No. 23-12155

UNITED STATES COURT OF APPEALS
FOR THE ELEVENTH CIRCUIT

August Dekker et al.,
Plaintiffs-Appellees,

v.

Secretary, Florida Agency for Health Care Administration et al.,
Defendants-Appellants.

U.S. District Court for the Northern District of Florida, No. 4:22-cv-325
(Hinkle, J.)

APPELLANTS' APPENDIX – VOLUME VI OF XXI
PART 1 OF 2

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Dated: October 13, 2023

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APPENDICES

Appendix 1

The Outcomes Studies of Childhood-Onset Gender Dysphoria

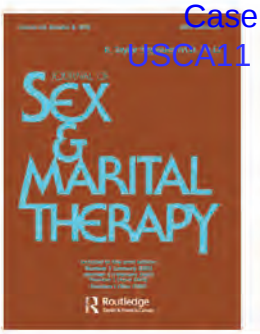
Appendix 2

Peer-reviewed article:

Cantor, J. M. (2020). Transgender and gender diverse children and adolescents: Fact-checking of AAP policy. *Journal of Sex & Marital Therapy, 46,* 307–313. doi: 10.1080/0092623X.2019.1698481

Prospective Outcomes Studies of Gender Dysphoric Children

2/16 4/16 10/16	gay trans-/crossdress straight/uncertain	Lebovitz, P. S. (1972). Feminine behavior in boys: Aspects of its outcome. *American Journal of Psychiatry, 128,* 1283–1289.
2/16 2/16 12/16	trans- uncertain gay	Zuger, B. (1978). Effeminate behavior present in boys from childhood: Ten additional years of follow-up. *Comprehensive Psychiatry, 19, 363–369.*
0/9 9/9	trans- gay	Money, J., & Russo, A. J. (1979). Homosexual outcome of discordant gender identity/role: Longitudinal follow-up. *Journal of Pediatric Psychology, 4,* 29–41.
2/45 10/45 33/45	trans-/crossdress uncertain gay	Zuger, B. (1984). Early effeminate behavior in boys: Outcome and significance for homosexuality. *Journal of Nervous and Mental Disease, 172,* 90–97.
1/10 2/10 3/10 4/10	trans- gay uncertain straight	Davenport, C. W. (1986). A follow-up study of 10 feminine boys. *Archives of Sexual Behavior, 15,*511–517.
1/44 43/44	trans- cis-	Green, R. (1987). *The "sissy boy syndrome" and the development of homosexuality.* New Haven, CT: Yale University Press.
0/8 8/8	trans- cis-	Kosky, R. J. (1987). Gender-disordered children: Does inpatient treatment help? *Medical Journal of Australia, 146,* 565–569.
21/54 33/54	trans- cis-	Wallien, M. S. C., & Cohen-Kettenis, P. T. (2008). Psychosexual outcome of gender-dysphoric children. *Journal of the American Academy of Child and Adolescent Psychiatry, 47,* 1413–1423.
3/25 6/25 16/25	trans- lesbian/bi- straight	Drummond, K. D., Bradley, S. J., Badali-Peterson, M., & Zucker, K. J. (2008). A follow-up study of girls with gender identity disorder. *Developmental Psychology, 44,* 34–45.
47/127 80/127	trans- cis-	Steensma, T. D., McGuire, J. K., Kreukels, B. P. C., Beekman, A. J., & Cohen-Kettenis, P. T. (2013). Factors associated with desistence and persistence of childhood gender dysphoria: A quantitative follow-up study. *Journal of the American Academy of Child and Adolescent Psychiatry, 52,* 582–590.
17/139 122/139	trans- cis-	Singh, D., Bradley, S. J., and Zucker, K. J. (2021) A follow-up study of boys with gender identity disorder. Frontiers in Psychiatry, 12, 632784. doi: 10.3389/fpsyt.2021.632784



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Transgender and Gender Diverse Children and Adolescents: Fact-Checking of AAP Policy

James M. Cantor

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Transgender and Gender Diverse Children and Adolescents: Fact-Checking of AAP Policy

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ABSTRACT

The American Academy of Pediatrics (AAP) recently published a policy statement: *Ensuring comprehensive care and support for transgender and gender-diverse children and adolescents*. Although almost all clinics and professional associations in the world use what's called the *watchful waiting* approach to helping gender diverse (GD) children, the AAP statement instead rejected that consensus, endorsing *gender affirmation* as the only acceptable approach. Remarkably, not only did the AAP statement fail to include any of the actual outcomes literature on such cases, but it also misrepresented the contents of its citations, which repeatedly said the very opposite of what AAP attributed to them.

The American Academy of Pediatrics (AAP) recently published a policy statement entitled, *Ensuring comprehensive care and support for transgender and gender-diverse children and adolescents* (Rafferty, AAP Committee on Psychosocial Aspects of Child and Family Health, AAP Committee on Adolescence, AAP Section on Lesbian, Gay, Bisexual, and Transgender Health and Wellness, 2018). These are children who manifest discontent with the sex they were born as and desire to live as the other sex (or as some alternative gender role). The policy was quite a remarkable document: Although almost all clinics and professional associations in the world use what's called the *watchful waiting* approach to helping transgender and gender diverse (GD) children, the AAP statement rejected that consensus, endorsing only *gender affirmation*. That is, where the consensus is to delay any transitions after the onset of puberty, AAP instead rejected waiting before transition. With AAP taking such a dramatic departure from other professional associations, I was immediately curious about what evidence led them to that conclusion. As I read the works on which they based their policy, however, I was pretty surprised—rather alarmed, actually: These documents simply did not say what AAP claimed they did. In fact, the references that AAP cited as the basis of their policy instead outright contradicted that policy, repeatedly endorsing *watchful waiting*.

The AAP statement was also remarkable in what it left out—namely, the actual outcomes research on GD children. In total, there have been 11 follow-up studies of GD children, of which AAP cited one (Wallien & Cohen-Kettenis, 2008), doing so without actually mentioning the outcome data it contained. The literature on outcomes was neither reviewed, summarized, nor subjected to meta-analysis to be considered in the aggregate—It was merely disappeared. (The list of all existing studies appears in the appendix.) As they make clear, *every* follow-up study of GD children, without exception, found the same thing: Over puberty, the majority of GD children cease to want to transition. AAP is, of course, free to establish whatever policy it likes on

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whatever basis it likes. But any assertion that their policy is based on evidence is demonstrably false, as detailed below.

AAP divided clinical approaches into three types—conversion therapy, watchful waiting, and gender affirmation. It rejected the first two and endorsed *gender affirmation* as the only acceptable alternative. Most readers will likely be familiar already with attempts to use conversion therapy to change sexual orientation. With regard to gender identity, AAP wrote:

> "[C]onversion" or "reparative" treatment models are used to prevent children and adolescents from identifying as transgender or to dissuade them from exhibiting gender-diverse expressions. … Reparative approaches have been proven to be not only unsuccessful[38] but also deleterious and are considered outside the mainstream of traditional medical practice.[29,39–42]

The citations were:

38. Haldeman DC. The practice and ethics of sexual orientation conversion therapy. *J Consult Clin Psychol.* 1994;62(2):221–227.
29. Adelson SL; American Academy of Child and Adolescent Psychiatry (AACAP) Committee on Quality Issues (CQI). Practice parameter on gay, lesbian, or bisexual sexual orientation, gender nonconformity, and gender discordance in children and adolescents. *J Am Acad Child Adolesc Psychiatry.* 2012;51(9):957–974.
39. Byne W. Regulations restrict practice of conversion therapy. *LGBT Health.* 2016;3(2):97–99.
40. Cohen-Kettenis PT, Delemarrevan de Waal HA, Gooren LJ. The treatment of adolescent transsexuals: changing insights. *J Sex Med.* 2008;5(8):1892–1897.
41. Bryant K. Making gender identity disorder of childhood: historical lessons for contemporary debates. *Sex Res Soc Policy.* 2006;3(3):23–39.
42. World Professional Association for Transgender Health. *WPATH De-Psychopathologisation Statement.* Minneapolis, MN: World Professional Association for Transgender Health; 2010.

AAP's claims struck me as odd because *there are no studies of conversion therapy for gender identity.* Studies of conversion therapy have been limited to *sexual orientation,* and, moreover, to the sexual orientation *of adults,* not to gender identity and not of children in any case. The article AAP cited to support their claim (reference number 38) is indeed a classic and well-known review, but it is a review of sexual orientation research *only.* Neither gender identity, nor even children, received a single mention in it. Indeed, the narrower scope of that article should be clear to anyone reading even just its title: "The practice and ethics of *sexual orientation* conversion therapy" [italics added].

AAP continued, saying that conversion approaches for GD children have already been rejected by medical consensus, citing five sources. This claim struck me as just as odd, however—I recalled associations banning conversion therapy for sexual orientation, but not for gender identity, exactly because there is no evidence for generalizing from adult sexual orientation to childhood gender identity. So, I started checking AAP's citations for that, and these sources too pertained only to sexual orientation, not gender identity (specifics below). What AAP's sources *did* repeatedly emphasize was that:

A. Sexual orientation of adults is unaffected by conversion therapy and any other [known] intervention;
B. Gender dysphoria in childhood before puberty desists in the majority of cases, becoming (cis-gendered) homosexuality in adulthood, again regardless of any [known] intervention; and
C. Gender dysphoria in childhood persisting after puberty tends to persist entirely.

That is, in the context of GD children, it simply makes no sense to refer to externally induced "conversion": The majority of children "convert" to cisgender or "desist" from transgender

regardless of any attempt to change them. "Conversion" only makes sense with regard to adult sexual orientation because (unlike childhood gender identity), adult homosexuality never or nearly never spontaneously changes to heterosexuality. Although gender identity and sexual orientation may often be analogous and discussed together with regard to social or political values and to civil rights, they are nonetheless distinct—with distinct origins, needs, and responses to medical and mental health care choices. Although AAP emphasized to the reader that "gender identity is not synonymous with 'sexual orientation'" (Rafferty et al., 2018, p. 3), they went ahead to treat them as such nonetheless.

To return to checking AAP's fidelity to its sources: Reference 29 was a practice guideline from the Committee on Quality Issues of the American Academy of Child and Adolescent Psychiatry (AACAP). Despite AAP applying this source to *gender identity*, AACAP was quite unambiguous regarding their intent to speak to sexual orientation and *only* to sexual orientation: "Principle 6. Clinicians should be aware that there is no evidence that *sexual orientation* can be altered through therapy, and that attempts to do so may be harmful. There is no established evidence that change in a predominant, enduring *homosexual* pattern of development is possible. Although sexual fantasies can, to some degree, be suppressed or repressed by those who are ashamed of or in conflict about them, sexual desire is not a choice. However, behavior, social role, and—to a degree—identity and self-acceptance are. Although operant conditioning modifies sexual fetishes, it does not alter *homosexuality*. Psychiatric efforts to alter *sexual orientation* through 'reparative therapy' *in adults* have found little or no change in *sexual orientation*, while causing significant risk of harm to self-esteem" (AACAP, 2012, p. 967, italics added).

Whereas AAP cites AACAP to support gender affirmation as the only alternative for treating GD children, AACAP's actual view was decidedly neutral, noting the lack of evidence: "Given the lack of empirical evidence from randomized, controlled trials of the efficacy of treatment aimed at eliminating gender discordance, the potential risks of treatment, and longitudinal evidence that gender discordance persists in only a small minority of untreated cases arising in childhood, further research is needed on predictors of persistence and desistence of childhood gender discordance as well as the long-term risks and benefits of intervention before any treatment to eliminate gender discordance can be endorsed" (AACAP, 2012, p. 969). Moreover, whereas AAP rejected watchful waiting, what AACAP recommended was: "In general, it is desirable to help adolescents who may be experiencing gender distress and dysphoria to defer sex reassignment until adulthood" (AACAP, 2012, p. 969). So, not only did AAP attribute to AACAP something AACAP never said, but also AAP withheld from readers AACAP's actual view.

Next, in reference 39, Byne (2016) also addressed only sexual orientation, doing so very clearly: "Reparative therapy is a subset of conversion therapies based on the premise that *same-sex attraction* are reparations for childhood trauma. Thus, practitioners of reparative therapy believe that exploring, isolating, and repairing these childhood emotional wounds will often result in reducing *same-sex attractions*" (Byne, 2016, p. 97). Byne does not say this of gender identity, as the AAP statement misrepresents.

In AAP reference 40, Cohen-Kettenis et al. (2008) did finally pertain to gender identity; however, this article never mentions conversion therapy. (!) Rather, in this study, the authors presented that clinic's lowering of their minimum age for cross-sex hormone treatment from age 18 to 16, which they did on the basis of a series of studies showing the high rates of success with this age group. Although it did strike me as odd that AAP picked as support against conversion therapy an article that did not mention conversion therapy, I could imagine AAP cited the article as an example of what the "mainstream of traditional medical practice" consists of (the logic being that conversion therapy falls outside what an 'ideal' clinic like this one provides). However, what this clinic provides is the very *watchful waiting* approach that AAP rejected. The approach

espoused by Cohen-Kettenis (and the other clinics mentioned in the source—Gent, Boston, Oslo, and now formerly, Toronto) is to make puberty-halting interventions available at age 12 because: "[P]ubertal suppression may give adolescents, together with the attending health professional, more time to explore their gender identity, without the distress of the developing secondary sex characteristics. The precision of the diagnosis may thus be improved" (Cohen-Kettenis et al., 2008, p. 1894).

Reference 41 presented a very interesting history spanning the 1960s–1990s about how feminine boys and tomboyish girls came to be recognized as mostly pre-homosexual, and how that status came to be entered into the DSM at the same time as homosexuality was being *removed* from the DSM. Conversion therapy is never mentioned. Indeed, to the extent that Bryant mentions treatment at all, it is to say that treatment is entirely irrelevant to his analysis: "An important omission from the *DSM* is a discussion of the kinds of treatment that GIDC children should receive. (This omission is a general orientation of the DSM and not unique to GIDC)" (Bryant, 2006, p. 35). How this article supports AAP's claim is a mystery. Moreover, how AAP could cite a 2006 history discussing events of the 1990s and earlier to support a claim about the *current* consensus in this quickly evolving discussion remains all the more unfathomable.

Cited last in this section was a one-paragraph press release from the World Professional Association for Transgender Health. Written during the early stages of the American Psychiatric Association's (APA's) update of the DSM, the statement asserted simply that "The WPATH Board of Directors strongly urges the de-psychopathologisation of gender variance worldwide." Very reasonable debate can (and should) be had regarding whether gender dysphoria should be removed from the DSM as homosexuality was, and WPATH was well within its purview to assert that it should. Now that the DSM revision process is years completed however, history has seen that APA ultimately retained the diagnostic categories, rejecting WPATH's urging. This makes AAP's logic entirely backwards: That WPATH's request to depathologize gender dysphoria was *rejected* suggests that it is *WPATH's* view—and therefore the AAP policy—which fall "outside the mainstream of traditional medical practice." (!)

AAP based this entire line of reasoning on their belief that conversion therapy is being used "to prevent children and adolescents from identifying as transgender" (Rafferty et al., 2018, p. 4). That claim is left without citation or support. In contrast, what is said by AAP's sources is "delaying affirmation should *not* be construed as conversion therapy or an attempt to change gender identity" in the first place (Byne, 2016, p. 2). Nonetheless, AAP seems to be doing exactly that: simply relabeling any alternative approach as equivalent to conversion therapy.

Although AAP (and anyone else) may reject (what they label to be) conversion therapy purely on the basis of political or personal values, there is no evidence to back the AAP's stated claim about the existing science on gender identity at all, never mind gender identity of children.

AAP also dismissed the watchful waiting approach out of hand, not citing any evidence, but repeatedly calling it "outdated." The criticisms AAP provided, however, again defied the existing evidence, with even its own sources repeatedly calling watchful waiting the current standard. According to AAP:

> [G]ender affirmation is in contrast to the outdated approach in which a child's gender-diverse assertions are held as "possibly true" until an arbitrary age (often after pubertal onset) when they can be considered valid, an approach that authors of the literature have termed "watchful waiting." This outdated approach does not serve the child because critical support is withheld. Watchful waiting is based on binary notions of gender in which gender diversity and fluidity is pathologized; in watchful waiting, it is also assumed that notions of gender identity become fixed at a certain age. The approach is also influenced by a group of early studies with validity concerns, methodologic flaws, and limited follow-up on children who identified as TGD and, by adolescence, did not seek further treatment ("desisters").[45,47]

The citations from AAP's reference list are:

45. Ehrensaft D, Giammattei SV, Storck K, Tishelman AC, Keo-Meier C. Prepubertal social gender transitions: what we know; what we can learn—a view from a gender affirmative lens. *Int J Transgend.* 2018;19(2):251–268

47. Olson KR. Prepubescent transgender children: what we do and do not know. *J Am Acad Child Adolesc Psychiatry.* 2016;55(3):155–156.e3

I was surprised first by the AAP's claim that watchful waiting's delay to puberty was somehow "arbitrary." The literature, including AAP's sources, repeatedly indicated the pivotal importance of puberty, noting that outcomes strongly diverge at that point. According to AAP reference 29, in "*prepubertal* boys with gender discordance—including many without any mental health treatment—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" (Adelson & AACAP, 2012, p. 963, italics added), whereas "when gender variance with the desire to be the other sex is present *in adolescence*, this desire usually does persist through adulthood" (Adelson & AACAP, 2012, p. 964, italics added). Similarly, according to AAP reference 40, "Symptoms of GID *at prepubertal ages* decrease or even disappear in a considerable percentage of children (estimates range from 80–95%). Therefore, any intervention in childhood would seem premature and inappropriate. However, GID persisting *into early puberty* appears to be highly persistent" (Cohen-Kettenis et al., 2008, p. 1895, italics added). That follow-up studies of prepubertal transition differ from postpubertal transition is the very meaning of non-arbitrary. AAP gave readers exactly the reverse of what was contained in its own sources. If AAP were correct in saying that puberty is an arbitrarily selected age, then AAP will be able to offer another point to wait for with as much empirical backing as puberty has.

Next, it was not clear on what basis AAP could say that watchful waiting withholds support—AAP cited no support for its claim. The people in such programs often receive substantial support during this period. Also unclear is on what basis AAP could already know exactly which treatments are "critical" and which are not—Answering that question is the very purpose of this entire endeavor. Indeed, the logic of AAP's claim appears entirely circular: It is only if one were already pre-convinced that gender affirmation is the only acceptable alternative that would make watchful waiting seem to withhold critical support—What it delays is gender affirmation, the method one has already decided to be critical.

Although AAP's next claim did not have a citation appearing at the end of its sentence, binary notions of gender were mentioned both in references 45 and 47. Specifically, both pointed out that existing outcome studies have been about people transitioning from one sex to the other, rather than from one sex to an in-between status or a combination of masculine/feminine features. Neither reference presented this as a reason to reject the results from the existing studies of complete transition however (which is how AAP cast it). Although it is indeed true that the outcome data have been about complete transition, some future study showing that partial transition shows a different outcome would not invalidate what is known about complete transition. Indeed, data showing that partial transition gives better outcomes than complete transition would, once again, support the watchful waiting approach which AAP rejected.

Next was a vague reference alleging concerns and criticisms about early studies. Had AAP indicated what those alleged concerns and flaws were (or which studies they were), then it would be possible to evaluate or address them. Nonetheless, the argument is a red herring: Because all of the later studies showed the same result as did the early studies, any such allegation is necessarily moot.

Reference 47 was a one-and-a-half page commentary in which the author off-handedly mentions criticisms previously made of three of the eleven outcome studies of GD children, but does not provide any analysis or discussion. The only specific claim was that studies (whether early or late) had limited follow-up periods—the logic being that had outcome researchers lengthened the follow-up period, then people who seemed to have desisted might have returned to the clinic as

cases of "persistence-after-interruption." Although one could debate the merits of that prediction, AAP instead simply withheld from the reader the result from the original researchers having tested that very prediction directly: Steensma and Cohen-Kettenis (2015) conducted another analysis of their cohort, by then ages 19–28 (mean age 25.9 years), and found that 3.3% (5 people of the sample of 150) later returned. That is, in long-term follow-up, the childhood sample showed 66.7% desistence instead of 70.0% desistance.

Reference 45 did not support the claim that watchful-waiting is "outdated" either. Indeed, that source said the very opposite, explicitly referring to watchful waiting as the *current* approach: "Put another way, if clinicians are straying from SOC 7 guidelines for social transitions, not abiding by the watchful waiting model *favored by the standards*, we will have adolescents who have been consistently living in their affirmed gender since age 3, 4, or 5" (Ehrensaft et al., 2018, p. 255). Moreover, Ehrensaft et al. said there are cases in which they too would still use watchful waiting: "When a child's gender identity is unclear, the watchful waiting approach can give the child and their family time to develop a clearer understanding and is not necessarily in contrast to the needs of the child" (p. 259). Ehrensaft et al. are indeed critical of the watchful waiting model (which they feel is applied too conservatively), but they do not come close to the position the AAP policy espouses. Where Ehrensaft summaries the potential benefits and potential risks both to transitioning and not transitioning, the AAP presents an ironically binary narrative.

In its policy statement, AAP told neither the truth nor the whole truth, committing sins both of commission and of omission, asserting claims easily falsified by anyone caring to do any fact-checking at all. AAP claimed, "This policy statement is focused specifically on children and youth that identify as TGD rather than the larger LGBTQ population"; however, much of that evidence was about sexual orientation, not gender identity. AAP claimed, "Current available research and expert opinion from clinical and research leaders … will serve as the basis for recommendations" (pp. 1–2); however, they provided recommendations entirely unsupported and even in direct opposition to that research and opinion.

AAP is advocating for something far in excess of mainstream practice and medical consensus. In the presence of compelling evidence, that is just what is called for. The problems with Rafferty, however, do not constitute merely a misquote, a misinterpretation of an ambiguous statement, or a missing reference or two. Rather, AAP's statement is a systematic exclusion and misrepresentation of entire literatures. Not only did AAP fail to provide compelling evidence, it failed to provide the evidence at all. Indeed, AAP's recommendations are *despite* the existing evidence.

Disclosure statement

No potential conflict of interest was reported by the author.

References

Rafferty, J., AAP Committee on Psychosocial Aspects of Child and Family Health, AAP Committee on Adolescence, AAP Section on Lesbian, Gay, Bisexual, and Transgender Health and Wellness. (2018). Ensuring comprehensive care and support for transgender and gender-diverse children and adolescents. *Pediatrics*, *142*(4), e20182162 doi:10.1542/peds.2018-2162

Steensma, T. D., & Cohen-Kettenis, P. T. (2015). More than two developmental pathways in children with gender dysphoria? *Journal of the American Academy of Child and Adolescent Psychiatry*, *52*, 147–148. doi:10.1016/j.jaac.2014.10.016

Wallien, M. S. C., & Cohen-Kettenis, P. T. (2008). Psychosexual outcome of gender-dysphoric children. *Journal of the American Academy of Child and Adolescent Psychiatry*, *47*, 1413–1423. doi:10.1097/CHI.0b013e31818956b9

Appendix

Count	Group	Study
2/16 4/16 10/16	gay* trans-/crossdress straight*/uncertain	Lebovitz, P. S. (1972). Feminine behavior in boys: Aspects of its outcome. *American Journal of Psychiatry, 128,* 1283–1289.
2/16 2/16 12/16	trans- uncertain gay	Zuger, B. (1978). Effeminate behavior present in boys from childhood: Ten additional years of follow-up. *Comprehensive Psychiatry, 19,* 363–369.
0/9 9/9	trans- gay	Money, J., & Russo, A. J. (1979). Homosexual outcome of discordant gender identity/role: Longitudinal follow-up. *Journal of Pediatric Psychology, 4,* 29–41.
2/45 10/45 33/45	trans-/crossdress uncertain gay	Zuger, B. (1984). Early effeminate behavior in boys: Outcome and significance for homosexuality. *Journal of Nervous and Mental Disease, 172,* 90–97.
1/10 2/10 3/10 4/10	trans- gay uncertain straight	Davenport, C. W. (1986). A follow-up study of 10 feminine boys. *Archives of Sexual Behavior, 15,* 511–517.
1/44 43/44	trans- cis-	Green, R. (1987). *The "sissy boy syndrome" and the development of homosexuality.* New Haven, CT: Yale University Press.
0/8 8/8	trans- cis-	Kosky, R. J. (1987). Gender-disordered children: Does inpatient treatment help? *Medical Journal of Australia, 146,* 565–569.
21/54 33/54	trans- cis-	Wallien, M. S. C., & Cohen-Kettenis, P. T. (2008). Psychosexual outcome of gender-dysphoric children. *Journal of the American Academy of Child and Adolescent Psychiatry, 47,* 1413–1423.
3/25 6/25 16/25	trans- lesbian/bi- straight	Drummond, K. D., Bradley, S. J., Badali-Peterson, M., & Zucker, K. J. (2008). A follow-up study of girls with gender identity disorder. *Developmental Psychology, 44,* 34–45.
17/139 122/139	trans- cis-	Singh, D. (2012). *A follow-up study of boys with gender identity disorder.* Unpublished doctoral dissertation, University of Toronto.
47/127 80/127	trans- cis-	Steensma, T. D., McGuire, J. K., Kreukels, B. P. C., Beekman, A. J., & Cohen-Kettenis, P. T. (2013). Factors associated with desistence and persistence of childhood gender dysphoria: A quantitative follow-up study. *Journal of the American Academy of Child and Adolescent Psychiatry, 52,* 582–590.

