMAGES; and
- 3. [Proposed] ORDER In SUPPORT OF PLAINTIFF CHLOE E. BROCKMAN'S MEMORANDUM OF POINTS AND AUTHORITIES IN SUPPORT OF MOTION TO SEAL DOCUMENTS LODGED IN SUPPORT OF MOTION FOR LEAVE TO AMEND COMPLAINT TO STATE CLAIM FOR PUNITIVE DAMAGES

by one or more of the following methods of service to:

**SE	SEE ATTACHED SERVICE LIST			
		be sealed in envelopes, and with the correct postage ited States Postal Service or placed for collection and		
X	(BY E-MAIL/ELECTRONIC MAIL) I caused a copy of the foregoing document(s) to be sent to the persons at the e-mail addresses listed above, this date via internet/electronic mail.			
X	(BY ELECTRONIC FILING/SERVICE) I cau Service through OneLegal.	used such document(s) to be Electronically Filed and/or		
corre	1 1 1 1	s of the State of California that the foregoing is true and		
00110	Executed on April 18, 2024	Rebecca M. Oakley		

COURT OF THE STATE OF CALIFORNIA SAN JOAQUIN SUPERIOR COURT – STOCKTON BRANCH

Chloe E. Brockman v. Kaiser Foundation Hospitals, Inc., et al. CASE NO.: STK-CV-UMM-2023-0001612

SERVICE LIST

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