*For brevity, the list uses "gay" for "gay and cis-", "straight" for "straight and cis-", etc.

Appendix Attachment

5

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF FLORIDA
TALLAHASSEE DIVISION

AUGUST DEKKER, et al.,

Plaintiffs,

v. Case No. 4:22-cv-00325-RH-MAF

SIMONE MARSTILLER, et al.,

Defendants.
_____/

DECLARATION OF QUENTIN L. VAN METER, MD

I, Quentin L. Van Meter., hereby declare and state as follows:

1. I am over the age of 18, of sound mind, and in all respects competent to testify. I have personal knowledge of the information contained in this declaration and would testify completely to those facts if called to do so.

2. I received my B.A. in Science at the College of William and Mary and my M.D. from the Medical College of Virginia, Virginia Commonwealth University. I am currently a pediatric endocrinologist in private practice in Atlanta, Georgia. I am the President of Van Meter Pediatric Endocrinology, P.C. I am on the clinical faculties of Emory University School of Medicine and Morehouse College of Medicine, in the role of adjunct Associate Professor of Pediatrics. I am board certified in Pediatrics and Pediatric Endocrinology. I have been licensed to practice medicine in Georgia since 1991. I have been previously licensed to practice medicine in California, Louisiana, and Maryland.

3. I did my Pediatric Endocrine fellowship at Johns Hopkins Hospital from 1978-1980. The faculty present at that time had carried on the tradition of excellence established by Lawson Wilkins, M.D. Because of the reputation of the endocrine program as a center for exceptional care for children with disorders of sexual differentiation, I had well-above average exposure to such patients. As a

Pediatric Fellow, I was also exposed to adults with Gender Identity Disorder, then called Trans-Sexuality, and received training from John Money, Ph.D., in his Psycho-hormonal Division. Over the past 44 years, I have closely followed the topic of incongruent gender in children adolescents and adults.

4. I am the author of a report attached to the Florida Agency for Healthcare Administration's Generally Accepted Professional Medical Standards on the Treatment of Gender Dysphoria. A copy of my report is attached and incorporated by reference as Exhibit "A" to this declaration.

5. I have been retained by the Defendants in this case to respond to statements of Johanna Olsen-Kennedy about my report.

6. I have testified in deposition or at trial in the following cases within the last four years: Siefert *v.* Hamilton County, Ohio, Grahm *v.* Gloucester County Schools, Virginia, Ray et al *v.*Himes et al, U.S. District Court for the Southern District, Ohio, A.Loughman *v* .C. Loughman 311th Judicial District Court, Harris County TX, L.C. Cauthen *v.* J.B. Cauthen Cobb Country Superior Court, Georgia, and LL Spahr *v.* R.S.Spahr, St. Louis County Court, MO.

7. A list of my publications is included in my curriculum vitae, which is attached.

8. I was compensated $350 per hour for preparing my initial report ("Exhibit "A")I am being compensated at an hourly rate of $450 per hour for my time preparing this declaration. My compensation does not depend on the outcome of this litigation, the opinions I express, or the testimony I may provide.

7. In paragraph 63 of her declaration, Dr. Olsen-Kennedy states that I "incorrectly allege that an increase in numbers of youth presenting for care related to GD provides support for the social contagion theory." In doing so, she summarily dismisses the fact that the numbers of children and adolescents presenting with gender identity incongruence (GII) has increased because of social

contagion and asserts that the "old numbers" were from the time when the diagnosis was for Gender Identity Disorder (GID), not Gender Dysphoria. She categorizes GID as a completely separate disorder from Gender Dysphoria, which is patently wrong. GID was banished from the DSM-V because the committee that was in charge of revising the DSM-IV threatened its chairman, Kenneth Zucker, with loss of his position at the prestigious clinic in Toronto where so much work had been done with children and adolescents using counseling therapies to bring about desistance of the gender identity incongruence. Zucker, in order to protect his patients from losing all health care funding for their counseling therapies, pleaded that erasing GID would leave the patients with no diagnosis at all and that, at least Gender Dysphoria would allow these patients to seek the care they needed and not have to pay out of pocket. His efforts still got him fired.

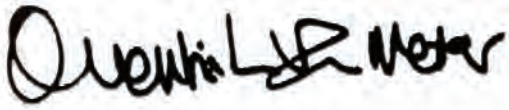
8. It flies in the face of reality that online communication is the not the first and foremost place where the patient with GII searches. If you search transgender on Google, you find 513,000,000 entries, with Planned Parenthood at the top of the list. This is social contagion by definition. At 5000% increase in clinic consultations over 10 years in the Tavistock clinic does not happen with resolution of the minority stress theory.

9. In paragraphs 89-91 of her declaration, Dr. Olson-Kennedystates that "[b]oth the GAPMS Memo and Dr. Van Meter repeatedly express concern that the U.S. Food and Drug Administration (FDA) has not approved puberty blockers or hormone therapy for the treatment of gender dysphoria." In doing so, she argues that many drugs are used off label and therefore the use of off-label drugs for gender dysphoria is no different. Those drugs that are used off-label are either not shown to have any significant adverse outcome, or they are used in a very limited fashion until it can be proven they are safe and efficacious. An example of this is the use of aromatase inhibitors in adolescent males to stall off epiphyseal closure in hopes of achieving a better final height. This class of drugs was brought under scrutiny by the Pediatric Endocrine Society Committee on

Pharmacotherapeutics, and very strict safety monitoring standards were proposed. There are unquestionable issues with adverse outcomes using GnRH analogs in adolescents: bone density, interruption of gonadal maturation, inhibition of brain development are just a few. There is no ongoing, centralized unbiased assessment of these issues, despite the clear call by the Endocrine Society Guidelines of 2009 and revised Guidelines of 2017. Because the necessary, RECOMMENDED controlled studies are not being done, proceeding with the use of GNRH agonists is unquestionably experimenting on children.

I declare under penalty of perjury that the foregoing is true and correct. Executed this 2nd day of October, 2022.

Respectfully submitted,



Quentin L. Van Meter, MD

QUENTIN L. VAN METER, M.D. **updated 29 April, 2022**
1800 Howell Mill Road NW, Suite 475
Atlanta, Georgia 30318 **(678) 961-2100**

PERSONAL

Home Address:	1080 Peachtree St. NE #3507, Atlanta, GA 30309
Home Phone:	(404) 963-5618
Date of Birth:	September 13, 1947
Place of Birth:	Laramie, Wyoming
Citizenship:	USA

EDUCATION:

Undergraduate:	College of William & Mary, 1969 B.S. – 1969
Medical School:	Medical College of Virginia, 1973 M.D. – 1973

CLINICAL TRAINING:

Institution:	The University of California, San Francisco
Hospital:	Naval Regional Medical Center, Oakland
Position:	Pediatric Intern – 1973 – 1974 Pediatric Resident – 1974 – 1976
Institution:	Johns Hopkins University
Hospital:	Johns Hopkins Hospital
Position:	Fellow, Pediatric Endocrinology 1978 – 1980 Fellowship Program Director: Claude Migeon, M.D.
Current Position:	Pediatric Endocrinologist Van Meter Pediatric Endocrinology, P.C. 1800 Howell Mill Road, Suite 475 Atlanta, Georgia 30318

PROFESSIONAL CERTIFICATION & SOCIETIES:

Diplomate, National Board of Medical Examiners, 1974

American Board of Pediatrics, certified in general pediatrics, 1978, sub-board certified in Pediatric Endocrinology, 1983

Fellow:	American Academy of Pediatrics, Georgia Chapter 1975 -present President, Uniformed Services West Chapter, 1987 – 1990 District VIII member, AAP Committee on Awards for Excellence in Research, 1990-1994 Editor, The Georgia Pediatrician, 1994 – 1998 Chairman, Georgia Chapter Legislative Committee, 1996 – 2006
Fellow:	The American College of Pediatricians, 2007 – present Member of the Board of Directors, 2008- present President, 2018-present
Member:	Pediatric Endocrine Society, 1989 – present
Member:	American Diabetes Association Professional Section, 1988 – present
Member:	Endocrine Society, 1994-present
Member:	Southern Pediatric Endocrine Society, 1992 – Present
Member:	American Association of Clinical Endocrinologists, 2005 – present
Licensure:	Georgia, #34734

FACULTY POSITIONS:

Institution:	Morehouse School of Medicine
Position:	Associate Clinical Professor, Pediatrics, 2004 – present
Institution:	Emory University School of Medicine
Position:	Adjunct Associate Professor, Pediatrics, 1991 – present
Institution:	University of California, San Francisco
Position:	Associate Clinical Professor, Pediatrics, 1989 – 1991
Institution:	University of California, San Diego, School of Medicine
Position:	Assistant Clinical Professor, Pediatrics, 1980 – 1986
Institution:	LSU School of Medicine, Clinical Instructor, Pediatrics, 1977 – 1978

MILITARY SERVICE:

Commission:	Medical Corps, United States Navy, August 1971
Rank:	Captain, retired
Duty Stations:	Health Professional Scholarship Student, 1971 – 1974
	Intern and Resident, Pediatrics, Naval Regional Medical Center, Oakland, 1973 – 1976
	Staff Pediatrician, Naval Regional Medical Center, Oakland, 1976

Staff Pediatrician, Naval Regional Medical Center,
New Orleans, 1976 – 1978

Full time out-service fellow in Pediatric Endocrinology,
Johns Hopkins Hospital, 1978 – 1980

Staff Pediatric Endocrinologist, Naval Hospital San Diego,
1980 – 1986

Chairman and Director, Residency Training, Department of Pediatrics
Naval Hospital Oakland, 1986 – 1991

OTHER PROFESSIONAL ACTIVITIES:

Consultant, Pediatric Endocrinology,
Nellis Air Force Base Hospital, Las Vegas, Nevada
1981 – 1991

Consultant, Pediatric Endocrinology,
Naval Hospital Lemoore, CA
1986 – 1991

Consultant, Pediatric Endocrinology,
Letterman Army Medical Center, Presidio of San Francisco, CA
1990 – 1991

Consulting Endocrinologist,
Columbus Regional Medical Center, Columbus, GA
1991 – 1994

Pediatrician and Pediatric Endocrinologist, partner
Fayette Medical Clinic
Peachtree City, Georgia 30269
September 1991 – October 2003

Pediatric Endocrinologist Peer Reviewer 2006 – present
MCMC, LLC, Boston, MA
IMEDECS, Lansdale PA

Speaker's Bureau
Novo Nordisk
AAP Eqipp course on Growth- development committee- 2012

PUBLICATIONS: (Articles in Peer Reviewed Journals)

Riddick, JR, Flora R., Van Meter, QL:
"Computerized Preparation of Two-Way Analysis of Variance Control Charts for Clinical Chemistry," Clinical Chemistry, 18:250, March 1972.

Van Meter, QL, Gareis FJ, Hayes, JW, Wilson, CB:
"Galactorrhea in a 12 Year Old Boy with Chromophobe Adenoma," J. Pediatrics 90:756, May 1977.

Plotnick, LP, Van Meter, QL, Kowarski, AA, "Human Growth Hormone Treatment of Children with Growth Failure and Normal Growth Hormone Levels by Immunoassay: Lack of Correlation with Somatomedin Generation: Pediatrics 71:324, March 1983.

Brawley, RW, Van Meter, QL, "Mebendazole Ascaris Migration," W.J. Med, 145:514015, October 1986.

Van Meter, QL, "The Role of the Primary Care Physician in Caring for Patients with Type-1 Diabetes," Comp Ther 1998; 24(2):93–101

Midyett LK, Rogol AD, Van Meter QL, Frane J, and Bright GM, "Recombinant Insulin-Like Growth factor (IGF)-I Treatment in Short Children with Low IGF-I Levels: First-Year Results from a Randomized Clinical Trial," J Clin Endocrinol Metab, 2010;95:611–619.

Laidlaw MK, Van Meter QL, Hruz PW, Von Mol A, and Malone WJ, Letter to the Editor: "Endocrine Treatment of Gender-Dysphoric/Gender-Incongruent Persons: An Endocrine Society Clinical Practice Guideline," J CLin Endo Metab 2019;104: 1-2.

Van Meter QL, Bringing Transparency to the Treatment of Transgender Persons, Issues in Law and Medicine 2019:34;147-152.

Laidlaw, MK Von Mol A,Van Meter Q, and Hansen JE, Letter to the Editor from Laidlaw et al: "erythrocytoisis in a large cohort of thansgender Men using testosterone: a long-term follow-up study on prevalence, determinants, and exposure years" J Clin Endocrinol Metab, 2021 December 2021, e5275-35276 Https://doi/10.1210/clinem/dg ab514

ABSTRACTS/LETTERS:

Van Meter,Q L, & Lee, PA: "Evaluation of Puberty in Male and Female Patients with Noonan Syndrome," Pediatric Research 14:485, 1980.

Van Meter, QL, et al: "Characterization of Pituitary Function in Double Bolus GnRH Infusion as a Diagnostic Tool," Pediatric Research 32:111, 1984.

Van Meter, QL, Felix, SD, Lin, FL: "Evaluation of the Pituitary-Adrenal Axis in Patients Treated with nasal Beclomethasone," (Presented at the 1991 Annual Meeting of the Endocrine Society and the 6th Annual Naval Academic Research Competition, Bethesda, MD, 17 May, 1991).

Rogol AD Midyett LK Van Meter Q, Frane J, Baily J, and Bright GM, Recombinant Human IGF-1 for Children with Primary IGF-1 Deficiency (IGFD): Safety Data from Ongoing Clinical Trials (presented at the PAS 2007, Toronto).

Van Meter Q, Midyett LK, Deeb L et al, Prevalence of primary IGFD among untreated children with short stature in a prospective, multicenter study (Poster POO715) ICE Rio de Janeiro, Brazil 2008.

G.M. Bright[1], W.V.Moore[2], J.Nguyen[3], G. Kletter[4], B. S. Miller[5], Q. L. Van Meter[6], E. Humphriss[1], J.A. Moore[7] and J.L. Cleland[1] Results of a Phase 1b Study of a new long-acting human growth hormone (VRS-317) in pediatric growth hormone deficiency (PGHD). PAS 2014 May 2014

Van Meter Q, Welstead B and Low J, Characteristics of a Population of Obese Children and Adolescents: Suggesting a New Paradigm, presented at ESPE meeting, Dublin 2014.

Wayne V. Moore[1], Patricia Y. Fechner[2], Huong Jil Nguyen[3], Quentin L. Van Meter[4], John S. Fuqua[5] , Bradley S. Miller[6], David Ng[7], Eric Humphriss[8], R. W. Charlton[8], George M. Bright[8], Safety and Efficacy of Somavaratan (VRS-317), a Long-Acting rhGH, in Children with Growth Hormone Deficiency (GHD): 3-Year Update of the VERTICAL & VISTA Trials, presented at the 2017 Endocrine Society meeting in Orlando FL

Bradley S. Miller[1], Wayne V. Moore[2], Patricia Y. Fechner[3], Huong Jil Nguyen[4], Quentin L. Van Meter[5], John S. Fuqua[6], David Ng[7], Eric Humphriss[8], R. W. Charlton[8], George M. Bright[8], 3-Year Update of the Phase 2a and Long-term Safety Studies (VERTICAL and VISTA) of Somavaratan (VRS-317), a Long-acting rhGH for the Treatment of Pediatric Growth Hormone Deficiency, presented at the 2017 IMPE meeting in Washington D.C.

ADDITIONAL PRESENTATIONS/LECTURES:

Pediatrics Update, CME Associates, San Diego – Orlando Annual Conferences: Lectures on Pediatric Endocrine Subjects – 1986 – 2001. Course Moderator, 1997, 1998, 1999, 2000, 2001

Endocrine and Gastroenterology Update, CME Associates, Maui HI Nov 2001, Lecturer and Course Moderator

Lecture on Panhypopitutarism, Pharmacia Conference, Nashville TN April 2002.

Family Medicine Review Course, Orlando, FL, 1992 – 2001

Pediatric Grand Rounds, Tanner Medical Center, October 1997

Pediatric Grand Rounds, Hughes Spaulding Children's Hospital, September, 2003

Pediatrics in the Park, Fall CME meeting for the Georgia Chapter of the American Academy of Pediatrics, November 2003

Pediatric Grand Rounds, Columbus Regional Medical Center, January 2004

Frontiers in Pediatrics CME Course, sponsored by the Atlanta Children's Health Network, Atlanta, March 2004.

Pediatric Grand Rounds, Eggleston Children's Hospital, May 2004.

Sue Schley Matthews Pediatric Conference, Columbus Regional Medical Center, September 2004

56th Annual Scientific Assembly and Exhibition of the Georgia Academy of Family Physicians, Nov 2004

Program Co-Chairman: Southern Pediatric Endocrine Society Annual meeting, Nov 2004, November 2014

Presentations on Diabetes, Growth Failure, and Thyroid Disease to the Postgraduate Pediatric Nurse Practitioner Program, Georgia State University, Nov 2005, June 2006, May 2007

Issues in Medicine, US Medical Congress Conference and Exhibition, Las Vegas, meeting planner and speaker, June, 2006

CME Presentations for the Georgia Chapter of the American Academy of Pediatrics Spring and Fall Meetings 2004-present

Pediatric Grand Rounds, Columbus Regional Medical Center, Columbus, GA, 2011-present

Human Growth Foundation Regional CME Conference, Atlanta GA March 2013, February 2014 Columbus Georgia

International Federation of Therapeutic Counseling Choice: Transgender Medicine, IFTCC Launch, October 15, 2018 London, Third International Congress, October 25 2018 Budapest.

Southern Pediatric Endocrine Society, Orlando FL, Feb 2019

Matthew Bulfin Conference, Indianapolis IN April 2019

CMDA annual conference, Ridgecrest NC, May 2019

Support 4 Family conference, London, UK June 2019

Audio Digest Pediatrics - ① v. 41, no. 4; ② v. 41, no. 20; ③ v. 43, no. 17

Audio Digest Family Practice - ① v. 42, no. 5; ② v. 44, no. 11; ③ v. 44, no. 44; ④ v. 45, no 15

Audio Digest Otolaryngology - ① v. 32, no. 14

CURRENT HOSPITAL APPOINTMENTS:

Eggleston/Scottish Rite Children's Hospitals, active staff, Pediatric Endocrinology

PAST AND CURRENT CLINICAL RESEARCH:

2006	Sanofi-Aventis HMR1964D/3001	study completed 2007
2006	Tercica MS301-	study completed 2008
2007	Tercica MS310-	study completed 2008
2007	Tercica MS306-	study completed 2010
2007	Tercica MS316-	study completed 2012
2008	EMD Serono 28358	study completed 2009
2012	Versartis 12VR2	study completed 2014
2012	Debiopharm 8206-CPP-301	study started July 2012
2013	Versartis 13 VR3	study started Dec 2013
2014	Novo-Nordisk Elipse	study started 2014
2015	Versartis 14 VR4	study completed 2017
2017	Mannkind MKC-TI-155	study completed 2019
2018	Abbvie M16-904	study started 2018
2019	Novo-Nordisk Real-4	study started 2019
2019	Lilly 18B-MC-ITSB	study started 2019
2021	Pfizer PROGRES	study started 2021

2021	Lumos OragrowtH210	study started July 2021
2022	Novo-Nordisk Real-8	study starts July 2022

LEGAL EXPERT WITNESS:

2017	North Carolina Legislature- transgender bathroom bill
2018	Jessica Siefert transgender case, Cincinnati, OH
2018	Alberta, Canada school system transgender case
2018	Decatur GA School Board transgender case
2019	British Columbia transgender case
2019	Gavin Grimm transgender case, Gloucester County, VA
2019	Rowe vs Isle of Wight School Board, UK
2019	Younger transgender case, Dallas, TX
2020	Alabama State House and Senate committee hearings
2020	Pennsylvania State House Health Subcommittee hearings
2020	Iowa State House committee hearing
2020	California State House committee hearing
2020	Harris Count TX custody case
2021	Missouri State House committee hearing
2021	NAACP *v* State of Arkansas

EXHIBIT "A"

Concerns about Affirmation of an Incongruent Gender in a Child or Adolescent

Quentin L. Van Meter, M.D.
May 17, 2022

Qualifications

I received my B.A. in Science at the College of William and Mary and my M.D. from the Medical College of Virginia, Virginia Commonwealth University. I am currently a pediatric endocrinologist in private practice in Atlanta, Georgia. I am the President of Van Meter Pediatric Endocrinology, P.C. I am on the clinical faculties of Emory University School of Medicine and Morehouse College of Medicine, in the role of adjunct Associate Professor of Pediatrics. I am board certified in Pediatrics and Pediatric Endocrinology. I have been licensed to practice medicine in Georgia since 1991. I have been previously licensed to practice medicine in California, Louisiana, and Maryland.

I did my Pediatric Endocrine fellowship at Johns Hopkins Hospital from 1978-1980. The faculty present at that time had carried on the tradition of excellence established by Lawson Wilkins, M.D. Because of the reputation of the endocrine program as a center for exceptional care for children with disorders of sexual differentiation, I had well-above average exposure to such patients. As a Pediatric Fellow, I was also exposed to adults with Gender Identity Disorder, then called Trans-Sexuality, and received training from John Money, Ph.D., in his Psycho-hormonal Division. Over the past 44 years, I have closely followed the topic of incongruent gender in children adolescents and adults, but I am focusing in this document on working with children and adolescents. To get a more solid understanding of how male and female human beings develop in utero, it is important to start at the point when a sperm meets an egg.

Differentiation in the Fetus

From the moment of conception, a fetus is determined to be either a male (XY), female (XX), or in rare cases, to have a combination of sex-determining chromosomes, many of which are not compatible with life, and some of which are the cause of identifiable clinical syndromes. The presence of a Y chromosome in the developing fetus directs the developing gonadal tissue to develop as a testicle. The absence of a functional Y chromosome allows the gonadal tissue to develop as an ovary. Under the influence of the mother's placental hormones, the testicle will produce testosterone which directs the genital tissue to form a penis and a scrotum. Simultaneously, the testicle produces anti-Müllerian Hormone (AMH) which regresses development of the tissue that would otherwise develop into the uterus, fallopian tubes, and upper third of the vagina. This combination of actions in early fetal development is responsible for what we subsequently see on fetal sonograms, and what we observe at birth as male or female genitalia. It is only when the genital structures are ambiguous in appearance that sex determination is withheld until a thorough expert team evaluation has occurred.

For reasons most often occurring as random events, there are malfunctions of the normal differentiation. These aberrations of normal development are responsible for what we classify as Disorders of Sexual Differentiation (DSD), and they represent a very small fraction of the human population. The incidence of such circumstances occurs in 1:4500 to 1:5500 births.[1] Sex is binary, male or female, and is determined by chromosomal complement and corresponding reproductive role. The exceedingly rare DSDs are all medically identifiable deviations from this sexual binary norm. The 2006 consensus statement of the Intersex Society of North America and the 2015 revision of the Statement do not endorse DSD as a third sex.[2] DSD outcomes range from appearance of female external genitalia in an XY male (complete androgen insensitivity syndrome) to appearance of male external genitalia in an XX female (severe congenital adrenal hyperplasia).

As one would expect, there are variations of the degree of hormonally driven changes that create ambiguous genital development that prevent assigning of a specific classification as either male or female at birth. DSD patients are not "transgender"; they have an objective, physical, medically verifiable, physiologic condition. Transgender people generally do not have intersex conditions or any other verifiable physical anomaly. People who identify as "feeling like the opposite sex" or "somewhere in between" do not comprise a third sex. They remain biological men or biological women.

In some DSDs there exist more than one set of chromosomes. When there is a divergence of the appearance of the external genitalia from the chromosomally determined sex due to the presence of both an ovarian and testicular cell lines in a patient simultaneously, the patient is classified as having ovo-testicular DSD (formerly termed a true hermaphrodite). When there is a disruption in the development of genital structures but there is solely testicular tissue present in the chromosomal male or solely ovarian tissue in the chromosomal female, the term 46 XY DSD or 46 XX DSD is used instead respectively (formerly termed male pseudohermaphrodite or female pseudohermaphrodite).

The decision to assign a sex of rearing is complex and is specific to the diagnosis. Patients with complete androgen insensitivity (CAIS) are XY DSD but are never reared as a male. Because testosterone never influences development, they become happy, functional female adults with infertility. Females with severe congenital adrenal hyperplasia (CAH) are XX DSD but are not reared as males despite the male appearance of the genitalia at birth. Although these girls may show a tendency for male play behaviors as children, they generally assume a female sexual identity. Therapeutic interventions in the DSD individuals from infancy onward are aimed at what function can be expected from their disordered sexual anatomy in terms of function and fertility. Most often, the chromosomal sex aligns with the sex of rearing.

Gender Identity

"Gender" is a term that refers to the psychological and cultural characteristics associated with biological sex. It is a psychological concept and sociological term, not a biological one. The term gender possessed solely a linguistic meaning prior to the 1950s. This changed when sexologists of the 1950s and 1960s co-opted the term to conceptualize cross-dressing and transsexualism in their psychological practice. "Gender identity" is a term coined by my former endocrine faculty member John Money in the 1970s and has come to refer to an individual's mental and emotional sense of being male or female. The norm is for individuals to have a gender identity that aligns with one's biological sex.

Gender discordance (formerly Gender Identity Disorder) is used to describe a psychological condition in which a person experiences marked incongruence between his experienced gender and the gender associated with his biological sex. He will often express the belief that he is the opposite sex. Up until 2010, gender discordance occurred in 0.001% of biological females and in 0.0033% of biological males.[3] Exact numbers are hard to document since reporting is often anecdotal. Gender discordance is not considered a normal developmental variation.

"Gender Dysphoria" is a diagnostic term to describe the emotional distress caused by gender incongruity.[4] John Money played a prominent role in the early development of gender theory and transgenderism. He understood gender to be "the social performance indicative of an internal sexed identity."[5] He joined the Johns Hopkins faculty in 1951 specifically to have access to children diagnosed with DSD, hoping to prove his theory that gender was arbitrary and fluid. Money experimented with DSD infants by assigning them to the opposite biological sex through surgical revision, counseling, and hormonal manipulation during puberty. His mode of operation was to have a theory and then experiment with patients to see how his theory worked.

Ethics in Clinical Research on Human Subjects

It is important to discuss the need for ethics to play a role in the design of clinical studies involving human patients. To have a hypothesis, as did John Money, is not at issue. However, to clearly elucidate the potential for harm and balance that knowledge with the potential benefits is key and essential. After the travesties of open-ended experimentation in the Nazi concentration camps, international guidelines were established to protect human subjects from just such experimentation.[6] John Money ignored these guidelines as he assigned genders to infants and toddlers with ambiguous genitalia. There was no informed consent of the patients, who were infants and toddlers, and their parents were just told to follow the advice of Dr. Money and to trust that he had the correct information. There was no standardized protocol to follow, and no known outcome that could be guaranteed. This kind of endeavor did not anticipate or prevent adverse outcomes and was the antithesis of ethical science. Money never submitted his research proposals for review by an independent external review board. This left the patients unprotected and vulnerable to harm, and, indeed, in the case of the Reimer twins, to death due to drug addiction/overdose in one brother to and suicide in the other.[7]

Near the end of my fellowship training at Johns Hopkins, a male infant was sent to our clinic to assess the cause of his very small penis and testicles. My attending physician and I laid out a diagnostic work-up based on the known science which would help us understand whether the problem was due to a pituitary deficiency or an inability of tissue response to hormones. We purposely left John Money off the care "team," having some serious concerns about his tendency to dismiss science and to experiment. We sent the family home with their son and were quite surprised when the mother returned six weeks later with a baby wearing a pink dress and an eyelet bonnet. Without our knowledge, Dr. Money had intervened and told the family that our protocol was nonsense and the baby needed to be reared as female. On physical exam, there was clear evidence that not only was the baby able to produce testosterone, but his penis responded well, as expected, to the hormone production by his own body. The family was relieved but had not been spared suffering under the experimentation by Dr. Money. They had suffered deeply when they divulged to their extended family that their baby boy was actually a baby girl, and then they suffered even more when they recanted and resumed calling him a boy.

Because of his experience with infants, Money initially garnered support from endocrine colleagues and surgical colleagues, and Johns Hopkins became a renowned center for care of patients with DSD in the 1970s, receiving referrals from around the world. Follow-up studies on these infants later showed, however, that altering their natal sexual identity via social intervention could lead to severe psychological harm. Clinical case reports of children with DSD have revealed that gender identity is indeed not immune to environmental input.[8]

Meanwhile, Money had expanded into the field of adult patients with persistent gender identity disorder. This very small group of patients chose voluntarily, as adults, to enter a very precise protocol which began with living socially as the opposite sex for a year, eventually receiving hormonal therapy to change their physical appearance to some extent. The final step was surgical revision of the body structures that would otherwise be at odds with their desired gender identity. This small group of patients was followed for a number of years past their final surgical procedures and required continuous counseling. These patients expressed some degree of subjective satisfaction but showed no objective improvement in overall wellbeing.[9] The legacy of John Money fell into disrepute and the transsexual treatment program at Johns Hopkin was closed in the 1980s based on the lack of evidence that this protocol produced an effective cure.

Etiology of Gender Disorders

Transgender affirming professionals claim transgender individuals have a "feminized brain" trapped in a male body at birth and vice versa based upon various brain studies. Diffusion-weighted MRI scans have demonstrated that the pubertal testosterone surge in boys increases white matter volume. A study by Rametti and colleagues found that the white matter microstructure of the brains of female-to-male (FtM) transsexual adults, who had not begun testosterone treatment, more closely resembled that of men than that of women.[10] Other

diffusion-weighted MRI studies have concluded that the white matter microstructure in both FtM and male-to-female (MtF) transsexuals falls halfway between that of genetic females and males.[11] These studies, however, are of limited clinical significance due to the small number of subjects and failure to account for neuroplasticity.

Neuroplasticity is the well-established phenomenon in which long-term behavior alters brain microstructure. For example, the MRI scans of experienced cab drivers in London are distinctly different from those of non-cab drivers, and the changes noted are dependent on the years of experience.[12] There is no evidence that people are born with brain microstructures that are forever unalterable, but there is significant evidence that experience changes brain microstructure.[13,14] Therefore, any transgender brain differences would more likely be the result of transgender behavior than its cause.

Furthermore, infants' brains are imprinted prenatally by their own endogenous sex hormones, which are secreted from their gonads beginning at approximately eight weeks' gestation.[15,16,17] There are no published studies documenting MRI-verified differences in the brains of gender-disordered children or adolescents. The DSD guidelines also specifically state that current MRI technology cannot be used to identify those patients who should be raised as males or raised as females.[18] Behavior geneticists have known for decades that while genes and hormones influence behavior, they do not hard-wire a person to think, feel, or behave in a particular way. The science of epigenetics has established that genes are not analogous to rigid "blueprints" for behavior. Rather, humans "develop traits through the dynamic process of gene-environment interaction. ... [genes alone] don't determine who we are." [19]

Regarding transgenderism, twin studies of adults prove definitively that prenatal genetic and hormone influence is minimal. The largest twin study of transgender adults found that only 20 percent of identical twins were both transgender-identified.[20] Since identical twins contain 100 percent of the same DNA from conception and develop in exactly the same prenatal environment exposed to the same prenatal hormones, if genes and/or prenatal hormones contributed to a significant degree to transgenderism, the concordance rates would be close to 100 percent. Instead, 80 percent of identical twin pairs were discordant. This difference would indicate that at least 80 percent of what contributes to transgenderism as an adult in one co-twin consists of one or more non-shared post-natal experiences including but not limited to non-shared family experiences. These findings also mean that persistent GD is due predominately to the impact of nonshared environmental influences. These studies provide compelling evidence that discordant gender is not hard-wired genetically.

Gender Dysphoria vs. Gender Identity Disorder

Up until the recent revision of the DSM-IV criteria, the American Psychological Association (APA) held that Gender Identity Disorder (GID) was the mental disorder described as a discordance between the natal sex and the gender identity of the patient. Dr. Kenneth Zucker, who is a highly respected clinician and researcher from Toronto, carried on evaluation and

treatment of GID patients for forty years. His works, widely published, found that the vast majority of boys and girls with GID identify with their biological sex by the time they emerge from puberty to adulthood, through either watchful waiting or family and individual counseling.[21] His results were mirrored in studies from Europe.[22,23]

When the DSM-V revision of the diagnosis of GID was proposed by the APA committee responsible for revision, Dr. Zucker strongly opposed the change to the term Gender Dysphoria, which purposefully removed gender discordance as a mental disorder apart from the presence of significant emotional distress. With this revision, Gender Dysphoria describes the mental anguish which is experienced by the gender discordant patient. The theory that societal rejection is the root cause of Gender Dysphoria was validly questioned by a study from Sweden which showed that the dysphoria was not eliminated by hormones and sex reassignment surgery even with widespread societal acceptance.[24]

Treatment of Gender Dysphoria

The treatment of children and adolescents with gender discordance and accompanying gender dysphoria should include an in-depth evaluation of the child and family dynamics. This evaluation provides a basis on which to proceed with psychologic therapy. The entire biologic and social family should be involved in psychological therapy designed to assist the patient, if at all possible, to align gender identity with natal sex. Psychological support by competent counselors with an intent of resolving the gender conflict should be provided as long as the patient continues to suffer emotionally. Given the high degree of eventual desistance of gender discordance/dysphoria by the end of puberty, it would be ethical and logical to counsel the patient and family to rear the child in conformity with natal sex.

There should be no interruption of natural puberty. Natural pubertal maturation in accordance with one's natal sex is not a disease. It is designed to carry malleable, immature children forward to be healthy adults capable of conceiving their own progeny by providing either a sperm or an egg. Puberty affects physical changes, some of them painful, unique to the natal sex to reflect the laws of nature. Interruption of puberty has been reserved for children who begin puberty at an age much younger than normal in an effort to preserve final height potential and avoid the social consequences of precocious maturation.[25]

There are a number of physical changes that are a consequence of normally timed puberty that could be classified as disadvantageous: changes in body proportions can alter success with dance and gymnastics; acne can be severe and disfiguring; a boy soprano can suddenly hardly carry a tune. It has not been the ethical standard of care to stop puberty so that these changes can be circumvented. Erikson described the stage of adolescence as "Identity versus Role Confusion" during which the teen works at developing a sense of self by testing roles then integrating them into a single identity.[26] This process is often unpleasant regardless of the presence or absence of gender identity conflicts. The major benefit of enduring puberty in a GD patient is that it provides a strong likelihood of alignment of his gender identity with his

natal sex. There is no doubt that these patients need compassionate care to get them through their innate pubertal changes.

The light at the end of the tunnel is the proven scientific evidence that 80%- 95% of pre-pubertal children with GD will come to identify with their biological sex by late adolescence. Some will require lifelong supportive counseling while others will not.[27] Intervention at a young age with gonadotropin releasing hormone analogs (often referred to as puberty blockers) to either stop puberty early on or prevent it from starting before it naturally occurs is suggested by guidelines developed by WPATH without scientific basis. These guidelines are essentially nothing more than an open-ended experiment in the manner of John Money. They represent the ideas of their authors with clear admission that there is no long-term evidence that harm will exceed benefits as these patients grow to old age. There is evidence that bone mineral density is irreversibly decreased if puberty blockers are used during the years of adolescence.[28] To treat puberty as a pathologic state of health that should be avoided by using puberty blockers (GnRH analogs) is to interrupt a major necessary physiologic transformation at a critical age when such changes can effectively happen. We have definite evidence of the need for estrogen in females to store calcium in their skeleton in their teen years. That physiologic event can't be put off successfully to a later date. It is very difficult to imagine ethical controlled clinical trials that could elucidate the effects of delaying puberty until the age of consent.

The use of cross-sex hormones during this same time frame has no basis of safety and efficacy. The use of such treatment in adults raises scientifically valid concerns that were amply expressed in the 2009 Endocrine Society Guidelines on Transgender treatment. The next step in WPATH-recommended intervention is to use cross-sex hormone therapy during the time when the patient would naturally be experiencing endogenous pubertal changes. This too is not based on scientifically proven theories. The use of cross-sex hormones can cause permanent infertility.[29]

The final recommended step is so-called "sex reassignment surgery," which can include surgical removal of the breasts in natal females, or removal of the penis and scrotum in natal males. Each of these steps has adverse outcomes, some reversible and others not. Mastectomies leave scars, and there is great difficulty in creating a functional vaginal-like orifice, and certainly no success in creating an innervated erectile penis where none existed previously. Sex reassignment surgery is, by nature, permanent.

Recurrent Themes that Are Repeatedly Published

Puberty blockers are stated to be completely reversible in their effects on the adolescent who has entered puberty based on clinical studies in young children with precocious puberty who have been treated with these drugs. This is comparing apples to oranges. Precocious puberty, by definition, is defined as puberty which starts before the 8th birthday for a female child or the before the 9th birthday in a male child. The end of treatment is carefully timed so that resumption of puberty occurs at the average age for females (10.5 years) and males (11.5

years). This allows the necessary functions of puberty to prepare the body for reproduction and affects the bones, gonads, and brain, among other body systems. On the other hand, blocking puberty at the age of normal puberty prevents the needed accretion of calcium into the skeleton and prevents the maturation of the gonads. There is no long-term data that compares bone, gonad, and brain health in pubertal-aged patients who have had puberty interrupted and those who have not, as was noted as a concern in the Endocrine Society Guidelines. There are no such ongoing studies completed that guarantee the full reversibility of blocking puberty in this age group, but there is evidence that normal bone density can't be fully reestablished. Without any verifiable safety data, using the puberty blockers for interrupting normal puberty is not a sanctionable off-label use of these drugs and is therefore to be considered uncontrolled, non-consentable experimentation on children.

Advocates for the social, medical and surgical affirmation of gender incongruent children insist that they are only following established standards of care. There are no standards of care for transgender health. Standards of care established by broad consensus are reached by inclusion of the whole spectrum of opinions, clinical experience and published science in the formation thereof. The guidelines published by WPATH[30], the Endocrine Society,[29,31] the American Academy of Pediatrics[32], and the Pediatric Endocrine Society[33] are solely the opinions of like-minded practitioners who excluded any contrary opinion. The Endocrine Society Guidelines, as mentioned before, clearly stated that they are not to be considered standards of care. Before true consensus-driven standards of care are established for the treatment of transgender patients of all ages, following the current guidelines is risky experimentation in a manner reminiscent of John Money's tactics.

What We Do Know and Do Not Know

We do know that social affirmation of an incongruent gender tears the fabric of the patient's life into pieces- pitting family members against each other, ruining child friendships and it introduces the child to a fantasy world, much of it on the internet. Kenneth Zucker aptly documented the detrimental effects of such affirmation and the immense amount of work it takes to undo these effects when the child does come to realize they can't change their sex and wants to go back to identifying with their sex[34]. We do not know that social affirmation does anything other than push the child away from the proven, 80-90% effective, so-called watch-and wait treatment option. Embarrassingly unscientific short term convenience sample studies purport to show that all gender incongruent children who are socially affirmed have improved mental health and are therefore better off than those children who are not allowed to socially transition.[35]

We do know that blocking puberty during the age when puberty naturally happens lessens accretion of calcium into the skeleton and that this can't be regained by allowing puberty to resume or by using cross sex hormones. We do know that the ovary and testicle cease to mature with treatment. What we do not know is whether allowing puberty to resume will allow the ovary and testicle to fully mature and have full function in terms of fertility. We do

not know if brain development that is halted with puberty blockers can return to full function once puberty is allowed to resume.

We do know that elevated levels of testosterone in females and of estrogen in males create significant medical morbidity. This knowledge comes from the evaluation and treatment of naturally occurring disease states in children and adults. Treatment of these conditions is aimed at returning hormone levels to normal, thereby avoiding cancers, heart disease, and stroke. We do not know that elevating testosterone in females and estrogen in males to levels ten-fold higher than these known disease states is safe, but common sense would say it can't possibly be safe.

The Myth of Increased Suicide

The affirmation advocates repeatedly refer to the established increased risk of suicide if any of the affirmation strategies are not followed to completion. They point to their own published studies touting dramatic improvement in mental health status of patients who are affirmed in all three ways, but they cite data from convenience sampling, which never should be sued to prove anything other than association, at best. Such studies can never prove causation. There are only two total population studies in the peer-reviewed medical literature.[24,36,37] They show that when every recorded case in the population of Sweden was analyzed, neither medical affirmation nor medical affirmation followed by surgical affirmation improved the mental health of the patients in the long run.

What of the Nearly Logarithmic Increase in Incidence of Gender Incongruence?

Data collection in this regard is subject to estimates based on surveys, which can easily alter the numbers upward or downward, depending on who designed the survey and to whom it was presented. Fear, self-loathing or suicide will necessarily lower the numbers of survey participants whose lives are made miserable by the choice to affirm an incongruent gender. Instant gratification, payback to strict parents, and current celebrity will draw survey participants to express euphoric satisfaction with their decision to affirm their incongruent gender, especially when the surveys are circulated by trans-activist organizations, such as the Trevor Project. What had been in 2010 a nearly invisible fraction of adults who admitted to living with an incongruent gender has exponentially increased in frequency to as many as one out of five students in a suburban Pittsburgh school district in 2021. After I completed my fellowship at Johns Hopkins in 1980, it was not until 1993 that a biologic male presented to my private practice office with a desire to be treated with estrogen to feminize his body so that he could appear to be a female and identify as such. There was nothing in published medical literature that I could find to guide my treatment options. I canvassed my broad contact pediatric endocrinology network across the United States, and nobody had heard of such a clinical case, and none had any suggestions about what I should do. In the ensuing 19 years, the number of transgender treatment centers have burgeoned from zero to several hundred between university-based centers and Planned parenthood. Minority stress theory is frequently used to cover this explosion in numbers, but that is utterly impossible. What does

explain this increase is online recruiting and grooming of vulnerable children and adolescents by a generously funded political movement aimed at dissolving the reality and birthright of biologic sex. This will not end well. By the time a plethora of legal action against those who promoted and engineered the social, medical, and surgical affirmation of incongruent gender knocks down this house of cards, millions of children and adolescents will have been medically, surgically, and mentally maimed as well sterilized.

Endnotes

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Appendix Attachment

6

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF FLORIDA
TALLAHASSEE DIVISION

AUGUST DEKKER, et al.,

Plaintiffs,

v. Case No. 4:22-cv-00325-RH-MAF

SIMONE MARSTILLER, et al.,

Defendants.
_____/

DECLARATION OF ANDRE VAN MOL, MD

I, ANDRE VAN MOL, MD am submitting this declaration in support of the Agency for Healthcare Administration's (AHCA) response in opposition to the Plaintiffs' motion for preliminary injunction.

1. This declaration provides the following expert opinions, which are explained in further details below:

a. The expert declaration of Dr. Armand H. Matheny Antommaria is in error regarding his stated primary objections to the Florida Agency for Health Care Administration (AHCA) Medicaid's Generally Accepted Professional Medical Standards Determination of Treatment of Gender Dysphoria (GAPMS

Report) specified in his assertions that Florida AHCA "mischaracterizes":

i. "individuals as diagnosing themselves with gender dysphoria,"

ii. "treatments for gender dysphoria and "off-label" treatments as experimental,"

iii. "treatments of gender dysphoria as "eminence-based medicine" and

the evidence base supporting many medical treatments, and"

iv. the informed consent process for the treatment of gender dysphoria

BACKGROUND AND QUALIFICATIONS

2. I am a board-certified family physician in full-time practice in California where I am licensed to practice.

3. In 1986 I received my medical degree from the Medical College of Wisconsin. I completed flight surgeon training in the US Navy in 1988 at the Naval Aerospace Medical Institute in 1988. My family medicine residency was completed in 1992 at Charleston Naval Hospital in South Carolina.

4. I have been licensed to practice medicine in California since 1988 and have been certified by the American Board of Family Practice since 1993.

5. My practice of family medicine is entirely clinic based, caring for patients from neonates to the elderly. I have no academic appointments.

6. I serve the American College of Pediatricians, with whom I am a fellow, as Co-chair of the Council on Adolescent Sexuality and the Christian Medical & Dental Associations as Co-chair of the Sexual & Gender Identity Task Force. I am a member of the American Academic of Family Physicians. I work with Alliance Defending Freedom in a coalition of professionals advising on policy matters addressing sexual orientation and gender identity, including serving as amicus curiae/friend of court in federal appellate and SCOTUS cases.

7. I am author or co-author of six peer-reviewed commentaries and letters, and author of numerous articles in professional and general publications in the USA and abroad.

8. I am an active peer reviewer for several medical journals.

9. I previously offered an expert witness affidavit in Court of Appeal File No. CA45940, Vancouver Registry. B.C. Supreme Court File No. E190334, between A.B. Respondent/Claimant, and C.D. Appellant/Respondent, and E.F. Respondent/Respondent. July 23, 2019.

10. I have served federal courts as a medical professional *amicus curiae* in:

Harris Funeral Homes, Inc. v. EEOC, No. 18-107 (U.S. Supreme Court, July 24, 2018); *Adams v. School Board of St. Johns County, Florida*, No. 18-13592 (11th Cir. Aug. 23, 2018); *Doe v. Boyertown Area School District*, No. 18-658 (3rd Cir. Nov. 21, 2018); *Meriwether v. Trustees of Shawnee State University*, No. 20-3289 (6th Cir. Mar. 12, 2020); *Hecox v. Little*, Nos. 20-35813 (9th Cir., Nov. 19, 2020); *Adams v. School Board of St. Johns County, Florida*, No. 18-13592 (11th Circuit, Oct. 26, 2021); and *Brandt v. Rutledge*, No. 21-2875 (8th Circuit, Nov. 14, 2021).

11. I have provided written reports, consultation by teleconferences, and/or written testimony to many state legislatures and several parliaments on proposed legislation concerning gender dysphoria and sexual minority issues. I have testified in legislative committees in both California (2018) and Ohio (2022) regarding gender dysphoria related legislation.

12. I have been contracted by the state of Florida Department of Medicaid, and continue to work with them as a registered vendor in the state of Florida, in the preparation of the GAPMS Determination on the Treatment of Gender Dysphoria and the General Medicaid Policy Rule 59G-1.050 rule exclusion (7) Gender Dysphoria.

13. I am being compensated at a rate of $350 an hour for preparation of expert declarations and reports, and $600 per hour for time spent preparing for or giving deposition or trial testimony. My compensation is independent of the outcome of said efforts and litigation, my stated opinions, or the content of my testimony.

GENDER DYSPHORIA AS A MEDICAL DIAGNOSIS BUT ALSO A SELF-DIAGNOSIS

14. The Matheny Antommaria declaration is correct that gender dysphoria is a medical diagnosis, which is not quite the point addressed when the GAPMS report notes that it arrives as a self-diagnosis. The Matheny Antommaria declaration then concedes on page 7, "The diagnosis of gender dysphoria in adolescents and adults, like many other common medical diagnoses, relies on individuals' self-report of symptoms." Yes, it does. The problem is that proper, extensive psychological evaluation and support of the gender dysphoric patient and family both is not assured or even consistent. And there is tremendous pressure on the clinician to affirm upon request. This deficiency is internationally recognized.

15. Psychiatry professor Stephen B. Levine observed that "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)."[1] Self-diagnosis has limits, and the risk from it rises the further the self-diagnosis is allowed to mandate treatment options.

16. Professor Levine notes elsewhere that "The World Professional Association for Transgender Health's Standards of Care recommend an informed consent process, which is at odds with its recommendation of providing hormones on demand."[2] Again, the common practice of self-diagnosis leads to a common demand of medicalization.

17. The Interim Cass Review from the United Kingdom[3] resulted in the closure of the world's largest pediatric gender clinic, the National Health Service's Gender Identity Development service, or GIDS.[4] "The Cass Review specified on page 17, "1.14 Primary and secondary care staff have told us that they feel under pressure to adopt an unquestioning affirmative approach and that this is at odds with the standard process of clinical assessment and

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diagnosis that they have been trained to undertake in all other clinical encounters." Page 17 states "1.15 Another significant issue raised with us is one of diagnostic overshadowing – many of the children and young people presenting have complex needs, but once they are identified as having gender-related distress, other important healthcare issues that would normally be managed by local services can sometimes be overlooked." Thus, the very presence of gender-related distress resulted in other mental health concerns being pushed aside, or "overshadowed".

18. The UK NHS's GIDS experienced the resignation of thirty-five psychologists over a three year period due to the over-prescribing of the medicalization of minors with gender dysphoria "with psychologists unable to properly assess patients over fears they will be branded 'transphobic...'" It was added, "we fear that we have had front row seats to a medical scandal."[5]

19. A prospective study from an Australian multidisciplinary gender service in 2021 revealed "Key challenges faced by the clinicians included the following: the effects of increasingly dominant, polarized discourses on daily clinical practice; issues pertaining to patient and clinician safety (including pressures to abandon the holistic [biopsychosocial] model); the difficulties of

[5] "NHS 'over-diagnosing' children having transgender treatment, former staff warn," news.sky.com, 12 Dec. 2019. https://news.sky.com/story/nhs-over-diagnosing-children-having-transgender-treatment-former-staff-warn-11875624 .

untangling gender dysphoria from comorbid factors such as anxiety, depression, and sexual abuse; and the factual uncertainties present in the currently available literature on longitudinal outcomes."[6]

20. The Matheny Antommaria declaration furthermore states on page 7, "Like gender dysphoria, there is no confirmatory laboratory or radiographic study for the diagnosis of migraine headaches." But the approved and off-label treatments for migraines do not risk sterility, compromised sexual function, brain development, heart attacks, strokes, blood clots, or cancer in the way puberty blocking agents and cross-sex hormones do.[7][8][9][10]

21. One must weigh the risks against the benefits as well as alternatives, and the alternative of psychological treatment of patient and family is not proven inferior to gender (transition) affirming interventions, as

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[8] Alzahrani, Talal, et al. "Cardiovascular Disease Risk Factors and Myocardial Infarction in the Transgender Population." Circulation: Cardiovascular Quality and Outcomes, vol. 12, no. 4, 2019, doi:10.1161/circoutcomes.119.005597.

[9] Getahun D, Nash R, Flanders WD, Baird TC, Becerra-Culqui TA, Cromwell L, et al. Cross-sex Hormones and Acute Cardiovascular Events in Transgender Persons: A Cohort Study. Ann Intern Med. [Epub ahead of print 10 July 2018]169:205–213.doi: 10.7326/M17-2785.

[10] Irwig MS. Cardiovascular Health in Transgender People. Rev Endocr Metab Disord. 2018 Aug 3 epub.

noted in Dr. Cantor's Attachment D in the GAPMS report. Extensive and continuing psychological intervention is a priority in the new guidelines for treatment of gender dysphoria now noted in the United Kingdom, Sweden, Finland, and France, as noted adeptly in Dr. Cantor's Attachment D.

22. Self-reporting is a low-certainty form of diagnosis when other more precise diagnostic tools exist, such as the Diagnostic and Statistical Manual (DSM) of the American Psychiatric Association. When affirmation on demand is common, clear diagnosis and addressing of underlying factors becomes uncommon, leaving the patient to suffer with unresolved psychological distress, adverse childhood experiences, neurodevelopmental disorders like autism spectrum, and possible poor family dynamics, as noted in the literature.[11][12][13]

23. The Matheny Antommaria declaration states on page 8, "Only licensed healthcare providers or teams of providers, based on patient reports and, in the case of minors, parent reports, make the diagnosis of gender

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[11] Kozlowska K, McClure G, Chudleigh C, et al. Australian children and adolescents with gender dysphoria: Clinical presentations and challenges experienced by a multidisciplinary team and gender service. *Human Systems*. 2021;1(1):70-95. doi:10.1177/26344041211010777

[12] Becerra-Culqui TA, Liu Y, Nash R, et al. Mental Health of Transgender and Gender Nonconforming Youth Compared with Their Peers. Pediatrics. 2018;141(5):e20173845

[13] Heylens G, et al. "Psychiatric characteristics in transsexual individuals: multicentre study in four European countries," The British Journal of Psychiatry Feb 2014, 204 (2) 151-156; DOI: 10.1192/bjp.bp.112.121954.

dysphoria and any subsequent treatment recommendations." Were that the case, Planned Parenthood clinics would not be one of the largest sources of gender (transition) affirming hormones in the USA, with their availability boldly advertised on their web page.[14]

GENDER (TRANSITION) AFFIRMING MEDICAL INTERVENTIONS ARE VIEWED AS EXPERIMENTAL BY MANY

24. The Matheny Antommaria declaration stated on page 9, "the GAPMS Memo uses the term "experimental" or "investigational" to convey that gender-affirming medical care is new, untested, or different, that suggestion is baseless." Yes, it is not new, but assertions and evidence abound of gender (transition) affirming medical care being insufficiently tested, still investigational, and experimental despite its age. I will discuss this further in the section on lack of evidence-basing for G(T)AMC, but note here that the declaration paragraph 4 lists the 2011 de Vries, et al study[15] as the inaugural example of the "Prospective observational trials of puberty blockers" supporting their use in gender dysphoria.

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[14] Planned Parenthood "Transgender Hormone Therapy" web page https://www.plannedparenthood.org/get-care/our-services/transgender-hormone-therapy .

[15] de Vries AL, Steensma TD, Doreleijers TA, Cohen- Kettenis PT. Puberty suppression in adolescents with gender identity disorder: A prospective follow-up study. J Sex Med. 2011;8(8):2276-2283.

25. Levine, et al, wrote that both the 2011 de Vries, et al, puberty blocking study and its sister study dealing with surgeries "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..." and that "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." Levine, et al, conclude, "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." And this appears to be the case with this point of the Matheny Antommaria declaration.

26. Prof. Michael Biggs of Oxford published a recent detailed critique of the Dutch Protocols in which he asserted "The Dutch clinicians chose incommensurable scales to measure gender dysphoria, which calls into

question their finding that dysphoria declined following cross-sex hormones and surgery."[16]

27. One of those Dutch clinicians, Thomas Steensma, co-author of the studies in question, reported to the Dutch media "Little research has yet been done on the treatment with puberty inhibitors and in young people. That is why it is also seen as experimental." [17] Dr. Steensma cautioned that "The rest of the world is blindly adopting our research."

28. The Matheny Antommaria declaration protests in paragraphs 24 and 25 that "off-label" does not mean experimental, untested, or unsafe, and further specifies, "Once the FDA has approved a medication for one indication,[12] thereby agreeing that it is safe (i.e., its benefits outweigh its potential risks) and effective for this intended use, as is the case with the medications at issue here, prescribers are generally free to prescribe it for other indications." But a more direct quote from the FDA Website warns: "If you and your healthcare provider decide to use an approved drug for an

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[16] Michael Biggs (2022): The Dutch Protocol for Juvenile Transsexuals: Origins and Evidence, Journal of Sex & Marital Therapy, DOI: 10.1080/0092623X.2022.2121238.

[17] https://www.ad.nl/nijmegen/dringend-meer-onderzoek-nodig-naar-transgenderzorg-aan-jongeren-waar-komt-de-grote-stroom-kinderen-vandaan~aec79d00/ reported in "Dutch Doctor Who Pioneered Early Transgender Treatment Says World is "Blindly" Adopting His Approach," March 12, 2021, Minnesota Family Council The Family Beacon. https://www.mfc.org/familybeacon/dutch-doctor-who-pioneered-early-transgender-treatment-says-world-is-blindly-adopting-his-approach

unapproved use to treat your disease or medical condition, remember that FDA has not determined that the drug is safe and effective for the unapproved use."[18] Safe and effective for a given approved indication should not be assumed to mean safe and effective for any other.

29. The Matheny Antommaria declaration claims on page 13, "The GAPMS Memo misleadingly notes that testosterone is a Schedule III controlled substance because of its 'high probability of abuse.'" The US FDA does not support this Matheny Antommaria claim. An FDA statement from October 25, 2016 is titled, "FDA approves new changes to testosterone labeling regarding the risks associated with abuse and dependence of testosterone and other anabolic androgenic steroids (AAS)."[19] It details "class-wide labeling changes for all prescription testosterone products" to this effect, "to include new safety information from published literature and case reports regarding the risks associated with abuse and dependence of testosterone and other AAS."

GENDER (TRANSITION) AFFIRMING MEDICAL CARE LACKS THE EVIDENCE BASE IT SHOULD HAVE AT THIS POINT

[18] https://www.fda.gov/patients/learn-about-expanded-access-and-other-treatment-options/understanding-unapproved-use-approved-drugs-label .
[19] https://www.fda.gov/drugs/drug-safety-and-availability/fda-approves-new-changes-testosterone-labeling-regarding-risks-associated-abuse-and-dependence .

30. Paragraph 29 of the Matheny Antommaria Declaration protests, "AHCA also incorrectly characterizes gender-affirming medical treatment as lacking sufficient evidence of safety and efficacy." This accusation does not hold up well to scrutiny.

31. The Matheny Antommaria Declaration repeats a false belief stated in para. 35, "Under the applicable ethical standards, randomized, placebo-controlled

trials that compare pharmacological treatment to no pharmacological treatment in gender dysphoria are currently unethical." Para. 31 states, "randomized controlled trials may not be feasible or ethical..."

32. Oxford's Michael Biggs' critique of what has been known as the Dutch Protocol derived from de Vries, et al. ("The Dutch Protocol for Juvenile Transsexuals: Origins and Evidence")[20] targets this false claim and its pre-ordained conclusions, observing that the study authors excuse that ".. it would have been unethical to withhold GnRHa from the control group, because the clinicians believed the treatment to be beneficial—this rationale is circular because discovering whether a treatment is truly beneficial requires a randomized control trial." As a consequence of their choice, "The decision to

[20] Michael Biggs (2022): The Dutch Protocol for Juvenile Transsexuals: Origins and Evidence, Journal of Sex & Marital Therapy, DOI: 10.1080/0092623X.2022.2121238

rely on uncontrolled studies was exacerbated by other decisions. The Dutch clinicians chose incommensurable scales to measure gender dysphoria, which calls into question their finding that dysphoria declined following cross-sex hormones and surgery."

33. Yet reproducibility is critical to the advancement of science. A 2005 PLOS Medicine article by Stanford's P.A. Ioannidis was titled "Why Most Published Research Findings Are False." Ioannidis asserted this was true "for Most Research Designs and for Most Fields," adding "...research findings may often be... accurate measures of the prevailing bias," and that the hotter the field, the more likely the error.[21] And the gender dysphoria field would be accurately described as "hot." A 2015 study in Science journal assembled teams of 270 scientists on 5 continents to repeat 100 studies in three major psychology journals. The results were that only one-third to one-half of the studies were reproducible, meaning one-half to two-thirds were not.[22] The National Association of Scholars published "The Irreproducibility Crisis of

[21] "Why Most Published Research Findings Are False,' John P. A. Ioannidis, August 30, 2005 PLOS Medicine. DOI: 10.1371/journal.pmed.0020124.
[22] "Estimating the reproducibility of psychological science," Science, 28 August 2015: Vol. 349 no. 6251. DOI: 10.1126/science.aac4716.

Modern Science" in 2018, calling detailed attention to the problem, a problem which is abundant in gender (transition) affirming medical care.[23]

34. There is no field of science or medicine so nailed down, so certain, so overwhelmingly proven as to rise above the continuing need for controlled studies under strict ethical supervision and ongoing critical review. Assertions of it being unethical to do so in G(T)AMC are premature, pre-emptive, and unmerited.

35. There is another factor for those insisting that undertaking randomized, controlled trials in gender care would be unethical, and that is the mistaken premise that the gender dysphoric control group would be denied any therapy. But in clinical trials only the independent variable – the intervention under study -- is different between the control and the experimental groups. This means all study participants could benefit from all other treatments and support indicated for the diagnosis, particularly psychological support. The study group is not left out to flounder. Controlled clinical trials are essential to medical science and medical care, and gender (transition) affirming medical care is severely deficient in them.

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[23] David Randall and Christopher Welser, "The Irreproducibility Crisis of Modern Science," April 09, 2018. https://www.nas.org/reports/the-irreproducibility-crisis-of-modern-science/full-report

36. The Matheny Antommaria Declaration references de Vries 2011 several times, and it is a weak study of questionable findings, as I have noted. Para. 33 of the declaration offers up as evidence of "ongoing, federally funded, prospective observational studies of gender-affirming healthcare for adolescents with gender dysphoria in the U.S." the controversial National Institutes of Health study led by J. Olson-Kennedy, who also has submitted a declaration to this case.[24]

37. A letter (included as Attachment A) was signed and sent by 28 members of the Congress and Senate to NIH Secretary Alex Azar May 28, 2020 "to express our deep concerns regarding the above-mentioned study… This study clearly violates sound medical ethics with its experimental interventions into the normal physical development of children before they are old enough to understand or consent to such procedures." Among the numerous problems they found with the study were "there is no control group." "The minimum age for participation in the cross-sex hormone cohort

[24] National Institutes of Health Reporter, The impact of early medical treatment in transgender youth. Accessed August 25, 2022. Available at http://reporter.nih.gov/search/lGJnh68uokiic97N2X00kA/project-details/8965408 ; Olson-Kennedy J, Chan YM, Garofalo R, et al. Impact of early medical treatment for transgender youth: Protocol for the longitudinal, observational trans youth care study. JMIR Res Protoc. 2019;8(7):e14434.

of the study was originally 13, but the age was decreased to 8 years old in 2017, mid-study." (Attachment B.)

38. An additional Congressional concern regarding the J. Olson-Kennedy lead study was that "it also appears that the Children's Hospital of Los Angeles used funds from its grant to study the effects of double-mastectomies on girls as young as 13." They specifically call attention to J. Olson-Kennedy's 2018 JAMA Pediatrics "Chest Reconstruction and Chest Dysphoria…" study.[25] Allow me to present suspect items of that study. "Chest dysphoria" is a neologism of convenience, not a DSM-5 diagnosis but an invention of the paper. The "chest dysphoria scale" measuring tool of the authors (p. 435) "is not yet validated," thus another unproven invention of convenience. Mastectomies were done on girls as young as 13 or 14 years of age, who lacking the capacity for mature decision making or informed consent (I will discuss in a later section of this declaration). J. Olson-Kennedy is elsewhere quoted at a 2018 California symposium regarding such a life-altering decision for adolescents, stating "If you want breasts at a later point

[25] Olson-Kennedy J, Warus J, Okonta V, Belzer M, Clark LF. Chest Reconstruction and Chest Dysphoria in Transmasculine Minors and Young Adults: Comparisons of Nonsurgical and Postsurgical Cohorts. *JAMA Pediatr.*2018;172(5):431–436. doi:10.1001/jamapediatrics.2017.5440

in your life, you can go and get them."[26] No, in fact mastectomies are permanent. Implants can be acquired, functional breasts cannot. The highly consequential nature of these hormonal and surgical procedures should generate more pause and humility than the referenced comment or the documented procedures reflect.

39. Levine, Abbruzzese, and Mason note "the widely recognized deficiencies in the evidence supporting gender-affirmative interventions (National Institute for Health & Care Excellence, 2020a; 2020b)."[27] They add, "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)." The Hembree 2017

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[26] "Watch This 'Transyouth' Doctor Downplay The Significance Of 'Life Altering' Chest Surgery For Young Girls," May 25, 2021, Daily Caller News Foundation. https://www.tampafp.com/watch-this-transyouth-doctor-downplay-the-significance-of-life-altering-chest-surgery-for-young-girls/

[27] 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, DOI: 10.1080/0092623X.2022.2046221

citation is the Endocrine Society Guidelines for the treatment of "Gender Dysphoric/Gender-Incongruent Persons" and its recommendation of puberty blocking and cross-sex hormone administration for selected minors citing "low evidence" and genital surgery for selected adults citing "very low evidence."[28]

40. *British Medical Journal* editor in chief Carl Heneghan wrote in 2019, "The current evidence does not support informed decision making and safe practice in children."[29] A 2019 paper in *Archives of Disease in Childhood* by C. Richards, et al., carried the revealing title "Use of puberty blockers for gender dysphoria: a momentous step in the dark."[30]

41. The Cass Review Interim Report from the United Kingdom stated this on page 18 regarding the "Existing evidence base": "Evidence on the appropriate management of children and young people with gender incongruence and dysphoria is inconclusive both nationally and

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[28] Wylie C Hembree, et al. Endocrine Treatment of Gender-Dysphoric/Gender-Incongruent Persons: An Endocrine Society Clinical Practice Guideline, *The Journal of Clinical Endocrinology & Metabolism*, Volume 102, Issue 11, 1 November 2017, Pages 3869–3903, https://doi.org/10.1210/jc.2017-01658

[29] Heneghan, Carl. "Gender-Affirming Hormone in Children and Adolescents." BMJ EBM Spotlight, 21 May 2019, blogs.bmj.com/bmjebmspotlight/2019/02/25/gender-affirming-hormone-inchildren-and-adolescents-evidence-review/.

[30] Richards C, Maxwell J, McCune N. Use of puberty blockers for gender dysphoria: a momentous step in the dark. *Archives of Disease in Childhood* 2019;104:611-612.

internationally."[31] On page 19 the report states "1.26. Internationally as well as nationally, longer-term follow-up data on children and young people who have been seen by gender identity services is limited, including for those who have received physical interventions; who were transferred to adult services and/or accessed private services; or who desisted, experienced regret or detransitioned."

42. James Cantor's report to the Florida Agency for Healthcare Adminstration's GAPMS report Attachment D, section 3, "Follow-Up Studies of Puberty Blockers and Cross-Sex Hormones" found "I[n] total, there have been 11 prospective outcomes studies following up gender dysphoric children undergoing medically induced suppression of puberty or cross-sex hormone treatment. Four studies failed to find evidence of improvement in mental health functioning at all, and some groups deteriorated on some variables.20 Five studies successfully identified evidence of improvement, but because patients received psychotherapy along with medical services, which of those treatments caused the improvement is unknowable.21 In the remaining two studies, both psychotherapy and medical interventions were provided, but the studies were designed in such a way as to allow the effects of psychotherapy

[31] Cass Review, Interim Report. https://cass.independent-review.uk/publications/interim-report/.

to be separated from the effects of the puberty-blocking medications.22" The body of scientific evidence supporting gender (transition) affirming medical care is far less convincing than the Matheny Antommaria Declaration repeatedly states.

43. There are, however, two higher quality studies with more robust follow-up periods regarding the impact on mental health of gender (transition) affirming medical care, and they show poor results. A 30-year population-based matched cohort study of all 324 sex-reassigned adult persons in Sweden was published in 2011 by Dhejne, et al., which revealed they demonstrated a completed suicide rate 19 times that of the general population 10 years post-transition, along with nearly 3 times the rate of all-cause (overall) mortality and psychiatric inpatient care.[32] A 2020 study by Branstrom and Pachankis was the first total population study of 9.7 million Swedish residents, and it ultimately showed that neither "gender affirming hormone treatment" nor "gender affirming surgeries" achieved improvement in the mental health service usages and endpoints assessed.[33]

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[32] Dhejne C, Lichtenstein P, Boman M, Johansson ALV, Langstrom N, et al. (2011) Long-Term Follow-Up of Transsexual Persons Undergoing Sex Reassignment Surgery: Cohort Study in Sweden. PLoS ONE 6(2): e16885. doi:10.1371/journal.pone.0016885.
[33] Branstrom, R., & Pachankis, J. E. (2020a). Reduction in mental health treatment utilization among transgender individuals after gender-affirming surgeries: A total population study. American Journal of Psychiatry, 177(8),727–734. doi:10.1176/appi.ajp.2019.19010080

44. James Cantor's report to the Florida Agency for Healthcare Adminstration's GAPMS report Attachment D, Section IV "International Health Care Consensus" (pages 42-46) offers an excellent and concise summary of the dissatisfaction with the lack of convincing evidence for the effectiveness and long-term safety of hormonal and surgical interventions for gender dysphoria in minors and the resultant retreat from them in favor of strong emphasis on psychological evaluation and intervention currently underway in the United Kingdom, Sweden, Finland, and France.

45. Para. 38 of the Matheny Antommaria Declaration states, "One directly relevant example of a widely accepted and Florida Medicaid program covered treatment that is based on prospective observational studies is the use of puberty blockers to treat central precocious puberty." Furthermore, "There are no randomized controlled trials evaluating the adult height of treated and untreated individuals." The analogy to gender (transition) affirming medical care is a non sequitur in that precocious puberty is a disease state in a compromised body, whereas gender dysphoria is neither. The natural course of untreated precocious puberty involves lasting physical

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Branstrom, R., & Pachankis, J. E. (2020b). Correction to Br.nstr.m and Pachankis. (2020). American Journal of Psychiatry, 177(8), 734–734. doi:10.1176/appi.ajp.2020.1778correction

problems and complications, whereas the natural history of gender dysphoria in minors is desistance and a body with a healthy and intact endocrine system. The Endocrine Society Guidelines state, "... the large majority (about 85%) of prepubertal children with a childhood diagnosis (of GD) did not remain gender dysphoric in adolescence."[34] A 2021 study by Singh, Bradley, Zucker, 2021 found a desistance rate of 87.8% in "largest sample to date of boys clinic-referred for gender dysphoria."[35] The gender dysphoric usually carry no inherent defect in sex organ development, function, or fertility. A 2020 study from the UK's Gender Identity Development Service found that "All had normal karyotype and endocrinology" function in 44 GD youth.[36]

GENDER (TRANSITION) AFFIRMING MEDICAL INTERVENTION IS NOT THE STANDARD OF CARE

46. Para. 39 of the Matheny Antommaria Declaration notes, "Professional medical organizations develop evidence-based clinical practice guidelines to provide clinicians with helpful, evidence-based

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[34] Hembree, W., Cohen-Kettenis, et al., (2017) Endocrine treatment of gender-dysphoric/gender-incongruent persons: An Endocrine Society clinical practice guildeline. J Clin Endocrinol Metab,102:1–35.
[35] Singh D, Bradley SJ and Zucker KJ (2021) A Follow-Up Study of Boys With Gender Identity Disorder. *Front. Psychiatry* 12:632784. doi: 10.3389/fpsyt.2021.632784
[36] Polly Carmichael, Gary Butler, et al. Short-term outcomes of pubertal suppression in a selected cohort of 12 to 15 year old young people with persistent gender dysphoria in the UK. medRxiv 2020.12.01.20241653; doi:https://doi.org/10.1101/2020.12.01.20241653

recommendations and improve patient care and outcomes." But the declaration states repeatedly that the quality of said evidence, namely the "low" to "very low" quality recognized in studies supporting gender (transition) affirming medical interventions, is of little consequence to medical practice along with the invalid assertion that controlled trials of high quality would of necessity be unethical. This invites several observations. If the quality of the data is of limited consequence to practice, what is the point of grading systems and guidelines? What is the point of evidence at all if its quality is superfluous? And why is there such international pushback and retraction of gender (transition) medical interventions as noted in the United Kingdom, Sweden, Finland, and France, as notes previously in the declaration along with the GAPMS Report Attachment D from Dr. Cantor?

47. The Matheny Antommaria Declaration para. 42 states that "...none of the Endocrine Society's 84 recommendations in 2 of its other guidelines that focus on the pediatric population—guidelines on pediatric obesity and congenital adrenal hyperplasia—is based on "high quality" evidence. Twenty-four (29%) of the recommendations are based on "moderate," and 49 (58%) on "low" or "very low quality" evidence." This evades the fact that nearly all the Endocrine Society Guidelines for gender (transition) affirming interventions are graded as low to very low quality, not

a mixed bag. Also, pediatric obesity and congenital adrenal hyperplasia are disease states, whereas gender dysphoria and incongruence are not. The consequences of proposed medicinal and surgical interventions must continuously be viewed in that light.

48. Levine, Abbruzzese, and Mason observe, "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).[37]

[37] 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, DOI: 10.1080/0092623X.2022.2046221

49. The Levine, et al., clarification that "the endorsement of this treatment pathway by a number of professional medical societies" despite contradicting the "best available evidence" is precisely what is meant by the term "eminence-based" as opposed to "evidence-based" medicine. The weight of the organizational name is used as its own proof of concept. That is not evidence-based care.

50. Any mention of the Endocrine Society Guidelines merits squaring with these quotes from it on page 3985, "The guidelines should not be considered inclusive of all proper approaches or methods, or exclusive of others. The guidelines cannot guarantee any specific outcome, nor do they establish a standard of care. The guidelines are not intended to dictate the treatment of a particular patient." To reiterate, "The guidelines should not be considered inclusive of all proper approaches or methods, or exclusive of others[,]" "nor do they establish a standard of care."

51. The American Academic of Pediatrics appears in several declarations. Dr. Cantor's GAPMS Report Attachment D, Section V "Assessing Statements from Professional Associations" (pages 31-41) with its included Appendix 2 peer-reviewed "point-by-point check" of the American Academic of Pediatrics policy on "transgender and gender diverse children and

adolescents"[38] provides an excellent review of their policy contents, their misrepresentation, and where merited, their failures. In para. 108 of page 40 of Attachment D, Dr. Cantor asserts, "The policy of the American Academy of Pediatrics (AAP) is unique among the major medical associations in being the only one to endorse an affirmation-on-demand policy, including social transition before puberty without any watchful waiting period. Although changes in recommendations can obviously be appropriate in response to new research evidence, the AAP provided none. Rather, the research studies AAP cited in support of its policy simply did not say what AAP claimed they did. In fact, the references that AAP cited as the basis of their policy instead outright contradicted that policy, repeatedly endorsing watchful waiting."

52. Dr. Cantor's included 2019 peer-review article on the AAP policy concluded, "Rather, AAP's statement is a systematic exclusion and misrepresentation of entire literatures. Not only did AAP fail to provide *extraordinary* evidence, it failed to provide the evidence at all. Indeed, AAP's recommendations are *despite* the existing evidence."[39]

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[38] As Appendix 2 to attachment D Dr. Cantor included his peer-reviewed "point-by-point fact-check" of the AAP claims. (Cantor, J. M. (2020). Transgender and gender diverse children and adolescents: Fact-checking of AAP policy. Journal of Sex & Marital Therapy, 46, 307–313. doi: 10.1080/0092623X.2019.1698481)

[39] James M. Cantor (2019): Transgender and Gender Diverse Children and Adolescents: Fact-Checking of AAP Policy, Journal of Sex & Marital Therapy, DOI:10.1080/0092623X.2019.1698481

53. The international standard of care is watchful waiting, including psychological evaluation of the child and family both, not gender (transition) affirming therapy.[40] James Cantor asserts, "...almost all clinics and professional associations in the world use what's called the *watchful waiting* approach to helping GD children...."[41] Michael Laidlaw, et al., agree "...watchful waiting with support for gender-dysphoric children and adolescents up to the age of 16 years is the current standard of care worldwide, not gender affirmative therapy...."[42]

INFORMED CONSENT AND MINORS

54. The Matheny Antommaria Declaration para. 47 claims, "Adolescents generally possess comparable medical decision-making capacity to adults.39 There is evidence that most adolescents with gender dysphoria have sufficient medical decision-making capacity to make decisions regarding

[40] Michael Laidlaw, Michelle Cretella & Kevin Donovan (2019) The Right to Best Care for Children Does Not Include the Right to Medical Transition, The American Journal of Bioethics, 19:2, 75-77, DOI: 10.1080/15265161.2018.1557288
[41] James M. Cantor (2019): Transgender and Gender Diverse Children and Adolescents: Fact-Checking of AAP Policy, Journal of Sex & Marital Therapy, DOI:10.1080/0092623X.2019.1698481
[42] Michael Laidlaw, Michelle Cretella & Kevin Donovan (2019) The Right to Best Care for Children Does Not Include the Right to Medical Transition, The American Journal of Bioethics, 19:2, 75-77, DOI: 10.1080/15265161.2018.1557288

puberty blockers." Para. 48 adds, "The current standard of care for treating gender dysphoria in minors is

consistent with general ethical principles instantiated in the practices of informed consent and shared decision-making." There is much to object to in these assertions.

55. Levine, Abbruzzese, and Mason observe, "...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."[43]

56. The Swedish Pediatric Society issues a letter supporting the Swedish National Council for Medical Ethics' (SMER) proposed systematic review of gender dysphoria treatment in which they cautioned, "Giving children the right to independently make vital decisions whereby at that age they cannot be expected to understand the consequences of their decisions is not scientifically founded and contrary to medical practice."[44]

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[43] 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, DOI: 10.1080/0092623X.2022.2046221

[44] http://www.barnlakarforeningen.se/2019/05/02/blf-staller-sig-bakom-smers-skrivelse-angaende-konsdysfori/

57. A United Kingdom High Court in Bell vs. Tavistock (December 12, 2020) ruled that gender (transition) affirming medical care in minors was experimental and could not, in most cases, be given to minors under 16 without court order, and that such was advisable for those 16-17. They added in para. 144, "There is no age appropriate way to explain to many of these children what losing their fertility or full sexual function may mean to them in later years."[45] In para. 141 it explained, "That adolescents find it difficult to contemplate or comprehend what their life will be like as adults and that they do not always consider the longer-term consequences of their actions is perhaps a statement of the obvious." Obvious, indeed.

58. Anthony Latham, family physician and chair of the Scottish Council on Human Bioethics, published a 2022 paper "Puberty Blockers for Children: Can They Consent?" in which he asserted, "The young brain is biologically and socially immature, tends towards short-term risk taking, does not possess the ability to comprehend long term consequences and is highly influenced by peers…" He concluded, "Children cannot consent, and therefore should not be asked to consent to being treated with puberty blockers for gender dysphoria. This does not deny the reality of GD or that future forms of

[45] https://www.judiciary.uk/wp-content/uploads/2020/12/Bell-v-Tavistock-Judgment.pdf

treatment may be acceptable, but it does rule out such an experimental medication which has such profound and potentially very harmful irreversible consequences."

59. The Matheny Antommaria Declaration para. 48 states, "The current version of

guideline states clinicians should individualize decision-making for chest surgery in

transgender males (individuals assigned female at birth who identify as male) and

that chest surgery may be considered in some instances for individuals under 18

years old." Please review para. 38 of my declaration regarding J. Olson-Kennedy 's 2018 JAMA Pediatrics article "Chest Reconstruction and Chest Dysphoria..."[46]

Double-mastectomies, the "chest surgery" in question, are being performed on biological females as young as 13.

[46] Olson-Kennedy J, Warus J, Okonta V, Belzer M, Clark LF. Chest Reconstruction and Chest Dysphoria in Transmasculine Minors and Young Adults: Comparisons of Nonsurgical and Postsurgical Cohorts. *JAMA Pediatr.*2018;172(5):431–436. doi:10.1001/jamapediatrics.2017.5440

60. The Matheny Antommaria Declaration notes in para. 50 that, "...Medicaid beneficiaries are provided coverage for comparable surgeries, such as those for gynecomastia." This is followed in para. 51 with the statement, "There is nothing unique about chest surgery for gender dysphoria that justifies singling out this and other medical treatments for gender dysphoria for noncoverage..." Yes, there clearly is. Gynecomastia is a disease state in biological males and the surgery for it removes the small amount of additional glandular breast tissue it represents. It is not a complete mastectomy on a biological female with total loss of healthy functional breasts.

THE FLORIDA MEDICAID RULE IS NON-DISCRIMINATORY

61. Implicit in the Matheny Antommaria Declaration, and explicit in some organizational complaints, against the Florida Medicaid rule excluding gender (transition) affirming medical interventions is the charge of discrimination.

62. Florida Medicaid rules state that "As a condition of coverage, sex reassignment treatment must be "consistent with generally accepted

professional medical standards (GAPMS) and not experimental or investigational" (Rule 59G-1.035, F.A.C....).[47]

63. The GAPMS report concludes: "Considering the weak evidence supporting the use of puberty suppression, cross-sex hormones, and surgical procedures when compared to the stronger research demonstrating the permanent effects they cause, these treatments do not conform to GAPMS and are experimental and investigational."

64. Declining to provide gender (transition) affirming health care is non-discriminatory and appropriate both professionally and scientifically.

a. G(T)AHC has not been proven safe, effective, or of more benefit than harm particularly long term. This was emphasized in the 2020 UK High Court Bell v Tavistock case,[48] the UK's Cass Interim Report of 2022,[49] the UK's 2020 National Institute for Health and Care Excellence reviews of puberty blockers and cross-sex hormones,[50] the UK's NHS closure of the world's largest pediatric gender clinic,[51] the Swedish Agency for Health Technology

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47 https://www.ahca.myflorida.com/Medicaid/review/General/59G_1035_Determining_Generally_Accepted_Professional_Medical_Standards.pdf

48 https://www.judiciary.uk/wp-content/uploads/2020/12/Bell-v-Tavistock-Judgment.pdf

49 https://cass.independent-review.uk/publications/interim-report/

50 https://arms.nice.org.uk/resources/hub/1070871/attachment and https://arms.nice.org.uk/resources/hub/1070905/attachment

51 https://www.bbc.com/news/uk-62335665

Assessment and Assessment of Social Services' 2019 literature review,[52] Sweden's Karolinska Hospital (affecting Astrid Lindgren Children's Hospital's pediatric gender services) 2021 policy change,[53] Finland's COHERE 2020 policy reform,[54] and the French National Academy of Medicine press release.[55]

b. Physicians take an oath to do no harm, and G(T)AHC is documented to lead to significant harm without proof of compensatory benefit.

c. Withholding unproven interventions is non-discriminatory.

d. The problem of diagnosis: "There is currently no way to predict who will desist and who will remain dysphoric."[56] Withholding unproven treatments for uncertain diagnostic or ideological identifications is non-discriminatory and simply wise medical practice protecting both the patient and physician.

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[52] https://www.sbu.se/en/publications/sbu-bereder/gender-dysphoria-in-children-and-adolescents-an-inventory-of-the-literature/

[53] Karolinska Policyförändring K2021-3343 March 2021 (Swedish).pdf; Karolinska Policy Change K2021-3343 March 2021 (English, unofficial translation).pdf

[54] https://palveluvalikoima.fi/documents/1237350/22895008/Summary_minors_en.pdf/aaf9a6e7-b970-9de9-165c-abedfae46f2e/Summary_minors_en.pdf

[55] https://www.academie-medecine.fr/la-medecine-face-a-la-transidentite-de-genre-chez-les-enfants-et-les-adolescents/

[56] Michael K Laidlaw; Quentin L Van Meter; Paul W Hruz; Andre Van Mol; William J Malone. Letter to the Editor: "Endocrine Treatment of Gender-Dysphoric/Gender-Incongruent Persons: An Endocrine Society Clinical Practice Guideline" The Journal of Clinical Endocrinology & Metabolism, Volume 104, Issue 3, 1 March 2019, Pages 686–687, https://doi.org/10.1210/jc.2018-01925, Online, November 23, 2018.

e. There are alternative treatments of mental health natures which are at least as effective and without the harms of hormonal and surgical interventions.

CONCLUSION

65. Gender (transition) affirming health care imperils already at-risk gender dysphoric youth with experimental and unproven hormonal and surgical interventions which medicalize prematurely and permanently. G(T)AHC is not proven effective, not proven to have long-term safety, does not reduce suicides, and is not the standard of care for gender dysphoria. Scientific and legal evidence is driving an international pushback against G(T)AHC in favor of intensive psychological evaluation and support, and the lawsuits over the harms of G(T)AHC have begun. Florida Medicaid is on solid ground in excluding gender (transition) affirming medical interventions from payment.

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

Executed on September 27, 2022

//s//Andre Van Mol, MD
ANDRE VAN MOL, MD

Appendix Attachment

7

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF FLORIDA
TALLAHASSEE DIVISION

AUGUST DEKKER, et al.,

Plaintiffs,

v. Case No. 4:22-cv-00325-RH-MAF

SIMONE MARSTILLER, et al.,

Defendants.
_____/

DECLARATION OF PATRICK W. LAPPERT, MD

I, Patrick W. Lappert, MD., hereby declare and state as follows:

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

2. I have been retained by counsel for the defendants in the above captioned lawsuit to provide an expert opinion concerning the nature of gender surgery. That opinion will be based primarily in my own experience as a physician and surgeon. It will also be based in an evaluation of the scientific publications that Plaintiffs have provided to the court in support of their complaint. It will additionally include an examination the world literature on the subject, as well as an examination of the massive public controversies that have led to near complete reversal of public health policy in multiple European states who have turned away from the social, medical, and surgical transitioning of minors.

3. I am a retired plastic surgeon, as well as a retired senior medical officer in the United States Navy. I have been a physician for 40 years. I completed my undergraduate education at the University of California, Santa Barbara. While there I had significant experience in university level research having been invited to be an undergraduate research assistant, working in the laboratory of Dr. Philip C. Laris. It gave me experience in the evaluation of research publications. We were involved in the collaborative work of elucidating the electrodynamic and stoichiometric quantification of the sodium and potassium pump, located in every living cell. I completed my undergraduate degree in four years, and went directly to medical school.

4. I completed my preliminary medical training while on active duty in the US Navy. I attended the Uniformed Services University of the Health Sciences, F. Edward Hebert School of Medicine, graduating as Doctor of Medicine in 1983.

5. I completed a surgical internship at the Oakland Naval Hospital, followed by Aerospace Medicine/ Flight Surgeon Training at the Naval Aerospace Medical Institute, Naval Air Station Pensacola.

6. I then served for 2 1/2 years with a deploying, front-line Marine Corps fighter squadron, serving in the dual functions of medical department head, and squadron Radar Intercept Officer flying in the F-4 Phantom. I was deployed to Asia and the Western Pacific. I provided medical care to squadron personnel while deployed in Japan, Korea, and the Philippines.

7. I completed my General Surgery residency at the Oakland Naval Hospital-University of California, Davis/ East Bay Consortium. Following residency, I was retained there as a staff surgeon, and was responsible for the training of surgical residents. I was awarded the inaugural "Resident's Choice" award given to the attending surgeon deemed most effective by the residents in training, and presented by Claude Organ, MD, past President, American College of Surgeons.

8. I trained in Plastic and Reconstructive Surgery at the University of Tennessee, Memphis, graduating in 1994. During that training I traveled to Peru and provided craniofacial surgical care for indigent Peruvian children. This included the publication of a case report of surgical management of a very late post traumatic ectopic frontal sinus mucocele.

9. I received Board Certification in General Surgery from the American Board of Surgery in 1992. I received Board Certification in Plastic and Reconstructive Surgery in 1997 from the American Board of Plastic Surgery. I re-certified in Plastic and Reconstructive Surgery in 2008.

10. I served as a staff plastic surgeon at Naval Hospital Portsmouth, Virginia from 1994 to 2002. I became Department Chairman in 1998, and served in that office until my retirement. We had 5 staff plastic surgeons, and 10 Enlisted and civilian members. I established the Wound Care Center, providing specialized wound care services to a global catchment area. For example, our department was responsible for the limb and pelvic reconstruction of some of the sailors wounded when the USS Cole was attacked while at anchor at Aden in Yemen. I also established and chaired the

multi-disciplinary Cleft Palate, Craniofacial Board. We provided comprehensive services for congenital pediatric deformities to a global catchment area.

11. Following selection to the rank of Captain, USN, I was selected to serve as Specialty Leader, Plastic and Reconstructive Surgery for the office of the Surgeon General, USN. In addition to being responsible for the selection and training of surgical residents, I was also responsible for Navy Medical Department policy concerning coverage for services, and medical evaluation and evacuation policy. I was responsible for the resolution of issues concerning what conditions constitute a requirement for immediate care in military hospitals, what may be purchased from civilian medical organizations and provided to eligible members on a delayed (elective) basis, and what is to be considered cosmetic surgery and therefore not an obligation of the government. I served in that position until my retirement. While serving as Department Chairman, I co-authored a textbook chapter on the management of combat injuries with the Chairman of Plastic Surgery at Harvard University, Dr. Eloff Ericksson. During that time I also published the first case report in the world literature detailing the use of endoscopic technique for reduction and plate fixation of a fronto-facial fracture.

12. I retired from the Navy after 24 years of continuous active duty. I was invited to join a surgical group in Scottsbluff Nebraska, primarily to provide comprehensive reconstructive surgery for women suffering breast cancer. I also provided reconstructive services to a very large regional catchment served by the Level II trauma center at Regional West Medical Center (RWMC). I established and chaired the Cleft Palate/ Craniofacial multi-specialty clinic at RWMC. I also established comprehensive wound care services for the many rural community hospitals in the western prairie including Nebraska, Eastern Wyoming, southwest South Dakota and northeast Colorado.

13. For reasons pertaining to the education of our six children, I moved my practice to Northern Alabama in 2005. I have been a solo practitioner here for the last 17 years. I was brought here by a local hospital that wanted to offer comprehensive breast reconstruction to women affected by breast cancer. I also started a comprehensive wound care center. I have also had a very active practice in aesthetic/ cosmetic surgery. I maintained my own surgical suite for in-office facial rejuvenation procedures as well as minimally invasive body contouring procedures. I was an early adopter of advanced techniques in autologous fat grafting for facial re- contouring as well as for the resolution of radiation burn wounds of the skin. I continued to serve in the training of medical students in my office practice.

14. Although I maintain a practice in wound consultation, skin care, and laser services, I retired from my surgical practice in 2020, after having practiced as a plastic and reconstructive surgeon for 30 years. I was an Active Member in good standing of the American Society of Plastic Surgery for all but the last two years in practice. With only two years remaining in my practice, I elected to forgo a third certification by the American Board of Plastic Surgery. The certification was no longer necessary for maintaining my hospital credentials, and I saw it as an unjustifiable expense for a solo practitioner planning retirement.

15. As can be gleaned from this summary, I have a meaningful breadth of experience, not only in the advanced surgical care of trauma, cancer, head/ neck disease, as well as cranial and facial birth defects. Many of those procedures require the use of the most advanced sensate, microvascular flaps, including composite and pre- fabricated flaps. These are all the same techniques employed by today's gender surgeons. As regards surgery of the breast, I co-authored a ground-breaking article regarding pre-operative plastic surgical planning in the care of women suffering from breast cancer. It is among the most frequently cited papers in the field of breast reconstruction.[1]

16. Since 2014 I have made a concerted effort to examine the medical literature as it pertains to the care of self-identified transgender persons including children and adults. I have had an eight year long running discussion on these issues with Family Practitioners, Pediatricians, Pediatric and Adult Psychologists and Psychiatrists, Pediatric Endocrinologists, as well as PhDs who specialize in the evaluation of the validity of scientific publications. During that time I have made many public presentations to teachers, counselors, pastors, and administrators on the subject of transgender, and the medical-scientific evidence that informs that care.

17. My curriculum vitae, which is attached as Exhibit "A", provides a list of my publications

18. I prepared a report which is attached to the Florida Agency for Healthcare Administration's "Generally Accepted Professional Medical Standards Determination for the Treatment of Gender Dysphoria" A copy of my report is attached and incorporated by reference as Exhibit "B" to this declaration.

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[1] Toth, B.A. and Lappert, P. (1991) Modified Skin Incisions for Mastectomy: The Need for Plastic Surgical Input in Pre-Operative Planning. Plastic and Reconstructive Surgery, 87, 1048-1053. http://dx.doi.org/10.1097/00006534-199106000-00006

19. I have offered testimony, both written and in person on this issue to state legislators, state health benefits management agencies, as well as to State Attorneys General.

20. I have also had experience in making judgements concerning distinctions between reconstructive surgery and cosmetic surgery. I gained this experience while serving in senior leadership for a government medical care system in which I had no financial stake. I have no financial interests in the matter in question, and the professional opinion that I offer is not influenced by my sources of income nor by my position in any organization that financially benefits from medical services that are discussed in this opinion.

21. For my services as an expert witness I am being compensated at an hourly rate of $400 for preparation of my written testimony as well for deposition and hearing. Additionally my travel expenses will be reimbursed. My compensation is not dependent upon the substance of my opinion nor upon the outcome of the litigation.

22. If called to testify in this matter I will do so truthfully, and to the best of my ability.

23. The Plaintiffs, supported by the opinions of Dr. Schechter, among others, are making the claim that "gender affirmation care" including "gender affirming (or confirming) surgery" should be paid for by the State of Florida because such care has scientifically proven efficacy, and safety. Furthermore they claim that there is such an abundance of scientific support for these treatments that they must be understood to be the standard of care, and that there is no controversy in the matter. In support of this position they have provided in their declaration an abundance of citations from professional scientific publications that they expect will furnish the court with sufficient reliable evidence that Plaintiffs claims will be upheld. As shall be seen in this response, their claims are not supported in the science. This will be seen in the examination of those scientific documents which they have cited.

24. In recent years professional medical societies have been making a concerted effort to strengthen the scientific basis upon which their particular specialties stand. This effort is commonly given the name "evidence based medicine". It is a systematic effort to categorize the quality of prognostic and therapeutic studies so that physicians reading these publications can distinguish what is vague and speculative from what is a matter of high likelihood, or grave certainty. Tools for making such

distinctions have been developed that categorize clinical or experimental findings on the basis of how that data was obtained, the reliability of the test instruments used, the variability of the results, the sample size, and the likelihood of bias among other factors. For the purposes of this response, I will use the tool developed by the American Society of Plastic Surgery.[2] For prognostic studies, the categorization of evidence is divided into Levels I- V, with Level I being the most rigorous and having the highest likelihood of scientific certainty, and Level V having the least rigor, and having very little certainty. Here are the definitions of those levels according to the American Society of Plastic Surgery:

Level I: High quality prospective cohorts study with adequate power or systematic review of these studies.

Level II: Lesser quality prospective cohort, retrospective cohort study, untreated controls from an RCT (randomized control study), or systematic review of these studies.

Level III: Case- control study or systematic review of these studies.

Level IV: Case series

Level V: Expert opinion; case report or clinical example; or evidence based on physiology, bench research or "first principles".

23. For therapeutic studies, the ASPS categorization is similar, but with a few helpful distinctions:

Leve	Type of evidence
1A	Systematic review (with homogeneity) of RCTs
1B	Individual RCT (with narrow confidence intervals)
1C	All or none study
2A	Systematic review (with homogeneity) of cohort studies

[2] The Levels of Evidence and their role in Evidence-Based Medicine Patricia B. Burns, MPH,1 Rod J. Rohrich, MD,2 and Kevin C. Chung, MD, MS3 Plast Reconstr Surg. 2011 Jul; 128(1): 305–310. http://www.plasticsurgery.org/Medical_Professionals/Health_Policy_and_Advocacy/Health_Policy_Resources/Evidence-based_GuidelinesPractice_Parameters/Description_and_Development_of_Evidence-based_Practice_Guidelines/ASPS_Evidence_Rating_Scales.html.

2B	Individual Cohort study (including low quality RCT, e.g.
2C	"Outcomes" research; Ecological studies
3A	Systematic review (with homogeneity) of case-control studies
3B	Individual Case-control study
4	Case series (and poor quality cohort and case-control study
5	Expert opinion without explicit critical appraisal or based on physiology bench research or "first principles"

24. These distinctions are very important to physicians who seek to understand the weight of the evidence presented in support of a change in therapeutic care. Sometimes such scientific findings can be so compelling regarding an issue, that professional societies will publish clinical guidelines that strongly suggest conformity to a new treatment plan based in that evidence. Occasionally the evidence will be of such certainty, on a matter that is so grave, that professional societies and even public law will assert that there exists a standard of care based in this evidence that if ignored has a high probability of injury or harm to the patient. That is what is implied when the phrase "standard of care" is used.

25. To that end, the ASPS document provides a grading system for Practice Recommendations that helps in the decision making. It is a synthesis of the breadth of scientific data that addresses the issue in question. In the case of Grade A ther is an accompanying "Strong recommendation", versus Grade D where the evidence is so lacking in empirical value that the proposed treatment can only be offered as an option if at all, depending upon the strength of existing or alternative treatments, and the particular issues of a particular patient.

26. To summarize, it can be said that Level-V evidence is anecdotal, and in the world of surgery it is typified by the phrase "expert opinion". Such evidence is not to be dismissed since it is the known starting point for much meaningful research and discovery. A surgeon with great experience and unassailable credentials will observe something peculiar. He will form a hypothesis about its cause or treatment. Hopefully he will publish his single case report, and share his thoughts with the wider surgical community. Perhaps one of his residents will start a hunt for other cases. Perhaps

surgeons who read his paper will report similar cases. Eventually it might lead the surgeon to apply his new principal to a series of cases. The series may already be there in his own case files. If he publishes his series of cases, that would constitute an improvement to Level-IV evidence. Even then, it would be considered "poor" evidence because it suffers from the fact that it is a small collection of cases, from a single surgeon, and perhaps no one has yet replicated his observations. Additionally it may suffer from "selection bias" (as when the patient decides if he will receive long term follow up), lack of proper controls (which help us to separate out what is the result of our treatment, and what is within the range of normal variation in the population), inadequate study duration (if you claim a long term improvement in survival, you have to follow the patients long-term).

27. An example from the history of surgery will serve to illustrate how Level-IV and V evidence, when widely encouraged and applied through expert opinion, can result in grave missteps. For over 100 years, ulcer disease of the stomach was considered a surgical problem. This very debilitating disease did not appear to be manageable through medical means. Laboratory study of the stomach had already demonstrated that acid production in the stomach is regulated by particular nerves. That finding suggested that if those nerves are cut, acid production will decline, and the ulcer will heal. It was also determined that the surgery must include some form of "drainage procedure" because cutting the nerves would also impair the muscular contracture of the stomach. Through the course of the decades many of the greatest surgeons gave their names to the elegant techniques for selectively cutting the nerves, or draining the stomach in ways that hopefully would not result in a "gastric cripple" (an all too common outcome). Long hospitalizations, and many months spent accommodating to the reordering of their digestive tract was expected. There is a syndrome of bad effects from these surgeries that most people adapt to but some never do. Nonetheless, untreated peptic ulcer disease was often deadly, either from peritoneal sepsis, or bleeding to death. Because of the gravity of ulcer disease, it was ethically sound to risk "post gastrectomy syndrome" if it meant saving a life.[3] By the 1980s, level II and I studies had demonstrated that peptic ulcer disease is actually a bacterial infection that can be treated with antibiotics and an acid-reducing medication. This had been very seriously suspected for at least 30 years. However, poorly designed studies published by the greatest academic surgeons of the day had utterly suppressed the bacterial explanation in favor of the surgical solution. A very well reasoned 2014 paper by Seselja and Strasser[4] shows the heuristic pitfalls that can result in unintended harms to

[3] History and evolution of peptic ulcer surgery; John B.BlalockJr.MD1; The American Journal of Surgery Volume 141, Issue 3, March 1981, Pages 317-322

patients when surgical decision making is driven by expert opinions that aren't well supported by quality scientific evidence.

28. Generations of surgeons will follow what is taught to them by the academic surgeons. These are esteemed mentors who are responsible for training the next generation of surgeons. That is how it has always been. However today, medical science has advanced in crucial ways through the application of the "science of science". We understand better now how to examine the evidence. We are less likely to make needless errors of judgment because we are better able to analyze the data particularly with regard to its reliability. This is indispensable when studying biological systems that, in every measurable trait, demonstrate great variability. It is particularly essential when examining and caring for the human person, because you have the added dimension of their subjective interior life.

29. Dr. Schechter, by every measure known to me, is of very accomplishmed in the world of plastic surgery. It is on that basis that we can expect that the published literature which he has offered in support of Plaintiff's assertions will be of the highest level available to him. But the literature he offered does not bear out his conclusions

30. In para. 21, Dr. Schechter defines the word "transgender" on the basis of a subjective conflict within the patient's internal sense of themselves. He affirms this interior subjective division on the basis of an idea that sex is somehow "assigned" at birth, rather than scientifically discovered through tissue sampling, in utero ultrasound, or simple inspection at birth. In 99.98% of cases, simple inspection correctly detects the sex of the subject. Furthermore, this test can be administered by untrained personnel. His use of the term "assigned" implies that there can be errors of "assignment". Such an assertion demands not only that we examine the result, but we must also look at the consistency of the data. We have seen previously that consistency of the data is one of the hallmarks of good evidence. Any test that can be correct 99.98% of the time regardless of who administers the test is perhaps unequaled in scientific medicine.

31. Gender, on the other hand, as it relates to sex, is a very different matter. While there are some aspects of gender that are more fixedly related to the sex, there are large areas of gender that are learned within the milieu of the local culture, and find their origins in family life. There is no objective, repeatable test, with known error rates that can be used to detect "gender". Gender, as the term is used in the world of medicine and surgery is not objectively measurable. Such traits as hair length,

[4] Dunja Šešelja 1, Christian Straßer; Heuristic reevaluation of the bacterial hypothesis of peptic ulcer disease in the 1950s; Acta Biotheor 2014 Dec;62(4):429-54.

occupation, preference for violent sport, clothing selection, among others, may have vague gender associations, but are so variable from culture to culture as to be useless for our purposes. This is because "gender" is one of the many expressions of the interior life of the person. It is a mercurial thing because it is not entirely fixed to that part of the patient that is a reliable object for examination and treatment. That difficulty with diagnosis and prognosis is further complicated by the fact that variability in gender presentation doesn't just occur within any particular human grouping, it is also known to vary within the span of the life of a single patient.(Zucker)

33. Beginning in 23, Dr. Schechter makes the claim that "hormone therapy and gender confirmation surgeries can help alleviate gender dysphoria" and that these treatments "have been shown to be an effective treatment for gender dysphoria". In para. 24 he further states that it is his professional opinion "supported by prevailing consensus of the medical community" that these treatments are medically necessary, and are "safe and effective treatments for gender dysphoria". We will examine the claims of efficacy, and safety by examining the papers offered in support of his claim. We will examine the world literature more broadly in order to examine Dr. Schechter's claim that there is a "prevailing consensus", which is a claim that suggests that there is no meaningful controversy surrounding the use of social, medical, and surgical gender affirmation, particularly with regard to the young.

34. The first support that Dr. Schechter offers is the WPATH "Standards of Care". This document is the product of the World Professional Association of Transgender Health. It has had 7 iterations, with the 8th version now pending publication. This document has been, and continues to be produced through a process of consensus-seeking within working committees of experts. As we have seen in our discussion about the grading of scientific evidence, expert opinion is the most rudimentary level of evidence. It is the starting point of scientific investigation, not the end. As any medical subject is investigated over time, the expert opinion becomes better supported by well developed and monitored scientific processes. In short, expert consensus is only as valuable as the scientific evidence that can be reviewed and evaluated which supports the opinion. If the evidence hasn't progressed very far beyond the category of expert opinion, then we are speaking about evidence that is not sufficiently developed so as too drive either clinical decision making, nor fiduciary decision making when public or invested resources are involved.

35. It will be recalled that the use of the words "standards of care" imply that a particular treatment or clinical principle, if not employed, would have an unacceptable probability of harm to the patient. The term "standard of care" addresses issues of

duty, negligence, harm, and causation. It is a legal term that is applied when evaluating the malpractice of medicine. In its Introduction to the WPATH standards, the authors acknowledge that their document is meant to be a guideline only, and subject to individual and local adaptation, and that it is not binding in any way. On page 2 of v.7 in bold face it states "The Standards of Care are flexible clinical guidelines". This calls into question the motivation for the use of the phrase "standards of care" in all of its publications and statements.

36. If the WPATH document is actually a collection of clinical guidelines, then we must examine how such guidelines are developed. In the International Journal of Quality in Healthcare (2016) Kredo et al.[5] (&) offer a helpful examination of that process. They point out that in the past they were just consensus statements offered by experts in the field. They were "'systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances." With the push toward evidence based medicine, it was realized that guidelines required more scientific rigor, so in 2011 the definition was changed to, "statements that include recommendations intended to optimize patient care that are informed by a systematic review of evidence and an assessment of the benefits and harms of alternative care options'". In order to have real value, clinical practice guidelines must therefore do two things: Use high quality scientific data to evaluate risks, and beneficial results while presenting alternative approaches for the practitioner and patient to consider.

37. As Dr. Schechter has stated in his expert declaration, he is a co-author of the WPATH chapter on surgery in version 7, and is the co-lead author of the same chapter in version 8. It would be expected therefore that what Dr. Schechter has offered to the court is "high quality scientific data to evaluate risks, and results while presenting alternative approaches for the practitioner and patient to consider", since it is precisely that which is the question here.

38. The first scientific publication he offers is one that is in support of hormonal treatment of transgender persons. It is a paper by Hembree et al.[6] which is itself a clinical practice guideline promulgated by the Endocrine Society (hereafter ES). This guideline was produced in order to update an earlier guideline from 2009. It was produced using GRADE consensus methodology, and is the product of 9 experts who

[5] Guide to clinical practice guidelines: the current state of play; Kredo et al. Int J Qual Health Care. 2016 Feb; 28(1): 122–128.Published online 2016 Jan 21. doi: 10.1093/ intqhc/mzv115

[6] Wylie C Hembree, et al. Endocrine Treatment of Gender-Dysphoric/Gender- Incongruent Persons: An Endocrine Society Clinical Practice Guideline, The Journal of Clinical Endocrinology & Metabolism, Volume 102, Issue 11, 1 November 2017, Pages 3869–3903, https://doi.org/10.1210/jc.2017-01658

formed the committee. The GRADE methodology cautions its users that "inconsistency of result across multiple studies", "indirectness of evidence", "imprecision in measurement", and "publication bias" are to be watched for in its application; essentially that doctors must watch out for sloppy measurement, and bias in the working group. The scientific evidence used to support the Endocrine Society's special treatment guidelines for gender dysphoric/ gender incongruent persons appears to be of low to very low quality, since the clinical recommendations were so equivocal. It was published in 2017 and includes the statement:

"guidelines cannot guarantee any specific outcome, nor do they establish a standard of care": "The guidelines should not be considered inclusive of all proper approaches or methods, or exclusive of others. The guidelines cannot guarantee any specific outcome, nor do they establish a standard of care. The guidelines are not intended to dictate the treatment of a particular patient." P. 3895.

39. As was discussed earlier, this language of uncertainty when included in a clinical practice guideline is what we would expect with low quality evidence. This is what the ASPS would call a Grade D result that rests on level IV-V evidence, and is therefore not useful in directing clinical decision making. This consensus process described by Hembree et al. would likely appear very similar to the decision making that drove peptic ulcer surgery in opposition to evidence that it is a bacterial disease. Academic physicians of the highest caliber were making recommendations to their fellow practitioners, as they are now, based upon anecdotal experience and low level evidence.

40. Just 2 years later, in 2019, the ES , along with an international panel of endocrinology societies, concluded "**the only evidence-based indication for testosterone therapy for women is for the treatment of HSDD** [Hypoactive sexual desire disorder]," and that "There are **insufficient data to support the use of testosterone for the treatment of any other symptom or clinical condition,** or for disease prevention." Also, "The **safety of** long-term testosterone therapy has not been established."[7] It is somewhat alarming to note that these findings are entirely consistent with a consensus statement from 5 years earlier in 2014. In the span of just 5 years, the Endocrine Society consensus has swung from "no other indication for androgen in women" to something akin to, "it is crucial that androgens be given to women who are

[7] Endocrine Society Susan R Davis, et al, Global Consensus Position Statement on the Use of Testosterone Therapy for Women, The Journal of Clinical Endocrinology & Metabolism, Volume 104, Issue 10, October 2019, Pages 4660–4666, https://doi.org/10.1210/jc.2019-01603.

gender dysphoric", and then back to "no other indication for androgen". This kind of consensus oscillation is what you would expect when there is such scant scientific basis for the decision making.

41. Dr. Schechter presented the ES guidelines as the "criteria for initiation of surgical treatment". Between para. 27 and 28 he claims that gender surgery is "often necessary and effective" citing the same ES document. He also correctly reports parallel, committee based consensus statements by the numerous academic societies, produced in the same way, and resting upon similar evidence as discussed above re: ES guidelines, and WPATH "standard of care".

42. In para. 29 Dr. Schechter offers a listing of all of the surgeries that would be considered "generally accepted in the medical community". He does not explain how he measured the level of acceptance that transgender breast and genital surgery enjoys in the medical community. He further explains that all of the listed surgeries are "consistent with the standard of care". By the phrase "Standards of Care", he appears to refer to the WPATH document. The main salient chapter in that document was authored by Dr. Schechter, in his capacity as a leading academic expert in the field of transgender surgery. It is his own expert opinion that he cites as an authoritative guide in surgical decision making in matters relating to the care of transgender persons. Ipse dixit.

42. In para. 30, while discussing surgeries for women who seek to present as men, he describes the removal of healthy breasts and the cosmetic masculinizing procedure as "reconstructive". This is somewhat problematic, particularly as regards the duties of third party payors, including the State of Florida Medicaid program, which includes the management of payment for services. The distinction between what is cosmetic (aesthetic) versus reconstructive is one of the key issues in the just management of payments by insurers, including the State of Florida. This distinction was a daily issue for me when I was in Navy Medical Department leadership. The distinction between cosmetic and reconstructive surgery rests upon objective, observable, repeatably measurable markers of conditions that diminish or impair human functioning. It is based in comprehensive objective knowledge of human structure and function and is in the service of human flourishing.

Reconstructive surgery is the restoration of form and function for a person who has suffered a loss through genetic or developmental in utero accident, trauma, infection, or surgery for infectious events or cancer. It begins with the most comprehensive knowledge available concerning the nature and function of the injured part, and seeks to optimize function as the primary goal, while seeking to restoring the

natural form. Both form and function are understood objectively, and both have subjective effects. Restoration of form and function in a combat injured leg has measurable effects on mobility, range of motion, strength, and capacity for work. Subjectively, the impact is profound as well, but it is not the central purpose of the operation.

In contrast, aesthetic surgery begins in the subjective life of the patient. The patient presents seeking an opinion concerning the aesthetics of a particular feature, such as the nose. They will express a dislike of the feature. Their hope is that by modifying its appearance, they will improve their interior subjective life. What the patient is seeking is a normal human objective: to improve the aesthetics of things, for ourselves and for the people around us. When the surgeon is planning and performing the operation on the nose, there is great objective precision, however all of it is placed in the service of the subjective life of the patient. It is of no use for the surgeon to impress himself with a technically perfect result if the patient loathes it. The surgeon additionally has the grave duty of managing the risk for the patient and weighing it against the potential benefit. The patient must not be submitted for a surgery which entails a significant risk of loss if the surgery is being performed only to achieve an aesthetic outcome. If there is a certainty of loss, then there is a certainty of error. To give a young woman a perfect nose, and in the process destroy her ability to breath through it would be a terrible error of surgical decision making. It is axiomatic in plastic surgery that we are to avoid a predictable sacrificing function in the pursuit of cosmetic improvement.

The procedure which Dr. Schechter labels “chest reconstruction surgery” in female to male presentation patients actually begins with the known expectation that the surgery will produce a degradation or loss of two essential human functions, namely: sexual arousal, and breast feeding. Both functions are permanently and irretrievably lost, and that loss is one of the expected results or the surgery. This step is then followed by the cosmetic shaping of the chest through the use of liposuctioning in an effort to further masculinize the appearance of the chest. This surgery is now being routinely performed on minor girls, and version 8 of the WPATH “standards of care”, written by Dr. Schechter and presented here as authoritative, actually recommends mastectomy in girls as young as 15 years of age. This surgery does not involve the restoration of form and function, and is therefore not reconstructive. It is an operation that begins in the subjective life of the patient, and aims at a result that also resides entirely within the subjective life of the patient. It is thus by definition an aesthetic (cosmetic) surgery. Because it includes the 100% likelihood of a massive functional loss, it must be considered unsupportable as a matter of policy.

Similarly, genital surgery procedures listed in Dr. Schechter's declaration can not be considered reconstructive because they do not meet the definition of reconstructive surgery. They begin with an obsessive concern or anxiety in the subjective life of an otherwise normal, healthy person. They involve the planned destruction of an essential human function, and they are not restoring a form that is missing due to trauma, genetic accident, in utero event, or disease. The surgery seeks to create counterfeit structures that never could have existed in the patient, except as an artifact of surgery. I have done many reconstructive surgeries involving the entire genital area in patients with military injuries and infectious illnesses. If the injury is so devastating as to require a counterfeit structure, and that is all that can be offered, then there is no question as to how the surgeon must proceed.

In contrast, gender affirmation surgery only produces counterfeit structures that are created to serve the subjective life of the patient. Because these surgeries are cosmetic, and because they are 100% certain to produce grave functional losses, they must not be supported as a matter of public policy, and never be paid for by use of public funds.

43. In para.31 Dr. Schechter discusses what he calls "medical necessity criteria for initiation of surgical treatment". His sole reference is the WPATH "standards of care" of which he is the principal author. It should be remembered that the WPATH standard of medical necessity is not supported in reliable scientific evidence, but only on rudimentary, low level data. His first criteria is that the patient must have "the capacity to make fully informed decisions and to consent for treatment". He adds that mental health concern must be "reasonably well controlled prior to surgery".

It is firmly established in high quality research that persons with gender dysphoria have a greater than 30% likelihood of being on the autism spectrum, and a nearly 40% probability of a diagnosis of depression or major anxiety disorder. The proponents of gender surgery will rightly point to the high probability of self-harming behavior, including suicide attempts and completed suicide among self-identified transgender persons.

In my experience as a surgeon, it is considered imprudent to obtain consent from patients suffering from psychological conditions that provoke the patient to acts of self-harm and/ or suicidal ideation. These psychological disturbances are known to impair the patient's capacity for understanding the information offered by the surgeon, interpreting that information, and reasoning from that information. If those capacities are

impaired by psychological disturbances sufficient to consider suicide, then meaningful consent must be questioned. Certainly in the case of conditions that constitute a threat to life and limb in a patient with decreased competence. consent may be obtained with the assistance of family, guardian, or in particularly urgent cases a group of professionals who agree on the grave necessity to proceed with surgery.

The difficulty here is that none of the surgeries on Dr. Schechter's list are emergency operations performed to save the life of the patient. They are all elective (scheduled when convenient and patient is deemed ready). Furthermore, an ever-growing percentage of patients submitted for gender surgeries are minors who by definition are not competent to consent. The claim is made that these surgeries are in fact "life saving". This is a claim that is not supported in high quality scientific evidence. In fact high quality evidence, which I will present below, shows that while self-harm and suicide rates are improved in the very short term for some sub-groupings of patients, in the long-term these problems remain if not worsen.

When Dr. Schechter speaks of the need to have these psychological disturbances "well- controlled" prior to surgery, he must certainly mean that self-harming or suicidal thoughts have been well controlled. If that is the case, then the chiefly claimed reason for the surgery has been successfully treated medically, and the patient would no longer require the surgery.

What is troubling is that the co-morbid conditions of autism spectrum disorder, clinical depression, and major anxiety disorder are never examined as the possible causes of the gender identity disturbance. These are conditions that, if treated, might improve if not resolve the gender problem. To the contrary, these serious problems are viewed as mere impediments to gender surgery that must be "reasonably well-controlled" so that surgery may proceed. This is consistent with the regnant WPATH model that there is a single explanation (disconnection between biological reality and subjective identity which has an as-yet undiscovered cause), and has only a single solution (social, medical, and surgical affirmation). Such a single cause/ single solution assumption would seem to be unlikely, given the massive range and the recent complete reversal in the demographics of transgenderism. What used to be a condition that was nearly exclusively found in little boys (and resolved nearly 90% of the time), is now predominantly a condition affecting young women, and at a rate that has risen between 4000 and 5000% in the course of the last decade.(Shreier et al.)

44. In para.33 Dr. Schechter begins the evidentiary support for the assertion that "Gender Confirmation Surgeries are Medically Necessary". In para.34 he states that the "medical community generally considers those surgeries to be medically

necessary". He makes this assertion of broad acceptance in the medical community without evidence to support it. How was the data gathered and interpreted to support the assertion that the medical community broadly shares his opinion? I am not aware of any published study that has measured the acceptance of this therapeutic model among the members of the medical community. The only evidence he has presented concerning the broader medical community is the collection of consensus statements, produced by the various specialty committees which was produced using the faulty methodology described above, and supported with the lowest levels of evidence.

45. In para.34 Dr. Schechter asserts that "gender confirming surgeries are not cosmetic because, when performed in accordance with the Standards of Care, they are clinically indicated to treat the underlying medical condition of gender dysphoria". He appears to be saying that medical necessity exists because he said so himself when he wrote the chapter for the Standards of Care. He is again standing upon his considerable expertise, but he hasn't up to this point supported the assertion with scientific evidence. This is entirely analogous to the history of peptic ulcer surgery: driven by the highest level of academic expertise, but lacking rigorous scientific support.

46. In para. 35 he continues his assertion that gender surgery is not cosmetic by making the claim that gender dysphoria is a medical diagnosis. This is an extremely problematic statement for him to make, given that the diagnosis comes to us from the Diagnostic and Statistical Manual of Mental Disorders (DSM) vol. 5 (2013). As Dr. Schechter described in his outline of the diagnostic and pre-operative selection for surgery, the patients are referred to him by a process that begins in psychology, continues with psycholgical support, and concludes with certification by psychological services that the patient is ready for surgical modification. At no point has he described any medical diagnostic process of history-taking, physical examination, laboratory evaluation, or radiographic examination that he has used to confirm a diagnosis which was produced and sustained by psychological services. The indication for surgery begins in the subjective life of the patient. Surgery is offered to the patient with the assurance that it is likely to improve the subjective life of the patient, and is therefore by definition cosmetic surgery.

47. One of the essential mechanisms that third-party payors (including state Medicaid agencies) have for distinguishing reconstructive surgery from cosmetic surgery is found in the pathology department. Two operations may be outwardly identical even while one is reconstructive and the other cosmetic. An excellent example is the breast reduction surgery which I discussed in my previously submitted assessment. This surgery may be reconstructive when the size of the breast is being

sufficiently reduced in order to remedy a condition of orthopedic pain. These patients suffer from chronic neck, back, and shoulder pain caused by the orthopedic effects of their heavy breasts. The same, technically identical operation, might be done for purely cosmetic reasons. In the case of reconstruction, the patient has a condition that causes lost time from work, frequent covered visits to physical therapy, or to pain clinics, chiropractors and radiologists. There is abundant actuarial data, based upon the highest levels of scientific support, that a breast reduction of sufficient weight (based upon the anthropometric measurement of the patient) has a very high probability of resolving the chronic pain. High quality medical literature that addresses this issue, and its importance to insurance plans, is typically very precise in its data gathering and actuarial interpretation.[8] However, pain cannot really be measured. Pain is reported by the patient. Health insurance plans are able to distinguish cosmetic breast lift from reconstructive breast reduction based upon the reported weights of the breast tissue that is submitted to pathology. An objective, repeatable medical test, with known error rates is used to confirm the diagnosis, ensure correct care for the patient, and separate cosmetic surgery from reconstructive surgery in the interest of preserving medical resources and preventing fraud. No such process exists in the case of mastectomy for chest masculinization. There is no physical, biochemical, hormonal or tissue pathology, that can be demonstrated to localize the patient's condition in her healthy breasts. It is the young woman's subjective sense of revulsion when she looks at herself that has caused her to believe that mastectomy might make her feel better.

48. Similarly, the pathology department helps us to make distinctions between reconstructive and cosmetic surgery in the case of gynecomastia, which is a condition that affects biological males, and results in the growth of female glandular breast tissue. Men who have enlargement of the soft tissue of the chest area may come to the surgeon seeking improvement in appearance. Most often this problem is caused by varying degrees of obesity, and in such cases surgical improvement would be rightly categorized as cosmetic. The patient is motivated by a dissatisfaction with his appearance, which he wishes to improve, so that he can feel better about his appearance. In contrast, the man with gynecomastia might present with a mass behind one nipple, that is tender, and disfiguring. Perhaps it interferes with his occupation because it is impinged upon by safety equipment that he has to wear in his occupation. In this case, the surgical removal of the mass (gynecomastectomy) would rightly be considered reconstructive because surgery is used to restore function and form in a person who has an objective finding (female glandular tissue in a male chest). As in the earlier case, insurance plans rely on the evaluation provided by the pathology

[8] Accuracy of Predicted Resection Weights in Breast Reduction Surgery: Kung, Theodore A. MD; Plastic and Reconstructive Surgery - Global Open: June 2018 - Volume 6 - Issue 6 - p e1830

department when surgical specimens are submitted. The lab, using proven, repeatable, accurate testing methodologies can report either the presence of nothing more than adult fat tissue, as would be expected in the case of the cosmetic chest re-contouring, or they would report the presence of "fibroglandular breast tissue", which would be the expected and necessary finding that would warrant payment for a reconstructive surgery that is a covered benefit in the insurance plan. Thus, the findings provided by the pathology department serve to confirm what expert opinion, supported by high quality evidence, diagnosed before the patient was brought to surgery. Such objective, measurable, repeatable findings from pathology help to advance the quality of care because outcomes of care can be evaluated in the long term, and the consistent language and data can be compared among multiple studies from multiple centers of care, thus increasing the reliability of expert opinion throughout the medical community.

In footnote #8 of Dr. Schechter's declaration he says that "Dr. Lappert incorrectly refers to breast growth in transgender women as "gynecomastia", and that "Gynecomastia refers to enlargement of the male breast, not to breast growth in transgender women" (biological males who present as women). From the standpoint of the validity of scientific-medical information, this is a very troubling statement for Dr. Schechter to make. He is essentially saying that the validity of objective, measurable, repeatable findings of the pathology department are completely negated by the subjective condition of the patient. The patient's subjective interior sense of themself cancels the objective validity of medical knowledge.

49. In para. 38 Dr. Schechter begins the assertion that gender surgery "has been demonstrated to have other salutary effects, such as improving quality of life and reducing negative health outcomes". In support of this assertion he cites a 2019 publication by Miller et al. He summarizes the findings of the paper with a declaration of subjective satisfaction on the part of the patients (that 100% would do it again). Upon examination of Dr. Miller's paper we see that it is a report of a single surgeon retrospective review. It begins with a chart review of only 34 patients, only 12 of whom responded to the quality of life questionaire. This means 74% of the study patients dropped out (patient self-selection bias, with drop out rate greater than 20%). All of the data is based in subjective reporting by the patients, rather than objective findings (such as substance abuse rates, psychiatric hospitalization rates, suicide attempt etc.). Such reporting which is purely subjective (satisfaction survey, quality of life survey etc.) is characteristic of the cosmetic surgery literature, not the reconstructive surgery literature. He reports that "every patient surveyed at 1 year" reported that "their life had changed for the better". This statement is again reporting only subjective data, this time following a meaninglessly short follow-up of a very small group that has been biased by

self-selection. The overall study is little better from the standpoint of the duration of the study because the final follow-up was only 4 to 7 years. This paper presents level-IV and level-V (low to very low quality) evidence, and is therefore only useful in suggesting further research, particularly since it is authored and cited by subject matter experts. It is not useful for clinical decision making. Neither can it be presented as evidence for anything more than a cautiously worded practice guideline (as in the ES guideline concerning the use of cross-sex hormones presented above), and certainly can never be used in support of a "standard of care". It is important that this was the first paper Dr. Schechter cited in support of efficacy, given the weakness of its content.

50. In para. 40, Dr. Schechter continues his presentation of the scientific evidence that demonstrates the efficacy of gender surgery by citing a 2006 paper by Newfield et al. Dr. Schechter summarizes the paper's findings saying that mastectomy and chest masculinization in transgender biological females "increases self-esteem and improves body image" while providing the patient with "some security and safety for those who remove their shirts in public areas such as gyms or beaches". In reading the entirety of the paper I found that it did not demonstrate that at all. The passage Dr. Schechter quotes is a personal editorial opinion expressed by the authors in support of transgender surgery. It is found in the preamble to the paragraphs that describe their study of the self-identified, but never verified, post surgical patients.

This paper is a report of an anonymous survey. It claims to provide meaningful information about the effect of female to male transitioning medicine and surgery without even verifying that the subjects who responded to the survey have in fact undergone medical and surgical gender transition. Subjects were recruited **"via online promotion and printed materials, including flyers and postcards that were distributed to San Francisco Bay Area community centers, cafes, stores, and health clinics that serve the transgender community."** In terms of self-selection bias (patient determines who is followed by the study) it is hard to imagine a more problematic patient selection process. The researchers even admit that they were unable to determine how many surveys may have been submitted multiple times by the same study respondent. They write: "Although this procedure *helped* (italics mine) prevent duplicate submissions by the same participant, we could not employ more sophisticated computerized systems due to administrative and financial constraints".

All of the demographic information contained in the study was self-reported but not verified, including age, sex, health status, history of hormonal therapy, and history of gender surgery. The study uses a quality of life survey with 36 questions in 8 areas of interest, producing only self-reported subjective information. Even the claim of simple

benefit is poorly support, as is reflected in the conclusion to the paper. The authors write, **"The 376 US FTM transgender participants analyzed in this sample had diminished mental-health related QOL compared with the general US population, as measured by the SF36v2. These findings are consistent when compared against specific age and sex norms."** This statement demonstrates the lack of value in the study. The study participants demonstrated a quality of life that is statistically significantly lower than the age/ sex comparison cohort, and the authors can only speculate as to the cause. There is no way to tell if treatment helped, had no effect, or harmed the patients because there was no information available about the anonymous subjects. This is because the anonymous test subjects hadn't received pre-treatment evaluation using the same or comparable test instrument. This study, selected by Dr. Schechter to support the claim of efficacy is of the lowest evidentiary value, may be useful for suggesting future research, but is of no value in directing clinical decision making, or meaningful allocation of public resources in the service of health.

On the Safety of Transgender Surgery

51. A discussion of surgical safety must include anticipated losses which are either expected, or even remotely possible. In order to examine the comparable issues in transgender versus reconstructive surgery our effort is simplified by comparing identical operations.

On several occasions I have performed the reconstructive surgery called "Sensate radial- forearm microvascular free flap hypopharyngeal reconstruction". I operated in order to reconstruct the tongue and throat of patients who had suffered a grievous wound of the mouth and throat that resulted from removal of an aggressive cancer. The defects caused by that wounding needed to be replaced with thin, pliant, abrasion and lfluid resistant tissue. It needed to provide the patient with sensation in the reconstructed area so that they can feel the food and liquids in their mouth, and manipulate the food so as to swallow it. We selected an area of skin on the inside of the forearm that has regular and robust blood allow, is thin and durable, and has an easily dissected sensory nerve that can be attached to the nerves in the wound. The forearm flap satisfied all the requirements. An operation of this complexity, duration, and technical requirements has many issues, big and small, that can diminish or destroy the result.

That throat reconstruction operation is in almost every way identical to the second most commonly performed female to male (FtM) genital surgery, the "Sensate

radial forearm microvascular free flap phalloplasty", which I understand is performed by Dr. Schechter. In that operation, the identical flap is raised and transferred. It also must be resistant to abrasion, be water tight, pliant, sensate, and of correct volume. Through a process of incision, plication and suturing, a tubular phallus is constructed within which is a skin lined tube which will serve as the urethra. The suture closures in both flaps is where most things go wrong because the skin edges that define the suture line can lose sufficient blood supply. In the phalloplasty, when this happens, the patient suffers from delayed healing, urine leakage, varying degrees tissue death, and scarring. All of those problems can happen with either the throat flap, or the phallus flap. When the phallus flap fails, the patient suffers due to varying degrees of tissue loss, chronic urinary leakage, or urinary obstruction due to scarring that can cause kidney injury if left un-treated. When the throat flap fails, bacteria laden saliva will leak into the neck where it can cause fulminant infections, or erode into a major artery and cause the patient to bleed to death in a matter of moments. A singularly terrible event.

In the case of the throat operation, if the removal of the cancer had not been performed, there was a known and significant probability that the cancer would have eroded into the tissues of the neck and caused a fulminant infection, or eroded into a large blood vessel, as described above. In contrast, if the phallus flap operation, had not been performed, the patient would have remained fully functional in every human capacity, though suffering from an inner subjective disturbance called gender dysphoria, which has not yet been adequately addressed.

Both operations involve the use of a highly complex surgical techniques to remedy a wound. In the case of the cancer operation the wound was the result of a cancer that would have ended in a terrible death. In the case of the phallus operation the surgeon is creating multiple physical wounds (castration, loss of pelvic organs of reproduction, de-gloving injury of the forearm, skin graft donor site injury), with their associated risks of complications. The surgery is performed in attempt to remedy a subjective, patient-reported sense of their identity.

Clearly the pre-operative condition of the cancer patient is far more grievous than the condition of the young person who is suffering from gender dysphoria. The cancer patient would likely be more than willing to endure significant loss, such as voice, or teeth, or the sense of smell. And yet, if I were discussing surgical risk pre-operatively with my patient who has the throat cancer, and told him that there was a certainty that in the course of the operation he would lose all of his reproductive organs, he would be justified in asking why he was being subjected to such an unsafe operation. The patient wouldn't be even slightly interested in any discussion of infection risk, wound healing

problems, or scarring. The question of safety addresses itself to the question of potential loss. Transgender surgery of the genital apparatus predictably causes grievous loss that dwarfs such complications as infection, local tissue loss, urinary leakage or scarring.

52. Returning from safety to efficacy in para. 43, we have a reiteration of an expert, professional opinion, and referring to a "substantial body of peer reviewed research". This is the next issue we must address: the use of the phrase "peer reviewed". Peer review is the very important process by which highly educated and trained experts review scientific medical papers for publication. They are examined in order to ensure that the corpus of medical literature is protected from imprecise, substantively erroneous, or conceptually flawed publications. It is an essential part of the historic, magisterial process in medicine. In fact, it is so much a part of the life-long learning process of the doctor that any worthy training program will have a robust "journal club" in which doctors at every level of training take a turn at publicly "peer reviewing" an article and leading a lively discussion of its value. A good doctor is constantly peer reviewing. It is an essential element of good medical care.

Establishing that an article is peer-reviewed is a basic, and essential practice. You might read a medical paper with level-III evidence of high quality, or a paper that is level-V evidence of low or questionable quality, both of which undergo peer review, and are published. The level-III will likely drive decision making, and possibly a recommendation as high as "standard of care", while the poor-evidence paper drives research, or perhaps the consideration of an alternative approach, if that approach does not put the patient in any significant risk.

53. In para. 44 he presents another peer reviewed article from 2013 by Weigert et al. which he summarizes. He asserts that the article demonstrates a statistically significant improvement in "psychosocial well-being" following cosmetic breast augmentation in biological males who are presenting as women. This paper is very simple to analyze and classify as not meaningful for informing clinical-therapeutic decision making. At the bottom of the published abstract, and on the front page of the full article is written, "Clinical question/level of evidence: Therapeutic, IV." As was discussed above, this paper is at the same low level, because it is a single-center sampling of a small cohort of patients, that relies on subjective, self-reporting through questionnaire, over a short study duration. Patient collection was made between 2008-2012. The paper was published in 2013. If the peer review process followed the usual time-line, it is likely that there are a significant number of patients in the study who were followed for less than a year. The authors, in the abstract only claim the pre-surgery, and the 4th month post-surgery as assured time points. This is remarkably short follow

up even for a cosmetic breast augmentation cohort. The article is perhaps useful in suggesting inquiry into why their cohort reported no improvement in physical well-being, given the known association between emotional health and physical health. There is nothing in the article that would rise even to the level of a guardedly worded clinical guideline suggestion.

54. The next citation offered in support of gender surgery is another peer-reviewed study by Horbach et al. published in 2015. This is a review of transgender surgical literature published between 1995 and encompassing nearly 20 years. It yielded 26 papers that satisfied the search criteria, and includes 1,461 patients. As Dr. Schechter quoted, the paper claims that "transgender women (biological males presenting as women) who had vaginoplasty found that study participants' mean improvement in quality of life after surgery was 7.9 on a scale of one to ten". In the conclusion of the paper the authors write, ""Sexual function and patient satisfaction were overall acceptable, but many different outcome measures were used. QoL was only reported in one study. Comparison between techniques was difficult due to the lack of standardization."

Of the merely 26 studies out of a sampling that spanned 20 years, only one paper was found to have used a standardized metric, one that only measures subjective, patient reported information, and the rest could not even be compared to each other. The authors write, **"The available literature is heterogeneous in patient groups, surgical procedure, outcome measurement tools, and follow-up. Standardized protocols and prospective study designs are mandatory for correct interpretation and comparability of data."**

56. This result is startlingly reminiscent of a paper published by Tolstrup et al. published in 2020. It is a comprehensive literature review on the subject of breast surgery in transgender patients, including both male to female, and female to male presentation. It is a scoping review that yielded 849 papers of which 47 papers met the inclusion criteria based upon title, abstract, and full text. In the study results,the authors report that,

"The summary of outcome domains and classifications showed that there are large variations in outcome evaluation between studies. Although several studies reported on similar outcome categories, there was a high level of heterogeneity of domains and classifications of outcomes." The authors then conclude by explaining that **"Evaluation of outcomes in gender-confirming chest**

surgery showed large variations in reporting, and further streamlining of reporting is therefore required to be able to compare surgical outcomes between studies."

None of the articles examined rates of psychiatric hospitalization, substance abuse,

self-harm behaviors, or suicide. This tells us that the most compelling reason offered for performing these surgeries (psychological distress and suicide risk) isn't even evaluated with regard to efficacy in the world transgender surgery literature.

55. Professionally speaking, these are very disappointing findings from comprehensive examination of the transgender surgery literature. To have a surgical sub-specialty working diligently, and guided by professionals at the highest levels of academic expertise, that has only produced case-series reports, retrospective case collections, and fruitless 20 year literature reviews, and still only have level-IV and V evidence to show for it is alarming. It shows that the sub-specialty has not developed uniform descriptive language, standardized reporting nor test instruments that might raise the value of expert opinion to a level that could make reliable recommendations that might help in surgical decision making, rightly inform the consent process, or guide decision making by officials entrusted with the care of public and private medical resources. It would cause me to make a sober review of the medical and surgical principles that are guiding this work.

56. The next article cited by Dr. Schechter is one presented in support of masculinizing chest surgery in minors and young adults. This is the mastectomy and liposuctioning surgery discussed above. It is a 2017 paper, published in the peer reviewed journal JAMA Pediatrics. Dr. Schechter asserts that the paper demonstrates that "surgical intervention (mastectomy)positively affected both minors and adults". This paper is perhaps the most alarming of all the citations offered.

The principle author, Dr. Olson-Kennedy is also an academic expert in her capacity as Associate Professor of Clinical Pediatrics, Keck School of Medicine of USC, and Medical Director of The Center for Transyouth Health and Development in Los Angeles. She holds professional membership in The Society for Pediatric Research, the World Professional Association for Transgender Health(WPATH), and the Society for Adolescent Health and Medicine. If any expert would be in a position to offer high quality, evidence based publications, she would certainly be in contention.

In their summary of findings, the authors report that "chest dysphoria" is common

among "trans males" (natal females seeking to present as males), and that the dysphoria is decreased by surgery. They claim that regret for surgery is "rare". The article reports breast removal surgery on at least one girl aged 13 years. The average age was 19. Children were entered into the study through recruitment from among patients visiting the clinic, and by telephone over a six month period. The authors found that patients recruited from among visitors to the clinic (convenience sampling) yielded an abundance of non-operated patients, so they were forced to reach out to all the post surgical patients by phone. 26% of the clinic's post surgical patients could not be reached for various reasons including no working phone, or failure to respond to multiple messages. A 26% drop-out rate is never questioned by the authors. Were they lost to follow up because of dissatisfaction, psychiatric hospitalization, or suicide? This problem is called "self-selection bias", and is evidence of careless study design. Of the remaining 74% of patients, only 72% of them (only 53% of the study patients) completed the survey. This is a second example of self-selection bias. Why would some post surgical patients who had been successfully contacted, not complete the survey? The authors do not ask the question.

In the study, dysphoria was measured using "a novel measure" (an unproven test instrument) which was a series of subjective questions about happiness. Among the designers of this novel test instrument were some of the adolescent patients themselves. Their flawed methodology included the use of an entirely unvalidated test instrument, with no known error rates, or proven predictive power, **that was in part designed by the minors and young adults who were the subject of the study.**.

Furthermore, the post surgical patients were given the survey at varying time intervals post surgery. The longest interval between surgery and the satisfaction survey was 5 years, but children less than a year post surgery were included in their flawed sample, and yet the authors claim evidence of "negligible regret." This is a remarkable claim given that long term, longitudinal population studies show that there is a dramatic rise in post surgical problems such as depression, hospitalization, substance abuse, and suicide beginning at around year 7 post surgery(Dhejne). Surely Dr. Olson-Kennedy is familiar with the international literature on transgender outcomes?

Having promised in the introduction to her paper that "chest dysphoria" is reduced by surgery, at the conclusion they confess the fact that the study design and execution produced very low quality data that is not useful for patient selection, or prediction of outcomes. They even confess that the study does not address the efficacy of surgery in improving outcomes regarding the single most compelling reason for

performing the operation: mitigation of depression and suicide. The authors write: **" An additional limitation of the study was the small sample size. The nonsurgical cohort was a convenience sample, recruited from those with appointments during the data collection period. There could be unknown imbalances between the nonsurgical and postsurgical cohorts that could have confounded the study findings.**

Finally, the Chest Dysphoria Scale is not yet validated, and may not represent distress or correlate with validated measures of quality of life, depression, anxiety, or functioning."

This paper is a typical example of a publications which are used to support transgender medicine and surgery, written by board certified transgender expert physicians who practice in our nation's largest pediatric gender clinics, and was published in peer-reviewed medical journals. The article is essentially useless in making any clinical decisions regarding who should be offered surgery, what the likelihood is that they will benefit from it, or the likelihood that they will regret their decision. Most importantly, it can not even vaguely estimate if the risk of hospitalization, incarceration, or suicide will be reduced. For the same reason that the paper is not useful in clinical decision making, it is likewise not meaningful in decision- making for persons charged with the just management of public and private medical resources.

On the Experimental Nature of Transgender Surgery

57. In para. 47 Dr. Schechter brings into question the assertion that transgender surgery is experimental in nature. He begins this response with the claim that referring to transgender surgery as experimental is "unsupported by the professional medical consensus and prevailing standards of care for treating gender dysphoria, and is inconsistent with mainstream medical standards." We previously discussed the lack of intrinsic validity of consensus methodology when evidence to support the consensus is weak. We discussed the evidentiary requirements for claiming a "standard of care"; that one must present evidence that is high (III or better) and consistent over multiple studies (with obvious exceptions when the consequences of error are minor). We also reviewed the historic meaninglessness of the phrase "mainstream medical standards" when trying to resolve the issue of the validity of novel research finding.

It is to be remembered that whenever there is a breakthrough in medical-scientific knowledge, it is characteristic that academic experts are proven to have been

in error. This is in the nature of the scientific method. As will be recalled from earlier discussion, the greatest names in academic surgery for 100 years wrote papers, published books, trained residents, wrote board questions, and examined candidates for board certification fully convinced that ulcer disease of the stomach is a surgical disease that demanded some of the most advanced operations known at the time. They considered it not only necessary, but in fact lifesaving beyond a shadow of doubt. These were great, and well-intentioned surgeons laboring under a poverty of information for 70 years, then laboring under an abundance of confidence that they could not possibly be wrong about their condemnation of the infection theory of ulcer disease. Eventually, high quality evidence proved them wrong, and now surgery for gastric ulcer disease is rarely seen. Through the whole history of ulcer surgery, the principle of acid reduction through nerve sectioning and drainage was "mainstream". This test of mainstream acceptance in the medical community, which Dr. Schechter offers, is a test with no predictive value in making either clinical or medical executive decisions on the question of the validity of transgender surgery.

58. One of the important usages of the term "experimental" in the world of medical care is in the domain of insurance services, both public and private. Leadership in these agencies is charged with the responsibility of managing medical resources in a way that both preserves resources, while at the same time applying those resources to the patient as correctly as medical science and their own actuarial information will allow. Whenever a novel therapy is proposed for a given condition, insurance services will examine the medical and actuarial data to see if the proposed therapy is likely to yield a result that serves those two purposes (health of the patient, and financial soundness of the insurance process). Typically, in the early years of a new treatment there is resistance on the part of the payors because early on (as discussed in detail above) all that the proponents are able to present is low-level scientific papers that present anecdotal case collections without controls, or multiple studies that can not be compared due to methodological variation, or are methodologically questionable due to unvalidated test instruments. We surgeons are inclined to think uncharitable thoughts when reading letters from insurance plan managers. But history has shown, and the fact remains, that good surgery demands good evidence, particularly when permanent damage to the client is a possible result.

Nonetheless, if the reviewer see evidence that a new approach may be helpful, they prudently insist that therapies of known value be tried to their reasonable limit , and that they be found to fail in solving the patient's condition, before considering the new treatment.

This dynamic process between the patient, the physicians, and the insurance industry has many problems, but good, well validated scientific evidence is not one of those problems. In fact well validated science is typically the best remedy for those problems. Sometime the good science is from the doctors, and sometimes the good science comes from the actuaries. In both cases the patient benefits.

59. From the perspective of the case in question, this sense of the term "experimental surgery" may be the most important. How did the affirmation care scientific model and its associated social, medical and surgical treatments enter into the mainstream of the medical community. Did it follow this same process of gradual acceptance in both the medical and insurance communities through a process of steadily improving evidence levels? Was it used on a careful trial basis after having exhausted treatment by established methods? The answer is, "in a way, yes it did".

60. The historically validated treatment model for what is today called gender dysphoria is what is called "watchful waiting". On hearing the name one is tempted to think of this as a resignation to inaction. It is not. It is a psychotherapeutic process that is rooted first in an examination of the cognitive processes of the child, and seeing how the child has responded to the reality of their life. For this reason, in order to be effective, it must include family therapy. The goal is to keep the anxious and confused child in loving contact with reality, while seeking to understand and remedy the dynamic that is provoking the condition of distress. Occasionally, short courses of anxiety medications may be used to manage the intensity of obsessive thinking that has become centered on their physical appearance. It is essentially the same process used in helping persons who suffer other obsessive- compulsive issues, like eating disorders. Psychological research, having high level evidence, has shown that over the course of time this approach results in over 80% resolution of the cross-sex self identification during adolescence, and nearly 92% by young adulthood.[9]

61. This watchful-waiting approach is likely the reason why transgenderism used to be a rare diagnosis. The vast majority of people with the condition resolved the issues, and went on to live their lives without the need for life-long medications, without destructive surgeries, without the loss of their sexual faculties, and without the loss of fertility. What has happened, however, is that the dynamic between patient, physician,

[9] Zucker, K. J. (2018). The myth of persistence: response to "A critical commentary on follow-up studies and 'desistance' theories about transgender and gender nonconforming children" by Temple Newhook et al. International Journal of Transgenderism, 19(2), 231–245. Published online May 29, 2018. http://doi.org/10.1080/15532739.2018.1468293

and insurance services has been severely disrupted. The science based medical and actuarial management of this condition has been separated from the evidence, and now rests entirely on the opinions of academic experts who have managed to influence the decision makers in their favor. In large part, they have accomplished this by never speaking about watchful waiting except to dismiss it as folly. This process of silence and dismissal is exactly what ulcer surgeons did to the proponents of the scientifically correct infection model of ulcer disease.

62. Sadly, silence and dismissal about watchful waiting is not the only reason for the 5,000% increase in the diagnosis of transgender over the past decade. Surgeons who were seeking to achieve the best results for their transgender patients came to realize that most of the difficulty with good cosmetic results was that young men seeking to present as women looked too masculine, and young women seeking to present as men looked to feminine. If their masculine or feminine development had been arrested early, the surgeons theorized that they would achieve better results. It was reasonable, in light of their treatment model, to think that a better cosmetic result would mean a better resolution of the gender incongruence. Thus the idea was born that the earlier the child was transitioned, the better the cosmetic surgical result, and thus the better psychological result, which was the goal.

This theoretical improvement in outcomes for transgender persons through early transition was certainly an idea worth investigating. Because the lifelong effects of the approach might include some really bad outcomes for the children, and because the actual outcomes were unknown at the time, it would have been prudent, and scientifically consistent to categorize this from the above described insurance industry perspective, as experimental. It would have required that the patients exhaust the fully established and proven treatment model of watchful waiting. If that treatment failed to resolve the issue, then on a trial basis, and supervised under very strenuous human experimentation oversight, the affirmation model could be tried.

In order for this highly supervised experimental approach to pass ethical standards in human experimentation there would have to have been a previously established diagnostic and patient selection process of very high specificity. If the proven and established method of watchful waiting is yielding 92% resolution, then what the ethically minded surgeon is really supposed to be doing is trying to find that 8% of children who would have failed watchful waiting, and select them out for surgery earlier in their life. Then studying the result on a very long-term and comprehensive basis, he would have been able to provide high-value evidence that his hypothesis about the

successful early management of transgenderism is a safe and valid option for his patient. This was not done. Instead, the routine social and medical transitioning of children began, which includes puberty blockade, and cross-sex hormones in children and youth.

Instead of seeking the historic, and small cohort of patients who would have carried the condition into adulthood and treating them, physicians and surgeons are treating all of those children now. Instead of seeking the scientific methodology with which to make a correct diagnosis so as to increase the likelihood that you are operating on the right person, the transgender treatment model is essentially turning all affected children into "the right person". By the time the youth or young adult person arrives in the surgeon's office the process has been locked into place.

63. It would seem that the best course of action for those who serve the insurance industry is to return this process to the time tested dynamic model of patient, physician, and insurance plan discussed above. Because the affirmation model rests upon such low quality evidence, it seems justifiable to suspend financial support until such time as testing and patient selection processes are improved to acceptable levels of reliability. Given the serious, life long consequences of mis-diagnosis, and the misapplication of surgery, levels of patient selection reliability would have to be quite high.

64. There is the additional issue of liability for insurance providers, including the state. The massive surge of patient numbers over the past 10 years would predict that large numbers of patients are reaching the point where affirmation interventions will have been exhausted, and the numbers of treatment failures will start to rise dramatically. We are beginning to see this in the increasing numbers of "regretters" whose support groups and legal representatives are sounding the alarm. This may represent a serious liability to insurers in addition to the physicians and hospital systems that have taken such an active role in promoting this unproven treatment model.

65. A review of the European literature on this topic forms the basis for this anticipation of liability and merits review here. As we have seen in this review of Dr. Schechter's expert declaration, the American literature used in support of the claim of benefit is of low reliability. We make this assertion based on the expectation the Dr. Schechter has provided the court with the best evidence available. One of the features of all those papers taken in aggregate is that they report studies of short duration. Follow up durations of less than 3 years are common. Some, as we have seen are as

short as 4 months. This fact helps us to understand why proponents of the affirmation model are enthusiastic. We see in the European literature that there is a trend line that looks favorable for up to 7 or 8 years, after which result decline precipitously.

66. As described in my previous report, the Swedish medical establishment maintains an excellent and centralized data base of all episodes of care for beneficiaries. It uses uniform language, and captures treatment events at all levels, from school clinics, to psychiatric hospitals, to prison infirmaries, to public clinics. The database can be analyzed for such things as emergency room visits, drug addiction treatment, hospitalization for suicide, psychiatric admissions for self-harming event etc.

In 2011, Dhejne et al.,published a population based, longitudinal cohort study of the database that sought to examine the lifetime hazard ratio of such things as substance abuse, incarceration for violent behavior, psychiatric hospitalization, and completed suicide.[10] This is level-III evidence of high order given the methodology employed and the proven reliability of the database. It examined persons who have fully completed transition and compared them to age and sex matched controls in the Swedish population. It did not use anonymous surveys, or other faulty convenience sampling. It found the post-transition patients by finding the associated episodes of care, such as i hormone therapy prescriptions began, or admission for gender surgery occurred. The data set spans 30 years. What it shows is that fully transitioned subjects showed a relative risk of suicide roughly equal to the age/ sex matched controls, but the effect appears to last for just a few years. The trend line for death from any cause begins a sharp drop at approximately 10 years and continues to drop massively over the subsequent 15 years. When the researchers looked at the aggregate life-time relative risk of suicide, persons who fully transitioned were 19.1 times more likely to have killed themselves when compared to age and sex matched controls. If you only look at the subgroup of biological females who transitioned to male-presentation, the risk of suicide is 40 times higher than the control group. Results such as these, because they are obtained using tested and reliable methodology, are able to help meaningfully in clinical and administrative decision making, and in several European countries it has.

67. Over the past several years, the medical systems in Great Britain, Sweden, Finland, and France have stepped away from early medical and surgical

[10] Long-Term Follow-Up of Transsexual Persons Undergoing Sex Reassignment Surgery: Cohort Study in SwedenPLoS One. 2011; 6(2): e16885.
Published online 2011 Feb 22. doi: 10.1371/journal.pone.0016885

transitioning of the young. The Tavistock-Portman Institute in London, which was the sole provider of these services to children in Great Britain was closed recently following the public declaration by a review committee that the Institute was "unsafe for children".[11] Similarly, the Karolinska Institute in Stockholm reversed its policy by suspending the medical and surgical transitioning of the young in favor or psychological support and treatment.[12] Similar changes in treatment guidelines for self-identified transgender youth have been published in Finland. Based upon these developments in Europe, it is very troubling to read assessments or declarations by leaders in the field of transgender surgery which assert that these treatments are mainstream and beyond controversy, or that they are part of a core curriculum of surgical training, or that an oral board examiner might fail a candidate surgeon if their answers reveal a reticence to join the mainstream that Dr. Schechter has described. The world literature demonstrates emphatically that early medical and surgical transitioning is in fact so controversial that medical leadership in multiple countries has put a stop to it.

68. In summary, transgender surgery is based in a treatment model of affirmation that lacks scientific support based in quality evidence. The scientific support offered by the leaders in the field is entirely composed of small studies, single provider /single center studies that are lacking in control cohorts, and are often rendered uninterpretable due to haphazard case-collections such as the solicitation of study participants without methodology to confirm that the patient is a treatment subject. All of the studies cited have short follow-up, and most studies suffer from massive self-selection bias and high drop-out rates. The studies often employ untested assessment methodologies, and all of the literature cited by experts report only subjective data, which is typical of papers that address outcomes in cosmetic surgery. Transgender surgery is, by definition, cosmetic surgery. The move towards surgery begins in the subjective life of the patient, is conducted with the aim of improving the subjective life of the patient, and outcomes are measured in subjective terms based in satisfaction surveys. Transgender surgery violates fundamental principle of cosmetic surgery, because it predictably destroys essential functions of the human person. It is not reconstructive surgery because the patient is physically healthy before the surgery, and has no definable deficit that can be objectively characterized to be the cause of the presenting complaint. There is no objective test to confirm the diagnosis of transgender, and no way to correctly select patients for surgery from among the young. The enterprise of gender affirmation medicine and surgery is based entirely in a consensus

[11] NHS to close Tavistock child gender identity clinic https://www.bbc.com/news/uk-62335665

[12] rSweden's Karolinska Ends All Use of Puberty Blockers and Cross-Sex Hormones for Minors Outside of Clinical Studies https://segm.org/Sweden_ends_use_of_Dutch_protocol

of expert opinion of low reliability because it is supported by unreliable scientific evidence.

69. Based upon all of the above examined findings, it is my professional opinion that leaders in the medical community must stop the application of the affirmation care model to the young. The earlier model of watchful waiting, which gender affirmation unjustly replaced, must be restored as the tested and proven basis for care until such time as better, scientifically proven methods are found. Leaders in medical administration have a duty to the patients, and to their healthcare systems, to stop the financial support of this untested, demonstrably harmful treatment model, and to direct practitioners to the fullest use of the proven treatment model of watchful waiting. American physicians who care for persons who experience gender discordance likewise have a duty to follow evidence that has been offered by our European colleagues, and to seriously consider the fact that long term evidence now shows that gender transitioning medicine and surgery do not reduce lifetime risk of self-harm. Physicians must instead seek more effective ways to treat this community of persons who are suffering greatly, and who deserve care based in the objective truths that are revealed by good science.

I declare under penalty of perjury that the foregoing is true and correct. Executed this 2nd day of October, 2022.

//s//Patrick W. Lappert, MD
Patrick W. Lappert, MD

EXHIBIT "A"

Curriculum Vitae- Patrick W. Lappert, MD

Education and Training :

— Bachelor of Arts in Biological Sciences at the University of California, Santa Barbara, 1979. Research in cell membrane physiology with Dr. Philip C. Laris, studying stoichiometry of the sodium: potassium ATPase pump.

— M.D., Doctor of Medicine degree at the Uniformed Services University of the Health Sciences, 1983 at Bethesda, Md.

— General Surgery Residency at the Naval Hospital Oakland/ UC Davis East Bay Consortium, 1987-1991

— Chief Resident, Department of Surgery, Naval Hospital Oakland, 1990-1991.

— Plastic Surgery Residency at the University of Tennessee- Memphis, 1992-1994.

Board Certifications in Medicine :

— Board Certified in Surgery — American Board of Surgery, 1992-2002

— Board Certified in Plastic Surgery — American Board of Plastic Surgery, 1997-2018

Medical Staff Appointments :

— Staff General Surgeon at the Naval Hospital Oakland, CA 1991-1992

— Associate Professor of Surgery, UC Davis-East Bay, 1991-1992.

— Plastic and Reconstructive Surgeon, Naval Medical Center, Portsmouth, VA 1994-2002

— Chairman, Department of Plastic and Reconstructive Surgery, Naval Hospital Portsmouth, VA 1996-2002.

— Clinical Assistant Professor, Department of Surgery, Uniformed Services University of the Health Sciences, 1995-2002

— Founding Director, Pediatric Cleft Palate and Craniofacial Deformities Clinic, Naval Hospital Portsmouth, VA 1996-20002

— Founding Director, Wound Care Center, Naval Hospital Portsmouth, VA 1995-2002.

— Staff Plastic Surgeon in Nebraska, and Alabama.

U.S.N. Surgeon General Service:

— Specialty Leader, Plastic and Reconstructive Surgery, Office of the Surgeon General-USN, 1997-2002

Faculty Appointments:

— Teaching Faculty at Eastern Virginia Medical School, Division of Plastic Surgery, 1995-2002

Military Service :

— Aviation Officer Candidate, Naval Aviation Schools Command, NAS Pensacola, 1978

— Commissioned an Ensign, MC, USNR 1979 and Commissioned as a Lieutenant, MC, USN 1983 .

— Designated Naval Flight Surgeon, Naval Aerospace Medical Institute, 1985

— Flight Surgeon, Marine Fighter/ Attack Squadron-451

— Radar Intercept Officer in the Marine F-4S Phantom, accumulating 235 flight hours, and trained for qualification as an Air Combat Tactics Instructor.

— Deployed to the Western Pacific as UDP forward deployed fighter squadron in Korea, Japan, and the Philippines.

— Service in the US Navy for 24 years

— Service in the US Marine Corp. for 3 years.

— Retired with the rank of Captain, USN in 2002

Military Awards:

— Navy Commendation Medal - For service with Marine Fighter/Attack Squadron - 451

— Meritorious Unit Citation- 3rd award

— Humanitarian Service Medal - For service in the aftermath of the Loma Prieta earthquake.

Publications - Peer Reviewed Medical Journals :

— Lappert PW. Peritoneal Fluid in Human Acute Pancreatitis. Surgery. 1987 Sep;102(3):553-4

— Toth B, Lappert P. Modified Skin Incisions for Mastectomy: The Need for Plastic Surgical Input in Preoperative Planning. J Plastic and Reconstructive Surgery. 1991; 87: 1048-53

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— Lappert PW. Scarless Fetal Skin Repair: "Unborn Patients" and "Fetal Material". J Plastic and Reconstructive Surgery. 1996 Nov;98(6):1125

— Lappert PW, Lee JW. Treatment of an isolated outer table frontal sinus fracture using endoscopic reduction and fixation. P!astic and Reconstructive Surgery 1998;102(5):1642-5.

Publications - Medical Textbooks:

— Wound Management in the Military. Lappert PW, Weiss DD, Eriksson E. Plastic Surgery: Indications, Operations, and Outcomes, Vol. 1; 53-63. Mosby. St. Louis, MO 2000

Operations and Clinical Experience - Consultations and Discussions : As a physician and surgeon, I have treated many thousands of patients in 7 states and 4 foreign nations. My practice has included Primary Care, Family Medicine, Aerospace Medicine, General Surgery, Reconstructive Surgery for combat injured, cancer reconstructive surgeries including extensive experience with microvascular surgery, Pediatric Congenital Deformity, and the care of chronic wounds. I have practiced in rural medicine, urban trauma centers, military field hospitals, university teaching hospitals, and as a solo private practitioner. In my private practice I have had occasion to treat many self-identified transgender patients for skin pathologies related to their use of high dose sex steroids, laser therapies for management of facial hair both in transitioners and detransitioners. I have performed breast reversal surgeries for detransitioning patients. My practice is rated as "LGBTQ friendly" on social media. I have consulted with families with children who are experiencing gender discordance. I have given many presentations to professional meetings of educators and counselors on the subject of transgender, and the present state of the science and treatment. I have discussed the scientific issues relevant to the case with many physicians and experts over a number of years and also discussed related issues with parents and others.

EXHIBIT "B"

Florida Medicaid Project: Surgical Procedures and Gender Dysphoria

Patrick Lappert, M.D.

May 17, 2022

Florida Medicaid Project: Surgical Procedures and Gender Dysphoria

Patrick Lappert, M.D.

Overview

The "Gender Affirmation" care model for children who suffer from gender identity issues is experimental in nature because it is based in low to very low-quality scientific evidence. There is no body of quality scientific evidence to support the hypothesis that gender dysphoria with its associated problems of self-harm and suicide, is improved long-term by gender affirmation surgical procedures.

The best evidence available today demonstrates that transgender is not a single condition that can be explained by any single factor. There are vast differences in age of presentation, predominant sex, persistence into adulthood, and resolution during adolescent development. Moreover, there are numerous and common co-morbid conditions such as autism-spectrum disorder, major anxiety disorders, and clinical depression that severely affect any sense of certainty about the true cause of the child's dysphoria, as well as their capacity to understand and give assent to irreversible medical and surgical procedures that lead to permanent sterility, sexual impotence, and a lifetime of medical problems associated with affirmation care.

The process of obtaining medical informed consent as part of gender affirming surgery is morally indefensible, and likely legally indefensible as well. Parents of suffering children are led by medical professionals to believe that there is only one valid option of care (affirmation medicine and surgery), utterly concealing the historic reality that greater than 92% of children desist in their cross-sex self-identification when treated using the "watchful waiting" therapeutic strategy. Parents are told that if they do not consent to affirmation care, there is a high likelihood that their child will die from suicide. This is not informed consent, but rather consent under duress.

Gender identity is being presented as a fixed and unchanging, biologically determined, personal characteristic. It is not. The medical literature has consistently shown over many years that the vast majority of children with cross-sex gender identity resolve the issue during adolescence and adopt a gender identity that is congruent with their biological sex.

Because surgeons who perform gender affirmation surgeries have no diagnostic test to predict who among the self-identified transgender minors would have persisted in their cross-sex self-identification into adulthood, and who among those children would have desisted, they have no way to know, in any particular case if the irreversible surgery is being performed on a person who would have continued to self-identify in the cross-sex persona into adulthood. Given the historically well-known desistance rate, it is possible that as many as 90% of children are undergoing surgery based upon an incorrect diagnosis.

"Gender Affirming" breast surgery for self-identifying transgender minors is not medically and ethically equivalent to similar procedures performed for objectively identifiable medical conditions. Transgender breast surgery is always cosmetic (aesthetic) in nature because the indication is a hoped-for improvement in the interior emotional life of the patient. Transgender surgery is not based in any medical diagnosis and does not seek to restore any form or function that may have been lost due to trauma, disease, or developmental accident. It begins with normal structures and changes their appearance in order to achieve a subjective improvement and is therefore cosmetic surgery.

Because gender affirming surgery is cosmetic (aesthetic) in nature, such surgeries must never be offered if they are known to predictably produce an irreversible loss of function. To knowingly sacrifice a human capacity (breast feeding, capacity for sexual intimacy, fertility) in the pursuit of a cosmetic result in a minor who is incapable of giving informed consent, is morally indefensible. The hoped-for subjective improvement that is sought in transgender surgery is a short-lived improvement and is only supported by low to very low-quality scientific evidence. Long term longitudinal cohort studies that are based in level III evidence show that affirmation surgical care is of no benefit in reducing self-harm including suicide.

Problems with Informed Consent

The protection of children in situations requiring informed consent is a crucial problem that the state has a historic and abiding interest in. In the particular situation of self-identified transgender children, it becomes a most significant problem, given that they are being submitted for permanently life-altering interventions. In my opinion as a plastic and reconstructive surgeon, the life-altering nature of hormonal and surgical interventions needs to be addressed from the moment of the child's entry into the gender-transition system, given the fact that the overwhelming majority of children who first begin puberty blockade, go onto the physically altering and permanent changes produced by cross sex hormones, and many ultimately also pursue surgery, as is attested to by multiple papers, the content of which is examined below. Informed consent has several requirement that need to be met if such consent is to be deemed valid. These requirements include a thorough discussion of the details of the proposed procedure including risks, known complications, and some measure of the likelihood of a favorable outcome. The discussion must include alternative treatments, and their risks, known complications and their likelihood of a favorable outcome. In the case of the interventions associated with gender-transition medicine and surgery, the favorable outcomes should be evident over the lifetime of the patient, given that they are permanently sacrificing structures and capacities (breasts and breast-feeding, or genitals and fertility).

Because the commonly cited medical literature used in support of these surgeries is of low to very low quality, it must be recognized that such surgeries must be considered experimental in nature given the unknown long-term effects of treatment, and the vast uncertainty in the patient selection and diagnostic processes. Yet the experts who provide opinion in support of these surgeries speak with absolute certainty of their efficacy, and the absence of any alternative treatment. Considering these factors severally and together it becomes difficult to imagine a

more flawed consent process. It also becomes understandable how parents can be drawn into uninformed participation given the simultaneous presentation of dire consequences if gender dysphoria is left untreated, and the insistence that affirmation care including surgery is the only way to bring lasting happiness to the child.

Chest Masculinization" in Natal Females is Not Ethically Equivalent to Mastectomies for Breast Cancer

When mastectomy is performed for the management of breast cancer, or to mitigate the proven risk of developing breast cancer in women, it is done on the basis of objective diagnoses either by pathological examination of biopsy tissue, or as in the case of prophylactic mastectomy, on the basis of genetic analysis that shows known markers of increased risk of developing breast cancer. These tests (microscopic examination of tissue specimens, detection of cell surface markers with proven association with malignancy, and genetic screening of at-risk patients) have known positive predictive value for the diagnosis of breast cancer, and these tests have known error rates that can be used when obtaining informed consent for mastectomy. The validity of these tests has been proven using scientific methodologies that produce high quality evidence in longitudinal population studies with control populations, and very long follow up. As the result, when a woman gives consent for mastectomy to control or prevent the potentially lethal disease, it is with a clear and proven evaluation of the risks and benefits that consent is obtained. Mastectomy is being performed based upon an objective diagnosis of a potentially lethal condition, and the surgical procedure has proven benefit in management of that condition.

In stark contrast, this is not the case when mastectomy is performed to "masculinize" the chest of girls and women who self-identify as transgender or who self-report symptoms of dysphoria. In the self-identified transgender adolescent, breasts are being removed on the basis of a diagnosis that is made by the patient since there are no tests with known error rates that can be used to predict who will benefit from this disfiguring and irreversible surgery. The claim is made that chest masculinization has proven benefit in reducing dysphoria and the associated risk of suicide. But published studies that make this claim of benefit offer evidence that is low to very low quality, typically small case collections with self-selection bias, very short follow up, and no case controls.

The best data presently available on the long-term effects of medical and surgical transitioning are long-term, longitudinal, population-based studies. For example, Dehjne, et al., examined the putative long-term benefit of full transitioning (including hormonal and surgical treatments) found in the Swedish medical database. (See Long-Term Follow-Up of Transsexual Persons Undergoing Sex Reassignment Surgery: Cohort Study in Sweden; Cecilia Dhejne, Paul Lichtenstein, Marcus Boman, Anna L. V. Johansson, Niklas Långström, Mikael Landén; PLOSOne February 22, 2011 https://doi.org/10.1371/journal.pone.0016885). That database includes all persons in the Swedish medical system, from pre-natal to death. It reports all episodes of care and all demographic information in a uniform vocabulary. Furthermore, Sweden has been on the forefront of "gender affirmation" long before the American medical

system seriously considered its claims. Because of the nature of Sweden's database, it is possible to study a cohort of patients that very closely matches the inquiry group with regards to age, sex, economic status, etc. It is possible to ask with great precision such questions as, "What is the likelihood that a fully transitioned transgender male will be hospitalized for psychiatric illness when compared to the age/sex matched control group?" Even more, one could urgently ask, "What is the relative risk of suicide in transgender persons, when compared to age/sex matched controls?"

Why are such longitudinal, population-based studies superior to the case-collection/case series methodology? Because confounding variables such as age, sex, and self-selection biases are removed. In the flawed case-collection methodology, the reported cases are typically only those who return for follow up. You have no way of knowing if the patient had a good outcome or didn't return for follow up because they were in a psychiatric hospital, were incarcerated, or committed suicide. In the Swedish longitudinal study, the suicide is in the same database, as are the other issues of hospitalization, incarceration, and addiction treatment, among other rates of comorbidity. Thus the longitudinal population study can give us what is called a "hazard ratio" for a particular study population (patients who have completed transgender transition in this case).

What this Swedish study shows us that the risk of completed suicide in all transgender persons is 19.1 times higher than in the control cohort. If you look only at patients who have transitioned — patients after "treatment" — from female to "male presentation," the risk of completed suicide is 40 times higher than in the general population. (Note: this finding is consistent with the historic Branstrom 10-year follow up study, which found no benefits to "transitioning treatments" but did note an increased risk of serious suicide attempts and anxiety disorders AFTER "treatment.") (Correction to Bränström and Pachankis, Am J Psychiatry 177:8, August 2020; see detailed citations in the "Notes" section of this report below).

Another cautionary note was added to the literature by the reputed Cochrane Review, a UK based international association of researchers who examine the quality of scientific evidence used in medical decision making. The Cochrane Review recently published findings concerning the medical evidence used to support the decision to give young women cross sex hormones as part of the transition process. The authors summarize the world literature review thus: "We found insufficient evidence to determine the efficacy or safety of hormonal treatment approaches for transgender women in transition. This lack of studies shows a gap between current clinical practice and clinical research." (Does hormone therapy help transgender women undergoing gender reassignment to transition? See, Haupt C, Henke M, Kutschmar A, Hauser B, Baldinger S, Saenz SR, Schreiber G., Cochrane Review, 28 Nov 2020).

Similar issues of very poor, low quality scientific support for chest masculinization surgery can be seen in a recent article by Tolstrup et al. published in the journal Aesthetic Plastic Surgery (See Anders Tolstrup, Dennis Zetner, Jacob Rosenberg, Outcome Measures in Gender-Confirming Chest Surgery: A Systematic Scoping Review, Aesthetic Plast Surg 2020 Feb;44(1):219-228. doi: 10.1007/s00266-019-01523-1. Epub 2019 Oct 29). The article reports a

CERTIFICATE OF SERVICE

I certify that I e-filed this appendix on ECF, which will email everyone requiring notice.

Dated: October 13, 2023 /s/ Mohammad O. Jazil